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# SOCIAL SECURITY ACT

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## TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

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### PART A—GENERAL PROVISIONS

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#### CENTER FOR MEDICARE AND MEDICAID INNOVATION

SEC. 1115A. (a) CENTER FOR MEDICARE AND MEDICAID INNOVATION ESTABLISHED.—

(1) IN GENERAL.—There is created within the Centers for Medicare & Medicaid Services a Center for Medicare and Medicaid Innovation (in this section referred to as the "CMI") to carry out the duties described in this section. The purpose of the CMI is to test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles. In selecting such models, the Secretary shall give preference to models that also improve the coordination, quality, and efficiency of health care services furnished to applicable individuals defined in paragraph (4)(A).

(2) DEADLINE.—The Secretary shall ensure that the CMI is carrying out the duties described in this section by not later than January 1, 2011.

(3) CONSULTATION.—In carrying out the duties under this section, the CMI shall consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management. The CMI shall use open door forums or other mechanisms to seek input from interested parties.

(4) DEFINITIONS.—In this section:

(A) APPLICABLE INDIVIDUAL.—The term "applicable individual" means—

(i) an individual who is entitled to, or enrolled for, benefits under part A of title XVIII or enrolled for benefits under part B of such title;

(ii) an individual who is eligible for medical assistance under title XIX, under a State plan or waiver; or

(iii) an individual who meets the criteria of both clauses (i) and (ii).

(B) APPLICABLE TITLE.—The term "applicable title" means title XVIII, title XIX, or both.

(5) TESTING WITHIN CERTAIN GEOGRAPHIC AREAS.—For purposes of testing payment and service delivery models under this section, the Secretary may elect to limit testing of a model to certain geographic areas.

(b) TESTING OF MODELS (PHASE I).—

(1) IN GENERAL.—The CMI shall test payment and service delivery models in accordance with selection criteria under paragraph (2) to determine the effect of applying such models

under the applicable title (as defined in subsection (a)(4)(B)) on program expenditures under such titles and the quality of care received by individuals receiving benefits under such title.

(2) SELECTION OF MODELS TO BE TESTED.—

(A) IN GENERAL.—The Secretary shall select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title. The models selected under this subparagraph may include, but are not limited to, the models described in subparagraph (B).

(B) OPPORTUNITIES.—The models described in this subparagraph are the following models:

(i) Promoting broad payment and practice reform in primary care, including patient-centered medical home models for high-need applicable individuals, medical homes that address women's unique health care needs, and models that transition primary care practices away from fee-for-service based reimbursement and toward comprehensive payment or salary-based payment.

(ii) Contracting directly with groups of providers of services and suppliers to promote innovative care delivery models, such as through risk-based comprehensive payment or salary-based payment.

(iii) Utilizing geriatric assessments and comprehensive care plans to coordinate the care (including through interdisciplinary teams) of applicable individuals with multiple chronic conditions and at least one of the following:

(I) An inability to perform 2 or more activities of daily living.

(II) Cognitive impairment, including dementia.

(iv) Promote care coordination between providers of services and suppliers that transition health care providers away from fee-for-service based reimbursement and toward salary-based payment.

(v) Supporting care coordination for chronically-ill applicable individuals at high risk of hospitalization through a health information technology-enabled provider network that includes care coordinators, a chronic disease registry, and home tele-health technology.

(vi) Varying payment to physicians who order advanced diagnostic imaging services (as defined in section 1834(e)(1)(B)) according to the physician's adherence to appropriateness criteria for the ordering of such services, as determined in consultation with physician specialty groups and other relevant stakeholders.

(vii) Utilizing medication therapy management services, such as those described in section 935 of the Public Health Service Act.

(viii) Establishing community-based health teams to support small-practice medical homes by assisting the primary care practitioner in chronic care management, including patient self-management, activities.

(ix) Assisting applicable individuals in making informed health care choices by paying providers of services and suppliers for using patient decision-support tools, including tools that meet the standards developed and identified under section 936(c)(2)(A) of the Public Health Service Act, that improve applicable individual and caregiver understanding of medical treatment options.

(x) Allowing States to test and evaluate fully integrating care for dual eligible individuals in the State, including the management and oversight of all funds under the applicable titles with respect to such individuals.

(xi) Allowing States to test and evaluate systems of all-payer payment reform for the medical care of residents of the State, including dual eligible individuals.

(xii) Aligning nationally recognized, evidence-based guidelines of cancer care with payment incentives under title XVIII in the areas of treatment planning and follow-up care planning for applicable individuals described in clause (i) or (iii) of subsection (a)(4)(A) with cancer, including the identification of gaps in applicable quality measures.

(xiii) Improving post-acute care through continuing care hospitals that offer inpatient rehabilitation, long-term care hospitals, and home health or skilled nursing care during an inpatient stay and the 30 days immediately following discharge.

(xiv) Funding home health providers who offer chronic care management services to applicable individuals in cooperation with interdisciplinary teams.

(xv) Promoting improved quality and reduced cost by developing a collaborative of high-quality, low-cost health care institutions that is responsible for—

(I) developing, documenting, and disseminating best practices and proven care methods;

(II) implementing such best practices and proven care methods within such institutions to demonstrate further improvements in quality and efficiency; and

(III) providing assistance to other health care institutions on how best to employ such best practices and proven care methods to improve health care quality and lower costs.

(xvi) Facilitate inpatient care, including intensive care, of hospitalized applicable individuals at their local hospital through the use of electronic monitoring by specialists, including intensivists and critical care specialists, based at integrated health systems.

(xvii) Promoting greater efficiencies and timely access to outpatient services (such as outpatient physical therapy services) through models that do not require a physician or other health professional to refer the service or be involved in establishing the plan of care for the service, when such service is furnished by a health professional who has the authority to furnish the service under existing State law.

(xviii) Establishing comprehensive payments to Healthcare Innovation Zones, consisting of groups of providers that include a teaching hospital, physicians, and other clinical entities, that, through their structure, operations, and joint-activity deliver a full spectrum of integrated and comprehensive health care services to applicable individuals while also incorporating innovative methods for the clinical training of future health care professionals.

(xix) Utilizing, in particular in entities located in medically underserved areas and facilities of the Indian Health Service (whether operated by such Service or by an Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act)), telehealth services—

(I) in treating behavioral health issues (such as post-traumatic stress disorder) and stroke; and

(II) to improve the capacity of non-medical providers and non-specialized medical providers to provide health services for patients with chronic complex conditions.

(xx) Utilizing a diverse network of providers of services and suppliers to improve care coordination for applicable individuals described in subsection (a)(4)(A)(i) with 2 or more chronic conditions and a history of prior-year hospitalization through interventions developed under the Medicare Coordinated Care Demonstration Project under section 4016 of the Balanced Budget Act of 1997 (42 U.S.C. 1395b–1 note).

(xxi) Focusing primarily on physicians' services (as defined in section 1848(j)(3)) furnished by physicians who are not primary care practitioners.

(xxii) Focusing on practices of 15 or fewer professionals.

(xxiii) Focusing on risk-based models for small physician practices which may involve two-sided risk and prospective patient assignment, and which examine risk-adjusted decreases in mortality rates, hospital readmissions rates, and other relevant and appropriate clinical measures.

(xxiv) Focusing primarily on title XIX, working in conjunction with the Center for Medicaid and CHIP Services.

*(xxv) Providing, for the adoption and use of certified EHR technology (as defined in section 1848(o)(4)) to improve the quality and coordination of care through the electronic documentation and exchange of health information, incentive payments to behavioral health providers (such as psychiatric hospitals (as defined in section 1861(f)), community mental health centers (as defined in section 1861(ff)(3)(B)), hospitals that participate in a State plan under title XIX or a waiver of such plan, treatment facilities that participate in such a State plan or such a waiver, mental health or substance use disorder providers that participate in such a State plan or such a waiver, clinical psychologists (as defined in section 1861(ii)), nurse practitioners (as defined in section*

*1861(aa)(5)) with respect to the provision of psychiatric services, and clinical social workers (as defined in section 1861(hh)(1))).*

*(xxv) Supporting ways to familiarize individuals with the availability of coverage under part B of title XVIII for qualified psychologist services (as defined in section 1861(ii)).*

*(xxvi) Exploring ways to avoid unnecessary hospitalizations or emergency department visits for mental and behavioral health services (such as for treating depression) through use of a 24-hour, 7-day a week help line that may inform individuals about the availability of treatment options, including the availability of qualified psychologist services (as defined in section 1861(ii)).*

(C) ADDITIONAL FACTORS FOR CONSIDERATION.—In selecting models for testing under subparagraph (A), the CMI may consider the following additional factors:

(i) Whether the model includes a regular process for monitoring and updating patient care plans in a manner that is consistent with the needs and preferences of applicable individuals.

(ii) Whether the model places the applicable individual, including family members and other informal caregivers of the applicable individual, at the center of the care team of the applicable individual.

(iii) Whether the model provides for in-person contact with applicable individuals.

(iv) Whether the model utilizes technology, such as electronic health records and patient-based remote monitoring systems, to coordinate care over time and across settings.

(v) Whether the model provides for the maintenance of a close relationship between care coordinators, primary care practitioners, specialist physicians, community-based organizations, and other providers of services and suppliers.

(vi) Whether the model relies on a team-based approach to interventions, such as comprehensive care assessments, care planning, and self-management coaching.

(vii) Whether, under the model, providers of services and suppliers are able to share information with patients, caregivers, and other providers of services and suppliers on a real time basis.

(viii) Whether the model demonstrates effective linkage with other public sector payers, private sector payers, or statewide payment models.

(3) BUDGET NEUTRALITY.—

(A) INITIAL PERIOD.—The Secretary shall not require, as a condition for testing a model under paragraph (1), that the design of such model ensure that such model is budget neutral initially with respect to expenditures under the applicable title.

(B) TERMINATION OR MODIFICATION.—The Secretary shall terminate or modify the design and implementation of a model unless the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services, with respect to program spending under the applicable title, certifies), after testing has begun, that the model is expected to—

(i) improve the quality of care (as determined by the Administrator of the Centers for Medicare & Medicaid Services) without increasing spending under the applicable title;

(ii) reduce spending under the applicable title without reducing the quality of care; or

(iii) improve the quality of care and reduce spending.

Such termination may occur at any time after such testing has begun and before completion of the testing.

(4) EVALUATION.—

(A) IN GENERAL.—The Secretary shall conduct an evaluation of each model tested under this subsection. Such evaluation shall include an analysis of—

(i) the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary; and

(ii) the changes in spending under the applicable titles by reason of the model.

(B) INFORMATION.—The Secretary shall make the results of each evaluation under this paragraph available to the public in a timely fashion and may establish requirements for States and other entities participating in the testing of models under this section to collect

and report information that the Secretary determines is necessary to monitor and evaluate such models.

(C) MEASURE SELECTION.—To the extent feasible, the Secretary shall select measures under this paragraph that reflect national priorities for quality improvement and patient-centered care consistent with the measures described in 1890(b)(7)(B).

(c) EXPANSION OF MODELS (PHASE II).—Taking into account the evaluation under subsection (b)(4), the Secretary may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested under subsection (b) or a demonstration project under section 1866C, to the extent determined appropriate by the Secretary, if—

(1) the Secretary determines that such expansion is expected to—

(A) reduce spending under applicable title without reducing the quality of care; or

(B) improve the quality of patient care without increasing spending;

(2) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and

(3) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals.

In determining which models or demonstration projects to expand under the preceding sentence, the Secretary shall focus on models and demonstration projects that improve the quality of patient care and reduce spending.

(d) IMPLEMENTATION.—

(1) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b).

(2) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of—

(A) the selection of models for testing or expansion under this section;

(B) the selection of organizations, sites, or participants to test those models selected;

(C) the elements, parameters, scope, and duration of such models for testing or dissemination;

(D) determinations regarding budget neutrality under subsection (b)(3);

(E) the termination or modification of the design and implementation of a model under subsection (b)(3)(B); and

(F) determinations about expansion of the duration and scope of a model under subsection (c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection.

(3) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models or expansion of such models under this section.

(e) APPLICATION TO CHIP.—The Center may carry out activities under this section with respect to title XXI in the same manner as provided under this section with respect to the program under the applicable titles.

(f) FUNDING.—

(1) IN GENERAL.—There are appropriated, from amounts in the Treasury not otherwise appropriated—

(A) $5,000,000 for the design, implementation, and evaluation of models under subsection (b) for fiscal year 2010;

(B) $10,000,000,000 for the activities initiated under this section for the period of fiscal years 2011 through 2019; and

(C) the amount described in subparagraph (B) for the activities initiated under this section for each subsequent 10-year fiscal period (beginning with the 10-year fiscal period beginning with fiscal year 2020).

Amounts appropriated under the preceding sentence shall remain available until expended.

(2) USE OF CERTAIN FUNDS.—Out of amounts appropriated under subparagraphs (B) and (C) of paragraph (1), not less than $25,000,000 shall be made available each such fiscal year to design, implement, and evaluate models under subsection (b).

(g) REPORT TO CONGRESS.—Beginning in 2012, and not less than once every other year thereafter, the Secretary shall submit to Congress a report on activities under this section. Each such report shall describe the models tested under subsection (b), including the number of individuals

described in subsection (a)(4)(A)(i) and of individuals described in subsection (a)(4)(A)(ii) participating in such models and payments made under applicable titles for services on behalf of such individuals, any models chosen for expansion under subsection (c), and the results from evaluations under subsection (b)(4). In addition, each such report shall provide such recommendations as the Secretary determines are appropriate for legislative action to facilitate the development and expansion of successful payment models.

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**SEC. 1139B. ADULT HEALTH QUALITY MEASURES.**

(a) DEVELOPMENT OF CORE SET OF HEALTH CARE QUALITY MEASURES FOR ADULTS ELIGIBLE FOR BENEFITS UNDER MEDICAID.—The Secretary shall identify and publish a recommended core set of adult health quality measures for Medicaid eligible adults in the same manner as the Secretary identifies and publishes a core set of child health quality measures under section 1139A, including with respect to identifying and publishing existing adult health quality measures that are in use under public and privately sponsored health care coverage arrangements, or that are part of reporting systems that measure both the presence and duration of health insurance coverage over time, that may be applicable to Medicaid eligible adults.

(b) DEADLINES.—

(1) RECOMMENDED MEASURES.—Not later than January 1, 2011, the Secretary shall identify and publish for comment a recommended core set of adult health quality measures for Medicaid eligible adults.

(2) DISSEMINATION.—Not later than January 1, 2012, the Secretary shall publish an initial core set of adult health quality measures that are applicable to Medicaid eligible adults.

(3) STANDARDIZED REPORTING.—[Not later than January 1, 2013]

*(A) VOLUNTARY REPORTING.—Not later than January 1, 2013*, the Secretary, in consultation with States, shall develop a standardized format for reporting information based on the initial core set of adult health quality measures and create procedures to encourage States to use such measures to voluntarily report information regarding the quality of health care for Medicaid eligible adults.

*(B) MANDATORY REPORTING WITH RESPECT TO BEHAVIORAL HEALTH MEASURES.—Beginning with the State report required under subsection (d)(1) for 2024, the Secretary shall require States to use all behavioral health measures included in the core set of adult health quality measures and any updates or changes to such measures to report information, using the standardized format for reporting information and procedures developed under subparagraph (A), regarding the quality of behavioral health care for Medicaid eligible adults.*

(4) REPORTS TO CONGRESS.—Not later than January 1, 2014, and every 3 years thereafter, the Secretary shall include in the report to Congress required under section 1139A(a)(6) information similar to the information required under that section with respect to the measures established under this section.

(5) ESTABLISHMENT OF MEDICAID QUALITY MEASUREMENT PROGRAM.—

(A) IN GENERAL.—Not later than 12 months after the release of the recommended core set of adult health quality measures under paragraph (1)), the Secretary shall establish a Medicaid Quality Measurement Program in the same manner as the Secretary establishes the pediatric quality measures program under section 1139A(b).

(B) REVISING, STRENGTHENING, AND IMPROVING INITIAL CORE MEASURES.—Beginning not later than 24 months after the establishment of the Medicaid Quality Measurement Program, and annually thereafter, the Secretary shall publish recommended changes to the initial core set of adult health quality measures that shall reflect the results of the testing, validation, and consensus process for the development of adult health quality measures.

*(C) BEHAVIORAL HEALTH MEASURES.—Beginning with respect to State reports required under subsection (d)(1) for 2024, the core set of adult health quality measures maintained under this paragraph (and any updates or changes to such measures) shall include behavioral health measures.*

(c) CONSTRUCTION.—Nothing in this section shall be construed as supporting the restriction of coverage, under title XIX or XXI or otherwise, to only those services that are evidence-based, or in anyway limiting available services.

(d) ANNUAL STATE REPORTS REGARDING STATE-SPECIFIC QUALITY OF CARE MEASURES APPLIED UNDER MEDICAID.—

(1) ANNUAL STATE REPORTS.—Each State with a State plan or waiver approved under title XIX shall annually report (separately or as part of the annual report required under section 1139A(c)), to the Secretary on the—

(A) State-specific adult health quality measures applied by the State under [the such plan] *such plan*, including measures described in [subsection (a)(5)] *subsection (b)(5) and, beginning with the report for 2024, all behavioral health measures included in the core set of adult health quality measures maintained under such subsection (b)(5) and any updates or changes to such measures (as required under subsection (b)(3))*; and

(B) State-specific information on the quality of health care furnished to Medicaid eligible adults under such plan, including information collected through external quality reviews of managed care organizations under section 1932 and benchmark plans under section 1937.

(2) PUBLICATION.—Not later than September 30, 2014, and annually thereafter, the Secretary shall collect, analyze, and make publicly available the information reported by States under paragraph (1).

(e) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated for each of fiscal years 2010 through 2014, $60,000,000 for the purpose of carrying out this section. Funds appropriated under this subsection shall remain available until expended. Of the funds appropriated under this subsection, not less than $15,000,000 shall be used to carry out section 1139A(b).

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## TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

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### NOTICE OF MEDICARE BENEFITS; MEDICARE AND MEDIGAP INFORMATION

SEC. 1804. (a) The Secretary shall prepare (in consultation with groups representing the elderly and with health insurers) and provide for distribution of a notice containing—

(1) a clear, simple explanation of the benefits available under this title and the major categories of health care for which benefits are not available under this title,

(2) the limitations on payment (including deductibles and coinsurance amounts) that are imposed under this title, and

(3) a description of the limited benefits for long-term care services available under this title and generally available under State plans approved under title XIX.

Such notice shall be mailed annually to individuals entitled to benefits under part A or part B of this title and when an individual applies for benefits under part A or enrolls under part B.

(b) The Secretary shall provide information via a toll-free telephone number on the programs under this title. The Secretary shall provide, through the toll-free telephone number 1–800–MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the toll-free number listed for general information and assistance in the annual notice under subsection (a) instead of the listing of numbers of individual contractors.

(c) The notice provided under subsection (a) shall include—

(1) a statement which indicates that because errors do occur and because medicare fraud, waste, and abuse is a significant problem, beneficiaries should carefully check any explanation of benefits or itemized statement furnished pursuant to section 1806 for accuracy and report any errors or questionable charges by calling the toll-free phone number described in paragraph (4);

(2) a statement of the beneficiary's right to request an itemized statement for medicare items and services (as provided in section 1806(b));

(3) a description of the program to collect information on medicare fraud and abuse established under section 203(b) of the Health Insurance Portability and Accountability Act of 1996; and

(4) a toll-free telephone number maintained by the Inspector General in the Department of Health and Human Services for the receipt of complaints and information about waste, fraud, and abuse in the provision or billing of services under this title.

*(d) The notice provided under subsection (a) shall include—*

*(1) educational resources, compiled by the Secretary, regarding opioid use and pain management; and*

*(2) a description of alternative, non-opioid pain management treatments covered under this title.*

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PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

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PAYMENT OF BENEFITS

SEC. 1833.. (a) Except as provided in section 1876, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—(1) in the case of services described in section 1832(a)(1)—80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis (and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services) may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b), (B) with respect to items and services described in section 1861(s)(10)(A), the amounts paid shall be 100 percent of the reasonable charges for such items and services, (C) with respect to expenses incurred for those physicians' services for which payment may be made under this part that are described in section 1862(a)(4), the amounts paid shall be subject to such limitations as may be prescribed by regulations, (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I) on the basis of a fee schedule under subsection (h)(1) (for tests furnished before January 1, 2017) or section 1834(d)(1), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (II) undersection 1834A (for tests furnished on or after January1, 2017), the amount paid shall be equal to 80 percent(or 100 percent, in the case of such tests for whichpayment is made on an assignment-related basis) ofthe lesser of the amount determined under such sectionor the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017,on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate,,(E) with respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1881,(F) with respect to clinical social worker services under section 1861(s)(2)(N), the amounts paid shall be 80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist under clause (L),

(G) with respect to facility services furnished in connection with a surgical procedure specified pursuant to subsection (i)(1)(A) and furnished to an individual in an ambulatory surgical center described in such subsection, for services furnished beginning with the implementation date of a revised payment system for such services in such facilities specified in subsection (i)(2)(D), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system,

(H) with respect to services of a certified registered nurse anesthetist under section 1861(s)(11), the amounts paid shall be 80 percent of the least of the actual charge, the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1848) if the services had been performed by an anesthesiologist, or the fee schedule for such services established by the Secretary in accordance with subsection (l), (I) with respect to covered items (described in section 1834(a)(13)), the amounts paid shall be the amounts described in section 1834(a)(1), and(J) with respect to

expenses incurred for radiologist services (as defined in section 1834(b)(6)), subject to section 1848, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount provided under the fee schedule established under section 1834(b), (K) with respect to certified nurse-midwife services under section 1861(s)(2)(L), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph (but in no event shall such fee schedule exceed 65 percent of the prevailing charge that would be allowed for the same service performed by a physician, or, for services furnished on or after January 1, 1992, 65 percent (or 100 percent for services furnished on or after January 1, 2011) of the fee schedule amount provided under section 1848 for the same service performed by a physician), (L) with respect to qualified psychologist services under section 1861(s)(2)(M), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, (M) with respect to prosthetic devices and orthotics and prosthetics (as defined in section 1834(h)(4)), the amounts paid shall be the amounts described in section 1834(h)(1), (N) with respect to expenses incurred for physicians' services (as defined in section 1848(j)(3)) other than personalized prevention plan services (as defined in section 1861(hhh)(1)), the amounts paid shall be 80 percent of the payment basis determined under section 1848(a)(1), (O) with respect to services described in section 1861(s)(2)(K) (relating to services furnished by physician assistants, nurse practitioners, or clinic nurse specialists), the amounts paid shall be equal to 80 percent of (i) the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1848, or (ii) in the case of services as an assistant at surgery, the lesser of the actual charge or 85 percent of the amount that would otherwise be recognized if performed by a physician who is serving as an assistant at surgery, (P) with respect to surgical dressings, the amounts paid shall be the amounts determined under section 1834(i), (Q) with respect to items or services for which fee schedules are established pursuant to section 1842(s), the amounts paid shall be 80 percent of the lesser of the actual charge or the fee schedule established in such section, (R) with respect to ambulance services, (i) the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary under section 1834(l) and (ii) with respect to ambulance services described in section 1834(l)(8), the amounts paid shall be the amounts determined under section 1834(g) for outpatient critical access hospital services, (S) with respect to drugs and biologicals (including intravenous immune globulin (as defined in section 1861(zz))) not paid on a cost or prospective payment basis as otherwise provided in this part (other than items and services described in subparagraph (B)), the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1842(o) (or, if applicable, under section 1847, 1847A, or 1847B), (T) with respect to medical nutrition therapy services (as defined in section 1861(vv)), the amount paid shall be 80 percent (or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual) of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) for the same services if furnished by a physician, (U) with respect to facility fees described in section 1834(m)(2)(B), the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section, (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1842(s) items), with respect to competitively priced items and services (described in section 1847(a)(2)) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1847(b)(5), (W) with respect to additional preventive services (as defined in section 1861(ddd)(1)), the amount paid shall be (i) in the case of such services which are clinical diagnostic laboratory tests, the amount determined under subparagraph (D) (if such subparagraph were applied, by substituting "100 percent" for "80 percent"), and (ii) in the case of all other such services, 100 percent of the lesser of the actual charge for the service or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph, (X) with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)), the amount paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined under the payment basis determined under section 1848, (Y) with respect to preventive services described in subparagraphs (A) and (B) of section 1861(ddd)(3) that are appropriate for the individual and, in the case of such services described

in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population, the amount paid shall be 100 percent of (i) except as provided in clause (ii), the lesser of the actual charge for the services or the amount determined under the fee schedule that applies to such services under this part, and (ii) in the case of such services that are covered OPD services (as defined in subsection (t)(1)(B)), the amount determined under subsection (t), (Z) with respect to Federally qualified health center services for which payment is made under section 1834(o), the amounts paid shall be 80 percent of the lesser of the actual charge or the amount determined under such section, (AA) with respect to an applicable disposable device (as defined in paragraph (2) of section 1834(s)) furnished to an individual pursuant to paragraph (1) of such section, the amount paid shall be equal to 80 percent of the lesser of the actual charge or the amount determined under paragraph (3) of such section, [and] (BB) with respect to home infusion therapy, the amount paid shall be an amount equal to 80 percent of the lesser of the actual charge for the services or the amount determined under section 1834(u)*, and (CC) with respect to opioid use disorder treatment services furnished during an episode of care, the amount paid shall be equal to the amount payable under section 1834(w) less any copayment required as specified by the Secretary*;

(2) in the case of services described in section 1832(a)(2) (except those services described in subparagraphs (C), (D), (E), (F), (G), (H), and (I) of such section and unless otherwise specified in section 1881)—

(A) with respect to home health services (other than a covered osteoporosis drug) (as defined in section 1861(kk)), the amount determined under the prospective payment system under section 1895;

(B) with respect to other items and services (except those described in subparagraph (C), (D), or (E) of this paragraph and except as may be provided in section 1886 or section 1888(e)(9))—

(i) furnished before January 1, 1999, the lesser of—

(I) the reasonable cost of such services, as determined under section 1861(v), or

(II) the customary charges with respect to such services,—less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A), but in no case may the payment for such other services exceed 80 percent of such reasonable cost, or

(ii) if such services are furnished before January 1, 1999, by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this clause), free of charge or at nominal charges to the public, 80 percent of the amount determined in accordance with section 1814(b)(2), or

(iii) if such services are furnished on or after January 1, 1999, the amount determined under subsection (t), or

(iv) if (and for so long as) the conditions described in section 1814(b)(3) are met, the amounts determined under the reimbursement system described in such section;

(C) with respect to services described in the second sentence of section 1861(p), 80 percent of the reasonable charges for such services;

(D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I)on the basis of a fee schedule determined under subsection(h)(1) (for tests furnished before January 1, 2017) or section 1834(d)(1), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1866) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (II) under section 1834A (for tests furnished on or after January 1, 2017), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1866) of the lesser of the amount determined under such section or the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017, on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate for such tests;

(E) with respect to—

(i) outpatient hospital radiology services (including diagnostic and therapeutic radiology, nuclear medicine and CAT scan procedures, magnetic resonance imaging, and ultrasound and other imaging services, but excluding screening mammography and, for services furnished on or after January 1, 2005, diagnostic mammography), and

(ii) effective for procedures performed on or after October 1, 1989, diagnostic procedures (as defined by the Secretary) described in section 1861(s)(3) (other than diagnostic x-ray tests and diagnostic laboratory tests),

the amount determined under subsection (n) or, for services or procedures performed on or after January 1, 1999, subsection (t);

(F) with respect to a covered osteoporosis drug (as defined in section 1861(kk)) furnished by a home health agency, 80 percent of the reasonable cost of such service, as determined under section 1861(v);

(G) with respect to items and services described in section 1861(s)(10)(A), the lesser of—

(i) the reasonable cost of such services, as determined under section 1861(v), or

(ii) the customary charges with respect to such services; and

(H) with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)) furnished by an outpatient department of a hospital, the amount determined under paragraph (1)(X),

or, if such services are furnished by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this provision), free of charge or at nominal charges to the public, the amount determined in accordance with section 1814(b)(2);

(3) in the case of services described in section 1832(a)(2)(D)—

(A) except as provided in subparagraph (B), the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1861(v)(1)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A), but in no case may the payment for such services (other than for items and services described in section 1861(s)(10)(A)) exceed 80 percent of such costs; or

(B) with respect to the services described in clause (ii) of section 1832(a)(2)(D) that are furnished to an individual enrolled with a MA plan under part C pursuant to a written agreement described in section 1853(a)(4), the amount (if any) by which—

(i) the amount of payment that would have otherwise been provided (I) under subparagraph (A) (calculated as if "100 percent" were substituted for "80 percent" in such subparagraph) for such services if the individual had not been so enrolled, or (II) in the case of such services furnished on or after the implementation date of the prospective payment system under section 1834(o), under such section (calculated as if "100 percent" were substituted for "80 percent" in such section) for such services if the individual had not been so enrolled; exceeds

(ii) the amount of the payments received under such written agreement for such services (not including any financial incentives provided for in such agreement such as risk pool payments, bonuses, or withholds),

less the amount the federally qualified health center may charge as described in section 1857(e)(3)(B);

(4) in the case of facility services described in section 1832(a)(2)(F), and outpatient hospital facility services furnished in connection with surgical procedures specified by the Secretary pursuant to section 1833(i)(1)(A), the applicable amount as determined under paragraph (2) or (3) of subsection (i) or subsection (t);

(5) in the case of covered items (described in section 1834(a)(13)) the amounts described in section 1834(a)(1);

(6) in the case of outpatient critical access hospital services, the amounts described in section 1834(g);

(7) in the case of prosthetic devices and orthotics and prosthetics (as described in section 1834(h)(4)), the amounts described in section 1834(h);

(8) in the case of—

(A) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a rehabilitation agency, public health agency, clinic, comprehensive outpatient rehabilitation facility, or skilled nursing facility,

(ii) by a home health agency to an individual who is not homebound, or

(iii) by another entity under an arrangement with an entity described in clause (i) or (ii); and

(B) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a hospital to an outpatient or to a hospital inpatient who is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness or is not so entitled to benefits under part A, or

(ii) by another entity under an arrangement with a hospital described in clause (i),

the amounts described in section 1834(k); and

(9) in the case of services described in section 1832(a)(2)(E) that are not described in paragraph (8), the amounts described in section 1834(k).

Paragraph (3)(A) shall not apply to Federally qualified health center services furnished on or after the implementation date of the prospective payment system under section 1834(0).

(b) Before applying subsection (a) with respect to expenses incurred by an individual during any calendar year, the total amount of the expenses incurred by such individual during such year (which would, except for this subsection, constitute incurred expenses from which benefits payable under subsection (a) are determinable) shall be reduced by a deductible of $75 for calendar years before 1991, $100 for 1991 through 2004, $110 for 2005, and for a subsequent year the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) ending with such subsequent year (rounded to the nearest $1); except that (1) such total amount shall not include expenses incurred for preventive services described in subparagraph (A) of section 1861(ddd)(3) that are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual., (2) such deductible shall not apply with respect to home health services (other than a covered osteoporosis drug (as defined in section 1861(kk))), (3) such deductible shall not apply with respect to clinical diagnostic laboratory tests for which payment is made under this part (A) under subsection (a)(1)(D)(i) or (a)(2)(D)(i) on an assignment-related basis, or to a provider having an agreement under section 1866, or (B) for tests furnished before January 1, 2017,on the basis of a negotiated rate determined under subsection (h)(6), (4) such deductible shall not apply to Federally qualified health center services, (5) such deductible shall not apply with respect to screening mammography (as described in section 1861(jj)), (6) such deductible shall not apply with respect to screening pap smear and screening pelvic exam (as described in section 1861(nn)), (7) such deductible shall not apply with respect to ultrasound screening for abdominal aortic aneurysm (as defined in section 1861(bbb)), (8) such deductible shall not apply with respect to colorectal cancer screening tests (as described in section 1861(pp)(1)), (9) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1861(ww)), and (10) such deductible shall not apply with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)). The total amount of the expenses incurred by an individual as determined under the preceding sentence shall, after the reduction specified in such sentence, be further reduced by an amount equal to the expenses incurred for the first three pints of whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished to the individual during the calendar year, except that such deductible for such blood shall in accordance with regulations be appropriately reduced to the extent that there has been a replacement of such blood (or equivalent quantities of packed red blood cells, as so defined); and for such purposes blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual shall be deemed replaced when the institution or other person furnishing such blood (or such equivalent quantities of packed red blood cells, as so defined) is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is made under this sentence. The deductible under the previous sentence for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1813(a)(2) to blood or blood cells furnished the individual in the year. Paragraph (1) of the first sentence of this subsection shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue

or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

(c)(1) Notwithstanding any other provision of this part, with respect to expenses incurred in a calendar year in connection with the treatment of mental, psychoneurotic, and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b)—

(A) for expenses incurred in years prior to 2010, only 62½ percent of such expenses;

(B) for expenses incurred in 2010 or 2011, only 68¾ percent of such expenses;

(C) for expenses incurred in 2012, only 75 percent of such expenses;

(D) for expenses incurred in 2013, only 81¼ percent of such expenses; and

(E) for expenses incurred in 2014 or any subsequent calendar year, 100 percent of such expenses.

(2) For purposes of subparagraphs (A) through (D) of paragraph (1), the term "treatment" does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by a physician

(d) No payment may be made under this part with respect to any services furnished an individual to the extent that such individual is entitled (or would be entitled except for section 1813) to have payment made with respect to such services under part A.

(e) No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

(f) In establishing limits under subsection (a) on payment for rural health clinic services provided by rural health clinics (other than such clinics in hospitals with less than 50 beds), the Secretary shall establish such limit, for services provided—

(1) in 1988, after March 31, at $46 per visit, and

(2) in a subsequent year, at the limit established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) applicable to primary care services (as defined in section 1842(i)(4)) furnished as of the first day of that year.

(g)(1)(A) Subject to paragraphs (4) and (5), in the case of physical therapy services of the type described in section 1861(p) and speech-language pathology services of the type described in such section through the application of section 1861(ll)(2), but (except as provided in paragraph (6)) not described in subsection (a)(8)(B), and physical therapy services and speech-language pathology services of such type which are furnished by a physician or as incident to physicians' services, with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b). The preceding sentence shall not apply to expenses incurred with respect to services furnished after December 31, 2017.

(B) With respect to services furnished during 2018 or a subsequent year, in the case of physical therapy services of the type described in section 1861(p), speech-language pathology services of the type described in such section through the application of section 1861(ll)(2), and physical therapy services and speech-language pathology services of such type which are furnished by a physician or as incident to physicians' services, with respect to expenses incurred in any calendar year, any amount that is more than the amount specified in paragraph (2) for the year shall not be considered as incurred expenses for purposes of subsections (a) and (b) unless the applicable requirements of paragraph (7) are met.

(2) The amount specified in this paragraph—

(A) for 1999, 2000, and 2001, is $1,500, and

(B) for a subsequent year is the amount specified in this paragraph for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year;

except that if an increase under subparagraph (B) for a year is not a multiple of $10, it shall be rounded to the nearest multiple of $10.

(3)(A) Subject to paragraphs (4) and (5), in the case of occupational therapy services (of the type that are described in section 1861(p) (but (except as provided in paragraph (6)) not described in subsection (a)(8)(B)) through the operation of section 1861(g) and of such type which are furnished by a physician or as incident to physicians' services), with respect to expenses incurred in

any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b). The preceding sentence shall not apply to expenses incurred with respect to services furnished after December 31, 2017.

(B) With respect to services furnished during 2018 or a subsequent year, in the case of occupational therapy services (of the type that are described in section 1861(p) through the operation of section 1861(g) and of such type which are furnished by a physician or as incident to physicians' services), with respect to expenses incurred in any calendar year, any amount that is more than the amount specified in paragraph (2) for the year shall not be considered as incurred expenses for purposes of subsections (a) and (b) unless the applicable requirements of paragraph (7) are met.

(4) This subsection shall not apply to expenses incurred with respect to services furnished during 2000, 2001, 2002, 2004, and 2005.

(5)(A) With respect to expenses incurred during the period beginning on January 1, 2006, and ending on December 31, 2017, for services, the Secretary shall implement a process under which an individual enrolled under this part may, upon request of the individual or a person on behalf of the individual, obtain an exception from the uniform dollar limitation specified in paragraph (2), for services described in paragraphs (1) and (3) if the provision of such services is determined to be medically necessary and if the requirement of subparagraph (B) is met. Under such process, if the Secretary does not make a decision on such a request for an exception within 10 business days of the date of the Secretary's receipt of the request made in accordance with such requirement, the Secretary shall be deemed to have found the services to be medically necessary.

(B) In the case of outpatient therapy services for which an exception is requested under the first sentence of subparagraph (A), the claim for such services shall contain an appropriate modifier (such as the KX modifier used as of the date of the enactment of this subparagraph) indicating that such services are medically necessary as justified by appropriate documentation in the medical record involved.

(C)(i) In applying this paragraph with respect to a request for an exception with respect to expenses that would be incurred for outpatient therapy services (including services described in subsection (a)(8)(B)) that would exceed the threshold described in clause (ii) for a year, the request for such an exception, for services furnished on or after October 1, 2012, shall be subject to a manual medical review process that, subject to subparagraph (E), is similar to the manual medical review process used for certain exceptions under this paragraph in 2006.

(ii) The threshold under this clause for a year is $3,700. Such threshold shall be applied separately—

(I) for physical therapy services and speech-language pathology services; and

(II) for occupational therapy services.

(E)(i) In place of the manual medical review process under subparagraph (C)(i), the Secretary shall implement a process for medical review under this subparagraph under which the Secretary shall identify and conduct medical review for services described in subparagraph (C)(i) furnished by a provider of services or supplier (in this subparagraph referred to as a "therapy provider") using such factors as the Secretary determines to be appropriate.

(ii) Such factors may include the following:

(I) The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this title.

(II) The therapy provider has a pattern of billing for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.

(III) The therapy provider is newly enrolled under this title or has not previously furnished therapy services under this part.

(IV) The services are furnished to treat a type of medical condition.

(V) The therapy provider is part of group that includes another therapy provider identified using the factors determined under this subparagraph.

(iii) For purposes of carrying out this subparagraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for fiscal years 2015 and 2016, to remain available until expended. Such funds may not be used by a contractor under section 1893(h) for medical reviews under this subparagraph.

(iv) The targeted review process under this subparagraph shall not apply to services for which expenses are incurred beyond the period for which the exceptions process under subparagraph (A) is implemented, except as such process is applied under paragraph (7)(B).

(6)(A) In applying paragraphs (1) and (3) to services furnished during the period beginning not later than October 1, 2012, and ending on December 31, 2017, the exclusion of services described in subsection (a)(8)(B) from the uniform dollar limitation specified in paragraph (2) shall not apply to such services furnished during 2012 through 2017.

(B)(i) With respect to outpatient therapy services furnished beginning on or after January 1, 2013, and before January 1, 2014, for which payment is made under section 1834(g), the Secretary shall count toward the uniform dollar limitations described in paragraphs (1) and (3) and the threshold described in paragraph (5)(C) the amount that would be payable under this part if such services were paid under section 1834(k)(1)(B) instead of being paid under section 1834(g).

(ii) Nothing in clause (i) shall be construed as changing the method of payment for outpatient therapy services under section 1834(g).

(7) For purposes of paragraphs (1)(B) and (3)(B), with respect to services described in such paragraphs, the requirements described in this paragraph are as follows:

(A) INCLUSION OF APPROPRIATE MODIFIER.—The claim for such services contains an appropriate modifier (such as the KX modifier described in paragraph (5)(B)) indicating that such services are medically necessary as justified by appropriate documentation in the medical record involved.

(B) TARGETED MEDICAL REVIEW FOR CERTAIN SERVICES ABOVE THRESHOLD.—

(i) IN GENERAL.—In the case where expenses that would be incurred for such services would exceed the threshold described in clause (ii) for the year, such services shall be subject to the process for medical review implemented under paragraph (5)(E).

(ii) THRESHOLD.—The threshold under this clause for—

(I) a year before 2028, is $3,000;

(II) 2028, is the amount specified in subclause (I) increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for 2028; and

(III) a subsequent year, is the amount specified in this clause for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year;

except that if an increase under subclause (II) or (III) for a year is not a multiple of $10, it shall be rounded to the nearest multiple of $10.

(iii) APPLICATION.—The threshold under clause (ii) shall be applied separately—

(I) for physical therapy services and speech-language pathology services; and

(II) for occupational therapy services.

(iv) FUNDING.—For purposes of carrying out this subparagraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of $5,000,000 for each fiscal year beginning with fiscal year 2018, to remain available until expended. Such funds may not be used by a contractor under section 1893(h) for medical reviews under this subparagraph.

(8) With respect to services furnished on or after January 1, 2013, where payment may not be made as a result of application of paragraphs (1) and (3), section 1879 shall apply in the same manner as such section applies to a denial that is made by reason of section 1862(a)(1).

(h)(1)(A) Subject to section 1834(d)(1), the Secretary shall establish fee schedules for clinical diagnostic laboratory tests (including prostate cancer screening tests under section 1861(oo) consisting of prostate-specific antigen blood tests) for which payment is made under this part, other than such tests performed by a provider of services for an inpatient of such provider.

(B) In the case of clinical diagnostic laboratory tests performed by a physician or by a laboratory (other than tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital), the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(C) In the case of clinical diagnostic laboratory tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital, the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(D) In this subsection, the term "qualified hospital laboratory" means a hospital laboratory, in a sole community hospital (as defined in section 1886(d)(5)(D)(iii)), which provides some clinical diagnostic laboratory tests 24 hours a day in order to serve a hospital emergency room which is available to provide services 24 hours a day and 7 days a week.

(2)(A)(i) Except as provided in clause (v), subparagraph (B), and paragraph (4), the Secretary shall set the fee schedules at 60 percent (or, in the case of a test performed by a qualified hospital laboratory (as defined in paragraph (1)(D)) for outpatients of such hospital, 62 percent) of the prevailing charge level determined pursuant to the third and fourth sentences of section 1842(b)(3) for similar clinical diagnostic laboratory tests for the applicable region, State, or area for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by, subject to clause (iv), a percentage increase or decrease equal to the percentage increase or decrease in the Consumer Price Index for All Urban Consumers (United States city average) minus, for each of the years 2009 and 2010, 0.5 percentage points, and, for tests furnished before the dateof enactment of section 1834A, subject to such other adjustments as the Secretary determines are justified by technological changes.

(ii) Notwithstanding clause (i)—

(I) any change in the fee schedules which would have become effective under this subsection for tests furnished on or after January 1, 1988, shall not be effective for tests furnished during the 3-month period beginning on January 1, 1988,

(II) the Secretary shall not adjust the fee schedules under clause (i) to take into account any increase in the consumer price index for 1988,

(III) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1991, 1992, and 1993 shall be 2 percent, and

(IV) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1994 and 1995, 1998 through 2002, and 2004 through 2008 shall be 0 percent.

(iii) In establishing fee schedules under clause (i) with respect to automated tests and tests (other than cytopathology tests) which before July 1, 1984, the Secretary made subject to a limit based on lowest charge levels under the sixth sentence of section 1842(b)(3) performed after March 31, 1988, the Secretary shall reduce by 8.3 percent the fee schedules otherwise established for 1988, and such reduced fee schedules shall serve as the base for 1989 and subsequent years.

(iv) After determining the adjustment to the fee schedules under clause (i), the Secretary shall reduce such adjustment—

(I) for 2011 and each subsequent year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(II) for each of 2011 through 2015, by 1.75 percentage points.

Subclause (I) shall not apply in a year where the adjustment to the fee schedules determined under clause (i) is 0.0 or a percentage decrease for a year. The application of the productivity adjustment under subclause (I) shall not result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year. The application of subclause (II) may result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

(v) The Secretary shall reduce by 2 percent the fee schedules otherwise determined under clause (i) for 2013, and such reduced fee schedules shall serve as the base for 2014 and subsequent years.

(B) The Secretary may make further adjustments or exceptions to the fee schedules to assure adequate reimbursement of (i) emergency laboratory tests needed for the provision of bona fide emergency services, and (ii) certain low volume high-cost tests where highly sophisticated equipment or extremely skilled personnel are necessary to assure quality.

(3) In addition to the amounts provided under the fee schedules (for tests furnished before January 1, 2017)or under section 1834A (for tests furnished on or afterJanuary 1, 2017), subject to subsection (b)(5) of such section, the Secretary shall provide for and establish (A) a nominal fee to cover the appropriate costs in collecting the sample on which a clinical diagnostic laboratory test was performed and for which payment is made under this part, except that not more than one such fee may be provided under this paragraph with respect to samples collected in the same encounter, and (B) a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). In establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample, but the Secretary shall only be required to apply such method in the case of tests furnished during the period beginning on April 1, 1989, and ending on December 31, 1990, by a laboratory that establishes to the satisfaction

of the Secretary (based on data for the 12-month period ending June 30, 1988) that (i) the laboratory is dependent upon payments under this title for at least 80 percent of its collected revenues for clinical diagnostic laboratory tests, (ii) at least 85 percent of its gross revenues for such tests are attributable to tests performed with respect to individuals who are homebound or who are residents in a nursing facility, and (iii) the laboratory provided such tests for residents in nursing facilities representing at least 20 percent of the number of such facilities in the State in which the laboratory is located.

(4)(A) In establishing any fee schedule under this subsection, the Secretary may provide for an adjustment to take into account, with respect to the portion of the expenses of clinical diagnostic laboratory tests attributable to wages, the relative difference between a region's or local area's wage rates and the wage rate presumed in the data on which the schedule is based.

(B) For purposes of subsections (a)(1)(D)(i) and (a)(2)(D)(i), the limitation amount for a clinical diagnostic laboratory test performed—

(i) on or after July 1, 1986, and before April 1, 1988, is equal to 115 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(ii) after March 31, 1988, and before January 1, 1990, is equal to the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iii) after December 31, 1989, and before January 1, 1991, is equal to 93 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iv) after December 31, 1990, and before January 1, 1994, is equal to 88 percent of such median,

(v) after December 31, 1993, and before January 1, 1995, is equal to 84 percent of such median,

(vi) after December 31, 1994, and before January 1, 1996, is equal to 80 percent of such median,

(vii) after December 31, 1995, and before January 1, 1998, is equal to 76 percent of such median, and

(viii) after December 31, 1997, is equal to 74 percent of such median (or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established under this subparagraph).

(5)(A) In the case of a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part on an assignment-related basis or under a provider agreement under section 1866, payment may be made only to the person or entity which performed or supervised the performance of such test; except that—

(i) if a physician performed or supervised the performance of such test, payment may be made to another physician with whom he shares his practice,

(ii) in the case of a test performed at the request of a laboratory by another laboratory, payment may be made to the referring laboratory but only if—

(I) the referring laboratory is located in, or is part of, a rural hospital,

(II) the referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly-owned by a third entity, or

(III) not more than 30 percent of the clinical diagnostic laboratory tests for which such referring laboratory (but not including a laboratory described in subclause (II)), receives requests for testing during the year in which the test is performed are performed by another laboratory, and

(iii) in the case of a clinical diagnostic laboratory test provided under an arrangement (as defined in section 1861(w)(1)) made by a hospital, critical access hospital, or skilled nursing facility, payment shall be made to the hospital or skilled nursing facility.

(B) In the case of such a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part, and which is not described in subparagraph (A), payment may be made to the beneficiary only on the basis of the itemized bill of the person or entity which performed or supervised the performance of the test.

(C) Payment for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic may only be made on an assignment-related basis or to a provider of services with an agreement in effect under section 1866.

(D) A person may not bill for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic, other than on an assignment-related basis. If a person knowingly and willfully and on a repeated basis bills for a clinical diagnostic laboratory test in violation of the previous sentence, the Secretary may apply sanctions against the person in the same manner as the Secretary may apply sanctions against a physician in accordance with paragraph (2) of section 1842(j) in the same manner such paragraphs apply with respect to a physician. Paragraph (4) of such section shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(6) For tests furnished before January 1, 2017, inthe case of any diagnostic laboratory test payment for which is not made on the basis of a fee schedule under paragraph (1), the Secretary may establish a payment rate which is acceptable to the person or entity performing the test and which would be considered the full charge for such tests. Such negotiated rate shall be limited to an amount not in excess of the total payment that would have been made for the services in the absence of such rate.

(7) Notwithstanding paragraphs (1) and (4)and section 1834A, the Secretary shall establish a national minimum payment amount under this part for a diagnostic or screening pap smear laboratory test (including all cervical cancer screening technologies that have been approved by the Food and Drug Administration as a primary screening method for detection of cervical cancer) equal to $14.60 for tests furnished in 2000. For such tests furnished in subsequent years, such national minimum payment amount shall be adjusted annually as provided in paragraph (2).

(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as "new tests").

(B) Determinations under subparagraph (A) shall be made only after the Secretary—

(i) makes available to the public (through an Internet website and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

(i) set forth the criteria for making determinations under subparagraph (A); and

(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

(E) For purposes of this paragraph:

(i) The term "HCPCS" refers to the Health Care Procedure Coding System.

(ii) A code shall be considered to be "substantially revised" if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).

(9) Notwithstanding any other provision in this part, in the case of any diagnostic laboratory test for HbA1c that is labeled by the Food and Drug Administration for home use and is furnished on or after April 1, 2008, the payment rate for such test shall be the payment rate established under this part for a glycated hemoglobin test (identified as of October 1, 2007, by HCPCS code 83036 (and any succeeding codes)).

(i)(1) The Secretary shall, in consultation with appropriate medical organizations—

(A) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ambulatory surgical center (meeting the standards specified under section 1832(a)(2)(F)(i)), critical access hospital, or hospital outpatient department, and

(B) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in a physician's office.

The lists of procedures established under subparagraphs (A) and (B) shall be reviewed and updated not less often than every 2 years, in consultation with appropriate trade and professional organizations.

(2)(A) For services furnished prior to the implementation of the system described in subparagraph (D), subject to subparagraph (E), the amount of payment to be made for facility services furnished in connection with a surgical procedure specified pursuant to paragraph (1)(A) and furnished to an individual in an ambulatory surgical center described in such paragraph shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which—

(i) takes into account the costs incurred by such centers, or classes of centers, generally in providing services furnished in connection with the performance of such procedure, as determined in accordance with a survey (based upon a representative sample of procedures and facilities) of the actual audited costs incurred by such centers in providing such services,

(ii) takes such costs into account in such a manner as will assure that the performance of the procedure in such a center will result in substantially less amounts paid under this title than would have been paid if the procedure had been performed on an inpatient basis in a hospital, and

(iii) in the case of insertion of an intraocular lens during or subsequent to cataract surgery includes payment which is reasonable and related to the cost of acquiring the class of lens involved.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(B) The amount of payment to be made under this part for facility services furnished, in connection with a surgical procedure specified pursuant to paragraph (1)(B), in a physician's office shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which—

(i) takes into account additional costs, not usually included in the professional fee, incurred by physicians in securing, maintaining, and staffing the facilities and ancillary services appropriate for the performance of such procedure in the physician's office, and

(ii) takes such items into account in such a manner which will assure that the performance of such procedure in the physician's office will result in substantially less amounts paid under this title than would have been paid if the services had been furnished on an inpatient basis in a hospital.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(C)(i) Notwithstanding the second sentence of each of subparagraphs (A) and (B), except as otherwise specified in clauses (ii), (iii), and (iv), if the Secretary has not updated amounts established under such subparagraphs or under subparagraph (D), with respect to facility services furnished during a fiscal year (beginning with fiscal year 1986 or a calendar year (beginning with 2006)), such amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(ii) In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.

(iii) In fiscal year 2004, beginning with April 1, 2004, the increase under this subparagraph shall be the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with March 31, 2003, minus 3.0 percentage points.

(iv) In fiscal year 2005, the last quarter of calendar year 2005, and each of calendar years 2006 through 2009, the increase under this subparagraph shall be 0 percent.

(D)(i) Taking into account the recommendations in the report under section 626(d) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall implement a revised payment system for payment of surgical services furnished in ambulatory surgical centers.

(ii) In the year the system described in clause (i) is implemented, such system shall be designed to result in the same aggregate amount of expenditures for such services as would be made if this subparagraph did not apply, as estimated by the Secretary and taking into account reduced expenditures that would apply if subparagraph (E) were to continue to apply, as estimated by the Secretary.

(iii) The Secretary shall implement the system described in clause (i) for periods in a manner so that it is first effective beginning on or after January 1, 2006, and not later than January 1, 2008.

(iv) The Secretary may implement such system in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).

(v) In implementing the system described in clause (i) for 2011 and each subsequent year, any annual update under such system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in such update being less than 0.0 for a year, and may result in payment rates under the system described in clause (i) for a year being less than such payment rates for the preceding year.

(vi) There shall be no administrative or judicial review under section 1869, 1878, or otherwise, of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, under this subparagraph.

(E) With respect to surgical procedures furnished on or after January 1, 2007, and before the effective date of the implementation of a revised payment system under subparagraph (D), if—

(i) the standard overhead amount under subparagraph (A) for a facility service for such procedure, without the application of any geographic adjustment, exceeds

(ii) the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of section 1833(t) for such service for such year, determined without regard to geographic adjustment under paragraph (2)(D) of such section,

the Secretary shall substitute under subparagraph (A) the amount described in clause (ii) for the standard overhead amount for such service referred to in clause (i).

*(F)(i) With respect to a targeted procedure (as defined in clause (ii)) furnished during 2020 or a subsequent year (before 2024) to an individual in an ambulatory surgical center, the payment amount for such procedure that would otherwise be determined under the revised payment system under subparagraph (D), without application of this subparagraph, shall be equal to the payment amount for such procedure furnished in 2016.*

*(ii) For purposes of clause (i), the term "targeted procedure" means a procedure to which Healthcare Common Procedure Coding System 62310 (or, for years beginning after 2016, 62321), 62311 (or, for years beginning after 2016, 62323), 62264, 64490, 64493, or G0260 (or any successor code) applies.*

*(iii) This subparagraph shall not be applied in a budget-neutral manner.*

(3)(A) The aggregate amount of the payments to be made under this part for outpatient hospital facility services or critical access hospital services furnished before January 1, 1999, in connection with surgical procedures specified under paragraph (1)(A) shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B); or

(ii) the blend amount (described in subparagraph (B)).

(B)(i) The blend amount for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)(I)) of the amount described in subparagraph (A)(i), and

(II) the ASC proportion (as defined in clause (ii)(II)) of the standard overhead amount payable with respect to the same surgical procedure as if it were provided in an ambulatory sur-

gical center in the same area, as determined under paragraph (2)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A).

(ii) Subject to paragraph (4), in this paragraph:

(I) The term "cost proportion" means 75 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 42 percent for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term "ASC proportion" means 25 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 58 percent for portions of cost reporting periods beginning on or after January 1, 1991.

(4)(A) In the case of a hospital that—

(i) makes application to the Secretary and demonstrates that it specializes in eye services or eye and ear services (as determined by the Secretary),

(ii) receives more than 30 percent of its total revenues from outpatient services, and

(iii) on October 1, 1987—

(I) was an eye specialty hospital or an eye and ear specialty hospital, or

(II) was operated as an eye or eye and ear unit (as defined in subparagraph (B)) of a general acute care hospital which, on the date of the application described in clause (i), operates less than 20 percent of the beds that the hospital operated on October 1, 1987, and has sold or otherwise disposed of a substantial portion of the hospital's other acute care operations,

the cost proportion and ASC proportion in effect under subclauses (I) and (II) of paragraph (3)(B)(ii) for cost reporting periods beginning in fiscal year 1988 shall remain in effect for cost reporting periods beginning on or after October 1, 1988, and before January 1, 1995.

(B) For purposes of this subparagraph (A)(iii)(II), the term "eye or eye and ear unit" means a physically separate or distinct unit containing separate surgical suites devoted solely to eye or eye and ear services.

(5)(A) The Secretary is authorized to provide by regulations that in the case of a surgical procedure, specified by the Secretary pursuant to paragraph (1)(A), performed in an ambulatory surgical center described in such paragraph, there shall be paid (in lieu of any amounts otherwise payable under this part) with respect to the facility services furnished by such center and with respect to all related services (including physicians' services, laboratory, X-ray, and diagnostic services) a single all-inclusive fee established pursuant to subparagraph (B), if all parties furnishing all such services agree to accept such fee (to be divided among the parties involved in such manner as they shall have previously agreed upon) as full payment for the services furnished.

(B) In implementing this paragraph, the Secretary shall establish with respect to each surgical procedure specified pursuant to paragraph (1)(A) the amount of the all-inclusive fee for such procedure, taking into account such factors as may be appropriate. The amount so established with respect to any surgical procedure shall be reviewed periodically and may be adjusted by the Secretary, when appropriate, to take account of varying conditions in different areas.

(6) Any person, including a facility having an agreement under section 1832(a)(2)(F)(i), who knowingly and willfully presents, or causes to be presented, a bill or request for payment, for an intraocular lens inserted during or subsequent to cataract surgery for which payment may be made under paragraph (2)(A)(iii), is subject to a civil money penalty of not to exceed $2,000. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(7)(A) For purposes of paragraph (2)(D)(iv), the Secretary may provide, in the case of an ambulatory surgical center that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to a year, any annual increase provided under the system established under paragraph (2)(D) for such year shall be reduced by 2.0 percentage points. A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing any annual increase factor for a subsequent year.

(B) Except as the Secretary may otherwise provide, the provisions of subparagraphs (B), (C), (D), and (E) of paragraph (17) of section 1833(t) shall apply with respect to services of ambulatory surgical centers under this paragraph in a similar manner to the manner in which they apply under such paragraph and, for purposes of this subparagraph, any reference to a hospital, out-

patient setting, or outpatient hospital services is deemed a reference to an ambulatory surgical center, the setting of such a center, or services of such a center, respectively.

*(8) The Secretary shall conduct a similar type of review as required under paragraph (22) of section 1833(t)), including the second sentence of subparagraph (C) of such paragraph, to payment for services under this subsection, and make such revisions under this paragraph, in an appropriate manner (as determined by the Secretary).*

(j) Whenever a final determination is made that the amount of payment made under this part either to a provider of services or to another person pursuant to an assignment under section 1842(b)(3)(B)(ii) was in excess of or less than the amount of payment that is due, and payment of such excess or deficit is not made (or effected by offset) within 30 days of the date of the determination, interest shall accrue on the balance of such excess or deficit not paid or offset (to the extent that the balance is owed by or owing to the provider) at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payments.

(k) With respect to services described in section 1861(s)(10)(B), the Secretary may provide, instead of the amount of payment otherwise provided under this part, for payment of such an amount or amounts as reasonably reflects the general cost of efficiently providing such services.

(l)(1)(A) The Secretary shall establish a fee schedule for services of certified registered nurse anesthetists under section 1861(s)(11).

(B) In establishing the fee schedule under this paragraph the Secretary may utilize a system of time units, a system of base and time units, or any appropriate methodology.

(C) The provisions of this subsection shall not apply to certain services furnished in certain hospitals in rural areas under the provisions of section 9320(k) of the Omnibus Budget Reconciliation Act of 1986, as amended by section 6132 of the Omnibus Budget Reconciliation Act of 1989.

(2) Except as provided in paragraph (3), the fee schedule established under paragraph (1) shall be initially based on audited data from cost reporting periods ending in fiscal year 1985 and such other data as the Secretary determines necessary.

(3)(A) In establishing the initial fee schedule for those services, the Secretary shall adjust the fee schedule to the extent necessary to ensure that the estimated total amount which will be paid under this title for those services plus applicable coinsurance in 1989 will equal the estimated total amount which would be paid under this title for those services in 1989 if the services were included as inpatient hospital services and payment for such services was made under part A in the same manner as payment was made in fiscal year 1987, adjusted to take into account changes in prices and technology relating to the administration of anesthesia.

(B) The Secretary shall also reduce the prevailing charge of physicians for medical direction of a certified registered nurse anesthetist, or the fee schedule for services of certified registered nurse anesthetists, or both, to the extent necessary to ensure that the estimated total amount which will be paid under this title plus applicable coinsurance for such medical direction and such services in 1989 and 1990 will not exceed the estimated total amount which would have been paid plus applicable coinsurance but for the enactment of the amendments made by section 9320 of the Omnibus Budget Reconciliation Act of 1986. A reduced prevailing charge under this subparagraph shall become the prevailing charge but for subsequent years for purposes of applying the economic index under the fourth sentence of section 1842(b)(3).

(4)(A) Except as provided in subparagraphs (C) and (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, by a certified registered nurse anesthetist who is not medically directed—

(i) the conversion factor shall be—

(I) for services furnished in 1991, $15.50,

(II) for services furnished in 1992, $15.75,

(III) for services furnished in 1993, $16.00,

(IV) for services furnished in 1994, $16.25,

(V) for services furnished in 1995, $16.50,

(VI) for services furnished in 1996, $16.75, and

(VII) for services furnished in calendar years after 1996, the previous year's conversion factor increased by the update determined under section 1848(d) for physician anesthesia services for that year;

(ii) the payment areas to be used shall be the fee schedule areas used under section 1848 (or, in the case of services furnished during 1991, the localities used under section 1842(b)) for purposes of computing payments for physicians' services that are anesthesia services;

(iii) the geographic adjustment factors to be applied to the conversion factor under clause (i) for services in a fee schedule area or locality is—

(I) in the case of services furnished in 1991, the geographic work index value and the geographic practice cost index value specified in section 1842(q)(1)(B) for physicians' services that are anesthesia services furnished in the area or locality, and

(II) in the case of services furnished after 1991, the geographic work index value, the geographic practice cost index value, and the geographic malpractice index value used for determining payments for physicians' services that are anesthesia services under section 1848,

with 70 percent of the conversion factor treated as attributable to work and 30 percent as attributable to overhead for services furnished in 1991 (and the portions attributable to work, practice expenses, and malpractice expenses in 1992 and thereafter being the same as is applied under section 1848).

(B)(i) Except as provided in clause (ii) and subparagraph (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, and before January 1, 1994, by a certified registered nurse anesthetist who is medically directed, the Secretary shall apply the same methodology specified in subparagraph (A).

(ii) The conversion factor used under clause (i) shall be—

(I) for services furnished in 1991, $10.50,

(II) for services furnished in 1992, $10.75, and

(III) for services furnished in 1993, $11.00.

(iii) In the case of services of a certified registered nurse anesthetist who is medically directed or medically supervised by a physician which are furnished on or after January 1, 1994, the fee schedule amount shall be one-half of the amount described in section 1848(a)(5)(B) with respect to the physician.

(C) Notwithstanding subclauses (I) through (V) of subparagraph (A)(i)—

(i) in the case of a 1990 conversion factor that is greater than $16.50, the conversion factor for a calendar year after 1990 and before 1996 shall be the 1990 conversion factor reduced by the product of the last digit of the calendar year and one-fifth of the amount by which the 1990 conversion factor exceeds $16.50; and

(ii) in the case of a 1990 conversion factor that is greater than $15.49 but less than $16.51, the conversion factor for a calendar year after 1990 and before 1996 shall be the greater of—

(I) the 1990 conversion factor, or

(II) the conversion factor specified in subparagraph (A)(i) for the year involved.

(D) Notwithstanding subparagraph (C), in no case may the conversion factor used to determine payment for services in a fee schedule area or locality under this subsection, as adjusted by the adjustment factors specified in subparagraphs (A)(iii), exceed the conversion factor used to determine the amount paid for physicians' services that are anesthesia services in the area or locality.

(5)(A) Payment for the services of a certified registered nurse anesthetist (for which payment may otherwise be made under this part) may be made on the basis of a claim or request for payment presented by the certified registered nurse anesthetist furnishing such services, or by a hospital, critical access hospital, physician, group practice, or ambulatory surgical center with which the certified registered nurse anesthetist furnishing such services has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, critical access hospital, physician, group practice, or ambulatory surgical center.

(B) No hospital or critical access hospital that presents a claim or request for payment for services of a certified nurse anesthetist under this part may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital or critical access hospital for purposes of this title.

(6) If an adjustment under paragraph (3)(B) results in a reduction in the reasonable charge for a physicians' service and a nonparticipating physician furnishes the service to an individual entitled to benefits under this part after the effective date of the reduction, the physician's actual charge is subject to a limit under section 1842(j)(1)(D).

(m)(1) In the case of physicians' services furnished in a year to an individual, who is covered under the insurance program established by this part and who incurs expenses for such services, in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area as identified by the Secretary prior to the beginning of such year, in addition to the amount otherwise paid under this part, there also shall be paid to the physician (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)) (on a month-

ly or quarterly basis) from the Federal Supplementary Medical Insurance Trust Fund an amount equal to 10 percent of the payment amount for the service under this part.

(2) For each health professional shortage area identified in paragraph (1) that consists of an entire county, the Secretary shall provide for the additional payment under paragraph (1) without any requirement on the physician to identify the health professional shortage area involved. The Secretary may implement the previous sentence using the method specified in subsection (u)(4)(C).

(3) The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a list of the health professional shortage areas identified in paragraph (1) that consist of a partial county to facilitate the additional payment under paragraph (1) in such areas.

(4) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, respecting—

(A) the identification of a county or area;

(B) the assignment of a specialty of any physician under this paragraph;

(C) the assignment of a physician to a county under this subsection; or

(D) the assignment of a postal ZIP Code to a county or other area under this subsection.

(n)(1)(A) The aggregate amount of the payments to be made for all or part of a cost reporting period for services described in subsection (a)(2)(E)(i) furnished under this part on or after October 1, 1988, and before January 1, 1999, and for services described in subsection (a)(2)(E)(ii) furnished under this part on or after October 1, 1989, and before January 1, 1999, shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B), or

(ii) the blend amount for radiology services and diagnostic procedures determined in accordance with subparagraph (B).

(B)(i) The blend amount for radiology services and diagnostic procedures for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)) of the amount described in subparagraph (A)(i); and

(II) the charge proportion (as defined in clause (ii)(II)) of 62 percent (for services described in subsection (a)(2)(E)(i)), or (for procedures described in subsection (a)(2)(E)(ii)), 42 percent or such other percent established by the Secretary (or carriers acting pursuant to guidelines issued by the Secretary) based on prevailing charges established with actual charge data, of the prevailing charge or (for services described in subsection (a)(2)(E)(i) furnished on or after January 1, 1989) the fee schedule amount established for participating physicians for the same services as if they were furnished in a physician's office in the same locality as determined under section 1842(b), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A).

(ii) In this subparagraph:

(I) The term "cost proportion" means 50 percent, except that such term means 65 percent in the case of outpatient radiology services for portions of cost reporting periods which occur in fiscal year 1989 and in the case of diagnostic procedures described in subsection (a)(2)(E)(ii) for portions of cost reporting periods which occur in fiscal year 1990, and such term means 42 percent in the case of outpatient radiology services for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term "charge proportion" means 100 percent minus the cost proportion.

(o)(1) In the case of shoes described in section 1861(s)(12)—

(A) no payment may be made under this part, with respect to any individual for any year, for the furnishing of—

(i) more than one pair of custom molded shoes (including inserts provided with such shoes) and 2 additional pairs of inserts for such shoes, or

(ii) more than one pair of extra-depth shoes (not including inserts provided with such shoes) and 3 pairs of inserts for such shoes, and

(B) with respect to expenses incurred in any calendar year, no more than the amount of payment applicable under paragraph (2) shall be considered as incurred expenses for purposes of subsections (a) and (b).

Payment for shoes (or inserts) under this part shall be considered to include payment for any expenses for the fitting of such shoes (or inserts).

(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra-depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1834(h).

(B) The Secretary may establish payment amounts for shoes and inserts that are lower than the amount established under section 1834(h) if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

(C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1861(s)(12) may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1834(h), a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.

(3) In this title, the term "shoes" includes, except for purposes of subparagraphs (A)(ii) and (B) of paragraph (2), inserts for extra-depth shoes.

(q)(1) Each request for payment, or bill submitted, for an item or service furnished by an entity for which payment may be made under this part and for which the entity knows or has reason to believe there has been a referral by a referring physician (within the meaning of section 1877) shall include the name and unique physician identification number for the referring physician.

(2)(A) In the case of a request for payment for an item or service furnished by an entity under this part on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included, payment may be denied under this part.

(B) In the case of a request for payment for an item or service furnished by an entity under this part not submitted on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included—

(i) if the entity knowingly and willfully fails to provide such information promptly upon request of the Secretary or a carrier, the entity may be subject to a civil money penalty in an amount not to exceed $2,000, and

(ii) if the entity knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection to provide the information required under paragraph (1), the entity may be subject to exclusion from participation in the programs under this Act for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1128.

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under clause (i) in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(r)(1) With respect to services described in section 1861(s)(2)(K)(ii) (relating to nurse practitioner or clinical nurse specialist services), payment may be made on the basis of a claim or request for payment presented by the nurse practitioner or clinical nurse specialist furnishing such services, or by a hospital, critical access hospital, skilled nursing facility or nursing facility (as defined in section 1919(a)), physician, group practice, or ambulatory surgical center with which the nurse practitioner or clinical nurse specialist has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, physician, group practice, or ambulatory surgical center.

(2) No hospital or critical access hospital that presents a claim or request for payment under this part for services described in section 1861(s)(2)(K)(ii) may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital for purposes of this title.

(s) The Secretary may not provide for payment under subsection (a)(1)(A) with respect to an organization unless the organization provides assurances satisfactory to the Secretary that the organization meets the requirement of section 1866(f) (relating to maintaining written policies and procedures respecting advance directives).

(t) PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.—

(1) AMOUNT OF PAYMENT.—

(A) IN GENERAL.—With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.

(B) DEFINITION OF COVERED OPD SERVICES.—For purposes of this subsection, the term "covered OPD services"—

(i) means hospital outpatient services designated by the Secretary;

(ii) subject to clause (iv), includes inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (I) is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (II) is not so entitled;

(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1861(s);

(iv) does not include any therapy services described in subsection (a)(8) or ambulance services, for which payment is made under a fee schedule described in section 1834(k) or section 1834(l) and does not include screening mammography (as defined in section 1861(jj)), diagnostic mammography, or personalized prevention plan services (as defined in section 1861(hhh)(1)); and

(v) does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph).

(2) SYSTEM REQUIREMENTS.—Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

For purposes of subparagraph (B), items and services within a group shall not be treated as "comparable with respect to the use of resources" if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the group; except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.

(3) CALCULATION OF BASE AMOUNTS.—

(A) AGGREGATE AMOUNTS THAT WOULD BE PAYABLE IF DEDUCTIBLES WERE DISREGARDED.—The Secretary shall estimate the sum of—

(i) the total amounts that would be payable from the Trust Fund under this part for covered OPD services in 1999, determined without regard to this subsection, as though the deductible under section 1833(b) did not apply, and

(ii) the total amounts of copayments estimated to be paid under this subsection by beneficiaries to hospitals for covered OPD services in 1999, as though the deductible under section 1833(b) did not apply.

(B) UNADJUSTED COPAYMENT AMOUNT.—

(i) IN GENERAL.—For purposes of this subsection, subject to clause (ii), the "unadjusted copayment amount" applicable to a covered OPD service (or group of such services) is 20 percent of the national median of the charges for the service (or services within the group) furnished during 1996, updated to 1999 using the Secretary's estimate of charge growth during the period.

(ii) ADJUSTED TO BE 20 PERCENT WHEN FULLY PHASED IN.—If the pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year would be equal to or exceed 80 percent, then the unadjusted copayment amount shall be 20 percent of amount determined under subparagraph (D).

(iii) RULES FOR NEW SERVICES.—The Secretary shall establish rules for establishment of an unadjusted copayment amount for a covered OPD service not furnished during 1996, based upon its classification within a group of such services.

(C) CALCULATION OF CONVERSION FACTORS.—

(i) FOR 1999.—

(I) IN GENERAL.—The Secretary shall establish a 1999 conversion factor for determining the medicare OPD fee schedule amounts for each covered OPD service (or group of such services) furnished in 1999. Such conversion factor shall be established on the basis of the weights and frequencies described in paragraph (2)(C) and in such a manner that the sum for all services and groups of the products (described in subclause (II) for each such service or group) equals the total projected amount described in subparagraph (A).

(II) PRODUCT DESCRIBED.—The Secretary shall determine for each service or group the product of the medicare OPD fee schedule amounts (taking into account appropriate adjustments described in paragraphs (2)(D) and (2)(E)) and the estimated frequencies for such service or group.

(ii) SUBSEQUENT YEARS.—Subject to paragraph (8)(B), the Secretary shall establish a conversion factor for covered OPD services furnished in subsequent years in an amount equal to the conversion factor established under this subparagraph and applicable to such services furnished in the previous year increased by the OPD fee schedule increase factor specified under clause (iv) for the year involved.

(iii) ADJUSTMENT FOR SERVICE MIX CHANGES.—Insofar as the Secretary determines that the adjustments for service mix under paragraph (2) for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments under this subsection during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service mix, the Secretary may adjust the conversion factor computed under this subparagraph for subsequent years so as to eliminate the effect of such coding or classification changes.

(iv) OPD FEE SCHEDULE INCREASE FACTOR.—For purposes of this subparagraph, subject to paragraph (17) and subparagraph (F) of this paragraph, the "OPD fee schedule increase factor" for services furnished in a year is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such factor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.

(D) CALCULATION OF MEDICARE OPD FEE SCHEDULE AMOUNTS.—The Secretary shall compute a medicare OPD fee schedule amount for each covered OPD service (or group of such services) furnished in a year, in an amount equal to the product of—

(i) the conversion factor computed under subparagraph (C) for the year, and

(ii) the relative payment weight (determined under paragraph (2)(C)) for the service or group.

(E) PRE-DEDUCTIBLE PAYMENT PERCENTAGE.—The pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year is equal to the ratio of—

(i) the medicare OPD fee schedule amount established under subparagraph (D) for the year, minus the unadjusted copayment amount determined under subparagraph (B) for the service or group, to

(ii) the medicare OPD fee schedule amount determined under subparagraph (D) for the year for such service or group.

(F) PRODUCTIVITY AND OTHER ADJUSTMENT.—After determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor—

(i) for 2012 and subsequent years, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(ii) for each of 2010 through 2019, by the adjustment described in subparagraph (G).

The application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment rates under the payment system under this subsection for a year being less than such payment rates for the preceding year.

(G) OTHER ADJUSTMENT.—For purposes of subparagraph (F)(ii), the adjustment described in this subparagraph is—

(i) for each of 2010 and 2011, 0.25 percentage point;

(ii) for each of 2012 and 2013, 0.1 percentage point;

(iii) for 2014, 0.3 percentage point;

(iv) for each of 2015 and 2016, 0.2 percentage point; and

(v) for each of 2017, 2018, and 2019, 0.75 percentage point.

(4) MEDICARE PAYMENT AMOUNT.—The amount of payment made from the Trust Fund under this part for a covered OPD service (and such services classified within a group) furnished in a year is determined, subject to paragraph (7), as follows:

(A) FEE SCHEDULE ADJUSTMENTS.—The medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).

(B) SUBTRACT APPLICABLE DEDUCTIBLE.—Reduce the adjusted amount determined under subparagraph (A) by the amount of the deductible under section 1833(b), to the extent applicable.

(C) APPLY PAYMENT PROPORTION TO REMAINDER.—The amount of payment is the amount so determined under subparagraph (B) multiplied by the pre-deductible payment percentage (as determined under paragraph (3)(E)) for the service or group and year involved, plus the amount of any reduction in the copayment amount attributable to paragraph (8)(C).

(5) OUTLIER ADJUSTMENT.—

(A) IN GENERAL.—Subject to subparagraph (D), the Secretary shall provide for an additional payment for each covered OPD service (or group of services) for which a hospital's charges, adjusted to cost, exceed—

(i) a fixed multiple of the sum of—

(I) the applicable medicare OPD fee schedule amount determined under paragraph (3)(D), as adjusted under paragraph (4)(A) (other than for adjustments under this paragraph or paragraph (6)); and

(II) any transitional pass-through payment under paragraph (6); and

(ii) at the option of the Secretary, such fixed dollar amount as the Secretary may establish.

(B) AMOUNT OF ADJUSTMENT.—The amount of the additional payment under subparagraph (A) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the applicable cutoff point under such subparagraph.

(C) LIMIT ON AGGREGATE OUTLIER ADJUSTMENTS.—

(i) IN GENERAL.—The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in

clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term "applicable percentage" means a percentage specified by the Secretary up to (but not to exceed)—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, 3.0 percent.

(D) TRANSITIONAL AUTHORITY.—In applying subparagraph (A) for covered OPD services furnished before January 1, 2002, the Secretary may—

(i) apply such subparagraph to a bill for such services related to an outpatient encounter (rather than for a specific service or group of services) using OPD fee schedule amounts and transitional pass-through payments covered under the bill; and

(ii) use an appropriate cost-to-charge ratio for the hospital involved (as determined by the Secretary), rather than for specific departments within the hospital.

(E) EXCLUSION OF SEPARATE DRUG AND BIOLOGICAL APCS FROM OUTLIER PAYMENTS.—No additional payment shall be made under subparagraph (A) in the case of ambulatory payment classification groups established separately for drugs or biologicals.

(6) TRANSITIONAL PASS-THROUGH FOR ADDITIONAL COSTS OF INNOVATIVE MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—

(A) IN GENERAL.—The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):

(i) CURRENT ORPHAN DRUGS.—A drug or biological that is used for a rare disease or condition with respect to which the drug or biological has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this subsection is implemented.

(ii) CURRENT CANCER THERAPY DRUGS AND BIOLOGICALS AND BRACHYTHERAPY.—A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy or temperature monitored cryoablation, if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.

(iii) CURRENT RADIOPHARMACEUTICAL DRUGS AND BIOLOGICAL PRODUCTS.—A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part was being made on such first date.

(iv) NEW MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—A medical device, drug, or biological not described in clause (i), (ii), or (iii) if—

(I) payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and

(II) the cost of the drug or biological or the average cost of the category of devices is not insignificant in relation to the OPD fee schedule amount (as calculated under paragraph (3)(D)) payable for the service (or group of services) involved.

(B) USE OF CATEGORIES IN DETERMINING ELIGIBILITY OF A DEVICE FOR PASS-THROUGH PAYMENTS.—The following provisions apply for purposes of determining whether a medical device qualifies for additional payments under clause (ii) or (iv) of subparagraph (A):

(i) ESTABLISHMENT OF INITIAL CATEGORIES.—

(I) IN GENERAL.—The Secretary shall initially establish under this clause categories of medical devices based on type of device by April 1, 2001. Such categories shall be established in a manner such that each medical device that meets the requirements of clause (ii) or (iv) of subparagraph (A) as of January 1, 2001, is included in such a category and no such device is included in more than one category. For purposes of the preceding sentence, whether a medical device meets such requirements as of such date shall be determined on the basis of the program memoranda issued before such date.

(II) AUTHORIZATION OF IMPLEMENTATION OTHER THAN THROUGH REGULATIONS.—The categories may be established under this clause by program memorandum or otherwise, after consultation with groups representing hospitals, manufacturers of medical devices, and other affected parties.

(ii) ESTABLISHING CRITERIA FOR ADDITIONAL CATEGORIES.—

(I) IN GENERAL.—The Secretary shall establish criteria that will be used for creation of additional categories (other than those established under clause (i)) through rulemaking (which may include use of an interim final rule with comment period).

(II) STANDARD.—Such categories shall be established under this clause in a manner such that no medical device is described by more than one category. Such criteria shall include a test of whether the average cost of devices that would be included in a category and are in use at the time the category is established is not insignificant, as described in subparagraph (A)(iv)(II).

(III) DEADLINE.—Criteria shall first be established under this clause by July 1, 2001. The Secretary may establish in compelling circumstances categories under this clause before the date such criteria are established.

(IV) ADDING CATEGORIES.—The Secretary shall promptly establish a new category of medical devices under this clause for any medical device that meets the requirements of subparagraph (A)(iv) and for which none of the categories in effect (or that were previously in effect) is appropriate.

(iii) PERIOD FOR WHICH CATEGORY IS IN EFFECT.—A category of medical devices established under clause (i) or (ii) shall be in effect for a period of at least 2 years, but not more than 3 years, that begins—

(I) in the case of a category established under clause (i), on the first date on which payment was made under this paragraph for any device described by such category (including payments made during the period before April 1, 2001); and

(II) in the case of any other category, on the first date on which payment is made under this paragraph for any medical device that is described by such category.

(iv) REQUIREMENTS TREATED AS MET.—A medical device shall be treated as meeting the requirements of subparagraph (A)(iv), regardless of whether the device meets the requirement of subclause (I) of such subparagraph, if—

(I) the device is described by a category established and in effect under clause (i); or

(II) the device is described by a category established and in effect under clause (ii) and an application under section 515 of the Federal Food, Drug, and Cosmetic Act has been approved with respect to the device, or the device has been cleared for market under section 510(k) of such Act, or the device is exempt from the requirements of section 510(k) of such Act pursuant to subsection (l) or (m) of section 510 of such Act or section 520(g) of such Act.

Nothing in this clause shall be construed as requiring an application or prior approval (other than that described in subclause (II)) in order for a covered device described by a category to qualify for payment under this paragraph.

(C) LIMITED PERIOD OF PAYMENT.—

(i) DRUGS AND BIOLOGICALS.—Subject to subparagraph (G), the payment under this paragraph with respect to a drug or biological shall only apply during a period of at least 2 years, but not more than 3 years, *or, in the case of an eligible non-opioid analgesic (as defined in subparagraph (J)), during a period of 5 years,* that begins—

(I) on the first date this subsection is implemented in the case of a drug or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug or biological described in subparagraph (A)(iv) and for which payment under this part is made as an outpatient hospital service before such first date; or

(II) in the case of a drug or biological described in subparagraph (A)(iv) not described in subclause (I), on the first date on which payment is made under this part for the drug or biological as an outpatient hospital service.

(ii) MEDICAL DEVICES.—Payment shall be made under this paragraph with respect to a medical device only if such device—

(I) is described by a category of medical devices established and in effect under subparagraph (B); and

(II) is provided as part of a service (or group of services) paid for under this subsection and provided during the period for which such category is in effect under such subparagraph.

(D) AMOUNT OF ADDITIONAL PAYMENT.—Subject to subparagraph (E)(iii), the amount of the payment under this paragraph with respect to a device, drug, or biological provided as part of a covered OPD service is—

(i) subject to subparagraph (H), in the case of a drug or biological, the amount by which the amount determined under section 1842(o) (or if the drug or biological is covered under a competitive acquisition contract under section 1847B, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph) for the drug or biological exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

(ii) in the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the device.

(E) LIMIT ON AGGREGATE ANNUAL ADJUSTMENT.—

(i) IN GENERAL.—The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year. This clause shall not apply for 2018.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term "applicable percentage" means—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

(iii) UNIFORM PROSPECTIVE REDUCTION IF AGGREGATE LIMIT PROJECTED TO BE EXCEEDED.—If the Secretary estimates before the beginning of a year that the amount of the additional payments under this paragraph for the year (or portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause, the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed such limit.

(F) LIMITATION OF APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.—

(i) IN GENERAL.—The Secretary may not publish regulations that apply a functional equivalence standard to a drug or biological under this paragraph.

(ii) APPLICATION.—Clause (i) shall apply to the application of a functional equivalence standard to a drug or biological on or after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 unless—

(I) such application was being made to such drug or biological prior to such date of enactment; and

(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this title.

(iii) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to effect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.

(G) PASS-THROUGH EXTENSION FOR CERTAIN DRUGS AND BIOLOGICALS.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a

payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, such pass-through status shall be extended for a 2-year period beginning on October 1, 2018.

(H) TEMPORARY PAYMENT RULE FOR CERTAIN DRUGS AND BIOLOGICALS.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, the payment amount for such drug or biological under this subsection that is furnished during the period beginning on October 1, 2018, and ending on March 31, 2019, shall be the greater of—

(i) the payment amount that would otherwise apply under subparagraph (D)(i) for such drug or biological during such period; or

(ii) the payment amount that applied under such subparagraph (D)(i) for such drug or biological on December 31, 2017.

(I) SPECIAL PAYMENT ADJUSTMENT RULES FOR LAST QUARTER OF 2018.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment amount for a covered OPD service (or group of services) beginning January 1, 2018, the following rules shall apply with respect to payment amounts under this subsection for covered a OPD service (or group of services) furnished during the period beginning on October 1, 2018, and ending on December 31, 2018:

(i) The Secretary shall remove the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged.

(ii) The Secretary shall not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (i).

*(J) ELIGIBLE NON-OPIOID ANALGESIC DEFINED.—In this paragraph, the term "eligible non-opioid analgesic" means a drug or biological—*

*(i) that is an analgesic that is not an opioid;*

*(ii) that demonstrated substantial clinical improvement; and*

*(iii) for which payment—*

*(I) as an outpatient hospital service under this part was not being made as of the date of the enactment of this subparagraph; or*

*(II) was being made under this paragraph as of such date.*

(7) TRANSITIONAL ADJUSTMENT TO LIMIT DECLINE IN PAYMENT.—

(A) BEFORE 2002.—Subject to subparagraph (D), for covered OPD services furnished before January 1, 2002, for which the PPS amount (as defined in subparagraph (E)) is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in subparagraph (F)), the amount of payment under this subsection shall be increased by 80 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.71 and the pre-BBA amount, exceeds (II) the product of 0.70 and the PPS amount;

(iii) at least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.63 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iv) less than 70 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 21 percent of the pre-BBA amount.

(B) 2002.—Subject to subparagraph (D), for covered OPD services furnished during 2002, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 70 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which

(I) the product of 0.61 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iii) less than 80 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 13 percent of the pre-BBA amount.

(C) 2003.—Subject to subparagraph (D), for covered OPD services furnished during 2003, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 60 percent of the amount of such difference; or

(ii) less than 90 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 6 percent of the pre-BBA amount.

(D) HOLD HARMLESS PROVISIONS.—

(i) TEMPORARY TREATMENT FOR CERTAIN RURAL HOSPITALS.—(I) In the case of a hospital located in a rural area and that has not more than 100 beds or a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) located in a rural area, for covered OPD services furnished before January 1, 2006, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(II) In the case of a hospital located in a rural area and that has not more than 100 beds and that is not a sole community hospital (as defined in section 1886(d)(5)(D)(iii)), for covered OPD services furnished on or after January 1, 2006, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the applicable percentage of the amount of such difference. For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to such services furnished in 2008, 2009, 2010, 2011, or 2012.

(III) In the case of a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) that has not more than 100 beds, for covered OPD services furnished on or after January 1, 2009, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by 85 percent of the amount of such difference. In the case of covered OPD services furnished on or after January 1, 2010, and before March 1, 2012, the preceding sentence shall be applied without regard to the 100-bed limitation.

(ii) PERMANENT TREATMENT FOR CANCER HOSPITALS AND CHILDREN'S HOSPITALS.—In the case of a hospital described in clause (iii) or (v) of section 1886(d)(1)(B), for covered OPD services for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(E) PPS AMOUNT DEFINED.—In this paragraph, the term "PPS amount" means, with respect to covered OPD services, the amount payable under this title for such services (determined without regard to this paragraph), including amounts payable as copayment under paragraph (8), coinsurance under section 1866(a)(2)(A)(ii), and the deductible under section 1833(b).

(F) PRE-BBA AMOUNT DEFINED.—

(i) IN GENERAL.—In this paragraph, the "pre-BBA amount" means, with respect to covered OPD services furnished by a hospital in a year, an amount equal to the product of the reasonable cost of the hospital for such services for the portions of the hospital's cost reporting period (or periods) occurring in the year and the base OPD payment-to-cost ratio for the hospital (as defined in clause (ii)).

(ii) BASE PAYMENT-TO-COST-RATIO DEFINED.—For purposes of this subparagraph, the "base payment-to-cost ratio" for a hospital means the ratio of—

(I) the hospital's reimbursement under this part for covered OPD services furnished during the cost reporting period ending in 1996 (or in the case of a hospital that did not submit a cost report for such period, during the first subsequent cost reporting period ending before 2001 for which the hospital submitted a cost report), including any reimbursement for such services through cost-sharing described in subparagraph (E), to

(II) the reasonable cost of such services for such period.

The Secretary shall determine such ratios as if the amendments made by section 4521 of the Balanced Budget Act of 1997 were in effect in 1996.

(G) INTERIM PAYMENTS.—The Secretary shall make payments under this paragraph to hospitals on an interim basis, subject to retrospective adjustments based on settled cost reports.

(H) NO EFFECT ON COPAYMENTS.—Nothing in this paragraph shall be construed to affect the unadjusted copayment amount described in paragraph (3)(B) or the copayment amount under paragraph (8).

(I) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The additional payments made under this paragraph—

(i) shall not be considered an adjustment under paragraph (2)(E); and

(ii) shall not be implemented in a budget neutral manner.

(8) COPAYMENT AMOUNT.—

(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), the copayment amount under this subsection is the amount by which the amount described in paragraph (4)(B) exceeds the amount of payment determined under paragraph (4)(C).

(B) ELECTION TO OFFER REDUCED COPAYMENT AMOUNT.—The Secretary shall establish a procedure under which a hospital, before the beginning of a year (beginning with 1999), may elect to reduce the copayment amount otherwise established under subparagraph (A) for some or all covered OPD services to an amount that is not less than 20 percent of the medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service involved. Under such procedures, such reduced copayment amount may not be further reduced or increased during the year involved and the hospital may disseminate information on the reduction of copayment amount effected under this subparagraph.

(C) LIMITATION ON COPAYMENT AMOUNT.—

(i) TO INPATIENT HOSPITAL DEDUCTIBLE AMOUNT.—In no case shall the copayment amount for a procedure performed in a year exceed the amount of the inpatient hospital deductible established under section 1813(b) for that year.

(ii) TO SPECIFIED PERCENTAGE.—The Secretary shall reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed the following percentage:

(I) For procedures performed in 2001, on or after April 1, 2001, 57 percent.

(II) For procedures performed in 2002 or 2003, 55 percent.

(III) For procedures performed in 2004, 50 percent.

(IV) For procedures performed in 2005, 45 percent.

(V) For procedures performed in 2006 and thereafter, 40 percent.

(D) NO IMPACT ON DEDUCTIBLES.—Nothing in this paragraph shall be construed as affecting a hospital's authority to waive the charging of a deductible under section 1833(b).

(E) COMPUTATION IGNORING OUTLIER AND PASS-THROUGH ADJUSTMENTS.—The copayment amount shall be computed under subparagraph (A) as if the adjustments under paragraphs (5) and (6) (and any adjustment made under paragraph (2)(E) in relation to such adjustments) had not occurred.

(9) PERIODIC REVIEW AND ADJUSTMENTS COMPONENTS OF PROSPECTIVE PAYMENT SYSTEM.—

(A) PERIODIC REVIEW.—The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) BUDGET NEUTRALITY ADJUSTMENT.—If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004

and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

(C) UPDATE FACTOR.—If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

(10) SPECIAL RULE FOR AMBULANCE SERVICES.—The Secretary shall pay for hospital outpatient services that are ambulance services on the basis described in section 1861(v)(1)(U), or, if applicable, the fee schedule established under section 1834(l).

(11) SPECIAL RULES FOR CERTAIN HOSPITALS.—In the case of hospitals described in clause (iii) or (v) of section 1886(d)(1)(B)—

(A) the system under this subsection shall not apply to covered OPD services furnished before January 1, 2000; and

(B) the Secretary may establish a separate conversion factor for such services in a manner that specifically takes into account the unique costs incurred by such hospitals by virtue of their patient population and service intensity.

(12) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise of—

(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

(13) AUTHORIZATION OF ADJUSTMENT FOR RURAL HOSPITALS.—

(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals located in rural areas by ambulatory payment classification groups (APCs) exceed those costs incurred by hospitals located in urban areas.

(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.

(14) DRUG APC PAYMENT RATES.—

(A) IN GENERAL.—The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

(i) in 2004, in the case of—

(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

(ii) in 2005, in the case of—

(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

(iii) in a subsequent year, shall be equal, subject to subparagraph (E)—

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

(B) SPECIFIED COVERED OUTPATIENT DRUG DEFINED.—

(i) IN GENERAL.—In this paragraph, the term "specified covered outpatient drug" means, subject to clause (ii), a covered outpatient drug (as defined in section 1927(k)(2)) for which a separate ambulatory payment classification group (APC) has been established and that is—

(I) a radiopharmaceutical; or

(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

(ii) EXCEPTION.—Such term does not include—

(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

(C) PAYMENT FOR DESIGNATED ORPHAN DRUGS DURING 2004 AND 2005.—The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B)(ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

(D) ACQUISITION COST SURVEY FOR HOSPITAL OUTPATIENT DRUGS.—

(i) ANNUAL GAO SURVEYS IN 2004 AND 2005.—

(I) IN GENERAL.—The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General shall furnish data from such surveys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

(II) RECOMMENDATIONS.—Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii).

(ii) SUBSEQUENT SECRETARIAL SURVEYS.—The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph (A).

(iii) SURVEY REQUIREMENTS.—The surveys conducted under clauses (i) and (ii) shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the justification for the size of the sample used in order to assure the validity of such estimates.

(iv) DIFFERENTIATION IN COST.—In conducting surveys under clause (i), the Comptroller General shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

(v) COMMENT ON PROPOSED RATES.—Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates based on the surveys the Comptroller General has conducted under clause (i).

(E) ADJUSTMENT IN PAYMENT RATES FOR OVERHEAD COSTS.—

(i) MEDPAC REPORT ON DRUG APC DESIGN.—The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

(I) a description and analysis of the data available with regard to such expenses;

(II) a recommendation as to whether such a payment adjustment should be made; and

(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

(ii) ADJUSTMENT AUTHORIZED.—The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i).

(F) CLASSES OF DRUGS.—For purposes of this paragraph:

(i) SOLE SOURCE DRUGS.—The term "sole source drug" means—

(I) a biological product (as defined under section 1861(t)(1)); or

(II) a single source drug (as defined in section 1927(k)(7)(A)(iv)).

(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—The term "innovator multiple source drug" has the meaning given such term in section 1927(k)(7)(A)(ii).

(iii) NONINNOVATOR MULTIPLE SOURCE DRUGS.—The term "noninnovator multiple source drug" has the meaning given such term in section 1927(k)(7)(A)(iii).

(G) REFERENCE AVERAGE WHOLESALE PRICE.—The term "reference average wholesale price" means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1842(o) as of May 1, 2003.

(H) INAPPLICABILITY OF EXPENDITURES IN DETERMINING CONVERSION, WEIGHTING, AND OTHER ADJUSTMENT FACTORS.—Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.

(15) PAYMENT FOR NEW DRUGS AND BIOLOGICALS UNTIL HCPCS CODE ASSIGNED.—With respect to payment under this part for an outpatient drug or biological that is covered under this part and is furnished as part of covered OPD services for which a HCPCS code has not been assigned, the amount provided for payment for such drug or biological under this part shall be equal to 95 percent of the average wholesale price for the drug or biological.

(16) MISCELLANEOUS PROVISIONS.—

(A) APPLICATION OF RECLASSIFICATION OF CERTAIN HOSPITALS.—If a hospital is being treated as being located in a rural area under section 1886(d)(8)(E), that hospital shall be treated under this subsection as being located in that rural area.

(B) THRESHOLD FOR ESTABLISHMENT OF SEPARATE APCS FOR DRUGS.—The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs or biologicals to $50 per administration for drugs and biologicals furnished in 2005 and 2006.

(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY AND THERAPEUTIC RADIOPHARMACEUTICALS AT CHARGES ADJUSTED TO COST.—Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before January 1, 2010, and for therapeutic radiopharmaceuticals furnished on or after January 1, 2008, and before January 1, 2010, the payment basis for the device or therapeutic radiopharmaceutical under this subsection shall be equal to the hospital's charges for each device or therapeutic radiopharmaceutical furnished, adjusted to cost. Charges for such devices or therapeutic radiopharmaceuticals shall not be included in determining any outlier payment under this subsection.

(D) SPECIAL PAYMENT RULE.—

(i) IN GENERAL.—In the case of covered OPD services furnished on or after April 1, 2013, in a hospital described in clause (ii), if—

(I) the payment rate that would otherwise apply under this subsection for stereotactic radiosurgery, complete course of treatment of cranial lesion(s) consisting of 1 session that is multi-source Cobalt 60 based (identified as of January

1, 2013, by HCPCS code 77371 (and any succeeding code) and reimbursed as of such date under APC 0127 (and any succeeding classification group)); exceeds

(II) the payment rate that would otherwise apply under this subsection for linear accelerator based stereotactic radiosurgery, complete course of therapy in one session (identified as of January 1, 2013, by HCPCS code G0173 (and any succeeding code) and reimbursed as of such date under APC 0067 (and any succeeding classification group)),

the payment rate for the service described in subclause (I) shall be reduced to an amount equal to the payment rate for the service described in subclause (II).

(ii) HOSPITAL DESCRIBED.—A hospital described in this clause is a hospital that is not—

(I) located in a rural area (as defined in section 1886(d)(2)(D));

(II) classified as a rural referral center under section 1886(d)(5)(C); or

(III) a sole community hospital (as defined in section 1886(d)(5)(D)(iii)).

(iii) NOT BUDGET NEUTRAL.—In making any budget neutrality adjustments under this subsection for 2013 (with respect to covered OPD services furnished on or after April 1, 2013, and before January 1, 2014) or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(E) APPLICATION OF APPROPRIATE USE CRITERIA FOR CERTAIN IMAGING SERVICES.—For provisions relating to the application of appropriate use criteria for certain imaging services, see section 1834(q).

(F) PAYMENT INCENTIVE FOR THE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY.—Notwithstanding the previous provisions of this subsection:

(i) LIMITATION ON PAYMENT FOR FILM X-RAY IMAGING SERVICES.—In the case of an imaging service that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 20 percent.

(ii) PHASED-IN LIMITATION ON PAYMENT FOR COMPUTED RADIOGRAPHY IMAGING SERVICES.—In the case of an imaging service that is an X-ray taken using computed radiography technology (as defined in section 1848(b)(9)(C))—

(I) in the case of such a service furnished during 2018, 2019, 2020, 2021, or 2022, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 7 percent; and

(II) in the case of such a service furnished during 2023 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 10 percent.

(iii) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The reductions made under this subparagraph—

(I) shall not be considered an adjustment under paragraph (2)(E); and

(II) shall not be implemented in a budget neutral manner.

(iv) IMPLEMENTATION.—In order to implement this subparagraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.

(17) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—For purposes of paragraph (3)(C)(iv) for 2009 and each subsequent year, in the case of a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to such a year, the OPD fee schedule increase factor under paragraph (3)(C)(iv) for such year shall be reduced by 2.0 percentage points.

(ii) NON-CUMULATIVE APPLICATION.—A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into ac-

count such reduction in computing the OPD fee schedule increase factor for a subsequent year.

(B) FORM AND MANNER OF SUBMISSION.—Each subsection (d) hospital shall submit data on measures selected under this paragraph to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this paragraph.

(C) DEVELOPMENT OF OUTPATIENT MEASURES.—

(i) IN GENERAL.—The Secretary shall develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(ii) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the Secretary from selecting measures that are the same as (or a subset of) the measures for which data are required to be submitted under section 1886(b)(3)(B)(viii).

(D) REPLACEMENT OF MEASURES.—For purposes of this paragraph, the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(E) AVAILABILITY OF DATA.—The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(18) AUTHORIZATION OF ADJUSTMENT FOR CANCER HOSPITALS.—

(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals described in section 1886(d)(1)(B)(v) with respect to ambulatory payment classification groups exceed those costs incurred by other hospitals furnishing services under this subsection (as determined appropriate by the Secretary). In conducting the study under this subparagraph, the Secretary shall take into consideration the cost of drugs and biologicals incurred by such hospitals.

(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals described in section 1886(d)(1)(B)(v) exceed those costs incurred by other hospitals furnishing services under this subsection, the Secretary shall, subject to subparagraph (C), provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.

(C) TARGET PCR ADJUSTMENT.—In applying section 419.43(i) of title 42 of the Code of Federal Regulations to implement the appropriate adjustment under this paragraph for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage points less than the target PCR that would otherwise apply. In addition to the percentage point reduction under the previous sentence, the Secretary may consider making an additional percentage point reduction to such target PCR that takes into account payment rates for applicable items and services described in paragraph (21)(C) other than for services furnished by hospitals described in section 1886(d)(1)(B)(v). In making any budget neutrality adjustments under this subsection for 2018 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(19) FLOOR ON AREA WAGE ADJUSTMENT FACTOR FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES IN FRONTIER STATES.—

(A) IN GENERAL.—Subject to subparagraph (B), with respect to covered OPD services furnished on or after January 1, 2011, the area wage adjustment factor applicable under the payment system established under this subsection to any hospital outpatient department which is located in a frontier State (as defined in section 1886(d)(3)(E)(iii)(II)) may not be less than 1.00. The preceding sentence shall not be applied in a budget neutral manner.

(B) LIMITATION.—This paragraph shall not apply to any hospital outpatient department located in a State that receives a non-labor related share adjustment under section 1886(d)(5)(H).

(20) NOT BUDGET NEUTRAL APPLICATION OF REDUCED EXPENDITURES RESULTING FROM QUALITY INCENTIVES FOR COMPUTED TOMOGRAPHY.—The Secretary shall not take into account the reduced expenditures that result from the application of section 1834(p) in making any budget neutrality adjustments this subsection.

(21) SERVICES FURNISHED BY AN OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.—

(A) APPLICABLE ITEMS AND SERVICES.—For purposes of paragraph (1)(B)(v) and this paragraph, the term "applicable items and services" means items and services other than items and services furnished by a dedicated emergency department (as defined in section 489.24(b) of title 42 of the Code of Federal Regulations).

(B) OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.—

(i) IN GENERAL.—For purposes of paragraph (1)(B)(v) and this paragraph, subject to the subsequent provisions of this subparagraph, the term "off-campus outpatient department of a provider" means a department of a provider (as defined in section 413.65(a)(2) of title 42 of the Code of Federal Regulations, as in effect as of the date of the enactment of this paragraph) that is not located—

(I) on the campus (as defined in such section 413.65(a)(2)) of such provider; or

(II) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section 413.65(a)(2)).

(ii) EXCEPTION.—For purposes of paragraph (1)(B)(v) and this paragraph, the term "off-campus outpatient department of a provider" shall not include a department of a provider (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to the date of the enactment of this paragraph.

(iii) DEEMED TREATMENT FOR 2017.—For purposes of applying clause (ii) with respect to applicable items and services furnished during 2017, a department of a provider (as so defined) not described in such clause is deemed to be billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015, if the Secretary received from the provider prior to December 2, 2015, an attestation (pursuant to section 413.65(b)(3) of title 42 of the Code of Federal Regulations) that such department was a department of a provider (as so defined).

(iv) ALTERNATIVE EXCEPTION BEGINNING WITH 2018.—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2018 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if—

(I) the Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than December 31, 2016 (or, if later, 60 days after the date of the enactment of this clause), that such department met the requirements of a department of a provider specified in section 413.65 of title 42 of the Code of Federal Regulations;

(II) the provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1866(j); and

(III) the department met the mid-build requirement of clause (v) and the Secretary receives, not later than 60 days after the date of the enactment of this clause, from the chief executive officer or chief operating officer of the provider a written certification that the department met such requirement.

(v) MID-BUILD REQUIREMENT DESCRIBED.—The mid-build requirement of this clause is, with respect to a department of a provider, that before November 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

(vi) EXCLUSION FOR CERTAIN CANCER HOSPITALS.—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2017 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not

described in clause (ii) if the provider is a hospital described in section 1886(d)(1)(B)(v) and—

(I) in the case of a department that met the requirements of section 413.65 of title 42 of the Code of Federal Regulations after November 1, 2015, and before the date of the enactment of this clause, the Secretary receives from the provider an attestation that such department met such requirements not later than 60 days after such date of enactment; or

(II) in the case of a department that meets such requirements after such date of enactment, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.

(vii) AUDIT.—Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance with such requirements with respect to the department. If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the department shall not be excluded from the term "off-campus outpatient department of a provider" under such clause.

(viii) IMPLEMENTATION.—For purposes of implementing clauses (iii) through (vii):

(I) Notwithstanding any other provision of law, the Secretary may implement such clauses by program instruction or otherwise.

(II) Subchapter I of chapter 35 of title 44, United States Code, shall not apply.

(III) For purposes of carrying out this subparagraph with respect to clauses (iii) and (iv) (and clause (vii) insofar as it relates to clause (iv)), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until December 31, 2018. For purposes of carrying out this subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), $2,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until expended.

(C) AVAILABILITY OF PAYMENT UNDER OTHER PAYMENT SYSTEMS.—Payments for applicable items and services furnished by an off-campus outpatient department of a provider that are described in paragraph (1)(B)(v) shall be made under the applicable payment system under this part (other than under this subsection) if the requirements for such payment are otherwise met.

(D) INFORMATION NEEDED FOR IMPLEMENTATION.—Each hospital shall provide to the Secretary such information as the Secretary determines appropriate to implement this paragraph and paragraph (1)(B)(v) (which may include reporting of information on a hospital claim using a code or modifier and reporting information about off-campus outpatient departments of a provider on the enrollment form described in section 1866(j)).

(E) LIMITATIONS.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(i) The determination of the applicable items and services under subparagraph (A) and applicable payment systems under subparagraph (C).

(ii) The determination of whether a department of a provider meets the term described in subparagraph (B).

(iii) Any information that hospitals are required to report pursuant to subparagraph (D).

(iv) The determination of an audit under subparagraph (B)(vii).

*(22) REVIEW AND REVISIONS OF PAYMENTS FOR NON-OPIOID ALTERNATIVE TREATMENTS.—*

*(A) IN GENERAL.—With respect to payments made under this subsection for covered OPD services (or groups of services), including covered OPD services assigned to a comprehensive ambulatory payment classification, the Secretary—*

*(i) shall, as soon as practicable, conduct a review (part of which may include a request for information) of payments for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injec-*

*tions, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives;*

*(ii) may, as the Secretary determines appropriate, conduct subsequent reviews of such payments; and*

*(iii) shall consider the extent to which revisions under this subsection to such payments (such as the creation of additional groups of covered OPD services to classify separately those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management.*

*(B) PRIORITY.—In conducting the review under clause (i) of subparagraph (A) and considering revisions under clause (iii) of such subparagraph, the Secretary shall focus on covered OPD services (or groups of services) assigned to a comprehensive ambulatory payment classification, ambulatory payment classifications that primarily include surgical services, and other services determined by the Secretary which generally involve treatment for pain management.*

*(C) REVISIONS.—If the Secretary identifies revisions to payments pursuant to subparagraph (A)(iii), the Secretary shall, as determined appropriate, begin making such revisions for services furnished on or after January 1, 2020. Revisions under the previous sentence shall be treated as adjustments for purposes of application of paragraph (9)(B).*

*(D) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed to preclude the Secretary—*

*(i) from conducting a demonstration before making the revisions described in subparagraph (C); or*

*(ii) prior to implementation of this paragraph, from changing payments under this subsection for covered OPD services (or groups of services) which include opioids or non-opioid alternatives for pain management.*

(u) INCENTIVE PAYMENTS FOR PHYSICIAN SCARCITY AREAS.—

(1) IN GENERAL.—In the case of physicians' services furnished on or after January 1, 2005, and before July 1, 2008—

(A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or

(B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part.

(2) DETERMINATION OF RATIOS OF PHYSICIANS TO MEDICARE BENEFICIARIES IN AREA.—Based upon available data, the Secretary shall establish for each county or equivalent area in the United States, the following:

(A) NUMBER OF PHYSICIANS PRACTICING IN THE AREA.—The number of physicians who furnish physicians' services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are—

(i) primary care physicians; or

(ii) physicians who are not primary care physicians.

(B) NUMBER OF MEDICARE BENEFICIARIES RESIDING IN THE AREA.—The number of individuals who are residing in the county and are entitled to benefits under part A or enrolled under this part, or both (in this subsection referred to as "individuals").

(C) DETERMINATION OF RATIOS.—

(i) PRIMARY CARE RATIO.—The ratio (in this paragraph referred to as the "primary care ratio") of the number of primary care physicians (determined under subparagraph (A)(i)), to the number of individuals determined under subparagraph (B).

(ii) SPECIALIST CARE RATIO.—The ratio (in this paragraph referred to as the "specialist care ratio") of the number of other physicians (determined under subparagraph (A)(ii)), to the number of individuals determined under subparagraph (B).

(3) RANKING OF COUNTIES.—The Secretary shall rank each such county or area based separately on its primary care ratio and its specialist care ratio.

(4) IDENTIFICATION OF COUNTIES.—

(A) IN GENERAL.—The Secretary shall identify—

(i) those counties and areas (in this paragraph referred to as "primary care scarcity counties") with the lowest primary care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph; and

(ii) those counties and areas (in this subsection referred to as "specialist care scarcity counties") with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph.

(B) PERIODIC REVISIONS.—The Secretary shall periodically revise the counties or areas identified in subparagraph (A) (but not less often than once every three years) unless the Secretary determines that there is no new data available on the number of physicians practicing in the county or area or the number of individuals residing in the county or area, as identified in paragraph (2).

(C) IDENTIFICATION OF COUNTIES WHERE SERVICE IS FURNISHED.—For purposes of paying the additional amount specified in paragraph (1), if the Secretary uses the 5-digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code (as determined by the United States Postal Service, or otherwise) shall be used to determine whether the postal ZIP Code is in a scarcity county identified in subparagraph (A) or revised in subparagraph (B).

(D) SPECIAL RULE.—With respect to physicians' services furnished on or after January 1, 2008, and before July 1, 2008, for purposes of this subsection, the Secretary shall use the primary care scarcity counties and the specialty care scarcity counties (as identified under the preceding provisions of this paragraph) that the Secretary was using under this subsection with respect to physicians' services furnished on December 31, 2007.

(E) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting—

116.(i) the identification of a county or area;

(ii) the assignment of a specialty of any physician under this paragraph;

(iii) the assignment of a physician to a county under paragraph (2); or

(iv) the assignment of a postal ZIP Code to a county or other area under this subsection.

(5) RURAL CENSUS TRACTS.—To the extent feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), as an equivalent area for purposes of qualifying as a primary care scarcity county or specialist care scarcity county under this subsection.

(6) PHYSICIAN DEFINED.—For purposes of this paragraph, the term "physician" means a physician described in section 1861(r)(1) and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

(7) PUBLICATION OF LIST OF COUNTIES; POSTING ON WEBSITE.—With respect to a year for which a county or area is identified or revised under paragraph (4), the Secretary shall identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the applicable year. The Secretary shall post the list of counties identified or revised under paragraph (4) on the Internet website of the Centers for Medicare & Medicaid Services.

(v) INCREASE OF FQHC PAYMENT LIMITS.—In the case of services furnished by Federally qualified health centers (as defined in section 1861(aa)(4)), the Secretary shall establish payment limits with respect to such services under this part for services furnished—

(1) in 2010, at the limits otherwise established under this part for such year increased by $5; and

(2) in a subsequent year, at the limits established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year.

(w) METHODS OF PAYMENT.—The Secretary may develop alternative methods of payment for items and services provided under clinical trials and comparative effectiveness studies sponsored

or supported by an agency of the Department of Health and Human Services, as determined by the Secretary, to those that would otherwise apply under this section, to the extent such alternative methods are necessary to preserve the scientific validity of such trials or studies, such as in the case where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design.

(x) INCENTIVE PAYMENTS FOR PRIMARY CARE SERVICES.—

(1) IN GENERAL.—In the case of primary care services furnished on or after January 1, 2011, and before January 1, 2016, by a primary care practitioner, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) DEFINITIONS.—In this subsection:

(A) PRIMARY CARE PRACTITIONER.—The term "primary care practitioner" means an individual—

(i) who—

(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)); and

(ii) for whom primary care services accounted for at least 60 percent of the allowed charges under this part for such physician or practitioner in a prior period as determined appropriate by the Secretary.

(B) PRIMARY CARE SERVICES.—The term "primary care services" means services identified, as of January 1, 2009, by the following HCPCS codes (and as subsequently modified by the Secretary):

(i) 99201 through 99215.

(ii) 99304 through 99340.

(iii) 99341 through 99350.

(3) COORDINATION WITH OTHER PAYMENTS.—The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

(4) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the identification of primary care practitioners under this subsection.

(y) INCENTIVE PAYMENTS FOR MAJOR SURGICAL PROCEDURES FURNISHED IN HEALTH PROFESSIONAL SHORTAGE AREAS.—

(1) IN GENERAL.—In the case of major surgical procedures furnished on or after January 1, 2011, and before January 1, 2016, by a general surgeon in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area as identified by the Secretary prior to the beginning of the year involved, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) DEFINITIONS.—In this subsection:

(A) GENERAL SURGEON.—In this subsection, the term "general surgeon" means a physician (as described in section 1861(r)(1)) who has designated CMS specialty code 02–General Surgery as their primary specialty code in the physician's enrollment under section 1866(j).

(B) MAJOR SURGICAL PROCEDURES.—The term "major surgical procedures" means physicians' services which are surgical procedures for which a 10-day or 90-day global period is used for payment under the fee schedule under section 1848(b).

(3) COORDINATION WITH OTHER PAYMENTS.—The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z) shall

be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

(4) APPLICATION.—The provisions of paragraph (2) and (4) of subsection (m) shall apply to the determination of additional payments under this subsection in the same manner as such provisions apply to the determination of additional payments under subsection (m).

(z) INCENTIVE PAYMENTS FOR PARTICIPATION IN ELIGIBLE ALTERNATIVE PAYMENT MODELS.—

(1) PAYMENT INCENTIVE.—

(A) IN GENERAL.—In the case of covered professional services furnished by an eligible professional during a year that is in the period beginning with 2019 and ending with 2024 and for which the professional is a qualifying APM participant with respect to such year, in addition to the amount of payment that would otherwise be made for such covered professional services under this part for such year, there also shall be paid to such professional an amount equal to 5 percent of the estimated aggregate payment amounts for such covered professional services under this part for the preceding year. For purposes of the previous sentence, the payment amount for the preceding year may be an estimation for the full preceding year based on a period of such preceding year that is less than the full year. The Secretary shall establish policies to implement this subparagraph in cases in which payment for covered professional services furnished by a qualifying APM participant in an alternative payment model—

(i) is made to an eligible alternative payment entity rather than directly to the qualifying APM participant; or

(ii) is made on a basis other than a fee-for-service basis (such as payment on a capitated basis).

(B) FORM OF PAYMENT.—Payments under this subsection shall be made in a lump sum, on an annual basis, as soon as practicable.

(C) TREATMENT OF PAYMENT INCENTIVE.—Payments under this subsection shall not be taken into account for purposes of determining actual expenditures under an alternative payment model and for purposes of determining or rebasing any benchmarks used under the alternative payment model.

(D) COORDINATION.—The amount of the additional payment under this subsection or subsection (m) shall be determined without regard to any additional payment under subsection (m) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (x) shall be determined without regard to any additional payment under subsection (x) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (y) shall be determined without regard to any additional payment under subsection (y) and this subsection, respectively.

(2) QUALIFYING APM PARTICIPANT.—For purposes of this subsection, the term "qualifying APM participant" means the following:

(A) 2019 AND 2020.—With respect to 2019 and 2020, an eligible professional for whom the Secretary determines that at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(B) 2021 AND 2022.—With respect to 2021 and 2022, an eligible professional described in either of the following clauses:

(i) MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional for whom the Secretary determines that at least 50 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) COMBINATION ALL-PAYER AND MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year), that at least 50 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other

than payments made under title XIX in a State in which no medical home or alternative payment model is available under the State program under that title),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause (iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) REQUIREMENT.—For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i) apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds expected aggregate expenditures; or

(BB) with respect to beneficiaries under title XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1115A(c).

(C) BEGINNING IN 2023.—With respect to 2023 and each subsequent year, an eligible professional described in either of the following clauses:

(i) MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional for whom the Secretary determines that at least 75 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) COMBINATION ALL-PAYER AND MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year), that at least 75 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under title XIX in a State in which no medical home or alternative payment model is available under the State program under that title),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause (iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) REQUIREMENT.—For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i) apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds expected aggregate expenditures; or

(BB) with respect to beneficiaries under title XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1115A(c).

(D) USE OF PATIENT APPROACH.—The Secretary may base the determination of whether an eligible professional is a qualifying APM participant under this subsection and the determination of whether an eligible professional is a partial qualifying APM participant under section 1848(q)(1)(C)(iii) by using counts of patients in lieu of using payments and using the same or similar percentage criteria (as specified in this subsection and such section, respectively), as the Secretary determines appropriate.

(3) ADDITIONAL DEFINITIONS.—In this subsection:

(A) COVERED PROFESSIONAL SERVICES.—The term "covered professional services" has the meaning given that term in section 1848(k)(3)(A).

(B) ELIGIBLE PROFESSIONAL.—The term "eligible professional" has the meaning given that term in section 1848(k)(3)(B) and includes a group that includes such professionals.

(C) ALTERNATIVE PAYMENT MODEL (APM).—The term "alternative payment model" means, other than for purposes of subparagraphs (B)(ii)(I)(bb) and (C)(ii)(I)(bb) of paragraph (2), any of the following:

(i) A model under section 1115A (other than a health care innovation award).

(ii) The shared savings program under section 1899.

(iii) A demonstration under section 1866C.

(iv) A demonstration required by Federal law.

(D) ELIGIBLE ALTERNATIVE PAYMENT ENTITY.—The term "eligible alternative payment entity" means, with respect to a year, an entity that—

(i) participates in an alternative payment model that—

(I) requires participants in such model to use certified EHR technology (as defined in subsection (o)(4)); and

(II) provides for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i); and

(ii)(I) bears financial risk for monetary losses under such alternative payment model that are in excess of a nominal amount; or

(II) is a medical home expanded under section 1115A(c).

(4) LIMITATION.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, of the following:

(A) The determination that an eligible professional is a qualifying APM participant under paragraph (2) and the determination that an entity is an eligible alternative payment entity under paragraph (3)(D).

(B) The determination of the amount of the 5 percent payment incentive under paragraph (1)(A), including any estimation as part of such determination.

**[**(z)**]** *(aa)* MEDICAL REVIEW OF SPINAL SUBLUXATION SERVICES.—

(1) IN GENERAL.—The Secretary shall implement a process for the medical review (as described in paragraph (2)) of treatment by a chiropractor described in section 1861(r)(5) by means of manual manipulation of the spine to correct a subluxation (as described in such sec-

tion) of an individual who is enrolled under this part and apply such process to such services furnished on or after January 1, 2017, focusing on services such as—

(A) services furnished by a such a chiropractor whose pattern of billing is aberrant compared to peers; and

(B) services furnished by such a chiropractor who, in a prior period, has a services denial percentage in the 85th percentile or greater, taking into consideration the extent that service denials are overturned on appeal.

(2) MEDICAL REVIEW.—

(A) PRIOR AUTHORIZATION MEDICAL REVIEW.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary shall use prior authorization medical review for services described in paragraph (1) that are furnished to an individual by a chiropractor described in section 1861(r)(5) that are part of an episode of treatment that includes more than 12 services. For purposes of the preceding sentence, an episode of treatment shall be determined by the underlying cause that justifies the need for services, such as a diagnosis code.

(ii) ENDING APPLICATION OF PRIOR AUTHORIZATION MEDICAL REVIEW.—The Secretary shall end the application of prior authorization medical review under clause (i) to services described in paragraph (1) by such a chiropractor if the Secretary determines that the chiropractor has a low denial rate under such prior authorization medical review. The Secretary may subsequently reapply prior authorization medical review to such chiropractor if the Secretary determines it to be appropriate and the chiropractor has, in the time period subsequent to the determination by the Secretary of a low denial rate with respect to the chiropractor, furnished such services described in paragraph (1).

(iii) EARLY REQUEST FOR PRIOR AUTHORIZATION REVIEW PERMITTED.—Nothing in this subsection shall be construed to prevent such a chiropractor from requesting prior authorization for services described in paragraph (1) that are to be furnished to an individual before the chiropractor furnishes the twelfth such service to such individual for an episode of treatment.

(B) TYPE OF REVIEW.—The Secretary may use pre-payment review or post-payment review of services described in section 1861(r)(5) that are not subject to prior authorization medical review under subparagraph (A).

(C) RELATIONSHIP TO LAW ENFORCEMENT ACTIVITIES.—The Secretary may determine that medical review under this subsection does not apply in the case where potential fraud may be involved.

(3) NO PAYMENT WITHOUT PRIOR AUTHORIZATION.—With respect to a service described in paragraph (1) for which prior authorization medical review under this subsection applies, the following shall apply:

(A) PRIOR AUTHORIZATION DETERMINATION.—The Secretary shall make a determination, prior to the service being furnished, of whether the service would or would not meet the applicable requirements of section 1862(a)(1)(A).

(B) DENIAL OF PAYMENT.—Subject to paragraph (5), no payment may be made under this part for the service unless the Secretary determines pursuant to subparagraph (A) that the service would meet the applicable requirements of such section 1862(a)(1)(A).

(4) SUBMISSION OF INFORMATION.—A chiropractor described in section 1861(r)(5) may submit the information necessary for medical review by fax, by mail, or by electronic means. The Secretary shall make available the electronic means described in the preceding sentence as soon as practicable.

(5) TIMELINESS.—If the Secretary does not make a prior authorization determination under paragraph (3)(A) within 14 business days of the date of the receipt of medical documentation needed to make such determination, paragraph (3)(B) shall not apply.

(6) APPLICATION OF LIMITATION ON BENEFICIARY LIABILITY.—Where payment may not be made as a result of the application of paragraph (2)(B), section 1879 shall apply in the same manner as such section applies to a denial that is made by reason of section 1862(a)(1).

(7) REVIEW BY CONTRACTORS.—The medical review described in paragraph (2) may be conducted by medicare administrative contractors pursuant to section 1874A(a)(4)(G) or by any other contractor determined appropriate by the Secretary that is not a recovery audit contractor.

(8) MULTIPLE SERVICES.—The Secretary shall, where practicable, apply the medical review under this subsection in a manner so as to allow an individual described in paragraph (1) to obtain, at a single time rather than on a service-by-service basis, an authorization in accordance with paragraph (3)(A) for multiple services.

(9) CONSTRUCTION.—With respect to a service described in paragraph (1) that has been affirmed by medical review under this subsection, nothing in this subsection shall be construed to preclude the subsequent denial of a claim for such service that does not meet other applicable requirements under this Act.

(10) IMPLEMENTATION.—

(A) AUTHORITY.—The Secretary may implement the provisions of this subsection by interim final rule with comment period.

(B) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to medical review under this subsection.

*(bb) ADDITIONAL PAYMENTS FOR CERTAIN RURAL HEALTH CLINICS WITH PHYSICIANS OR PRACTITIONERS RECEIVING DATA 2000 WAIVERS.—*

*(1) IN GENERAL.—In the case of a rural health clinic with respect to which, beginning on or after January 1, 2019, rural health clinic services (as defined in section 1861(aa)(1)) are furnished for the treatment of opioid use disorder by a physician or practitioner who meets the requirements described in paragraph (3), the Secretary shall, subject to availability of funds under paragraph (4), make a payment (at such time and in such manner as specified by the Secretary) to such rural health clinic after receiving and approving an application described in paragraph (2). Such payment shall be in an amount determined by the Secretary, based on an estimate of the average costs of training for purposes of receiving a waiver described in paragraph (3)(B). Such payment may be made only one time with respect to each such physician or practitioner.*

*(2) APPLICATION.—In order to receive a payment described in paragraph (1), a rural health clinic shall submit to the Secretary an application for such a payment at such time, in such manner, and containing such information as specified by the Secretary. A rural health clinic may apply for such a payment for each physician or practitioner described in paragraph (1) furnishing services described in such paragraph at such clinic.*

*(3) REQUIREMENTS.—For purposes of paragraph (1), the requirements described in this paragraph, with respect to a physician or practitioner, are the following:*

*(A) The physician or practitioner is employed by or working under contract with a rural health clinic described in paragraph (1) that submits an application under paragraph (2).*

*(B) The physician or practitioner first receives a waiver under section 303(g) of the Controlled Substances Acton or after January 1, 2019.*

*(4) FUNDING.—For purposes of making payments under this subsection, there are appropriated, out of amounts in the Treasury not otherwise appropriated, $2,000,000, which shall remain available until expended.*

SPECIAL PAYMENT RULES FOR PARTICULAR ITEMS AND SERVICES

SEC. 1834. (a) PAYMENT FOR DURABLE MEDICAL EQUIPMENT.—

(1) GENERAL RULE FOR PAYMENT.—

(A) IN GENERAL.—With respect to a covered item (as defined in paragraph (13)) for which payment is determined under this subsection, payment shall be made in the frequency specified in paragraphs (2) through (7) and in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) PAYMENT BASIS.—Subject to subparagraph (F)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item, or

(ii) the payment amount recognized under paragraphs (2) through (7) of this subsection for the item;

except that clause (i) shall not apply if the covered item is furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(C) EXCLUSIVE PAYMENT RULE.—Subject to subparagraph (F)(ii), this subsection shall constitute the exclusive provision of this title for payment for covered items under this part or under part A to a home health agency.

(D) REDUCTION IN FEE SCHEDULES FOR CERTAIN ITEMS.—With respect to a seat-lift chair or transcutaneous electrical nerve stimulator furnished on or after April 1, 1990, the Secretary shall reduce the payment amount applied under subparagraph (B)(ii) for such an item by 15 percent, and, in the case of a transcutaneous electrical nerve stimulator furnished on or after January 1, 1991, the Secretary shall further reduce such payment amount (as previously reduced) by 45 percent.

(E) CLINICAL CONDITIONS FOR COVERAGE.—

(i) IN GENERAL.—The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

(ii) REQUIREMENTS.—The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1861(r)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) and a prescription for the item.

(iii) PRIORITY OF ESTABLISHMENT OF STANDARDS.—In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.

(iv) STANDARDS FOR POWER WHEELCHAIRS.—Effective on the date of the enactment of this subparagraph, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) has conducted a face-to-face examination of the individual and written a prescription for the item.

(v) LIMITATION ON PAYMENT FOR COVERED ITEMS.—Payment may not be made for a covered item under this subsection unless the item meets any standards established under this subparagraph for clinical condition of coverage.

(F) APPLICATION OF COMPETITIVE ACQUISITION; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of covered items furnished on or after January 1, 2011, subject to subparagraphs (G) and (H), that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program;

(ii) the Secretary may (and, in the case of covered items furnished on or after January 1, 2016, subject to clause (iii), shall) use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 and in the case of such adjustment, paragraph (10)(B) shall not be applied; and

(iii) in the case of covered items furnished on or after January 1, 2016, the Secretary shall continue to make such adjustments described in clause (ii) as, under such competitive acquisition programs, additional covered items are phased in or information is updated as contracts under section 1847 are recompeted in accordance with section 1847(b)(3)(B).

(G) USE OF INFORMATION ON COMPETITIVE BID RATES.—The Secretary shall specify by regulation the methodology to be used in applying the provisions of subparagraph (F)(ii) and subsection (h)(1)(H)(ii). In promulgating such regulation, the Secretary shall consider the costs of items and services in areas in which such provisions would be applied compared to the payment rates for such items and services in competitive acquisition areas.In the case of items and services furnished on or after January 1, 2019, in making any ad-

justments under clause (ii) or (iii) of subparagraph (F), under subsection (h)(1)(H)(ii), or under section 1842(s)(3)(B), the Secretary shall—

(i) solicit and take into account stakeholder input; and

(ii) take into account the highest amount bid by a winning supplier in a competitive acquisition area and a comparison of each of the following with respect to non-competitive acquisition areas and competitive acquisition areas:

(I) The average travel distance and cost associated with furnishing items and services in the area.

(II) The average volume of items and services furnished by suppliers in the area.

(III) The number of suppliers in the area.

(H) DIABETIC SUPPLIES.—

(i) IN GENERAL.—On or after the date described in clause (ii), the payment amount under this part for diabetic supplies, including testing strips, that are non-mail order items (as defined by the Secretary) shall be equal to the single payment amounts established under the national mail order competition for diabetic supplies under section 1847.

(ii) DATE DESCRIBED.—The date described in this clause is the date of the implementation of the single payment amounts under the national mail order competition for diabetic supplies under section 1847.

(I) TREATMENT OF VACUUM ERECTION SYSTEMS.—Effective for items and services furnished on and after July 1, 2015, vacuum erection systems described as prosthetic devices described in section 1861(s)(8) shall be treated in the same manner as erectile dysfunction drugs are treated for purposes of section 1860D-2(e)(2)(A).

(2) PAYMENT FOR INEXPENSIVE AND OTHER ROUTINELY PURCHASED DURABLE MEDICAL EQUIPMENT.—

(A) IN GENERAL.—Payment for an item of durable medical equipment (as defined in paragraph (13))—

(i) the purchase price of which does not exceed $150,

(ii) which the Secretary determines is acquired at least 75 percent of the time by purchase,

(iii) which is an accessory used in conjunction with a nebulizer, aspirator, or a ventilator excluded under paragraph (3)(A), or

(iv) in the case of devices furnished on or after October 1, 2015, which serves as a speech generating device or which is an accessory that is needed for the individual to effectively utilize such a device,

shall be made on a rental basis or in a lump-sum amount for the purchase of the item. The payment amount recognized for purchase or rental of such equipment is the amount specified in subparagraph (B) for purchase or rental, except that the total amount of payments with respect to an item may not exceed the payment amount specified in subparagraph (B) with respect to the purchase of the item.

(B) PAYMENT AMOUNT.—For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to the purchase or rental of an item furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the purchase or rental, respectively, of the item for the 12-month period ending on June 30, 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year (reduced by 10

percent, in the case of a blood glucose testing strip furnished after 1997 for an individual with diabetes).

(C) COMPUTATION OF LOCAL PAYMENT AMOUNT AND NATIONAL LIMITED PAYMENT AMOUNT.—For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994 the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(3) PAYMENT FOR ITEMS REQUIRING FREQUENT AND SUBSTANTIAL SERVICING.—

(A) IN GENERAL.—Payment for a covered item (such as IPPB machines and ventilators, excluding ventilators that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices) for which there must be frequent and substantial servicing in order to avoid risk to the patient's health shall be made on a monthly basis for the rental of the item and the amount recognized is the amount specified in subparagraph (B).

(B) PAYMENT AMOUNT.—For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to an item or device furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the rental of the item or device for the 12-month period ending with June 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year.

(C) COMPUTATION OF LOCAL PAYMENT AMOUNT AND NATIONAL LIMITED PAYMENT AMOUNT.—For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994 the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(4) PAYMENT FOR CERTAIN CUSTOMIZED ITEMS.—Payment with respect to a covered item that is uniquely constructed or substantially modified to meet the specific needs of an individual patient, and for that reason cannot be grouped with similar items for purposes of payment under this title, shall be made in a lump-sum amount (A) for the purchase of the item in a payment amount based upon the carrier's individual consideration for that item, and (B) for the reasonable and necessary maintenance and servicing for parts and labor not covered by the supplier's or manufacturer's warranty, when necessary during the period of medical need, and the amount recognized for such maintenance and servicing shall be paid on a lump-sum, as needed basis based upon the carrier's individual consideration for that item. In the case of a wheelchair furnished on or after January 1, 1992, the wheelchair shall be treated as a customized item for purposes of this paragraph if the wheelchair has been measured, fitted, or adapted in consideration of the patient's body size, disability, period of need, or intended use, and has been assembled by a supplier or ordered from a manufacturer who makes available customized features, modifications, or components for wheelchairs that are intended for an individual patient's use in accordance with instructions from the patient's physician.

(5) PAYMENT FOR OXYGEN AND OXYGEN EQUIPMENT.—

(A) IN GENERAL.—Payment for oxygen and oxygen equipment shall be made on a monthly basis in the monthly payment amount recognized under paragraph (9) for oxygen and oxygen equipment (other than portable oxygen equipment), subject to subparagraphs (B), (C), (E), and (F).

(B) ADD-ON FOR PORTABLE OXYGEN EQUIPMENT.—When portable oxygen equipment is used, but subject to subparagraph (D), the payment amount recognized under subparagraph (A) shall be increased by the monthly payment amount recognized under paragraph (9) for portable oxygen equipment.

(C) VOLUME ADJUSTMENT.—When the attending physician prescribes an oxygen flow rate—

(i) exceeding 4 liters per minute, the payment amount recognized under subparagraph (A), subject to subparagraph (D), shall be increased by 50 percent, or

(ii) of less than 1 liter per minute, the payment amount recognized under subparagraph (A) shall be decreased by 50 percent.

(D) LIMIT ON ADJUSTMENT.—When portable oxygen equipment is used and the attending physician prescribes an oxygen flow rate exceeding 4 liters per minute, there shall only be an increase under either subparagraph (B) or (C), whichever increase is larger, and not under both such subparagraphs.

(E) RECERTIFICATION FOR PATIENTS RECEIVING HOME OXYGEN THERAPY.—In the case of a patient receiving home oxygen therapy services who, at the time such services are initiated, has an initial arterial blood gas value at or above a partial pressure of 56 or an arterial oxygen saturation at or above 89 percent (or such other values, pressures, or criteria as the Secretary may specify) no payment may be made under this part for such services after the expiration of the 90-day period that begins on the date the patient first receives such services unless the patient's attending physician certifies that, on the basis of a follow-up test of the patient's arterial blood gas value or arterial oxygen saturation conducted

during the final 30 days of such 90-day period, there is a medical need for the patient to continue to receive such services.

(F) RENTAL CAP.—

(i) IN GENERAL.—Payment for oxygen equipment (including portable oxygen equipment) under this paragraph may not extend over a period of continuous use (as determined by the Secretary) of longer than 36 months.

(ii) PAYMENTS AND RULES AFTER RENTAL CAP.—After the 36th continuous month during which payment is made for the equipment under this paragraph—

(I) the supplier furnishing such equipment under this subsection shall continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime of the equipment, as determined by the Secretary;

(II) payments for oxygen shall continue to be made in the amount recognized for oxygen under paragraph (9) for the period of medical need; and

(III) maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(6) PAYMENT FOR OTHER COVERED ITEMS (OTHER THAN DURABLE MEDICAL EQUIPMENT).—Payment for other covered items (other than durable medical equipment and other covered items described in paragraph (3), (4), or (5)) shall be made in a lump-sum amount for the purchase of the item in the amount of the purchase price recognized under paragraph (8).

(7) PAYMENT FOR OTHER ITEMS OF DURABLE MEDICAL EQUIPMENT.—

(A) PAYMENT.—In the case of an item of durable medical equipment not described in paragraphs (2) through (6), the following rules shall apply:

(i) RENTAL.—

(I) IN GENERAL.—Except as provided in clause (iii), payment for the item shall be made on a monthly basis for the rental of the item during the period of medical need (but payments under this clause may not extend over a period of continuous use (as determined by the Secretary) of longer than 13 months).

(II) PAYMENT AMOUNT.—Subject to subclause (III) and subparagraph (B), the amount recognized for the item, for each of the first 3 months of such period, is 10 percent of the purchase price recognized under paragraph (8) with respect to the item, and, for each of the remaining months of such period, is 7.5 percent of such purchase price.

(III) SPECIAL RULE FOR POWER-DRIVEN WHEELCHAIRS.—For purposes of payment for power-driven wheelchairs, subclause (II) shall be applied by substituting "15 percent" and "6 percent" for "10 percent" and "7.5 percent", respectively.

(ii) OWNERSHIP AFTER RENTAL.—On the first day that begins after the 13th continuous month during which payment is made for the rental of an item under clause (i), the supplier of the item shall transfer title to the item to the individual.

(iii) PURCHASE AGREEMENT OPTION FOR COMPLEX, REHABILITATIVE POWER-DRIVEN WHEELCHAIRS.—In the case of a complex, rehabilitative power-driven wheelchair, at the time the supplier furnishes the item, the supplier shall offer the individual the option to purchase the item, and payment for such item shall be made on a lump-sum basis if the individual exercises such option.

(iv) MAINTENANCE AND SERVICING.—After the supplier transfers title to the item under clause (ii) or in the case of a power-driven wheelchair for which a purchase agreement has been entered into under clause (iii), maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the particular type of durable medical equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(B) RANGE FOR RENTAL AMOUNTS.—

(i) FOR 1989.—For items furnished during 1989, the payment amount recognized under subparagraph (A)(i) shall not be more than 115 percent, and shall not be less than 85 percent, of the prevailing charge established for rental of the item in January

1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987.

(ii) FOR 1990.—For items furnished during 1990, clause (i) shall apply in the same manner as it applies to items furnished during 1989.

(C) REPLACEMENT OF ITEMS.—

(i) ESTABLISHMENT OF REASONABLE USEFUL LIFETIME.—In accordance with clause (iii), the Secretary shall determine and establish a reasonable useful lifetime for items of durable medical equipment for which payment may be made under this paragraph.

(ii) PAYMENT FOR REPLACEMENT ITEMS.—If the reasonable lifetime of such an item, as so established, has been reached during a continuous period of medical need, or the carrier determines that the item is lost or irreparably damaged, the patient may elect to have payment for an item serving as a replacement for such item made—

(I) on a monthly basis for the rental of the replacement item in accordance with subparagraph (A); or

(II) in the case of an item for which a purchase agreement has been entered into under subparagraph (A)(iii), in a lump-sum amount for the purchase of the item.

(iii) LENGTH OF REASONABLE USEFUL LIFETIME.—The reasonable useful lifetime of an item of durable medical equipment under this subparagraph shall be equal to 5 years, except that, if the Secretary determines that, on the basis of prior experience in making payments for such an item under this title, a reasonable useful lifetime of 5 years is not appropriate with respect to a particular item, the Secretary shall establish an alternative reasonable lifetime for such item.

(8) PURCHASE PRICE RECOGNIZED FOR MISCELLANEOUS DEVICES AND ITEMS.—For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for a covered item is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) COMPUTATION OF LOCAL PURCHASE PRICE.—Each carrier under section 1842 shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price, for each item described—

(I) in paragraph (6) equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987, or

(II) in paragraph (7) equal to the average of the purchase prices on the claims submitted on an assignment-related basis for the unused item supplied during the 6-month period ending with December 1986.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item—

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987,

(II) in 1991, equal to the local purchase price computed under this clause for the previous year, increased by the covered item update for 1991, and decreased by the percentage by which the average of the reasonable charges for claims paid for all items described in paragraph (7) is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988; or

(III) in 1992, 1993, and 1994 equal to the local purchase price computed under this clause for the previous year increased by the covered item update for the year.

(B) COMPUTATION OF NATIONAL LIMITED PURCHASE PRICE.—With respect to the furnishing of a particular item in a year, the Secretary shall compute a national limited purchase price—

(i) for 1991, equal to the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the median of all local purchase prices computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local purchase prices computed under such subparagraph for the item for the year; and

(iv) for each subsequent year, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year.

(C) PURCHASE PRICE RECOGNIZED.—For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for each item furnished—

(i) in 1989 or 1990, is 100 percent of the local purchase price computed under subparagraph (A)(ii)(I);

(ii) in 1991, is the sum of (I) 67 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1991, and (II) 33 percent of the national limited purchase price computed under subparagraph (B) for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local purchase price computed under subparagraph (A)(ii)(III) for 1992, and (II) 67 percent of the national limited purchase price computed under subparagraph (B) for 1992; and

(iv) in 1993 or a subsequent year, is the national limited purchase price computed under subparagraph (B) for that year.

(9) MONTHLY PAYMENT AMOUNT RECOGNIZED WITH RESPECT TO OXYGEN AND OXYGEN EQUIPMENT.—For purposes of paragraph (5), the amount that is recognized under this paragraph for payment for oxygen and oxygen equipment is the monthly payment amount described in subparagraph (C) of this paragraph. Such amount shall be computed separately (i) for all items of oxygen and oxygen equipment (other than portable oxygen equipment) and (ii) for portable oxygen equipment (each such group referred to in this paragraph as an "item").

(A) COMPUTATION OF LOCAL MONTHLY PAYMENT RATE.—Each carrier under this section shall compute a base local payment rate for each item as follows:

(i) The carrier shall compute a base local average monthly payment rate per beneficiary as an amount equal to (I) the total reasonable charges for the item during the 12-month period ending with December 1986, divided by (II) the total number of months for all beneficiaries receiving the item in the area during the 12-month period for which the carrier made payment for the item under this title.

(ii) The carrier shall compute a local average monthly payment rate for the item applicable—

(I) to 1989 and 1990, equal to 95 percent of the base local average monthly payment rate computed under clause (i) for the item increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987, or

(II) to 1991, 1992, 1993, and 1994 equal to the local average monthly payment rate computed under this clause for the item for the previous year increased by the covered item increase for the year.

(B) COMPUTATION OF NATIONAL LIMITED MONTHLY PAYMENT RATE.—With respect to the furnishing of an item in a year, the Secretary shall compute a national limited monthly payment rate equal to—

(i) for 1991, the local monthly payment rate computed under subparagraph (A)(ii)(II) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local monthly payment rate computed under subparagraph (A)(ii) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the median of all local monthly payment rates

computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year;

(iv) for 1995, 1996, and 1997, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(v) for 1998, 75 percent of the amount determined under this subparagraph for 1997; and

(vi) for 1999 and each subsequent year, 70 percent of the amount determined under this subparagraph for 1997.

(C) MONTHLY PAYMENT AMOUNT RECOGNIZED.—For purposes of paragraph (5), the amount that is recognized under this paragraph as the base monthly payment amount for each item furnished—

(i) in 1989 and in 1990, is 100 percent of the local average monthly payment rate computed under subparagraph (A)(ii) for the item;

(ii) in 1991, is the sum of (I) 67 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1991, and (II) 33 percent of the national limited monthly payment rate computed under subparagraph (B)(i) for the item for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1992, and (II) 67 percent of the national limited monthly payment rate computed under subparagraph (B)(ii) for the item for 1992; and

(iv) in a subsequent year, is the national limited monthly payment rate computed under subparagraph (B) for the item for that year.

(10) EXCEPTIONS AND ADJUSTMENTS.—

(A) AREAS OUTSIDE CONTINENTAL UNITED STATES.—Exceptions to the amounts recognized under the previous provisions of this subsection shall be made to take into account the unique circumstances of covered items furnished in Alaska, Hawaii, or Puerto Rico.

(B) ADJUSTMENT FOR INHERENT REASONABLENESS.—The Secretary is authorized to apply the provisions of paragraphs (8) and (9) of section 1842(b) to covered items and suppliers of such items and payments under this subsection in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(F).

(C) TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (TENS).—In order to permit an attending physician time to determine whether the purchase of a transcutaneous electrical nerve stimulator is medically appropriate for a particular patient, the Secretary may determine an appropriate payment amount for the initial rental of such item for a period of not more than 2 months. If such item is subsequently purchased, the payment amount with respect to such purchase is the payment amount determined under paragraph (2).

(11) IMPROPER BILLING AND REQUIREMENT OF PHYSICIAN ORDER.—

(A) IMPROPER BILLING FOR CERTAIN RENTAL ITEMS.—Notwithstanding any other provision of this title, a supplier of a covered item for which payment is made under this subsection and which is furnished on a rental basis shall continue to supply the item without charge (other than a charge provided under this subsection for the maintenance and servicing of the item) after rental payments may no longer be made under this subsection. If a supplier knowingly and willfully violates the previous sentence, the Secretary may apply sanctions against the supplier under section 1842(j)(2) in the same manner such sanctions may apply with respect to a physician.

(B) REQUIREMENT OF PHYSICIAN ORDER.—

(i) IN GENERAL.—The Secretary is authorized to require, for specified covered items, that payment may be made under this subsection with respect to the item only if a physician enrolled under section 1866(j) or an eligible professional under section 1848(k)(3)(B) that is enrolled under section 1866(j) has communicated to the supplier, before delivery of the item, a written order for the item.

(ii) REQUIREMENT FOR FACE TO FACE ENCOUNTER.—The Secretary shall require that such an order be written pursuant to a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) documenting such physician, physician assistant, practitioner, or spe-

cialist has had a face-to-face encounter (including through use of telehealth under subsection (m) and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary.

(12) REGIONAL CARRIERS.—The Secretary may designate, by regulation under section 1842, one carrier for one or more entire regions to process all claims within the region for covered items under this section.

(13) COVERED ITEM.—In this subsection, the term "covered item" means durable medical equipment (as defined in section 1861(n)), including such equipment described in section 1861(m)(5), but not including implantable items for which payment may be made under section 1833(t).

(14) COVERED ITEM UPDATE.—In this subsection, the term "covered item update" means, with respect to a year—

(A) for 1991 and 1992, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced by 1 percentage point;

(B) for 1993, 1994, 1995, 1996, and 1997, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year;

(C) for each of the years 1998 through 2000, 0 percentage points;

(D) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(E) for 2002, 0 percentage points;

(F) for 2003, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of 2002;

(G) for 2004 through 2006—

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) for the year involved; and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(H) for 2007—

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(I) for 2008—

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(J) for 2009—

(i) in the case of items and services furnished in any geographic area, if such items or services were selected for competitive acquisition in any area under the competitive acquisition program under section 1847(a)(1)(B)(i)(I) before July 1, 2008, including related accessories but only if furnished with such items and services selected for such competition and diabetic supplies but only if furnished through mail order, - 9.5 percent; or

(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2008;

(K) for 2010, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year; and

(L) for 2011 and each subsequent year—

(i) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—

(ii) the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

The application of subparagraph (L)(ii) may result in the covered item update under this paragraph being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.

(15) ADVANCE DETERMINATIONS OF COVERAGE FOR CERTAIN ITEMS.—

(A) DEVELOPMENT OF LISTS OF ITEMS BY SECRETARY.—The Secretary may develop and periodically update a list of items for which payment may be made under this subsection that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization throughout a carrier's entire service area or a portion of such area.

(B) DEVELOPMENT OF LISTS OF SUPPLIERS BY SECRETARY.—The Secretary may develop and periodically update a list of suppliers of items for which payment may be made under this subsection with respect to whom—

(i) the Secretary has found that a substantial number of claims for payment under this part for items furnished by the supplier have been denied on the basis of the application of section 1862(a)(1); or

(ii) the Secretary has identified a pattern of overutilization resulting from the business practice of the supplier.

(C) DETERMINATIONS OF COVERAGE IN ADVANCE.—A carrier shall determine in advance of delivery of an item whether payment for the item may not be made because the item is not covered or because of the application of section 1862(a)(1) if—

(i) the item is included on the list developed by the Secretary under subparagraph (A);

(ii) the item is furnished by a supplier included on the list developed by the Secretary under subparagraph (B); or

(iii) the item is a customized item (other than inexpensive items specified by the Secretary) and the patient to whom the item is to be furnished or the supplier requests that such advance determination be made.

(16) DISCLOSURE OF INFORMATION AND SURETY BOND.—The Secretary shall not provide for the issuance (or renewal) of a provider number for a supplier of durable medical equipment, for purposes of payment under this part for durable medical equipment furnished by the supplier, unless the supplier provides the Secretary on a continuing basis—

(A) with—

(i) full and complete information as to the identity of each person with an ownership or control interest (as defined in section 1124(a)(3)) in the supplier or in any subcontractor (as defined by the Secretary in regulations) in which the supplier directly or indirectly has a 5 percent or more ownership interest; and

(ii) to the extent determined to be feasible under regulations of the Secretary, the name of any disclosing entity (as defined in section 1124(a)(2)) with respect to which a person with such an ownership or control interest in the supplier is a person with such an ownership or control interest in the disclosing entity; and

(B) with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000 that the Secretary determines is commensurate with the volume of the billing of the supplier.

The Secretary may waive the requirement of a bond under subparagraph (B) in the case of a supplier that provides a comparable surety bond under State law. The Secretary, at the Secretary's discretion, may impose the requirements of the first sentence with respect to some or all providers of items or services under part A or some or all suppliers or other persons (other than physicians or other practitioners, as defined in section 1842(b)(18)(C)) who furnish items or services under this part.

(17) PROHIBITION AGAINST UNSOLICITED TELEPHONE CONTACTS BY SUPPLIERS.—

(A) IN GENERAL.—A supplier of a covered item under this subsection may not contact an individual enrolled under this part by telephone regarding the furnishing of a covered item to the individual unless 1 of the following applies:

(i) The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a covered item.

(ii) The supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such covered item.

(iii) If the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least 1 covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

(B) PROHIBITING PAYMENT FOR ITEMS FURNISHED SUBSEQUENT TO UNSOLICITED CONTACTS.—If a supplier knowingly contacts an individual in violation of subparagraph (A), no payment may be made under this part for any item subsequently furnished to the individual by the supplier.

(C) EXCLUSION FROM PROGRAM FOR SUPPLIERS ENGAGING IN PATTERN OF UNSOLICITED CONTACTS.—If a supplier knowingly contacts individuals in violation of subparagraph (A) to such an extent that the supplier's conduct establishes a pattern of contacts in violation of such subparagraph, the Secretary shall exclude the supplier from participation in the programs under this Act, in accordance with the procedures set forth in subsections (c), (f), and (g) of section 1128.

(18) REFUND OF AMOUNTS COLLECTED FOR CERTAIN DISALLOWED ITEMS.—

(A) IN GENERAL.—If a nonparticipating supplier furnishes to an individual enrolled under this part a covered item for which no payment may be made under this part by reason of paragraph (17)(B), the supplier shall refund on a timely basis to the patient (and shall be liable to the patient for) any amounts collected from the patient for the item, unless—

(i) the supplier establishes that the supplier did not know and could not reasonably have been expected to know that payment may not be made for the item by reason of paragraph (17)(B), or

(ii) before the item was furnished, the patient was informed that payment under this part may not be made for that item and the patient has agreed to pay for that item.

(B) SANCTIONS.—If a supplier knowingly and willfully fails to make refunds in violation of subparagraph (A), the Secretary may apply sanctions against the supplier in accordance with section 1842(j)(2).

(C) NOTICE.—Each carrier with a contract in effect under this part with respect to suppliers of covered items shall send any notice of denial of payment for covered items by reason of paragraph (17)(B) and for which payment is not requested on an assignment-related basis to the supplier and the patient involved.

(D) TIMELY BASIS DEFINED.—A refund under subparagraph (A) is considered to be on a timely basis only if—

(i) in the case of a supplier who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the supplier receives a denial notice under subparagraph (C), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the supplier receives notice of an adverse determination on reconsideration or appeal.

(19) CERTAIN UPGRADED ITEMS.—

(A) INDIVIDUAL'S RIGHT TO CHOOSE UPGRADED ITEM.—Notwithstanding any other provision of this title, the Secretary may issue regulations under which an individual may purchase or rent from a supplier an item of upgraded durable medical equipment for which payment would be made under this subsection if the item were a standard item.

(B) PAYMENTS TO SUPPLIER.—In the case of the purchase or rental of an upgraded item under subparagraph (A)—

(i) the supplier shall receive payment under this subsection with respect to such item as if such item were a standard item; and

(ii) the individual purchasing or renting the item shall pay the supplier an amount equal to the difference between the supplier's charge and the amount under clause (i).

In no event may the supplier's charge for an upgraded item exceed the applicable fee schedule amount (if any) for such item.

(C) CONSUMER PROTECTION SAFEGUARDS.—Any regulations under subparagraph (A) shall provide for consumer protection standards with respect to the furnishing of upgraded equipment under subparagraph (A). Such regulations shall provide for—

(i) determination of fair market prices with respect to an upgraded item;

(ii) full disclosure of the availability and price of standard items and proof of receipt of such disclosure information by the beneficiary before the furnishing of the upgraded item;

(iii) conditions of participation for suppliers in the billing arrangement;

(iv) sanctions of suppliers who are determined to engage in coercive or abusive practices, including exclusion; and

(v) such other safeguards as the Secretary determines are necessary.

(20) IDENTIFICATION OF QUALITY STANDARDS.—

(A) IN GENERAL.—Subject to subparagraph (C), the Secretary shall establish and implement quality standards for suppliers of items and services described in subparagraph (D) to be applied by recognized independent accreditation organizations (as designated under subparagraph (B)) and with which such suppliers shall be required to comply in order to—

(i) furnish any such item or service for which payment is made under this part; and

(ii) receive or retain a provider or supplier number used to submit claims for reimbursement for any such item or service for which payment may be made under this title.

(B) DESIGNATION OF INDEPENDENT ACCREDITATION ORGANIZATIONS.—Not later than the date that is 1 year after the date on which the Secretary implements the quality standards under subparagraph (A), notwithstanding section 1865(a), the Secretary shall designate and approve one or more independent accreditation organizations for purposes of such subparagraph.

(C) QUALITY STANDARDS.—The quality standards described in subparagraph (A) may not be less stringent than the quality standards that would otherwise apply if this paragraph did not apply and shall include consumer services standards.

(D) ITEMS AND SERVICES DESCRIBED.—The items and services described in this subparagraph are the following items and services, as the Secretary determines appropriate:

(i) Covered items (as defined in paragraph (13)) for which payment may otherwise be made under this subsection.

(ii) Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4).

(iii) Items and services described in section 1842(s)(2).

(E) IMPLEMENTATION.—The Secretary may establish by program instruction or otherwise the quality standards under this paragraph, including subparagraph (F), after consultation with representatives of relevant parties. Such standards shall be applied prospectively and shall be published on the Internet website of the Centers for Medicare & Medicaid Services.

(F) APPLICATION OF ACCREDITATION REQUIREMENT.—In implementing quality standards under this paragraph—

(i) subject to clause (ii) and subparagraph (G), the Secretary shall require suppliers furnishing items and services described in subparagraph (D) on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted to the Secretary evidence of accreditation by an accreditation organization designated under subparagraph (B) as meeting applicable quality standards, except that the Secretary shall not require under this clause pharmacies to obtain such accreditation before January 1, 2010, except that the Secretary shall not require a pharmacy to have submitted to the Secretary such evidence of accreditation prior to January 1, 2011; and

(ii) in applying such standards and the accreditation requirement of clause (i) with respect to eligible professionals (as defined in section 1848(k)(3)(B)), and including such other persons, such as orthotists and prosthetists, as specified by the Secretary, furnishing such items and services—

(I) such standards and accreditation requirement shall not apply to such professionals and persons unless the Secretary determines that the standards being applied are designed specifically to be applied to such professionals and persons; and

(II) the Secretary may exempt such professionals and persons from such standards and requirement if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons with respect to the furnishing of such items and services.

(G) APPLICATION OF ACCREDITATION REQUIREMENT TO CERTAIN PHARMACIES.—

(i) IN GENERAL.—With respect to items and services furnished on or after January 1, 2011, in implementing quality standards under this paragraph—

(I) subject to subclause (II), in applying such standards and the accreditation requirement of subparagraph (F)(i) with respect to pharmacies described in clause (ii) furnishing such items and services, such standards and accreditation requirement shall not apply to such pharmacies; and

(II) the Secretary may apply to such pharmacies an alternative accreditation requirement established by the Secretary if the Secretary determines such alternative accreditation requirement is more appropriate for such pharmacies.

(ii) PHARMACIES DESCRIBED.—A pharmacy described in this clause is a pharmacy that meets each of the following criteria:

(I) The total billings by the pharmacy for such items and services under this title are less than 5 percent of total pharmacy sales, as determined based on the average total pharmacy sales for the previous 3 calendar years, 3 fiscal years, or other yearly period specified by the Secretary.

(II) The pharmacy has been enrolled under section 1866(j) as a supplier of durable medical equipment, prosthetics, orthotics, and supplies, has been issued (which may include the renewal of) a provider number for at least 5 years, and for which a final adverse action (as defined in section 424.57(a) of title 42, Code of Federal Regulations) has not been imposed in the past 5 years.

(III) The pharmacy submits to the Secretary an attestation, in a form and manner, and at a time, specified by the Secretary, that the pharmacy meets the criteria described in subclauses (I) and (II). Such attestation shall be subject to section 1001 of title 18, United States Code.

(IV) The pharmacy agrees to submit materials as requested by the Secretary, or during the course of an audit conducted on a random sample of pharmacies selected annually, to verify that the pharmacy meets the criteria described in subclauses (I) and (II). Materials submitted under the preceding sentence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods, as requested by the Secretary.

(21) SPECIAL PAYMENT RULE FOR SPECIFIED ITEMS AND SUPPLIES.—

(A) IN GENERAL.—Notwithstanding the preceding provisions of this subsection, for specified items and supplies (described in subparagraph (B)) furnished during 2005, the payment amount otherwise determined under this subsection for such specified items and supplies shall be reduced by the percentage difference between—

(i) the amount of payment otherwise determined for the specified item or supply under this subsection for 2002, and

(ii) the amount of payment for the specified item or supply under chapter 89 of title 5, United States Code, as identified in the column entitled "Median FEHP Price" in the table entitled "SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS" included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002, or any subsequent report by the Inspector General.

(B) SPECIFIED ITEM OR SUPPLY DESCRIBED.—For purposes of subparagraph (A), a specified item or supply means oxygen and oxygen equipment, standard wheelchairs (including standard power wheelchairs), nebulizers, diabetic supplies consisting of lancets and testing strips, hospital beds, and air mattresses, but only if the HCPCS code for the item or supply is identified in a table referred to in subparagraph (A)(ii).

(C) APPLICATION OF UPDATE TO SPECIAL PAYMENT AMOUNT.—The covered item update under paragraph (14) for specified items and supplies for 2006 and each subsequent year shall be applied to the payment amount under subparagraph (A) unless payment is made for such items and supplies under section 1847.

(22) SPECIAL PAYMENT RULE FOR DIABETIC SUPPLIES.—Notwithstanding the preceding provisions of this subsection, for purposes of determining the payment amount under this subsection for diabetic supplies furnished on or after the first day of the calendar quarter during 2013 that is at least 30 days after the date of the enactment of this paragraph and before the date described in paragraph (1)(H)(ii), the Secretary shall recalculate and apply the covered item update under paragraph (14) as if subparagraph (J)(i) of such paragraph was amended by striking "but only if furnished through mail order".

(b) FEE SCHEDULES FOR RADIOLOGIST SERVICES.—

(1) DEVELOPMENT.—The Secretary shall develop—

(A) a relative value scale to serve as the basis for the payment for radiologist services under this part, and

(B) using such scale and appropriate conversion factors and subject to subsection (c)(1)(A), fee schedules (on a regional, statewide, locality, or carrier service area basis) for payment for radiologist services under this part, to be implemented for such services furnished during 1989.

(2) CONSULTATION.—In carrying out paragraph (1), the Secretary shall regularly consult closely with the Physician Payment Review Commission, the American College of Radiology, and other organizations representing physicians or suppliers who furnish radiologist services and shall share with them the data and data analysis being used to make the determinations under paragraph (1), including data on variations in current medicare payments by geographic area, and by service and physician specialty.

(3) CONSIDERATIONS.—In developing the relative value scale and fee schedules under paragraph (1), the Secretary—

(A) shall take into consideration variations in the cost of furnishing such services among geographic areas and among different sites where services are furnished, and

(B) may also take into consideration such other factors respecting the manner in which physicians in different specialties furnish such services as may be appropriate to assure that payment amounts are equitable and designed to promote effective and efficient provision of radiologist services by physicians in the different specialties.

(4) SAVINGS.—

(A) BUDGET NEUTRAL FEE SCHEDULES.—The Secretary shall develop preliminary fee schedules for 1989, which are designed to result in the same amount of aggregate payments (net of any coinsurance and deductibles under sections 1833(a)(1)(J) and 1833(b)) for radiologist services furnished in 1989 as would have been made if this subsection had not been enacted.

(B) INITIAL SAVINGS.—The fee schedules established for payment purposes under this subsection for services furnished in 1989 shall be 97 percent of the amounts permitted under these preliminary fee schedules developed under subparagraph (A).

(C) 1990 FEE SCHEDULES.—For radiologist services (other than portable X-ray services) furnished under this part during 1990, after March 31 of such year, the conversion factors used under this subsection shall be 96 percent of the conversion factors that applied under this subsection as of December 31, 1989.

(D) 1991 FEE SCHEDULES.—For radiologist services (other than portable X-ray services) furnished under this part during 1991, the conversion factors used in a locality under this subsection shall, subject to clause (vii), be reduced to the adjusted conversion factor for the locality determined as follows:

(i) NATIONAL WEIGHTED AVERAGE CONVERSION FACTOR.—The Secretary shall estimate the national weighted average of the conversion factors used under this subsection for services furnished during 1990 beginning on April 1, using the best available data.

(ii) REDUCED NATIONAL WEIGHTED AVERAGE.—The national weighted average estimated under clause (i) shall be reduced by 13 percent.

(iii) COMPUTATION OF 1990 LOCALITY INDEX RELATIVE TO NATIONAL AVERAGE.—The Secretary shall establish an index which reflects, for each locality, the ratio of the conversion factor used in the locality under this subsection to the national weighted average estimated under clause (i).

(iv) ADJUSTED CONVERSION FACTOR.—The adjusted conversion factor for the professional or technical component of a service in a locality is the sum of ½ of the lo-

cally-adjusted amount determined under clause (v) and ½ of the GPCI-adjusted amount determined under clause (vi).

(v) LOCALLY-ADJUSTED AMOUNT.—For purposes of clause (iv), the locally adjusted amount determined under this clause is the product of (I) the national weighted average conversion factor computed under clause (ii), and (II) the index value established under clause (iii) for the locality.

(vi) GPCI-ADJUSTED AMOUNT.—For purposes of clause (iv), the GPCI-adjusted amount determined under this clause is the sum of—

(I) the product of (a) the portion of the reduced national weighted average conversion factor computed under clause (ii) which is attributable to physician work and (b) the geographic work index value for the locality (specified in Addendum C to the Model Fee Schedule for Physician Services (published on September 4, 1990, 55 Federal Register pp. 36238–36243)); and

(II) the product of (a) the remaining portion of the reduced national weighted average conversion factor computed under clause (ii), and (b) the geographic practice cost index value specified in section 1842(b)(14)(C)(iv) for the locality.

In applying this clause with respect to the professional component of a service, 80 percent of the conversion factor shall be considered to be attributable to physician work and with respect to the technical component of the service, 0 percent shall be considered to be attributable to physician work.

(vii) LIMITS ON CONVERSION FACTOR.—The conversion factor to be applied to a locality to the professional or technical component of a service shall not be reduced under this subparagraph by more than 9.5 percent below the conversion factor applied in the locality under subparagraph (C) to such component, but in no case shall the conversion factor be less than 60 percent of the national weighted average of the conversion factors (computed under clause (i)).

(E) RULE FOR CERTAIN SCANNING SERVICES.—In the case of the technical components of magnetic resonance imaging (MRI) services and computer assisted tomography (CAT) services furnished after December 31, 1990, the amount otherwise payable shall be reduced by 10 percent.

(F) SUBSEQUENT UPDATING.—For radiologist services furnished in subsequent years, the fee schedules shall be the schedules for the previous year updated by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year.

(G) NONPARTICIPATING PHYSICIANS AND SUPPLIERS.—Each fee schedule so established shall provide that the payment rate recognized for nonparticipating physicians and suppliers is equal to the appropriate percent (as defined in section 1842(b)(4)(A)(iv)) of the payment rate recognized for participating physicians and suppliers.

(5) LIMITING CHARGES OF NONPARTICIPATING PHYSICIANS AND SUPPLIERS.—

(A) IN GENERAL.—In the case of radiologist services furnished after January 1, 1989, for which payment is made under a fee schedule under this subsection, if a nonparticipating physician or supplier furnishes the service to an individual entitled to benefits under this part, the physician or supplier may not charge the individual more than the limiting charge (as defined in subparagraph (B)).

(B) LIMITING CHARGE DEFINED.—In subparagraph (A), the term "limiting charge" means, with respect to a service furnished—

(i) in 1989, 125 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1),

(ii) in 1990, 120 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1), and

(iii) after 1990, 115 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1).

(C) ENFORCEMENT.—If a physician or supplier knowingly and willfully bills in violation of subparagraph (A), the Secretary may apply sanctions against such physician or supplier in accordance with section 1842(j)(2) in the same manner as such sanctions may apply to a physician.

(6) RADIOLOGIST SERVICES DEFINED.—For the purposes of this subsection and section 1833(a)(1)(J), the term "radiologist services" only includes radiology services performed by, or under the direction or supervision of, a physician—

(A) who is certified, or eligible to be certified, by the American Board of Radiology, or

(B) for whom radiology services account for at least 50 percent of the total amount of charges made under this part.

(c) PAYMENT AND STANDARDS FOR SCREENING MAMMOGRAPHY.—

(1) IN GENERAL.—With respect to expenses incurred for screening mammography (as defined in section 1861(jj)), payment may be made only—

(A) for screening mammography conducted consistent with the frequency permitted under paragraph (2); and

(B) if the screening mammography is conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act.

(2) FREQUENCY COVERED.—

(A) IN GENERAL.—Subject to revision by the Secretary under subparagraph (B)—

(i) no payment may be made under this part for screening mammography performed on a woman under 35 years of age;

(ii) payment may be made under this part for only one screening mammography performed on a woman over 34 years of age, but under 40 years of age; and

(iii) in the case of a woman over 39 years of age, payment may not be made under this part for screening mammography performed within 11 months following the month in which a previous screening mammography was performed.

(B) REVISION OF FREQUENCY.—

(i) REVIEW.—The Secretary, in consultation with the Director of the National Cancer Institute, shall review periodically the appropriate frequency for performing screening mammography, based on age and such other factors as the Secretary believes to be pertinent.

(ii) REVISION OF FREQUENCY.—The Secretary, taking into consideration the review made under clause (i), may revise from time to time the frequency with which screening mammography may be paid for under this subsection.

(d) FREQUENCY LIMITS AND PAYMENT FOR COLORECTAL CANCER SCREENING TESTS.—

(1) SCREENING FECAL-OCCULT BLOOD TESTS.—

(A) PAYMENT AMOUNT.—The payment amount for colorectal cancer screening tests consisting of screening fecal-occult blood tests is equal to the payment amount established for diagnostic fecal-occult blood tests under section 1833(h).

(B) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening fecal-occult blood test—

(i) if the individual is under 50 years of age; or

(ii) if the test is performed within the 11 months after a previous screening fecal-occult blood test.

(2) SCREENING FLEXIBLE SIGMOIDOSCOPIES.—

(A) FEE SCHEDULE.—With respect to colorectal cancer screening tests consisting of screening flexible sigmoidoscopies, payment under section 1848 shall be consistent with payment under such section for similar or related services.

(B) PAYMENT LIMIT.—In the case of screening flexible sigmoidoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic flexible sigmoidoscopy services.

(C) FACILITY PAYMENT LIMIT.—

(i) IN GENERAL.—Notwithstanding subsections (i)(2)(A) and (t) of section 1833, in the case of screening flexible sigmoidoscopy services furnished on or after January 1, 1999, that—

(I) in accordance with regulations, may be performed in an ambulatory surgical center and for which the Secretary permits ambulatory surgical center payments under this part, and

(II) are performed in an ambulatory surgical center or hospital outpatient department,

payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) LIMITATION ON COINSURANCE.—Notwithstanding any other provision of this title, in the case of a beneficiary who receives the services described in clause (i)—

(I) in computing the amount of any applicable copayment, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) SPECIAL RULE FOR DETECTED LESIONS.—If during the course of such screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening flexible sigmoidoscopy but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal.

(E) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening flexible sigmoidoscopy—

(i) if the individual is under 50 years of age; or

(ii) if the procedure is performed within the 47 months after a previous screening flexible sigmoidoscopy or, in the case of an individual who is not at high risk for colorectal cancer, if the procedure is performed within the 119 months after a previous screening colonoscopy.

(3) SCREENING COLONOSCOPY.—

(A) FEE SCHEDULE.—With respect to colorectal cancer screening test consisting of a screening colonoscopy, payment under section 1848 shall be consistent with payment amounts under such section for similar or related services.

(B) PAYMENT LIMIT.—In the case of screening colonoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic colonoscopy services.

(C) FACILITY PAYMENT LIMIT.—

(i) IN GENERAL.—Notwithstanding subsections (i)(2)(A) and (t) of section 1833, in the case of screening colonoscopy services furnished on or after January 1, 1999, that are performed in an ambulatory surgical center or a hospital outpatient department, payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) LIMITATION ON COINSURANCE.—Notwithstanding any other provision of this title, in the case of a beneficiary who receives the services described in clause (i)—

(I) in computing the amount of any applicable coinsurance, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) SPECIAL RULE FOR DETECTED LESIONS.—If during the course of such screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal.

(E) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening colonoscopy for individuals at high risk for colorectal cancer if the procedure is performed within the 23 months after a previous screening colonoscopy or for other individuals if the procedure is performed within the 119 months after a previous screening colonoscopy or within 47 months after a previous screening flexible sigmoidoscopy.

(e) ACCREDITATION REQUIREMENT FOR ADVANCED DIAGNOSTIC IMAGING SERVICES.—

(1) IN GENERAL.—

(A) IN GENERAL.—Beginning with January 1, 2012, with respect to the technical component of advanced diagnostic imaging services for which payment is made under the fee schedule established under section 1848(b) and that are furnished by a supplier, payment

may only be made if such supplier is accredited by an accreditation organization designated by the Secretary under paragraph (2)(B)(i).

(B) ADVANCED DIAGNOSTIC IMAGING SERVICES DEFINED.—In this subsection, the term "advanced diagnostic imaging services" includes—

(i) diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and

(ii) such other diagnostic imaging services, including services described in section 1848(b)(4)(B) (excluding X-ray, ultrasound, and fluoroscopy), as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

(C) SUPPLIER DEFINED.—In this subsection, the term "supplier" has the meaning given such term in section 1861(d).

(2) ACCREDITATION ORGANIZATIONS.—

(A) FACTORS FOR DESIGNATION OF ACCREDITATION ORGANIZATIONS.—The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B)(i) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

(i) The ability of the organization to conduct timely reviews of accreditation applications.

(ii) Whether the organization has established a process for the timely integration of new advanced diagnostic imaging services into the organization's accreditation program.

(iii) Whether the organization uses random site visits, site audits, or other strategies for ensuring accredited suppliers maintain adherence to the criteria described in paragraph (3).

(iv) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D)).

(v) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

(vi) Such other factors as the Secretary determines appropriate.

(B) DESIGNATION.—Not later than January 1, 2010, the Secretary shall designate organizations to accredit suppliers furnishing the technical component of advanced diagnostic imaging services. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

(C) REVIEW AND MODIFICATION OF LIST OF ACCREDITATION ORGANIZATIONS.—

(i) IN GENERAL.—The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

(ii) SPECIAL RULE FOR ACCREDITATIONS DONE PRIOR TO REMOVAL FROM LIST OF DESIGNATED ACCREDITATION ORGANIZATIONS.—In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

(3) CRITERIA FOR ACCREDITATION.—The Secretary shall establish procedures to ensure that the criteria used by an accreditation organization designated under paragraph (2)(B) to evaluate a supplier that furnishes the technical component of advanced diagnostic imaging services for the purpose of accreditation of such supplier is specific to each imaging modality. Such criteria shall include—

(A) standards for qualifications of medical personnel who are not physicians and who furnish the technical component of advanced diagnostic imaging services;

(B) standards for qualifications and responsibilities of medical directors and supervising physicians, including standards that recognize the considerations described in paragraph (4);

(C) procedures to ensure that equipment used in furnishing the technical component of advanced diagnostic imaging services meets performance specifications;

(D) standards that require the supplier have procedures in place to ensure the safety of persons who furnish the technical component of advanced diagnostic imaging services and individuals to whom such services are furnished;

(E) standards that require the establishment and maintenance of a quality assurance and quality control program by the supplier that is adequate and appropriate to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by such supplier; and

(F) any other standards or procedures the Secretary determines appropriate.

(4) RECOGNITION IN STANDARDS FOR THE EVALUATION OF MEDICAL DIRECTORS AND SUPERVISING PHYSICIANS.—The standards described in paragraph (3)(B) shall recognize whether a medical director or supervising physician—

(A) in a particular specialty receives training in advanced diagnostic imaging services in a residency program;

(B) has attained, through experience, the necessary expertise to be a medical director or a supervising physician;

(C) has completed any continuing medical education courses relating to such services; or

(D) has met such other standards as the Secretary determines appropriate.

(5) RULE FOR ACCREDITATIONS MADE PRIOR TO DESIGNATION.—In the case of a supplier that is accredited before January 1, 2010, by an accreditation organization designated by the Secretary under paragraph (2)(B) as of January 1, 2010, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2012, for the remaining period such accreditation is in effect.

(f) REDUCTION IN PAYMENTS FOR PHYSICIAN PATHOLOGY SERVICES DURING 1991.—

(1) IN GENERAL.—For physician pathology services furnished under this part during 1991, the prevailing charges used in a locality under this part shall be 7 percent below the prevailing charges used in the locality under this part in 1990 after March 31.

(2) LIMITATION.—The prevailing charge for the technical and professional components of an physician pathology service furnished by a physician through an independent laboratory shall not be reduced pursuant to paragraph (1) to the extent that such reduction would reduce such prevailing charge below 115 percent of the prevailing charge for the professional component of such service when furnished by a hospital-based physician in the same locality. For purposes of the preceding sentence, an independent laboratory is a laboratory that is independent of a hospital and separate from the attending or consulting physicians' office.

(g) PAYMENT FOR OUTPATIENT CRITICAL ACCESS HOSPITAL SERVICES.—

(1) IN GENERAL.—The amount of payment for outpatient critical access hospital services of a critical access hospital is equal to 101 percent of the reasonable costs of the hospital in providing such services, unless the hospital makes the election under paragraph (2).

(2) ELECTION OF COST-BASED HOSPITAL OUTPATIENT SERVICE PAYMENT PLUS FEE SCHEDULE FOR PROFESSIONAL SERVICES.—A critical access hospital may elect to be paid for outpatient critical access hospital services amounts equal to the sum of the following, less the amount that such hospital may charge as described in section 1866(a)(2)(A):

(A) FACILITY FEE.—With respect to facility services, not including any services for which payment may be made under subparagraph (B), 101 percent of the reasonable costs of the critical access hospital in providing such services.

(B) FEE SCHEDULE FOR PROFESSIONAL SERVICES.—With respect to professional services otherwise included within outpatient critical access hospital services, 115 percent of such amounts as would otherwise be paid under this part if such services were not included in outpatient critical access hospital services. Subsections (x) and (y) of section 1833 shall not be taken into account in determining the amounts that would otherwise be paid pursuant to the preceding sentence.

The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician or other practitioner providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to those physicians and practitioners who have not assigned such billing rights.

(3) DISREGARDING CHARGES.—The payment amounts under this subsection shall be determined without regard to the amount of the customary or other charge.

(4) TREATMENT OF CLINICAL DIAGNOSTIC LABORATORY SERVICES.—No coinsurance, deductible, copayment, or other cost-sharing otherwise applicable under this part shall apply with respect to clinical diagnostic laboratory services furnished as an outpatient critical access hospital service. Nothing in this title shall be construed as providing for payment for clinical diagnostic laboratory services furnished as part of outpatient critical access hospital services, other than on the basis described in this subsection. For purposes of the preceding sentence and section 1861(mm)(3), clinical diagnostic laboratory services furnished by a critical access hospital shall be treated as being furnished as part of outpatient critical access services without regard to whether the individual with respect to whom such services are furnished is physically present in the critical access hospital, or in a skilled nursing facility or a clinic (including a rural health clinic) that is operated by a critical access hospital, at the time the specimen is collected.

(5) COVERAGE OF COSTS FOR CERTAIN EMERGENCY ROOM ON-CALL PROVIDERS.—In determining the reasonable costs of outpatient critical access hospital services under paragraphs (1) and (2)(A), the Secretary shall recognize as allowable costs, amounts (as defined by the Secretary) for reasonable compensation and related costs for physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services but who are not present on the premises of the critical access hospital involved, and are not otherwise furnishing services covered under this title and are not on-call at any other provider or facility.

(h) PAYMENT FOR PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS.—

(1) GENERAL RULE FOR PAYMENT.—

(A) IN GENERAL.—Payment under this subsection for prosthetic devices and orthotics and prosthetics shall be made in a lump-sum amount for the purchase of the item in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) PAYMENT BASIS.—Except as provided in subparagraphs (C), (E), and (H)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item; or

(ii) the amount recognized under paragraph (2) as the purchase price for the item.

(C) EXCEPTION FOR CERTAIN PUBLIC HOME HEALTH AGENCIES.—Subparagraph (B)(i) shall not apply to an item furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(D) EXCLUSIVE PAYMENT RULE.—Subject to subparagraph (H)(ii), this subsection shall constitute the exclusive provision of this title for payment for prosthetic devices, orthotics, and prosthetics under this part or under part A to a home health agency.

(E) EXCEPTION FOR CERTAIN ITEMS.—Payment for ostomy supplies, tracheostomy supplies, and urologicals shall be made in accordance with subparagraphs (B) and (C) of section 1834(a)(2).

(F) SPECIAL PAYMENT RULES FOR CERTAIN PROSTHETICS AND CUSTOM-FABRICATED ORTHOTICS.—

(i) IN GENERAL.—No payment shall be made under this subsection for an item of custom-fabricated orthotics described in clause (ii) or for an item of prosthetics unless such item is—

(I) furnished by a qualified practitioner; and

(II) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate.

(ii) DESCRIPTION OF CUSTOM-FABRICATED ITEM.—

(I) IN GENERAL.—An item described in this clause is an item of custom-fabricated orthotics that requires education, training, and experience to custom-fabricate and that is included in a list established by the Secretary in subclause (II). Such an item does not include shoes and shoe inserts.

(II) LIST OF ITEMS.—The Secretary, in consultation with appropriate experts in orthotics (including national organizations representing manufacturers of orthotics), shall establish and update as appropriate a list of items to which this subparagraph applies. No item may be included in such list unless the item is individually fabricated for the patient over a positive model of the patient.

(iii) QUALIFIED PRACTITIONER DEFINED.—In this subparagraph, the term "qualified practitioner" means a physician or other individual who—

(I) is a qualified physical therapist or a qualified occupational therapist;

(II) in the case of a State that provides for the licensing of orthotics and prosthetics, is licensed in orthotics or prosthetics by the State in which the item is supplied; or

(III) in the case of a State that does not provide for the licensing of orthotics and prosthetics, is specifically trained and educated to provide or manage the provision of prosthetics and custom-designed or -fabricated orthotics, and is certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or is credentialed and approved by a program that the Secretary determines, in consultation with appropriate experts in orthotics and prosthetics, has training and education standards that are necessary to provide such prosthetics and orthotics.

(iv) QUALIFIED SUPPLIER DEFINED.—In this subparagraph, the term "qualified supplier" means any entity that is accredited by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or accredited and approved by a program that the Secretary determines has accreditation and approval standards that are essentially equivalent to those of such Board.

(G) REPLACEMENT OF PROSTHETIC DEVICES AND PARTS.—

(i) IN GENERAL.—Payment shall be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the provision of a replacement device, or a replacement part of such a device, is necessary because of any of the following:

(I) A change in the physiological condition of the patient.

(II) An irreparable change in the condition of the device, or in a part of the device.

(III) The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

(ii) CONFIRMATION MAY BE REQUIRED IF DEVICE OR PART BEING REPLACED IS LESS THAN 3 YEARS OLD.—If a physician determines that a replacement device, or a replacement part, is necessary pursuant to clause (i)—

(I) such determination shall be controlling; and

(II) such replacement device or part shall be deemed to be reasonable and necessary for purposes of section 1862(a)(1)(A);

except that if the device, or part, being replaced is less than 3 years old (calculated from the date on which the beneficiary began to use the device or part), the Secretary may also require confirmation of necessity of the replacement device or replacement part, as the case may be.

(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph (2)(C) of section 1847(a) furnished on or after January 1, 2009, subject to subsection (a)(1)(G), that are included in a competitive acquisition program in a competitive acquisition area under such section—

(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(ii) subject to subsection (a)(1)(G), the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.

(2) PURCHASE PRICE RECOGNIZED.—For purposes of paragraph (1), the amount that is recognized under this paragraph as the purchase price for prosthetic devices, orthotics, and prosthetics is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) COMPUTATION OF LOCAL PURCHASE PRICE.—Each carrier under section 1842 shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price for each item equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item—

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 6-month period ending with December 1987, or

(II) in 1991, 1992 or 1993, equal to the local purchase price computed under this clause for the previous year increased by the applicable percentage increase for the year.

(B) COMPUTATION OF REGIONAL PURCHASE PRICE.—With respect to the furnishing of a particular item in each region (as defined by the Secretary), the Secretary shall compute a regional purchase price—

(i) for 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local purchase prices for the carriers in the region computed under subparagraph (A)(ii)(II) for the year, and

(ii) for each subsequent year, equal to the regional purchase price computed under this subparagraph for the previous year increased by the applicable percentage increase for the year.

(C) PURCHASE PRICE RECOGNIZED.—For purposes of paragraph (1) and subject to subparagraph (D), the amount that is recognized under this paragraph as the purchase price for each item furnished—

(i) in 1989, 1990, or 1991, is 100 percent of the local purchase price computed under subparagraph (A)(ii);

(ii) in 1992, is the sum of (I) 75 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1992, and (II) 25 percent of the regional purchase price computed under subparagraph (B) for 1992;

(iii) in 1993, is the sum of (I) 50 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1993, and (II) 50 percent of the regional purchase price computed under subparagraph (B) for 1993; and

(iv) in 1994 or a subsequent year, is the regional purchase price computed under subparagraph (B) for that year.

(D) RANGE ON AMOUNT RECOGNIZED.—The amount that is recognized under subparagraph (C) as the purchase price for an item furnished—

(i) in 1992, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year; and

(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year.

(3) APPLICABILITY OF CERTAIN PROVISIONS RELATING TO DURABLE MEDICAL EQUIPMENT.—Paragraphs (12) and (17) and subparagraphs (A) and (B) of paragraph (10) and paragraph (11) of subsection (a) shall apply to prosthetic devices, orthotics, and prosthetics in the same manner as such provisions apply to covered items under such subsection.

(4) DEFINITIONS.—In this subsection—

(A) the term "applicable percentage increase" means—

(i) for 1991, 0 percent;

(ii) for 1992 and 1993, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(iii) for 1994 and 1995, 0 percent;

(iv) for 1996 and 1997, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(v) for each of the years 1998 through 2000, 1 percent;

(vi) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(vii) for 2002, 1 percent;

(viii) for 2003, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(ix) for 2004, 2005, and 2006, 0 percent;

(x) for for each of 2007 through 2010, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year; and

(xi) for 2011 and each subsequent year—

(I) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—

(II) the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

(B) the term "prosthetic devices" has the meaning given such term in section 1861(s)(8), except that such term does not include parenteral and enteral nutrition nutrients, supplies, and equipment and does not include an implantable item for which payment may be made under section 1833(t); and

(C) the term "orthotics and prosthetics" has the meaning given such term in section 1861(s)(9) (and includes shoes described in section 1861(s)(12)), but does not include intraocular lenses or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1861(m)(5).

The application of subparagraph (A)(xi)(II) may result in the applicable percentage increase under subparagraph (A) being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.

(5) DOCUMENTATION CREATED BY ORTHOTISTS AND PROSTHETISTS.—For purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by eligible professionals described in section 1848(k)(3)(B).

(i) PAYMENT FOR SURGICAL DRESSINGS.—

(1) IN GENERAL.—Payment under this subsection for surgical dressings (described in section 1861(s)(5)) shall be made in a lump sum amount for the purchase of the item in an amount equal to 80 percent of the lesser of—

(A) the actual charge for the item; or

(B) a payment amount determined in accordance with the methodology described in subparagraphs (B) and (C) of subsection (a)(2) (except that in applying such methodology, the national limited payment amount referred to in such subparagraphs shall be initially computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, increased by the covered item updates described in such subsection for 1993 and 1994).

(2) EXCEPTIONS.—Paragraph (1) shall not apply to surgical dressings that are—

(A) furnished as an incident to a physician's professional service; or

(B) furnished by a home health agency.

(j) REQUIREMENTS FOR SUPPLIERS OF MEDICAL EQUIPMENT AND SUPPLIES.—

(1) ISSUANCE AND RENEWAL OF SUPPLIER NUMBER.—

(A) PAYMENT.—Except as provided in subparagraph (C), no payment may be made under this part after the date of the enactment of the Social Security Act Amendments of 1994 for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number.

(B) STANDARDS FOR POSSESSING A SUPPLIER NUMBER.—A supplier may not obtain a supplier number unless—

(i) for medical equipment and supplies furnished on or after the date of the enactment of the Social Security Act Amendments of 1994 and before January 1, 1996, the supplier meets standards prescribed by the Secretary in regulations issued on June 18, 1992; and

(ii) for medical equipment and supplies furnished on or after January 1, 1996, the supplier meets revised standards prescribed by the Secretary (in consultation with

representatives of suppliers of medical equipment and supplies, carriers, and consumers) that shall include requirements that the supplier—

(I) comply with all applicable State and Federal licensure and regulatory requirements;

(II) maintain a physical facility on an appropriate site;

(III) have proof of appropriate liability insurance; and

(IV) meet such other requirements as the Secretary may specify.

(C) EXCEPTION FOR ITEMS FURNISHED AS INCIDENT TO A PHYSICIAN'S SERVICE.—Subparagraph (A) shall not apply with respect to medical equipment and supplies furnished incident to a physician's service.

(D) PROHIBITION AGAINST MULTIPLE SUPPLIER NUMBERS.—The Secretary may not issue more than one supplier number to any supplier of medical equipment and supplies unless the issuance of more than one number is appropriate to identify subsidiary or regional entities under the supplier's ownership or control.

(E) PROHIBITION AGAINST DELEGATION OF SUPPLIER DETERMINATIONS.—The Secretary may not delegate (other than by contract under section 1842) the responsibility to determine whether suppliers meet the standards necessary to obtain a supplier number.

(2) CERTIFICATES OF MEDICAL NECESSITY.—

(A) LIMITATION ON INFORMATION PROVIDED BY SUPPLIERS ON CERTIFICATES OF MEDICAL NECESSITY.—

(i) IN GENERAL.—Effective 60 days after the date of the enactment of the Social Security Act Amendments of 1994, a supplier of medical equipment and supplies may distribute to physicians, or to individuals entitled to benefits under this part, a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier:

(I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.

(II) A description of such medical equipment and supplies.

(III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary.

(ii) INFORMATION ON PAYMENT AMOUNT AND CHARGES.—If a supplier distributes a certificate of medical necessity containing any of the information permitted to be supplied under clause (i), the supplier shall also list on the certificate of medical necessity the fee schedule amount and the supplier's charge for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician.

(iii) PENALTY.—Any supplier of medical equipment and supplies who knowingly and willfully distributes a certificate of medical necessity in violation of clause (i) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an amount not to exceed $1,000 for each such certificate of medical necessity so distributed. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(B) DEFINITION.—For purposes of this paragraph, the term "certificate of medical necessity" means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(3) COVERAGE AND REVIEW CRITERIA.—The Secretary shall annually review the coverage and utilization of items of medical equipment and supplies to determine whether such items should be made subject to coverage and utilization review criteria, and if appropriate, shall develop and apply such criteria to such items.

(4) LIMITATION ON PATIENT LIABILITY.—If a supplier of medical equipment and supplies (as defined in paragraph (5))—

(A) furnishes an item or service to a beneficiary for which no payment may be made by reason of paragraph (1);

(B) furnishes an item or service to a beneficiary for which payment is denied in advance under subsection (a)(15); or

(C) furnishes an item or service to a beneficiary for which payment is denied under section 1862(a)(1);

any expenses incurred for items and services furnished to an individual by such a supplier not on an assigned basis shall be the responsibility of such supplier. The individual shall have no financial responsibility for such expenses and the supplier shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected from the individual for such items or services. The provisions of subsection (a)(18) shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such subsection.

(5) DEFINITION.—The term "medical equipment and supplies" means—

(A) durable medical equipment (as defined in section 1861(n));

(B) prosthetic devices (as described in section 1861(s)(8));

(C) orthotics and prosthetics (as described in section 1861(s)(9));

(D) surgical dressings (as described in section 1861(s)(5));

(E) such other items as the Secretary may determine; and

(F) for purposes of paragraphs (1) and (3)—

(i) home dialysis supplies and equipment (as described in section 1861(s)(2)(F)),

(ii) immunosuppressive drugs (as described in section 1861(s)(2)(J)),

(iii) therapeutic shoes for diabetics (as described in section 1861(s)(12)),

(iv) oral drugs prescribed for use as an anticancer therapeutic agent (as described in section 1861(s)(2)(Q)), and

(v) self-administered erythropoetin (as described in section 1861(s)(2)(P)).

(k) PAYMENT FOR OUTPATIENT THERAPY SERVICES AND COMPREHENSIVE OUTPATIENT REHABILITATION SERVICES.—

(1) IN GENERAL.—With respect to services described in section 1833(a)(8) or 1833(a)(9) for which payment is determined under this subsection, the payment basis shall be—

(A) for services furnished during 1998, the amount determined under paragraph (2); or

(B) for services furnished during a subsequent year, 80 percent of the lesser of—

(i) the actual charge for the services, or

(ii) the applicable fee schedule amount (as defined in paragraph (3)) for the services.

(2) PAYMENT IN 1998 BASED UPON ADJUSTED REASONABLE COSTS.—The amount under this paragraph for services is the lesser of—

(A) the charges imposed for the services, or

(B) the adjusted reasonable costs (as defined in paragraph (4)) for the services,

less 20 percent of the amount of the charges imposed for such services.

(3) APPLICABLE FEE SCHEDULE AMOUNT.—In this subsection, the term "applicable fee schedule amount" means, with respect to services furnished in a year, the amount determined under the fee schedule established under section 1848 for such services furnished during the year or, if there is no such fee schedule established for such services, the amount determined under the fee schedule established for such comparable services as the Secretary specifies.

(4) ADJUSTED REASONABLE COSTS.—In paragraph (2), the term "adjusted reasonable costs" means, with respect to any services, reasonable costs determined for such services, reduced by 10 percent. The 10-percent reduction shall not apply to services described in section 1833(a)(8)(B) (relating to services provided by hospitals).

(5) UNIFORM CODING.—For claims for services submitted on or after April 1, 1998, for which the amount of payment is determined under this subsection, the claim shall include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(6) RESTRAINT ON BILLING.—The provisions of subparagraphs (A) and (B) of section 1842(b)(18) shall apply to therapy services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1842(b)(18)(C).

(7) ADJUSTMENT IN DISCOUNT FOR CERTAIN MULTIPLE THERAPY SERVICES.—In the case of therapy services furnished on or after April 1, 2013, and for which payment is made under this subsection pursuant to the applicable fee schedule amount (as defined in paragraph (3)), instead of the 25 percent multiple procedure payment reduction specified in the final rule published by the Secretary in the Federal Register on November 29, 2010, the reduction percentage shall be 50 percent.

(l) ESTABLISHMENT OF FEE SCHEDULE FOR AMBULANCE SERVICES.—

(1) IN GENERAL.—The Secretary shall establish a fee schedule for payment for ambulance services whether provided directly by a supplier or provider or under arrangement with a provider under this part through a negotiated rulemaking process described in title 5, United States Code, and in accordance with the requirements of this subsection.

(2) CONSIDERATIONS.—In establishing such fee schedule, the Secretary shall—

(A) establish mechanisms to control increases in expenditures for ambulance services under this part;

(B) establish definitions for ambulance services which link payments to the type of services provided;

(C) consider appropriate regional and operational differences;

(D) consider adjustments to payment rates to account for inflation and other relevant factors; and

(E) phase in the application of the payment rates under the fee schedule in an efficient and fair manner consistent with paragraph (11), except that such phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported.

(3) SAVINGS.—In establishing such fee schedule, the Secretary shall—

(A) ensure that the aggregate amount of payments made for ambulance services under this part during 2000 does not exceed the aggregate amount of payments which would have been made for such services under this part during such year if the amendments made by section 4531(a) of the Balanced Budget Act of 1997 continued in effect, except that in making such determination the Secretary shall assume an update in such payments for 2002 equal to percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points;

(B) set the payment amounts provided under the fee schedule for services furnished in 2001 and each subsequent year at amounts equal to the payment amounts under the fee schedule for services furnished during the previous year, increased, subject to subparagraph (C) and the succeeding sentence of this paragraph, by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points; and

(C) for 2011 and each subsequent year, after determining the percentage increase under subparagraph (B) for the year, reduce such percentage increase by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

The application of subparagraph (C) may result in the percentage increase under subparagraph (B) being less than 0.0 for a year, and may result in payment rates under the fee schedule under this subsection for a year being less than such payment rates for the preceding year.

(4) CONSULTATION.—In establishing the fee schedule for ambulance services under this subsection, the Secretary shall consult with various national organizations representing individuals and entities who furnish and regulate ambulance services and share with such organizations relevant data in establishing such schedule.

(5) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869 or otherwise of the amounts established under the fee schedule for ambulance services under this subsection, including matters described in paragraph (2).

(6) RESTRAINT ON BILLING.—The provisions of subparagraphs (A) and (B) of section 1842(b)(18) shall apply to ambulance services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1842(b)(18)(C).

(7) CODING SYSTEM.—The Secretary may require the claim for any services for which the amount of payment is determined under this subsection to include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(8) SERVICES FURNISHED BY CRITICAL ACCESS HOSPITALS.—Notwithstanding any other provision of this subsection, the Secretary shall pay 101 percent of the reasonable costs incurred in furnishing ambulance services if such services are furnished—

(A) by a critical access hospital (as defined in section 1861(mm)(1)), or

(B) by an entity that is owned and operated by a critical access hospital,

but only if the critical access hospital or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of such critical access hospital.

(9) TRANSITIONAL ASSISTANCE FOR RURAL PROVIDERS.—In the case of ground ambulance services furnished on or after July 1, 2001, and before January 1, 2004, for which the transportation originates in a rural area (as defined in section 1886(d)(2)(D)) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 17 miles, and up to 50 miles, the rate otherwise established shall be increased by not less than ½ of the additional payment per mile established for the first 17 miles of such a trip originating in a rural area.

(10) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In carrying out the phase-in under paragraph (2)(E) for each level of ground service furnished in a year, the portion of the payment amount that is based on the fee schedule shall be the greater of the amount determined under such fee schedule (without regard to this paragraph) or the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

(A) For 2004 (for services furnished on or after July 1, 2004), the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

(B) For 2005, the blended rate shall be based 40 percent on the fee schedule under paragraph (1) and 60 percent on the regional fee schedule.

(C) For 2006, the blended rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

(D) For 2007, 2008, and 2009, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

(E) For 2010 and each succeeding year, the blended rate shall be based 100 percent on the fee schedule under paragraph (1).

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the nine census divisions (referred to in section 1886(d)(2)) using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.

(11) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2009, regardless of where the transportation originates, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by ¼ of the payment per mile otherwise applicable to miles in excess of 50 miles in such trip.

(12) ASSISTANCE FOR RURAL PROVIDERS FURNISHING SERVICES IN LOW POPULATION DENSITY AREAS.—

(A) IN GENERAL.—In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2023, for which the transportation originates in a qualified rural area (identified under subparagraph (B)(iii)), the Secretary shall provide for a percent increase in the base rate of the fee schedule for a trip established under this subsection. In establishing such percent increase, the Secretary shall estimate the average cost per trip for such services (not taking into account mileage) in the lowest quartile as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of all rural county populations.

(B) IDENTIFICATION OF QUALIFIED RURAL AREAS.—

(i) DETERMINATION OF POPULATION DENSITY IN AREA.—Based upon data from the United States decennial census for the year 2000, the Secretary shall determine, for each rural area, the population density for that area.

(ii) RANKING OF AREAS.—The Secretary shall rank each such area based on such population density.

(iii) IDENTIFICATION OF QUALIFIED RURAL AREAS.—The Secretary shall identify those areas (in subparagraph (A) referred to as "qualified rural areas") with the lowest population densities that represent, if each such area were weighted by the population

of such area (as used in computing such population densities), an aggregate total of 25 percent of the total of the population of all such areas.

(iv) RURAL AREA.—For purposes of this paragraph, the term "rural area" has the meaning given such term in section 1886(d)(2)(D). If feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725) as a rural area for purposes of this paragraph.

(v) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the identification of an area under this subparagraph.

(13) TEMPORARY INCREASE FOR GROUND AMBULANCE SERVICES.—

(A) IN GENERAL.—After computing the rates with respect to ground ambulance services under the other applicable provisions of this subsection, in the case of such services furnished on or after July 1, 2004, and before January 1, 2007, and for such services furnished on or after July 1, 2008, and before January 1, 2023, for which the transportation originates in—

(i) a rural area described in paragraph (9) or in a rural census tract described in such paragraph, the fee schedule established under this section shall provide that the rate for the service otherwise established, after the application of any increase under paragraphs (11) and (12), shall be increased by 2 percent (or 3 percent if such service is furnished on or after July 1, 2008, and before January 1, 2023); and

(ii) an area not described in clause (i), the fee schedule established under this subsection shall provide that the rate for the service otherwise established, after the application of any increase under paragraph (11), shall be increased by 1 percent (or 2 percent if such service is furnished on or after July 1, 2008, and before January 1, 2023).

(B) APPLICATION OF INCREASED PAYMENTS AFTER APPLICABLE PERIOD.—The increased payments under subparagraph (A) shall not be taken into account in calculating payments for services furnished after the applicable period specified in such subparagraph.

(14) PROVIDING APPROPRIATE COVERAGE OF RURAL AIR AMBULANCE SERVICES.—

(A) IN GENERAL.—The regulations described in section 1861(s)(7) shall provide, to the extent that any ambulance services (whether ground or air) may be covered under such section, that a rural air ambulance service (as defined in subparagraph (C)) is reimbursed under this subsection at the air ambulance rate if the air ambulance service—

(i) is reasonable and necessary based on the health condition of the individual being transported at or immediately prior to the time of the transport; and

(ii) complies with equipment and crew requirements established by the Secretary.

(B) SATISFACTION OF REQUIREMENT OF MEDICALLY NECESSARY.—The requirement of subparagraph (A)(i) is deemed to be met for a rural air ambulance service if—

(i) subject to subparagraph (D), such service is requested by a physician or other qualified medical personnel (as specified by the Secretary) who certifies or reasonably determines that the individual's condition is such that the time needed to transport the individual by land or the instability of transportation by land poses a threat to the individual's survival or seriously endangers the individual's health; or

(ii) such service is furnished pursuant to a protocol that is established by a State or regional emergency medical service (EMS) agency and recognized or approved by the Secretary under which the use of an air ambulance is recommended, if such agency does not have an ownership interest in the entity furnishing such service.

(C) RURAL AIR AMBULANCE SERVICE DEFINED.—For purposes of this paragraph, the term "rural air ambulance service" means fixed wing and rotary wing air ambulance service in which the point of pick up of the individual occurs in a rural area (as defined in section 1886(d)(2)(D)) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)).

(D) LIMITATION.—

(i) IN GENERAL.—Subparagraph (B)(i) shall not apply if there is a financial or employment relationship between the person requesting the rural air ambulance service and the entity furnishing the ambulance service, or an entity under common owner-

ship with the entity furnishing the air ambulance service, or a financial relationship between an immediate family member of such requester and such an entity.

(ii) EXCEPTION.—Where a hospital and the entity furnishing rural air ambulance services are under common ownership, clause (i) shall not apply to remuneration (through employment or other relationship) by the hospital of the requester or immediate family member if the remuneration is for provider-based physician services furnished in a hospital (as described in section 1887) which are reimbursed under part A and the amount of the remuneration is unrelated directly or indirectly to the provision of rural air ambulance services.

(15) PAYMENT ADJUSTMENT FOR NON-EMERGENCY AMBULANCE TRANSPORTS FOR ESRD BENEFICIARIES.—The fee schedule amount otherwise applicable under the preceding provisions of this subsection shall be reduced by 10 percent for ambulance services furnished during the period beginning on October 1, 2013, and ending on September 30, 2018, and by 23 percent for such services furnished on or after October 1, 2018, consisting of non-emergency basic life support services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B)) furnished other than on an emergency basis by a provider of services or a renal dialysis facility.

(16) PRIOR AUTHORIZATION FOR REPETITIVE SCHEDULED NON-EMERGENT AMBULANCE TRANSPORTS.—

(A) IN GENERAL.—Beginning January 1, 2017, if the expansion to all States of the model of prior authorization described in paragraph (2) of section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015 meets the requirements described in paragraphs (1) through (3) of section 1115A(c), then the Secretary shall expand such model to all States.

(B) FUNDING.—The Secretary shall use funds made available under section 1893(h)(10) to carry out this paragraph.

(C) CLARIFICATION REGARDING BUDGET NEUTRALITY.—Nothing in this paragraph may be construed to limit or modify the application of section 1115A(b)(3)(B) to models described in such section, including with respect to the model described in subparagraph (A) and expanded beginning on January 1, 2017, under such subparagraph.

(17) SUBMISSION OF COST AND OTHER INFORMATION.—

(A) DEVELOPMENT OF DATA COLLECTION SYSTEM.—The Secretary shall develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary with respect to providers of services (in this paragraph referred to as "providers") and suppliers of ground ambulance services. Such system shall be designed to collect information—

(i) needed to evaluate the extent to which reported costs relate to payment rates under this subsection;

(ii) on the utilization of capital equipment and ambulance capacity, including information consistent with the type of information described in section 1121(a); and

(iii) on different types of ground ambulance services furnished in different geographic locations, including rural areas and low population density areas described in paragraph (12).

(B) SPECIFICATION OF DATA COLLECTION SYSTEM.—

(i) IN GENERAL.—The Secretary shall—

(I) not later than December 31, 2019, specify the data collection system under subparagraph (A); and

(II) identify the providers and suppliers of ground ambulance services that would be required to submit information under such data collection system, including the representative sample described in clause (ii).

(ii) DETERMINATION OF REPRESENTATIVE SAMPLE.—

(I) IN GENERAL.—Not later than December 31, 2019, with respect to the data collection for the first year under such system, and for each subsequent year through 2024, the Secretary shall determine a representative sample to submit information under the data collection system.

(II) REQUIREMENTS.—The sample under subclause (I) shall be representative of the different types of providers and suppliers of ground ambulance services (such as those providers and suppliers that are part of an emergency service or part of a government organization) and the geographic locations in which ground

ambulance services are furnished (such as urban, rural, and low population density areas).

(III) LIMITATION.—The Secretary shall not include an individual provider or supplier of ground ambulance services in the sample under subclause (I) in 2 consecutive years, to the extent practicable.

(C) REPORTING OF COST INFORMATION.—For each year, a provider or supplier of ground ambulance services identified by the Secretary under subparagraph (B)(i)(II) as being required to submit information under the data collection system with respect to a period for the year shall submit to the Secretary information specified under the system. Such information shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) PAYMENT REDUCTION FOR FAILURE TO REPORT.—

(i) IN GENERAL.—Beginning January 1, 2022, subject to clause (ii), a 10 percent reduction to payments under this subsection shall be made for the applicable period (as defined in clause (ii)) to a provider or supplier of ground ambulance services that—

(I) is required to submit information under the data collection system with respect to a period under subparagraph (C); and

(II) does not sufficiently submit such information, as determined by the Secretary.

(ii) APPLICABLE PERIOD DEFINED.—For purposes of clause (i), the term "applicable period" means, with respect to a provider or supplier of ground ambulance services, a year specified by the Secretary not more than 2 years after the end of the period with respect to which the Secretary has made a determination under clause (i)(II) that the provider or supplier of ground ambulance services failed to sufficiently submit information under the data collection system.

(iii) HARDSHIP EXEMPTION.—The Secretary may exempt a provider or supplier from the payment reduction under clause (i) with respect to an applicable period in the event of significant hardship, such as a natural disaster, bankruptcy, or other similar situation that the Secretary determines interfered with the ability of the provider or supplier of ground ambulance services to submit such information in a timely manner for the specified period.

(iv) INFORMAL REVIEW.—The Secretary shall establish a process under which a provider or supplier of ground ambulance services may seek an informal review of a determination that the provider or supplier is subject to the payment reduction under clause (i).

(E) ONGOING DATA COLLECTION.—

(i) REVISION OF DATA COLLECTION SYSTEM.—The Secretary may, as the Secretary determines appropriate and, if available, taking into consideration the report (or reports) under subparagraph (F), revise the data collection system under subparagraph (A).

(ii) SUBSEQUENT DATA COLLECTION.—In order to continue to evaluate the extent to which reported costs relate to payment rates under this subsection and for other purposes the Secretary deems appropriate, the Secretary shall require providers and suppliers of ground ambulance services to submit information for years after 2024 as the Secretary determines appropriate, but in no case less often than once every 3 years.

(F) GROUND AMBULANCE DATA COLLECTION SYSTEM STUDY.—

(i) IN GENERAL.—Not later than March 15, 2023, and as determined necessary by the Medicare Payment Advisory Commission thereafter, such Commission shall assess, and submit to Congress a report on, information submitted by providers and suppliers of ground ambulance services through the data collection system under subparagraph (A), the adequacy of payments for ground ambulance services under this subsection, and geographic variations in the cost of furnishing such services.

(ii) CONTENTS.—A report under clause (i) shall contain the following:

(I) An analysis of information submitted through the data collection system.

(II) An analysis of any burden on providers and suppliers of ground ambulance services associated with the data collection system.

(III) A recommendation as to whether information should continue to be submitted through such data collection system or if such system should be revised under subparagraph (E)(i).

(IV) Other information determined appropriate by the Commission.

(G) PUBLIC AVAILABILITY.—The Secretary shall post information on the results of the data collection under this paragraph on the Internet website of the Centers for Medicare & Medicaid Services, as determined appropriate by the Secretary.

(H) IMPLEMENTATION.—The Secretary shall implement this paragraph through notice and comment rulemaking.

(I) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information required under this subsection.

(J) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the data collection system or identification of respondents under this paragraph.

(K) FUNDING FOR IMPLEMENTATION.—For purposes of carrying out subparagraph (A), the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $15,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for fiscal year 2018. Amounts transferred under this subparagraph shall remain available until expended.

(m) PAYMENT FOR TELEHEALTH SERVICES.—

(1) IN GENERAL.—The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician (as defined in section 1861(r)) or a practitioner (described in section 1842(b)(18)(C)) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary. For purposes of the preceding sentence, in the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term "telecommunications system" includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.

(2) PAYMENT AMOUNT.—

(A) DISTANT SITE.—The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system.

(B) FACILITY FEE FOR ORIGINATING SITE.—

(i) IN GENERAL.—Subject to clause (ii) *and paragraph (7)(E)*, with respect to a telehealth service, subject to section 1833(a)(1)(U), there shall be paid to the originating site a facility fee equal to—

(I) for the period beginning on October 1, 2001, and ending on December 31, 2001, and for 2002, $20; and

(II) for a subsequent year, the facility fee specified in subclause (I) or this subclause for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year.

(ii) NO FACILITY FEE IF ORIGINATING SITE FOR HOME DIALYSIS THERAPY IS THE HOME.—No facility fee shall be paid under this subparagraph to an originating site described in paragraph (4)(C)(ii)(X).

(C) TELEPRESENTER NOT REQUIRED.—Nothing in this subsection shall be construed as requiring an eligible telehealth individual to be presented by a physician or practitioner at the originating site for the furnishing of a service via a telecommunications system, unless it is medically necessary (as determined by the physician or practitioner at the distant site).

(3) LIMITATION ON BENEFICIARY CHARGES.—

(A) PHYSICIAN AND PRACTITIONER.—The provisions of section 1848(g) and subparagraphs (A) and (B) of section 1842(b)(18) shall apply to a physician or practitioner receiving payment under this subsection in the same manner as they apply to physicians or practitioners under such sections.

(B) ORIGINATING SITE.—The provisions of section 1842(b)(18) shall apply to originating sites receiving a facility fee in the same manner as they apply to practitioners under such section.

(4) DEFINITIONS.—For purposes of this subsection:

(A) DISTANT SITE.—The term "distant site" means the site at which the physician or practitioner is located at the time the service is provided via a telecommunications system.

(B) ELIGIBLE TELEHEALTH INDIVIDUAL.—The term "eligible telehealth individual" means an individual enrolled under this part who receives a telehealth service furnished at an originating site.

(C) ORIGINATING SITE.—

(i) IN GENERAL.—Except as provided in paragraph (6), the term"originating site" means only those sites described in clause (ii) at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system and only if such site is located—

(I) in an area that is designated as a rural health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A));

(II) in a county that is not included in a Metropolitan Statistical Area; or

(III) from an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

(ii) SITES DESCRIBED.—The sites referred to in clause (i) are the following sites:

(I) The office of a physician or practitioner.

(II) A critical access hospital (as defined in section 1861(mm)(1)).

(III) A rural health clinic (as defined in section 1861(aa)(2)).

(IV) A Federally qualified health center (as defined in section 1861(aa)(4)).

(V) A hospital (as defined in section 1861(e)).

(VI) A hospital-based or critical access hospital-based renal dialysis center (including satellites).

(VII) A skilled nursing facility (as defined in section 1819(a)).

(VIII) A community mental health center (as defined in section 1861(ff)(3)(B)).

(IX) A renal dialysis facility, but only for purposes of section 1881(b)(3)(B).

(X) The home of an individual, but only for purposes of section 1881(b)(3)(B).

(D) PHYSICIAN.—The term "physician" has the meaning given that term in section 1861(r).

(E) PRACTITIONER.—The term "practitioner" has the meaning given that term in section 1842(b)(18)(C).

(F) TELEHEALTH SERVICE.—

(i) IN GENERAL.—The term "telehealth service" means professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241–99275, 99201–99215, 90804–90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary.

(ii) YEARLY UPDATE.—The Secretary shall establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), as appropriate, to those specified in clause (i) for authorized payment under paragraph (1).

(5) TREATMENT OF HOME DIALYSIS MONTHLY ESRD-RELATED VISIT.—The geographic requirements described in paragraph (4)(C)(i) shall not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of section 1881(b)(3)(B), at an originating site described in subclause (VI), (IX), or (X) of paragraph (4)(C)(ii).

(6) TREATMENT OF STROKE TELEHEALTH SERVICES.—

(A) NON-APPLICATION OF ORIGINATING SITE REQUIREMENTS.—The requirements described in paragraph (4)(C) shall not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke, as determined by the Secretary.

(B) INCLUSION OF CERTAIN SITES.—With respect to telehealth services described in subparagraph (A), the term "originating site" shall include any hospital (as defined in section 1861(e)) or critical access hospital (as defined in section 1861(mm)(1)), any mobile stroke unit (as defined by the Secretary), or any other site determined appropriate by the Secretary, at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system.

(C) NO ORIGINATING SITE FACILITY FEE FOR NEW SITES.—No facility fee shall be paid under paragraph (2)(B) to an originating site with respect to a telehealth service described

in subparagraph (A) if the originating site does not otherwise meet the requirements for an originating site under paragraph (4)(C).

*(7) AUTHORITY NOT TO APPLY CERTAIN REQUIREMENTS IN THE CASE OF CERTAIN TREATMENT OF SUBSTANCE USE DISORDER OR CO-OCCURRING MENTAL HEALTH DISORDER.—*

*(A) IN GENERAL.—For purposes of payment under this subsection, in the case of telehealth services described in subparagraph (C) furnished on or after January 1, 2020, to an eligible beneficiary (as defined in subparagraph (F)) for the treatment of a substance use disorder or a mental health disorder that is co-occurring with a substance use disorder, the Secretary is authorized to, through rulemaking, not apply any of the requirements described in subparagraph (B).*

*(B) REQUIREMENTS DESCRIBED.—For purposes of this paragraph, the requirements described in this subparagraph are any of the following:*

*(i) Qualifications for an originating site under paragraph (4)(C)(ii).*

*(ii) Geographic limitations under paragraph (4)(C)(i).*

*(C) TELEHEALTH SERVICES DESCRIBED.—For purposes of this paragraph, the telehealth services described in this subparagraph are services that are both telehealth services and identified by the Secretary, through rulemaking, as services that are the most commonly furnished (as defined by the Secretary) under this part to individuals diagnosed with a substance use disorder or a mental health disorder that is co-occurring with a substance use disorder.*

*(D) CLARIFICATION.—Nothing in this paragraph shall be construed as limiting or otherwise affecting the authority of the Secretary to limit or eliminate the non-application pursuant to this paragraph of any of the requirements under subparagraph (B).*

*(E) TREATMENT OF ORIGINATING SITE FACILITY FEE.—No facility fee shall be paid under paragraph (2)(B) to an originating site with respect to a telehealth service described in subparagraph (B) for which payment is made under this subsection by reason of the non-application of a requirement described in subparagraph (B) pursuant to this paragraph if payment for such service would not otherwise be permitted under this subsection if such requirement were applied.*

*(F) ELIGIBLE BENEFICIARY DEFINED.—For purposes of this paragraph, the term "eligible beneficiary" means an individual who—*

*(i) is entitled to, or enrolled for, benefits under part A and enrolled for benefits under this part;*

*(ii) has a diagnosis for a substance use disorder; and*

*(iii) meets such other criteria as the Secretary determines appropriate.*

*(G) REPORT.—Not later than 5 years after the date of the enactment of this paragraph, the Secretary shall submit to Congress a report on the impact of any non-application under this paragraph of any of the requirements described in subparagraph (B) on*

*(i) the utilization of health care services related to substance use disorder, such as behavioral health services and emergency department visits; and*

*(ii) health outcomes related to substance use disorder, such as substance use overdose deaths.*

*(H) FUNDING.—For purposes of carrying out this paragraph, in addition to funds otherwise available, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $3,000,000 to the Centers for Medicare & Medicaid Services Program Management Account to remain available until expended.*

*(8) RULE OF CONSTRUCTION.—Nothing in this subsection may be construed as waiving requirements under this title to comply with applicable State law, including State licensure requirements.*

(n) AUTHORITY TO MODIFY OR ELIMINATE COVERAGE OF CERTAIN PREVENTIVE SERVICES.—Notwithstanding any other provision of this title, effective beginning on January 1, 2010, if the Secretary determines appropriate, the Secretary may—

(1) modify—

(A) the coverage of any preventive service described in subparagraph (A) of section 1861(ddd)(3) to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force; and

(B) the services included in the initial preventive physical examination described in subparagraph (B) of such section; and

(2) provide that no payment shall be made under this title for a preventive service described in subparagraph (A) of such section that has not received a grade of A, B, C, or I by such Task Force.

(o) DEVELOPMENT AND IMPLEMENTATION OF PROSPECTIVE PAYMENT SYSTEM.—

(1) DEVELOPMENT.—

(A) IN GENERAL.—The Secretary shall develop a prospective payment system for payment for Federally qualified health center services furnished by Federally qualified health centers under this title. Such system shall include a process for appropriately describing the services furnished by Federally qualified health centers and shall establish payment rates for specific payment codes based on such appropriate descriptions of services. Such system shall be established to take into account the type, intensity, and duration of services furnished by Federally qualified health centers. Such system may include adjustments, including geographic adjustments, determined appropriate by the Secretary.

(B) COLLECTION OF DATA AND EVALUATION.—By not later than January 1, 2011, the Secretary shall require Federally qualified health centers to submit to the Secretary such information as the Secretary may require in order to develop and implement the prospective payment system under this subsection, including the reporting of services using HCPCS codes.

(2) IMPLEMENTATION.—

(A) IN GENERAL.—Notwithstanding section 1833(a)(3)(A), the Secretary shall provide, for cost reporting periods beginning on or after October 1, 2014, for payments of prospective payment rates for Federally qualified health center services furnished by Federally qualified health centers under this title in accordance with the prospective payment system developed by the Secretary under paragraph (1).

(B) PAYMENTS.—

(i) INITIAL PAYMENTS.—The Secretary shall implement such prospective payment system so that the estimated aggregate amount of prospective payment rates (determined prior to the application of section 1833(a)(1)(Z)) under this title for Federally qualified health center services in the first year that such system is implemented is equal to 100 percent of the estimated amount of reasonable costs (determined without the application of a per visit payment limit or productivity screen and prior to the application of section 1866(a)(2)(A)(ii)) that would have occurred for such services under this title in such year if the system had not been implemented.

(ii) PAYMENTS IN SUBSEQUENT YEARS.—Payment rates in years after the year of implementation of such system shall be the payment rates in the previous year increased—

(I) in the first year after implementation of such system, by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year involved; and

(II) in subsequent years, by the percentage increase in a market basket of Federally qualified health center goods and services as promulgated through regulations, or if such an index is not available, by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year involved.

(C) PREPARATION FOR PPS IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may establish and implement by program instruction or otherwise the payment codes to be used under the prospective payment system under this section.

*(3) ADDITIONAL PAYMENTS FOR CERTAIN FQHCS WITH PHYSICIANS OR OTHER PRACTITIONERS RECEIVING DATA 2000 WAIVERS.—*

*(A) IN GENERAL.—In the case of a Federally qualified health center with respect to which, beginning on or after January 1, 2019, Federally-qualified health center services (as defined in section 1861(aa)(3)) are furnished for the treatment of opioid use disorder by a physician or practitioner who meets the requirements described in subparagraph (C) the Secretary shall, subject to availability of funds under subparagraph (D), make a payment (at such time and in such manner as specified by the Secretary) to such Federally qualified health center after receiving and approving an application submitted by such Federally qualified health center under subparagraph (B). Such a payment shall be in an amount determined by the Secretary, based on an estimate of the average costs of training for purposes of receiving a waiver described in subparagraph (C)(ii). Such a payment may be made only one time with respect to each such physician or practitioner.*

*(B) APPLICATION.—In order to receive a payment described in subparagraph (A), a Federally-qualified health center shall submit to the Secretary an application for such a payment at such time, in such manner, and containing such information as specified by the Secretary. A Federally-qualified health center may apply for such a payment for each physician or practitioner described in subparagraph (A) furnishing services described in such subparagraph at such center.*

*(C) REQUIREMENTS.—For purposes of subparagraph (A), the requirements described in this subparagraph, with respect to a physician or practitioner, are the following:*

*(i) The physician or practitioner is employed by or working under contract with a Federally qualified health center described in subparagraph (A) that submits an application under subparagraph (B).*

*(ii) The physician or practitioner first receives a waiver under section 303(g) of the Controlled Substances Acton or after January 1, 2019.*

*(D) FUNDING.—For purposes of making payments under this paragraph, there are appropriated, out of amounts in the Treasury not otherwise appropriated, $6,000,000, which shall remain available until expended.*

(p) QUALITY INCENTIVES TO PROMOTE PATIENT SAFETY AND PUBLIC HEALTH IN COMPUTED TOMOGRAPHY.—

(1) QUALITY INCENTIVES.—In the case of an applicable computed tomography service (as defined in paragraph (2)) for which payment is made under an applicable payment system (as defined in paragraph (3)) and that is furnished on or after January 1, 2016, using equipment that is not consistent with the CT equipment standard (described in paragraph (4)), the payment amount for such service shall be reduced by the applicable percentage (as defined in paragraph (5)).

(2) APPLICABLE COMPUTED TOMOGRAPHY SERVICES DEFINED.—In this subsection, the term "applicable computed tomography service" means a service billed using diagnostic radiological imaging codes for computed tomography (identified as of January 1, 2014, by HCPCS codes 70450–70498, 71250–71275, 72125–72133, 72191–72194, 73200–73206, 73700–73706, 74150–74178, 74261–74263, and 75571–75574 (and any succeeding codes).

(3) APPLICABLE PAYMENT SYSTEM DEFINED.—In this subsection, the term "applicable payment system" means the following:

(A) The technical component and the technical component of the global fee under the fee schedule established under section 1848(b).

(B) The prospective payment system for hospital outpatient department services under section 1833(t).

(4) CONSISTENCY WITH CT EQUIPMENT STANDARD.—In this subsection, the term "not consistent with the CT equipment standard" means, with respect to an applicable computed tomography service, that the service was furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled "Standard Attributes on CT Equipment Related to Dose Optimization and Management". Through rulemaking, the Secretary may apply successor standards.

(5) APPLICABLE PERCENTAGE DEFINED.—In this subsection, the term "applicable percentage" means—

(A) for 2016, 5 percent; and

(B) for 2017 and subsequent years, 15 percent.

(6) IMPLEMENTATION.—

(A) INFORMATION.—The Secretary shall require that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable computed tomography service was furnished that was not consistent with the CT equipment standard (described in paragraph (4)). Such information may be included on a claim and may be a modifier. Such information shall be verified, as appropriate, as part of the periodic accreditation of suppliers under section 1834(e) and hospitals under section 1865(a).

(B) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to information described in subparagraph (A).

(q) RECOGNIZING APPROPRIATE USE CRITERIA FOR CERTAIN IMAGING SERVICES.—

(1) PROGRAM ESTABLISHED.—

(A) IN GENERAL.—The Secretary shall establish a program to promote the use of appropriate use criteria (as defined in subparagraph (B)) for applicable imaging services (as

defined in subparagraph (C)) furnished in an applicable setting (as defined in subparagraph (D)) by ordering professionals and furnishing professionals (as defined in subparagraphs (E) and (F), respectively).

(B) APPROPRIATE USE CRITERIA DEFINED.—In this subsection, the term "appropriate use criteria" means criteria, only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based.

(C) APPLICABLE IMAGING SERVICE DEFINED.—In this subsection, the term "applicable imaging service" means an advanced diagnostic imaging service (as defined in subsection (e)(1)(B)) for which the Secretary determines—

(i) one or more applicable appropriate use criteria specified under paragraph (2) apply;

(ii) there are one or more qualified clinical decision support mechanisms listed under paragraph (3)(C); and

(iii) one or more of such mechanisms is available free of charge.

(D) APPLICABLE SETTING DEFINED.—In this subsection, the term "applicable setting" means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary.

(E) ORDERING PROFESSIONAL DEFINED.—In this subsection, the term "ordering professional" means a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who orders an applicable imaging service.

(F) FURNISHING PROFESSIONAL DEFINED.—In this subsection, the term "furnishing professional" means a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who furnishes an applicable imaging service.

(2) ESTABLISHMENT OF APPLICABLE APPROPRIATE USE CRITERIA.—

(A) IN GENERAL.—Not later than November 15, 2015, the Secretary shall through rulemaking, and in consultation with physicians, practitioners, and other stakeholders, specify applicable appropriate use criteria for applicable imaging services only from among appropriate use criteria developed or endorsed by national professional medical specialty societies or other provider-led entities.

(B) CONSIDERATIONS.—In specifying applicable appropriate use criteria under subparagraph (A), the Secretary shall take into account whether the criteria—

(i) have stakeholder consensus;

(ii) are scientifically valid and evidence based; and

(iii) are based on studies that are published and reviewable by stakeholders.

(C) REVISIONS.—The Secretary shall review, on an annual basis, the specified applicable appropriate use criteria to determine if there is a need to update or revise (as appropriate) such specification of applicable appropriate use criteria and make such updates or revisions through rulemaking.

(D) TREATMENT OF MULTIPLE APPLICABLE APPROPRIATE USE CRITERIA.—In the case where the Secretary determines that more than one appropriate use criterion applies with respect to an applicable imaging service, the Secretary shall apply one or more applicable appropriate use criteria under this paragraph for the service.

(3) MECHANISMS FOR CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(A) IDENTIFICATION OF MECHANISMS TO CONSULT WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(i) IN GENERAL.—The Secretary shall specify qualified clinical decision support mechanisms that could be used by ordering professionals to consult with applicable appropriate use criteria for applicable imaging services.

(ii) CONSULTATION.—The Secretary shall consult with physicians, practitioners, health care technology experts, and other stakeholders in specifying mechanisms under this paragraph.

(iii) INCLUSION OF CERTAIN MECHANISMS.—Mechanisms specified under this paragraph may include any or all of the following that meet the requirements described in subparagraph (B)(ii):

(I) Use of clinical decision support modules in certified EHR technology (as defined in section 1848(o)(4)).

(II) Use of private sector clinical decision support mechanisms that are independent from certified EHR technology, which may include use of clinical decision support mechanisms available from medical specialty organizations.

(III) Use of a clinical decision support mechanism established by the Secretary.

(B) QUALIFIED CLINICAL DECISION SUPPORT MECHANISMS.—

(i) IN GENERAL.—For purposes of this subsection, a qualified clinical decision support mechanism is a mechanism that the Secretary determines meets the requirements described in clause (ii).

(ii) REQUIREMENTS.—The requirements described in this clause are the following:

(I) The mechanism makes available to the ordering professional applicable appropriate use criteria specified under paragraph (2) and the supporting documentation for the applicable imaging service ordered.

(II) In the case where there is more than one applicable appropriate use criterion specified under such paragraph for an applicable imaging service, the mechanism indicates the criteria that it uses for the service.

(III) The mechanism determines the extent to which an applicable imaging service ordered is consistent with the applicable appropriate use criteria so specified.

(IV) The mechanism generates and provides to the ordering professional a certification or documentation that documents that the qualified clinical decision support mechanism was consulted by the ordering professional.

(V) The mechanism is updated on a timely basis to reflect revisions to the specification of applicable appropriate use criteria under such paragraph.

(VI) The mechanism meets privacy and security standards under applicable provisions of law.

(VII) The mechanism performs such other functions as specified by the Secretary, which may include a requirement to provide aggregate feedback to the ordering professional.

(C) LIST OF MECHANISMS FOR CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(i) INITIAL LIST.—Not later than April 1, 2016, the Secretary shall publish a list of mechanisms specified under this paragraph.

(ii) PERIODIC UPDATING OF LIST.—The Secretary shall identify on an annual basis the list of qualified clinical decision support mechanisms specified under this paragraph.

(4) CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(A) CONSULTATION BY ORDERING PROFESSIONAL.—Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service ordered by an ordering professional that would be furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), an ordering professional shall—

(i) consult with a qualified decision support mechanism listed under paragraph (3)(C); and

(ii) provide to the furnishing professional the information described in clauses (i) through (iii) of subparagraph (B).

(B) REPORTING BY FURNISHING PROFESSIONAL.—Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), payment for such service may only be made if the claim for the service includes the following:

(i) Information about which qualified clinical decision support mechanism was consulted by the ordering professional for the service.

(ii) Information regarding—

(I) whether the service ordered would adhere to the applicable appropriate use criteria specified under paragraph (2);

(II) whether the service ordered would not adhere to such criteria; or

(III) whether such criteria was not applicable to the service ordered.

(iii) The national provider identifier of the ordering professional (if different from the furnishing professional).

(C) EXCEPTIONS.—The provisions of subparagraphs (A) and (B) and paragraph (6)(A) shall not apply to the following:

(i) EMERGENCY SERVICES.—An applicable imaging service ordered for an individual with an emergency medical condition (as defined in section 1867(e)(1)).

(ii) INPATIENT SERVICES.—An applicable imaging service ordered for an inpatient and for which payment is made under part A.

(iii) SIGNIFICANT HARDSHIP.—An applicable imaging service ordered by an ordering professional who the Secretary may, on a case-by-case basis, exempt from the application of such provisions if the Secretary determines, subject to annual renewal, that consultation with applicable appropriate use criteria would result in a significant hardship, such as in the case of a professional who practices in a rural area without sufficient Internet access.

(D) APPLICABLE PAYMENT SYSTEM DEFINED.—In this subsection, the term "applicable payment system" means the following:

(i) The physician fee schedule established under section 1848(b).

(ii) The prospective payment system for hospital outpatient department services under section 1833(t).

(iii) The ambulatory surgical center payment systems under section 1833(i).

(5) IDENTIFICATION OF OUTLIER ORDERING PROFESSIONALS.—

(A) IN GENERAL.—With respect to applicable imaging services furnished beginning with 2017, the Secretary shall determine, on an annual basis, no more than five percent of the total number of ordering professionals who are outlier ordering professionals.

(B) OUTLIER ORDERING PROFESSIONALS.—The determination of an outlier ordering professional shall—

(i) be based on low adherence to applicable appropriate use criteria specified under paragraph (2), which may be based on comparison to other ordering professionals; and

(ii) include data for ordering professionals for whom prior authorization under paragraph (6)(A) applies.

(C) USE OF TWO YEARS OF DATA.—The Secretary shall use two years of data to identify outlier ordering professionals under this paragraph.

(D) PROCESS.—The Secretary shall establish a process for determining when an outlier ordering professional is no longer an outlier ordering professional.

(E) CONSULTATION WITH STAKEHOLDERS.—The Secretary shall consult with physicians, practitioners and other stakeholders in developing methods to identify outlier ordering professionals under this paragraph.

(6) PRIOR AUTHORIZATION FOR ORDERING PROFESSIONALS WHO ARE OUTLIERS.—

(A) IN GENERAL.—Beginning January 1, 2020, subject to paragraph (4)(C), with respect to services furnished during a year, the Secretary shall, for a period determined appropriate by the Secretary, apply prior authorization for applicable imaging services that are ordered by an outlier ordering professional identified under paragraph (5).

(B) APPROPRIATE USE CRITERIA IN PRIOR AUTHORIZATION.—In applying prior authorization under subparagraph (A), the Secretary shall utilize only the applicable appropriate use criteria specified under this subsection.

(C) FUNDING.—For purposes of carrying out this paragraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2019 through 2021. Amounts transferred under the preceding sentence shall remain available until expended.

(7) CONSTRUCTION.—Nothing in this subsection shall be construed as granting the Secretary the authority to develop or initiate the development of clinical practice guidelines or appropriate use criteria.

(r) PAYMENT FOR RENAL DIALYSIS SERVICES FOR INDIVIDUALS WITH ACUTE KIDNEY INJURY.—

(1) PAYMENT RATE.—In the case of renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14)) furnished under this part by a renal dialysis facility or provider of services paid under such section during a year (beginning with 2017) to an individual with acute

kidney injury (as defined in paragraph (2)), the amount of payment under this part for such services shall be the base rate for renal dialysis services determined for such year under such section, as adjusted by any applicable geographic adjustment factor applied under subparagraph (D)(iv)(II) of such section and may be adjusted by the Secretary (on a budget neutral basis for payments under this paragraph) by any other adjustment factor under subparagraph (D) of such section.

(2) INDIVIDUAL WITH ACUTE KIDNEY INJURY DEFINED.—In this subsection, the term "individual with acute kidney injury" means an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14).

(s) PAYMENT FOR APPLICABLE DISPOSABLE DEVICES.—

(1) SEPARATE PAYMENT.—The Secretary shall make a payment (separate from the payments otherwise made under section 1895) in the amount established under paragraph (3) to a home health agency for an applicable disposable device (as defined in paragraph (2)) when furnished on or after January 1, 2017, to an individual who receives home health services for which payment is made under section 1895(b).

(2) APPLICABLE DISPOSABLE DEVICE.—In this subsection, the term applicable disposable device means a disposable device that, as determined by the Secretary, is—

(A) a disposable negative pressure wound therapy device that is an integrated system comprised of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy; and

(B) a substitute for, and used in lieu of, a negative pressure wound therapy durable medical equipment item that is an integrated system of a negative pressure vacuum pump, a separate exudate collection canister, and dressings that would otherwise be covered for individuals for such wound therapy.

(3) PAYMENT AMOUNT.—The separate payment amount established under this paragraph for an applicable disposable device for a year shall be equal to the amount of the payment that would be made under section 1833(t) (relating to payment for covered OPD services) for the year for the Level I Healthcare Common Procedure Coding System (HCPCS) code for which the description for a professional service includes the furnishing of such device.

(t) SITE-OF-SERVICE PRICE TRANSPARENCY.—

(1) IN GENERAL.—In order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center under this title, the Secretary shall, for 2018 and each year thereafter, make available to the public via a searchable Internet website, with respect to an appropriate number of such items and services—

(A) the estimated payment amount for the item or service under the outpatient department fee schedule under subsection (t) of section 1833 and the ambulatory surgical center payment system under subsection (i) of such section; and

(B) the estimated amount of beneficiary liability applicable to the item or service.

(2) CALCULATION OF ESTIMATED BENEFICIARY LIABILITY.—For purposes of paragraph (1)(B), the estimated amount of beneficiary liability, with respect to an item or service, is the amount for such item or service for which an individual who does not have coverage under a Medicare supplemental policy certified under section 1882 or any other supplemental insurance coverage is responsible.

(3) IMPLEMENTATION.—In carrying out this subsection, the Secretary—

(A) shall include in the notice described in section 1804(a) a notification of the availability of the estimated amounts made available under paragraph (1); and

(B) may utilize mechanisms in existence on the date of enactment of this subsection, such as the portion of the Internet website of the Centers for Medicare & Medicaid Services on which information comparing physician performance is posted (commonly referred to as the Physician Compare Internet website), to make available such estimated amounts under such paragraph.

(4) FUNDING.—For purposes of implementing this subsection, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of $6,000,000 for fiscal year 2017, to remain available until expended.

(u) PAYMENT AND RELATED REQUIREMENTS FOR HOME INFUSION THERAPY.—

(1) PAYMENT.—

(A) SINGLE PAYMENT.—

(i) IN GENERAL.—Subject to clause (iii) and subparagraphs (B) and (C), the Secretary shall implement a payment system under which a single payment is made under this title to a qualified home infusion therapy supplier for items and services described in subparagraphs (A) and (B) of section 1861(iii)(2)) furnished by a qualified home infusion therapy supplier (as defined in section 1861(iii)(3)(D)) in coordination with the furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C)) under this part.

(ii) UNIT OF SINGLE PAYMENT.—A unit of single payment under the payment system implemented under this subparagraph is for each infusion drug administration calendar day in the individual's home. The Secretary shall, as appropriate, establish single payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type.

(iii) LIMITATION.—The single payment amount determined under this subparagraph after application of subparagraph (B) and paragraph (3) shall not exceed the amount determined under the fee schedule under section 1848 for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day.

(B) REQUIRED ADJUSTMENTS.—The Secretary shall adjust the single payment amount determined under subparagraph (A) for home infusion therapy services under section 1861(iii)(1) to reflect other factors such as—

(i) a geographic wage index and other costs that may vary by region; and

(ii) patient acuity and complexity of drug administration.

(C) DISCRETIONARY ADJUSTMENTS.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary may adjust the single payment amount determined under subparagraph (A) (after application of subparagraph (B)) to reflect outlier situations and other factors as the Secretary determines appropriate.

(ii) REQUIREMENT OF BUDGET NEUTRALITY.—Any adjustment under this subparagraph shall be made in a budget neutral manner.

(2) CONSIDERATIONS.—In developing the payment system under this subsection, the Secretary may consider the costs of furnishing infusion therapy in the home, consult with home infusion therapy suppliers, consider payment amounts for similar items and services under this part and part A, and consider payment amounts established by Medicare Advantage plans under part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy).

(3) ANNUAL UPDATES.—

(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall update the single payment amount under this subsection from year to year beginning in 2022 by increasing the single payment amount from the prior year by the percentage increase in the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

(B) ADJUSTMENT.—For each year, the Secretary shall reduce the percentage increase described in subparagraph (A) by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

(4) AUTHORITY TO APPLY PRIOR AUTHORIZATION.—The Secretary may, as determined appropriate by the Secretary, apply prior authorization for home infusion therapy services under section 1861(iii)(1).

(5) ACCREDITATION OF QUALIFIED HOME INFUSION THERAPY SUPPLIERS.—

(A) FACTORS FOR DESIGNATION OF ACCREDITATION ORGANIZATIONS.—The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

(i) The ability of the organization to conduct timely reviews of accreditation applications.

(ii) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D)).

(iii) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

(iv) Such other factors as the Secretary determines appropriate.

(B) DESIGNATION.—Not later than January 1, 2021, the Secretary shall designate organizations to accredit suppliers furnishing home infusion therapy. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

(C) REVIEW AND MODIFICATION OF LIST OF ACCREDITATION ORGANIZATIONS.—

(i) IN GENERAL.—The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

(ii) SPECIAL RULE FOR ACCREDITATIONS DONE PRIOR TO REMOVAL FROM LIST OF DESIGNATED ACCREDITATION ORGANIZATIONS.—In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

(D) RULE FOR ACCREDITATIONS MADE PRIOR TO DESIGNATION.—In the case of a supplier that is accredited before January 1, 2021, by an accreditation organization designated by the Secretary under subparagraph (B) as of January 1, 2019, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2023, for the remaining period such accreditation is in effect.

(6) NOTIFICATION OF INFUSION THERAPY OPTIONS AVAILABLE PRIOR TO FURNISHING HOME INFUSION THERAPY.—Prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan described in section 1861(iii)(1) for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.

(7) HOME INFUSION THERAPY SERVICES TEMPORARY TRANSITIONAL PAYMENT.—

(A) TEMPORARY TRANSITIONAL PAYMENT.—

(i) IN GENERAL.—The Secretary shall, in accordance with the payment methodology described in subparagraph (B) and subject to the provisions of this paragraph, provide a home infusion therapy services temporary transitional payment under this part to an eligible home infusion supplier (as defined in subparagraph (F)) for items and services described in subparagraphs (A) and (B) of section 1861(iii)(2)) furnished during the period specified in clause (ii) by such supplier in coordination with the furnishing of transitional home infusion drugs (as defined in clause (iii)).

(ii) PERIOD SPECIFIED.—For purposes of clause (i), the period specified in this clause is the period beginning on January 1, 2019, and ending on the day before the date of the implementation of the payment system under paragraph (1)(A).

(iii) TRANSITIONAL HOME INFUSION DRUG DEFINED.—For purposes of this paragraph, the term "transitional home infusion drug" has the meaning given to the term "home infusion drug" under section 1861(iii)(3)(C)), except that clause (ii) of such section shall not apply if a drug described in such clause is identified in clauses (i), (ii), (iii) or (iv) of subparagraph (C) as of the date of the enactment of this paragraph.

(B) PAYMENT METHODOLOGY.—For purposes of this paragraph, the Secretary shall establish a payment methodology, with respect to items and services described in subparagraph (A)(i). Under such payment methodology the Secretary shall—

(i) create the three payment categories described in clauses (i), (ii), and (iii) of subparagraph (C);

(ii) assign drugs to such categories, in accordance with such clauses;

(iii) assign appropriate Healthcare Common Procedure Coding System (HCPCS) codes to each payment category; and

(iv) establish a single payment amount for each such payment category, in accordance with subparagraph (D), for each infusion drug administration calendar day in the individual's home for drugs assigned to such category.

(C) PAYMENT CATEGORIES.—

(i) PAYMENT CATEGORY 1.—The Secretary shall create a payment category 1 and assign to such category drugs which are covered under the Local Coverage Determination on External Infusion Pumps (LCD number L33794) and billed with the following HCPCS codes (as identified as of January 1, 2018, and as subsequently modified by the Secretary): J0133, J0285, J0287, J0288, J0289, J0895, J1170, J1250, J1265, J1325, J1455, J1457, J1570, J2175, J2260, J2270, J2274, J2278, J3010, or J3285.

(ii) PAYMENT CATEGORY 2.—The Secretary shall create a payment category 2 and assign to such category drugs which are covered under such local coverage determination and billed with the following HCPCS codes (as identified as of January 1, 2018, and as subsequently modified by the Secretary): J1555 JB, J1559 JB, J1561 JB, J1562 JB, J1569 JB, or J1575 JB.

(iii) PAYMENT CATEGORY 3.—The Secretary shall create a payment category 3 and assign to such category drugs which are covered under such local coverage determination and billed with the following HCPCS codes (as identified as of January 1, 2018, and as subsequently modified by the Secretary): J9000, J9039, J9040, J9065, J9100, J9190, J9200, J9360, or J9370.

(iv) INFUSION DRUGS NOT OTHERWISE INCLUDED.—With respect to drugs that are not included in payment category 1, 2, or 3 under clause (i), (ii), or (iii), respectively, the Secretary shall assign to the most appropriate of such categories, as determined by the Secretary, drugs which are—

(I) covered under such local coverage determination and billed under HCPCS codes J7799 or J7999 (as identified as of July 1, 2017, and as subsequently modified by the Secretary); or

(II) billed under any code that is implemented after the date of the enactment of this paragraph and included in such local coverage determination or included in subregulatory guidance as a home infusion drug described in subparagraph (A)(i).

(D) PAYMENT AMOUNTS.—

(i) IN GENERAL.—Under the payment methodology, the Secretary shall pay eligible home infusion suppliers, with respect to items and services described in subparagraph (A)(i) furnished during the period described in subparagraph (A)(ii) by such supplier to an individual, at amounts equal to the amounts determined under the physician fee schedule established under section 1848 for services furnished during the year for codes and units of such codes described in clauses (ii), (iii), and (iv) with respect to drugs included in the payment category under subparagraph (C) specified in the respective clause, determined without application of the geographic adjustment under subsection (e) of such section.

(ii) PAYMENT AMOUNT FOR CATEGORY 1.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 1 described in subparagraph (C)(i), are one unit of HCPCS code 96365 plus three units of HCPCS code 96366 (as identified as of January 1, 2018, and as subsequently modified by the Secretary).

(iii) PAYMENT AMOUNT FOR CATEGORY 2.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 2 described in subparagraph (C)(i), are one unit of HCPCS code 96369 plus three units of HCPCS code 96370 (as identified as of January 1, 2018, and as subsequently modified by the Secretary).

(iv) PAYMENT AMOUNT FOR CATEGORY 3.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 3 described in subparagraph (C)(i), are one unit of HCPCS code 96413 plus three units of HCPCS code 96415 (as identified as of January 1, 2018, and as subsequently modified by the Secretary).

(E) CLARIFICATIONS.—

(i) INFUSION DRUG ADMINISTRATION DAY.—For purposes of this subsection, with respect to the furnishing of transitional home infusion drugs or home infusion drugs to

an individual by an eligible home infusion supplier or a qualified home infusion therapy supplier, a reference to payment to such supplier for an infusion drug administration calendar day in the individual's home shall refer to payment only for the date on which professional services (as described in section 1861(iii)(2)(A)) were furnished to administer such drugs to such individual. For purposes of the previous sentence, an infusion drug administration calendar day shall include all such drugs administered to such individual on such day.

(ii) TREATMENT OF MULTIPLE DRUGS ADMINISTERED ON SAME INFUSION DRUG ADMINISTRATION DAY.—In the case that an eligible home infusion supplier, with respect to an infusion drug administration calendar day in an individual's home, furnishes to such individual transitional home infusion drugs which are not all assigned to the same payment category under subparagraph (C), payment to such supplier for such infusion drug administration calendar day in the individual's home shall be a single payment equal to the amount of payment under this paragraph for the drug, among all such drugs so furnished to such individual during such calendar day, for which the highest payment would be made under this paragraph.

(F) ELIGIBLE HOME INFUSION SUPPLIERS.—In this paragraph, the term "eligible home infusion supplier" means a supplier that is enrolled under this part as a pharmacy that provides external infusion pumps and external infusion pump supplies and that maintains all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered.

(G) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(v) PAYMENT FOR OUTPATIENT PHYSICAL THERAPY SERVICES AND OUTPATIENT OCCUPATIONAL THERAPY SERVICES FURNISHED BY A THERAPY ASSISTANT.—

(1) IN GENERAL.—In the case of an outpatient physical therapy service or outpatient occupational therapy service furnished on or after January 1, 2022, for which payment is made under section 1848 or subsection (k), that is furnished in whole or in part by a therapy assistant (as defined by the Secretary), the amount of payment for such service shall be an amount equal to 85 percent of the amount of payment otherwise applicable for the service under this part. Nothing in the preceding sentence shall be construed to change applicable requirements with respect to such services.

(2) USE OF MODIFIER.—

(A) ESTABLISHMENT.—Not later than January 1, 2019, the Secretary shall establish a modifier to indicate (in a form and manner specified by the Secretary), in the case of an outpatient physical therapy service or outpatient occupational therapy service furnished in whole or in part by a therapy assistant (as so defined), that the service was furnished by a therapy assistant.

(B) REQUIRED USE.—Each request for payment, or bill submitted, for an outpatient physical therapy service or outpatient occupational therapy service furnished in whole or in part by a therapy assistant (as so defined) on or after January 1, 2020, shall include the modifier established under subparagraph (A) for each such service.

(3) IMPLEMENTATION.—The Secretary shall implement this subsection through notice and comment rulemaking.

*(w) OPIOID USE DISORDER TREATMENT SERVICES.—*

*(1) IN GENERAL.—The Secretary shall pay to an opioid treatment program (as defined in paragraph (2) of section 1861(jjj)) an amount that is equal to 100 percent of a bundled payment under this part for opioid use disorder treatment services (as defined in paragraph (1) of such section) that are furnished by such program to an individual during an episode of care (as defined by the Secretary) beginning on or after January 1, 2020. The Secretary shall ensure, as determined appropriate by the Secretary, that no duplicative payments are made under this part or part D for items and services furnished by an opioid treatment program.*

*(2) CONSIDERATIONS.—The Secretary may implement this subsection through one or more bundles based on the type of medication provided (such as buprenorphine, methadone, naltrexone, or a new innovative drug), the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determine appropriate. In developing such bundles, the Secretary may consider payment rates paid to opioid treatment programs for comparable services under State plans under title XIX or under the TRICARE program under chapter 55 of title 10 of the United States Code.*

*(3) ANNUAL UPDATES.—The Secretary shall provide an update each year to the bundled payment amounts under this subsection.*

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PART C—MEDICARE+CHOICE PROGRAM

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BENEFITS AND BENEFICIARY PROTECTIONS

SEC. 1852. (a) BASIC BENEFITS.—

(1) REQUIREMENT.—

(A) IN GENERAL.—Except as provided in section 1859(b)(3) for MSA plans and except as provided in paragraph (6) for MA regional plans, each Medicare+Choice plan shall provide to members enrolled under this part, through providers and other persons that meet the applicable requirements of this title and part A of title XI, benefits under the original medicare fee-for-service program option (and, for plan years before 2006, additional benefits required under section 1854(f)(1)(A)).

(B) BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION DEFINED.—

(i) IN GENERAL.—For purposes of this part, the term "benefits under the original medicare fee-for-service program option" means, subject to subsection (m), those items and services (other than hospice care or coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d)) for which benefits are available under parts A and B to individuals entitled to benefits under part A and enrolled under part B, with cost-sharing for those services as required under parts A and B or, subject to clause (iii), an actuarially equivalent level of cost-sharing as determined in this part.

(ii) SPECIAL RULE FOR REGIONAL PLANS.—In the case of an MA regional plan in determining an actuarially equivalent level of cost-sharing with respect to benefits under the original medicare fee-for-service program option, there shall only be taken into account, with respect to the application of section 1858(b)(2), such expenses only with respect to subparagraph (A) of such section.

(iii) LIMITATION ON VARIATION OF COST SHARING FOR CERTAIN BENEFITS.—Subject to clause (v), cost-sharing for services described in clause (iv) shall not exceed the cost-sharing required for those services under parts A and B.

(iv) SERVICES DESCRIBED.—The following services are described in this clause:

(I) Chemotherapy administration services.

(II) Renal dialysis services (as defined in section 1881(b)(14)(B)).

(III) Skilled nursing care.

(IV) Such other services that the Secretary determines appropriate (including services that the Secretary determines require a high level of predictability and transparency for beneficiaries).

(v) EXCEPTION.—In the case of services described in clause (iv) for which there is no cost-sharing required under parts A and B, cost-sharing may be required for those services in accordance with clause (i).

(2) SATISFACTION OF REQUIREMENT.—

(A) IN GENERAL.—A Medicare+Choice plan (other than an MSA plan) offered by a Medicare+Choice organization satisfies paragraph (1)(A), with respect to benefits for items and services furnished other than through a provider or other person that has a contract with the organization offering the plan, if the plan provides payment in an amount so that—

(i) the sum of such payment amount and any cost sharing provided for under the plan, is equal to at least

(ii) the total dollar amount of payment for such items and services as would otherwise be authorized under parts A and B (including any balance billing permitted under such parts).

(B) REFERENCE TO RELATED PROVISIONS.—For provision relating to—

(i) limitations on balance billing against Medicare+Choice organizations for non-contract providers, see sections 1852(k) and 1866(a)(1)(O), and

(ii) limiting actuarial value of enrollee liability for covered benefits, see section 1854(e).

(C) ELECTION OF UNIFORM COVERAGE DETERMINATION.—In the case of a Medicare+Choice organization that offers a Medicare+Choice plan in an area in which more than one local coverage determination is applied with respect to different parts of the area, the organization may elect to have the local coverage determination for the part of the area that is most beneficial to Medicare+Choice enrollees (as identified by the Secretary) apply with respect to all Medicare+Choice enrollees enrolled in the plan.

(3) SUPPLEMENTAL BENEFITS.—

(A) BENEFITS INCLUDED SUBJECT TO SECRETARY'S APPROVAL.—Subject to subparagraph (D), each Medicare+Choice organization may provide to individuals enrolled under this part, other than under an MSA plan (without affording those individuals an option to decline the coverage), supplemental health care benefits that the Secretary may approve. The Secretary shall approve any such supplemental benefits unless the Secretary determines that including such supplemental benefits would substantially discourage enrollment by Medicare+Choice eligible individuals with the organization.

(B) AT ENROLLEES' OPTION.—

(i) IN GENERAL.—Subject to clause (ii), a Medicare+Choice organization may provide to individuals enrolled under this part supplemental health care benefits that the individuals may elect, at their option, to have covered.

(ii) SPECIAL RULE FOR MSA PLANS.—A Medicare+Choice organization may not provide, under an MSA plan, supplemental health care benefits that cover the deductible described in section 1859(b)(2)(B). In applying the previous sentence, health benefits described in section 1882(u)(2)(B) shall not be treated as covering such deductible.

(C) APPLICATION TO MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS.—Nothing in this paragraph shall be construed as preventing a Medicare+Choice private fee-for-service plan from offering supplemental benefits that include payment for some or all of the balance billing amounts permitted consistent with section 1852(k) and coverage of additional services that the plan finds to be medically necessary. Such benefits may include reductions in cost-sharing below the actuarial value specified in section 1854(e)(4)(B).

(D) EXPANDING SUPPLEMENTAL BENEFITS TO MEET THE NEEDS OF CHRONICALLY ILL ENROLLEES.—

(i) IN GENERAL.—For plan year 2020 and subsequent plan years, in addition to any supplemental health care benefits otherwise provided under this paragraph, an MA plan, including a specialized MA plan for special needs individuals (as defined in section 1859(b)(6)), may provide supplemental benefits described in clause (ii) to a chronically ill enrollee (as defined in clause (iii)).

(ii) SUPPLEMENTAL BENEFITS DESCRIBED.—

(I) IN GENERAL.—Supplemental benefits described in this clause are supplemental benefits that, with respect to a chronically ill enrollee, have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee and may not be limited to being primarily health related benefits.

(II) AUTHORITY TO WAIVE UNIFORMITY REQUIREMENTS.—The Secretary may, only with respect to supplemental benefits provided to a chronically ill enrollee under this subparagraph, waive the uniformity requirements under this part, as determined appropriate by the Secretary.

(iii) CHRONICALLY ILL ENROLLEE DEFINED.—In this subparagraph, the term "chronically ill enrollee" means an enrollee in an MA plan that the Secretary determines—

(I) has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee;

(II) has a high risk of hospitalization or other adverse health outcomes; and

(III) requires intensive care coordination.

(4) ORGANIZATION AS SECONDARY PAYER.—Notwithstanding any other provision of law, a Medicare+Choice organization may (in the case of the provision of items and services to an individual under a Medicare+Choice plan under circumstances in which payment under this

title is made secondary pursuant to section 1862(b)(2)) charge or authorize the provider of such services to charge, in accordance with the charges allowed under a law, plan, or policy described in such section—

(A) the insurance carrier, employer, or other entity which under such law, plan, or policy is to pay for the provision of such services, or

(B) such individual to the extent that the individual has been paid under such law, plan, or policy for such services.

(5) NATIONAL COVERAGE DETERMINATIONS AND LEGISLATIVE CHANGES IN BENEFITS.—If there is a national coverage determination or legislative change in benefits required to be provided under this part made in the period beginning on the date of an announcement under section 1853(b) and ending on the date of the next announcement under such section and the Secretary projects that the determination will result in a significant change in the costs to a Medicare+Choice organization of providing the benefits that are the subject of such national coverage determination and that such change in costs was not incorporated in the determination of the annual Medicare+Choice capitation rate under section 1853 included in the announcement made at the beginning of such period, then, unless otherwise required by law—

(A) such determination or legislative change in benefits shall not apply to contracts under this part until the first contract year that begins after the end of such period, and

(B) if such coverage determination or legislative change provides for coverage of additional benefits or coverage under additional circumstances, section 1851(i)(1) shall not apply to payment for such additional benefits or benefits provided under such additional circumstances until the first contract year that begins after the end of such period.

The projection under the previous sentence shall be based on an analysis by the Chief Actuary of the Centers for Medicare & Medicaid Services of the actuarial costs associated with the coverage determination or legislative change in benefits.

(6) SPECIAL BENEFIT RULES FOR REGIONAL PLANS.—In the case of an MA plan that is an MA regional plan, benefits under the plan shall include the benefits described in paragraphs (1) and (2) of section 1858(b).

(7) LIMITATION ON COST-SHARING FOR DUAL ELIGIBLES AND QUALIFIED MEDICARE BENEFICIARIES.—In the case of an individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)) or a qualified medicare beneficiary (as defined in section 1905(p)(1)) and who is enrolled in a specialized Medicare Advantage plan for special needs individuals described in section 1859(b)(6)(B)(ii), the plan may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX if the individual were not enrolled in such plan.

(b) ANTIDISCRIMINATION.—

(1) BENEFICIARIES.—A Medicare Advantage organization may not deny, limit, or condition the coverage or provision of benefits under this part, for individuals permitted to be enrolled with the organization under this part, based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act. The Secretary shall not approve a plan of an organization if the Secretary determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals with the organization.

(2) PROVIDERS.—A Medicare+Choice organization shall not discriminate with respect to participation, reimbursement, or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification. This paragraph shall not be construed to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan.

(c) DISCLOSURE REQUIREMENTS.—

(1) DETAILED DESCRIPTION OF PLAN PROVISIONS.—A Medicare+Choice organization shall disclose, in clear, accurate, and standardized form to each enrollee with a Medicare+Choice plan offered by the organization under this part at the time of enrollment and at least annually thereafter, the following information regarding such plan:

(A) SERVICE AREA.—The plan's service area.

(B) BENEFITS.—Benefits offered under the plan, including information described in section 1851(d)(3)(A) and exclusions from coverage and, if it is an MSA plan, a comparison of benefits under such a plan with benefits under other Medicare+Choice plans.

(C) ACCESS.—The number, mix, and distribution of plan providers, out-of-network coverage (if any) provided by the plan, and any point-of-service option (including the supplemental premium for such option).

(D) OUT-OF-AREA COVERAGE.—Out-of-area coverage provided by the plan.

(E) EMERGENCY COVERAGE.—Coverage of emergency services, including—

(i) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;

(ii) the process and procedures of the plan for obtaining emergency services; and

(iii) the locations of (I) emergency departments, and (II) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.

(F) SUPPLEMENTAL BENEFITS.—Supplemental benefits available from the organization offering the plan, including—

(i) whether the supplemental benefits are optional,

(ii) the supplemental benefits covered, and

(iii) the Medicare+Choice monthly supplemental beneficiary premium for the supplemental benefits.

(G) PRIOR AUTHORIZATION RULES.—Rules regarding prior authorization or other review requirements that could result in nonpayment.

(H) PLAN GRIEVANCE AND APPEALS PROCEDURES.—All plan appeal or grievance rights and procedures.

(I) QUALITY IMPROVEMENT PROGRAM.—A description of the organization's quality improvement program under subsection (e).

(2) DISCLOSURE UPON REQUEST.—Upon request of a Medicare+Choice eligible individual, a Medicare+Choice organization must provide the following information to such individual:

(A) The general coverage information and general comparative plan information made available under clauses (i) and (ii) of section 1851(d)(2)(A).

(B) Information on procedures used by the organization to control utilization of services and expenditures.

(C) Information on the number of grievances, redeterminations, and appeals and on the disposition in the aggregate of such matters.

(D) An overall summary description as to the method of compensation of participating physicians.

(d) ACCESS TO SERVICES.—

(1) IN GENERAL.—A Medicare+Choice organization offering a Medicare+Choice plan may select the providers from whom the benefits under the plan are provided so long as—

(A) the organization makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits;

(B) when medically necessary the organization makes such benefits available and accessible 24 hours a day and 7 days a week;

(C) the plan provides for reimbursement with respect to services which are covered under subparagraphs (A) and (B) and which are provided to such an individual other than through the organization, if—

(i) the services were not emergency services (as defined in paragraph (3)), but (I) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition, and (II) it was not reasonable given the circumstances to obtain the services through the organization,

(ii) the services were renal dialysis services and were provided other than through the organization because the individual was temporarily out of the plan's service area, or

(iii) the services are maintenance care or post-stabilization care covered under the guidelines established under paragraph (2);

(D) the organization provides access to appropriate providers, including credentialed specialists, for medically necessary treatment and services; and

(E) coverage is provided for emergency services (as defined in paragraph (3)) without regard to prior authorization or the emergency care provider's contractual relationship with the organization.

(2) GUIDELINES RESPECTING COORDINATION OF POST-STABILIZATION CARE.—A Medicare+Choice plan shall comply with such guidelines as the Secretary may prescribe relating to promoting efficient and timely coordination of appropriate maintenance and post-stabilization care of an enrollee after the enrollee has been determined to be stable under section 1867.

(3) DEFINITION OF EMERGENCY SERVICES.—In this subsection—

(A) IN GENERAL.—The term "emergency services" means, with respect to an individual enrolled with an organization, covered inpatient and outpatient services that—

(i) are furnished by a provider that is qualified to furnish such services under this title, and

(ii) are needed to evaluate or stabilize an emergency medical condition (as defined in subparagraph (B)).

(B) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON.—The term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

(ii) serious impairment to bodily functions, or

(iii) serious dysfunction of any bodily organ or part.

(4) ASSURING ACCESS TO SERVICES IN MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS.—In addition to any other requirements under this part, in the case of a Medicare+Choice private fee-for-service plan, the organization offering the plan must demonstrate to the Secretary that the organization has sufficient number and range of health care professionals and providers willing to provide services under the terms of the plan. Subject to paragraphs (5) and (6), the Secretary shall find that an organization has met such requirement with respect to any category of health care professional or provider if, with respect to that category of provider—

(A) the plan has established payment rates for covered services furnished by that category of provider that are not less than the payment rates provided for under part A, part B, or both, for such services, or

(B) the plan has contracts or agreements (other than deemed contracts or agreements under subsection (j)(6)) with a sufficient number and range of providers within such category to meet the access standards in subparagraphs (A) through (E) of paragraph (1),

or a combination of both. The previous sentence shall not be construed as restricting the persons from whom enrollees under such a plan may obtain covered benefits, except that, if a plan entirely meets such requirement with respect to a category of health care professional or provider on the basis of subparagraph (B), it may provide for a higher beneficiary copayment in the case of health care professionals and providers of that category who do not have contracts or agreements (other than deemed contracts or agreements under subsection (j)(6)) to provide covered services under the terms of the plan.

(5) REQUIREMENT OF CERTAIN NONEMPLOYER MEDICARE ADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS TO USE CONTRACTS WITH PROVIDERS.—

(A) IN GENERAL.—For plan year 2011 and subsequent plan years, in the case of a Medicare Advantage private fee-for-service plan not described in paragraph (1) or (2) of section 1857(i) operating in a network area (as defined in subparagraph (B)), the plan shall meet the access standards under paragraph (4) in that area only through entering into written contracts as provided for under subparagraph (B) of such paragraph and not, in whole or in part, through the establishment of payment rates meeting the requirements under subparagraph (A) of such paragraph.

(B) NETWORK AREA DEFINED.—For purposes of subparagraph (A), the term "network area" means, for a plan year, an area which the Secretary identifies (in the Secretary's announcement of the proposed payment rates for the previous plan year under section 1853(b)(1)(B)) as having at least 2 network-based plans (as defined in subparagraph (C)) with enrollment under this part as of the first day of the year in which such announcement is made.

(C) NETWORK-BASED PLAN DEFINED.—

(i) IN GENERAL.—For purposes of subparagraph (B), the term "network-based plan" means—

(I) except as provided in clause (ii), a Medicare Advantage plan that is a coordinated care plan described in section 1851(a)(2)(A)(i);

(II) a network-based MSA plan; and

(III) a reasonable cost reimbursement plan under section 1876.

(ii) EXCLUSION OF NON-NETWORK REGIONAL PPOS.—The term "network-based plan" shall not include an MA regional plan that, with respect to the area, meets access adequacy standards under this part substantially through the authority of section 422.112(a)(1)(ii) of title 42, Code of Federal Regulations, rather than through written contracts.

(6) REQUIREMENT OF ALL EMPLOYER MEDICARE ADVANTAGE PRIVATE FEE-FOR-SERVICE PLANS TO USE CONTRACTS WITH PROVIDERS.—For plan year 2011 and subsequent plan years, in the case of a Medicare Advantage private fee-for-service plan that is described in paragraph (1) or (2) of section 1857(i), the plan shall meet the access standards under paragraph (4) only through entering into written contracts as provided for under subparagraph (B) of such paragraph and not, in whole or in part, through the establishment of payment rates meeting the requirements under subparagraph (A) of such paragraph.

(e) QUALITY IMPROVEMENT PROGRAM.—

(1) IN GENERAL.—Each MA organization shall have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees in each MA plan offered by such organization.

(2) CHRONIC CARE IMPROVEMENT PROGRAMS.—As part of the quality improvement program under paragraph (1), each MA organization shall have a chronic care improvement program. Each chronic care improvement program shall have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet criteria established by the organization for participation under the program.

(3) DATA.—

(A) COLLECTION, ANALYSIS, AND REPORTING.—

(i) IN GENERAL.—Except as provided in clauses (ii) and (iii) with respect to plans described in such clauses and subject to subparagraph (B), as part of the quality improvement program under paragraph (1), each MA organization shall provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality. With respect to MA private fee-for-service plans and MSA plans, the requirements under the preceding sentence may not exceed the requirements under this subparagraph with respect to MA local plans that are preferred provider organization plans, except that, for plan year 2010, the limitation under clause (iii) shall not apply and such requirements shall apply only with respect to administrative claims data.

(ii) SPECIAL REQUIREMENTS FOR SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—In addition to the data required to be collected, analyzed, and reported under clause (i) and notwithstanding the limitations under subparagraph (B), as part of the quality improvement program under paragraph (1), each MA organization offering a specialized Medicare Advantage plan for special needs individuals shall provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality with respect to the requirements described in paragraphs (2) through (5) of subsection (f). Such data may be based on claims data and shall be at the plan level.

(iii) APPLICATION TO LOCAL PREFERRED PROVIDER ORGANIZATIONS AND MA REGIONAL PLANS.—Clause (i) shall apply to MA organizations with respect to MA local plans that are preferred provider organization plans and to MA regional plans only insofar as services are furnished by providers or services, physicians, and other health care practitioners and suppliers that have contracts with such organization to furnish services under such plans.

(iv) DEFINITION OF PREFERRED PROVIDER ORGANIZATION PLAN.—In this subparagraph, the term "preferred provider organization plan" means an MA plan that—

(I) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(II) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and

(III) is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

(B) LIMITATIONS.—

(i) TYPES OF DATA.—The Secretary shall not collect under subparagraph (A) data on quality, outcomes, and beneficiary satisfaction to facilitate consumer choice and program administration other than the types of data that were collected by the Secretary as of November 1, 2003.

(ii) CHANGES IN TYPES OF DATA.—Subject to subclause (iii), the Secretary may only change the types of data that are required to be submitted under subparagraph (A) after submitting to Congress a report on the reasons for such changes that was prepared in consultation with MA organizations and private accrediting bodies.

(iii) CONSTRUCTION.—Nothing in the subsection shall be construed as restricting the ability of the Secretary to carry out the duties under section 1851(d)(4)(D).

(4) TREATMENT OF ACCREDITATION.—

(A) IN GENERAL.—The Secretary shall provide that a Medicare+Choice organization is deemed to meet all the requirements described in any specific clause of subparagraph (B) if the organization is accredited (and periodically reaccredited) by a private accrediting organization under a process that the Secretary has determined assures that the accrediting organization applies and enforces standards that meet or exceed the standards established under section 1856 to carry out the requirements in such clause.

(B) REQUIREMENTS DESCRIBED.—The provisions described in this subparagraph are the following:

(i) Paragraphs (1) through (3) of this subsection (relating to quality improvement programs).

(ii) Subsection (b) (relating to antidiscrimination).

(iii) Subsection (d) (relating to access to services).

(iv) Subsection (h) (relating to confidentiality and accuracy of enrollee records).

(v) Subsection (i) (relating to information on advance directives).

(vi) Subsection (j) (relating to provider participation rules).

(vii) The requirements described in section 1860D–4(j), to the extent such requirements apply under section 1860D–21(c).

(C) TIMELY ACTION ON APPLICATIONS.—The Secretary shall determine, within 210 days after the date the Secretary receives an application by a private accrediting organization and using the criteria specified in section 1865(a)(2), whether the process of the private accrediting organization meets the requirements with respect to any specific clause in subparagraph (B) with respect to which the application is made. The Secretary may not deny such an application on the basis that it seeks to meet the requirements with respect to only one, or more than one, such specific clause.

(D) CONSTRUCTION.—Nothing in this paragraph shall be construed as limiting the authority of the Secretary under section 1857, including the authority to terminate contracts with Medicare+Choice organizations under subsection (c)(2) of such section.

(f) GRIEVANCE MECHANISM.—Each Medicare+Choice organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and enrollees with Medicare+Choice plans of the organization under this part.

(g) COVERAGE DETERMINATIONS, RECONSIDERATIONS, AND APPEALS.—

(1) DETERMINATIONS BY ORGANIZATION.—

(A) IN GENERAL.—A Medicare+Choice organization shall have a procedure for making determinations regarding whether an individual enrolled with the plan of the organization under this part is entitled to receive a health service under this section and the amount (if any) that the individual is required to pay with respect to such service. Subject to paragraph (3), such procedures shall provide for such determination to be made on a timely basis.

(B) EXPLANATION OF DETERMINATION.—Such a determination that denies coverage, in whole or in part, shall be in writing and shall include a statement in understandable language of the reasons for the denial and a description of the reconsideration and appeals processes.

(2) RECONSIDERATIONS.—

(A) IN GENERAL.—The organization shall provide for reconsideration of a determination described in paragraph (1)(B) upon request by the enrollee involved. The reconsideration shall be within a time period specified by the Secretary, but shall be made, subject to paragraph (3), not later than 60 days after the date of the receipt of the request for reconsideration.

(B) PHYSICIAN DECISION ON CERTAIN RECONSIDERATIONS.—A reconsideration relating to a determination to deny coverage based on a lack of medical necessity shall be made only by a physician with appropriate expertise in the field of medicine which necessitates treatment who is other than a physician involved in the initial determination.

(3) EXPEDITED DETERMINATIONS AND RECONSIDERATIONS.—

(A) RECEIPT OF REQUESTS.—

(i) ENROLLEE REQUESTS.—An enrollee in a Medicare+Choice plan may request, either in writing or orally, an expedited determination under paragraph (1) or an expedited reconsideration under paragraph (2) by the Medicare+Choice organization.

(ii) PHYSICIAN REQUESTS.—A physician, regardless whether the physician is affiliated with the organization or not, may request, either in writing or orally, such an expedited determination or reconsideration.

(B) ORGANIZATION PROCEDURES.—

(i) IN GENERAL.—The Medicare+Choice organization shall maintain procedures for expediting organization determinations and reconsiderations when, upon request of an enrollee, the organization determines that the application of the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) EXPEDITION REQUIRED FOR PHYSICIAN REQUESTS.—In the case of a request for an expedited determination or reconsideration made under subparagraph (A)(ii), the organization shall expedite the determination or reconsideration if the request indicates that the application of the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(iii) TIMELY RESPONSE.—In cases described in clauses (i) and (ii), the organization shall notify the enrollee (and the physician involved, as appropriate) of the determination or reconsideration under time limitations established by the Secretary, but not later than 72 hours of the time of receipt of the request for the determination or reconsideration (or receipt of the information necessary to make the determination or reconsideration), or such longer period as the Secretary may permit in specified cases.

(4) INDEPENDENT REVIEW OF CERTAIN COVERAGE DENIALS.—The Secretary shall contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm denial of coverage, in whole or in part. The provisions of section 1869(c)(5) shall apply to independent outside entities under contract with the Secretary under this paragraph.

(5) APPEALS.—An enrollee with a Medicare+Choice plan of a Medicare+Choice organization under this part who is dissatisfied by reason of the enrollee's failure to receive any health service to which the enrollee believes the enrollee is entitled and at no greater charge than the enrollee believes the enrollee is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the same extent as is provided in section 205(b), and in any such hearing the Secretary shall make the organization a party. If the amount in controversy is $1,000 or more, the individual or organization shall, upon notifying the other party, be entitled to judicial review of the Secretary's final decision as provided in section 205(g), and both the individual and the organization shall be entitled to be parties to that judicial review. In applying subsections (b) and (g) of section 205 as provided in this paragraph, and in applying section 205(l) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively. The provisions of section 1869(b)(1)(E)(iii) shall apply with respect to dollar amounts specified in the first 2 sentences of this paragraph in the same manner as they apply to the dollar amounts specified in section 1869(b)(1)(E)(i).

(h) CONFIDENTIALITY AND ACCURACY OF ENROLLEE RECORDS.—Insofar as a Medicare+Choice organization maintains medical records or other health information regarding enrollees under this part, the Medicare+Choice organization shall establish procedures—

(1) to safeguard the privacy of any individually identifiable enrollee information;

(2) to maintain such records and information in a manner that is accurate and timely; and

(3) to assure timely access of enrollees to such records and information.

(i) INFORMATION ON ADVANCE DIRECTIVES.—Each Medicare+Choice organization shall meet the requirement of section 1866(f) (relating to maintaining written policies and procedures respecting advance directives).

(j) RULES REGARDING PROVIDER PARTICIPATION.—

(1) PROCEDURES.—Insofar as a Medicare+Choice organization offers benefits under a Medicare+Choice plan through agreements with physicians, the organization shall establish reasonable procedures relating to the participation (under an agreement between a physician and the organization) of physicians under such a plan. Such procedures shall include—

(A) providing notice of the rules regarding participation,

(B) providing written notice of participation decisions that are adverse to physicians, and

(C) providing a process within the organization for appealing such adverse decisions, including the presentation of information and views of the physician regarding such decision.

(2) CONSULTATION IN MEDICAL POLICIES.—A Medicare+Choice organization shall consult with physicians who have entered into participation agreements with the organization regarding the organization's medical policy, quality, and medical management procedures.

(3) PROHIBITING INTERFERENCE WITH PROVIDER ADVICE TO ENROLLEES.—

(A) IN GENERAL.—Subject to subparagraphs (B) and (C), a Medicare+Choice organization (in relation to an individual enrolled under a Medicare+Choice plan offered by the organization under this part) shall not prohibit or otherwise restrict a covered health care professional (as defined in subparagraph (D)) from advising such an individual who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the plan, if the professional is acting within the lawful scope of practice.

(B) CONSCIENCE PROTECTION.—Subparagraph (A) shall not be construed as requiring a Medicare+Choice plan to provide, reimburse for, or provide coverage of a counseling or referral service if the Medicare+Choice organization offering the plan—

(i) objects to the provision of such service on moral or religious grounds; and

(ii) in the manner and through the written instrumentalities such Medicare+Choice organization deems appropriate, makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization or plan adopts a change in policy regarding such a counseling or referral service.

(C) CONSTRUCTION.—Nothing in subparagraph (B) shall be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

(D) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this paragraph, the term "health care professional" means a physician (as defined in section 1861(r)) or other health care professional if coverage for the professional's services is provided under the Medicare+Choice plan for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

(4) LIMITATIONS ON PHYSICIAN INCENTIVE PLANS.—

(A) IN GENERAL.—No Medicare+Choice organization may operate any physician incentive plan (as defined in subparagraph (B)) unless the organization provides assurances satisfactory to the Secretary that the following requirements are met:

(i) No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the organization.

(ii) If the plan places a physician or physician group at substantial financial risk (as determined by the Secretary) for services not provided by the physician or physician group, the organization provides stop-loss protection for the physician or group that is adequate and appropriate, based on standards developed by the Secretary that take into account the number of physicians placed at such substantial financial risk in the group or under the plan and the number of individuals enrolled with the organization who receive services from the physician or group.

(B) PHYSICIAN INCENTIVE PLAN DEFINED.—In this paragraph, the term "physician incentive plan" means any compensation arrangement between a Medicare+Choice organization and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the organization under this part.

(5) LIMITATION ON PROVIDER INDEMNIFICATION.—A Medicare+Choice organization may not provide (directly or indirectly) for a health care professional, provider of services, or other entity providing health care services (or group of such professionals, providers, or entities) to indemnify the organization against any liability resulting from a civil action brought for any damage caused to an enrollee with a Medicare+Choice plan of the organization under this part by the organization's denial of medically necessary care.

(6) SPECIAL RULES FOR MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS.—For purposes of applying this part (including subsection (k)(1)) and section 1866(a)(1)(O), a hospital (or other provider of services), a physician or other health care professional, or other entity furnishing health care services is treated as having an agreement or contract in effect with a Medicare+Choice organization (with respect to an individual enrolled in a Medicare+Choice private fee-for-service plan it offers), if—

(A) the provider, professional, or other entity furnishes services that are covered under the plan to such an enrollee; and

(B) before providing such services, the provider, professional, or other entity —

(i) has been informed of the individual's enrollment under the plan, and

(ii) either—

(I) has been informed of the terms and conditions of payment for such services under the plan, or

(II) is given a reasonable opportunity to obtain information concerning such terms and conditions,

in a manner reasonably designed to effect informed agreement by a provider.

The previous sentence shall only apply in the absence of an explicit agreement between such a provider, professional, or other entity and the Medicare+Choice organization.

(7) PROMOTION OF E-PRESCRIBING BY MA PLANS.—

(A) IN GENERAL.—An MA–PD plan may provide for a separate payment or otherwise provide for a differential payment for a participating physician that prescribes covered part D drugs in accordance with an electronic prescription drug program that meets standards established under section 1860D–4(e).

(B) CONSIDERATIONS.—Such payment may take into consideration the costs of the physician in implementing such a program and may also be increased for those participating physicians who significantly increase—

(i) formulary compliance;

(ii) lower cost, therapeutically equivalent alternatives;

(iii) reductions in adverse drug interactions; and

(iv) efficiencies in filing prescriptions through reduced administrative costs.

(C) STRUCTURE.—Additional or increased payments under this subsection may be structured in the same manner as medication therapy management fees are structured under section 1860D–4(c)(2)(E).

(k) TREATMENT OF SERVICES FURNISHED BY CERTAIN PROVIDERS.—

(1) IN GENERAL.—Except as provided in paragraph (2), a physician or other entity (other than a provider of services) that does not have a contract establishing payment amounts for services furnished to an individual enrolled under this part with a Medicare+Choice organization described in section 1851(a)(2)(A) or with an organization offering an MSA plan shall ac-

cept as payment in full for covered services under this title that are furnished to such an individual the amounts that the physician or other entity could collect if the individual were not so enrolled. Any penalty or other provision of law that applies to such a payment with respect to an individual entitled to benefits under this title (but not enrolled with a Medicare+Choice organization under this part) also applies with respect to an individual so enrolled.

(2) APPLICATION TO MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS.—

(A) BALANCE BILLING LIMITS UNDER MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLANS IN CASE OF CONTRACT PROVIDERS.—

(i) IN GENERAL.—In the case of an individual enrolled in a Medicare+Choice private fee-for-service plan under this part, a physician, provider of services, or other entity that has a contract (including through the operation of subsection (j)(6)) establishing a payment rate for services furnished to the enrollee shall accept as payment in full for covered services under this title that are furnished to such an individual an amount not to exceed (including any deductibles, coinsurance, copayments, or balance billing otherwise permitted under the plan) an amount equal to 115 percent of such payment rate.

(ii) PROCEDURES TO ENFORCE LIMITS.—The Medicare+Choice organization that offers such a plan shall establish procedures, similar to the procedures described in section 1848(g)(1)(A), in order to carry out the previous sentence.

(iii) ASSURING ENFORCEMENT.—If the Medicare+Choice organization fails to establish and enforce procedures required under clause (ii), the organization is subject to intermediate sanctions under section 1857(g).

(B) ENROLLEE LIABILITY FOR NONCONTRACT PROVIDERS.—For provision—

(i) establishing minimum payment rate in the case of noncontract providers under a Medicare+Choice private fee-for-service plan, see section 1852(a)(2); or

(ii) limiting enrollee liability in the case of covered services furnished by such providers, see paragraph (1) and section 1866(a)(1)(O).

(C) INFORMATION ON BENEFICIARY LIABILITY.—

(i) IN GENERAL.—Each Medicare+Choice organization that offers a Medicare+Choice private fee-for-service plan shall provide that enrollees under the plan who are furnished services for which payment is sought under the plan are provided an appropriate explanation of benefits (consistent with that provided under parts A and B and, if applicable, under medicare supplemental policies) that includes a clear statement of the amount of the enrollee's liability (including any liability for balance billing consistent with this subsection) with respect to payments for such services.

(ii) ADVANCE NOTICE BEFORE RECEIPT OF INPATIENT HOSPITAL SERVICES AND CERTAIN OTHER SERVICES.—In addition, such organization shall, in its terms and conditions of payments to hospitals for inpatient hospital services and for other services identified by the Secretary for which the amount of the balance billing under subparagraph (A) could be substantial, require the hospital to provide to the enrollee, before furnishing such services and if the hospital imposes balance billing under subparagraph (A)—

(I) notice of the fact that balance billing is permitted under such subparagraph for such services, and

(II) a good faith estimate of the likely amount of such balance billing (if any), with respect to such services, based upon the presenting condition of the enrollee.

(l) RETURN TO HOME SKILLED NURSING FACILITIES FOR COVERED POST-HOSPITAL EXTENDED CARE SERVICES.—

(1) ENSURING RETURN TO HOME SNF.—

(A) IN GENERAL.—In providing coverage of post-hospital extended care services, a Medicare+Choice plan shall provide for such coverage through a home skilled nursing facility if the following conditions are met:

(i) ENROLLEE ELECTION.—The enrollee elects to receive such coverage through such facility.

(ii) SNF AGREEMENT.—The facility has a contract with the Medicare+Choice organization for the provision of such services, or the facility agrees to accept substantially similar payment under the same terms and conditions that apply to similarly situated skilled nursing facilities that are under contract with the Medicare+Choice organiza-

tion for the provision of such services and through which the enrollee would otherwise receive such services.

(B) MANNER OF PAYMENT TO HOME SNF.—The organization shall provide payment to the home skilled nursing facility consistent with the contract or the agreement described in subparagraph (A)(ii), as the case may be.

(2) NO LESS FAVORABLE COVERAGE.—The coverage provided under paragraph (1) (including scope of services, cost-sharing, and other criteria of coverage) shall be no less favorable to the enrollee than the coverage that would be provided to the enrollee with respect to a skilled nursing facility the post-hospital extended care services of which are otherwise covered under the Medicare+Choice plan.

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to do the following:

(A) To require coverage through a skilled nursing facility that is not otherwise qualified to provide benefits under part A for medicare beneficiaries not enrolled in a Medicare+Choice plan.

(B) To prevent a skilled nursing facility from refusing to accept, or imposing conditions upon the acceptance of, an enrollee for the receipt of post-hospital extended care services.

(4) DEFINITIONS.—In this subsection:

(A) HOME SKILLED NURSING FACILITY.—The term "home skilled nursing facility" means, with respect to an enrollee who is entitled to receive post-hospital extended care services under a Medicare+Choice plan, any of the following skilled nursing facilities:

(i) SNF RESIDENCE AT TIME OF ADMISSION.—The skilled nursing facility in which the enrollee resided at the time of admission to the hospital preceding the receipt of such post-hospital extended care services.

(ii) SNF IN CONTINUING CARE RETIREMENT COMMUNITY.—A skilled nursing facility that is providing such services through a continuing care retirement community (as defined in subparagraph (B)) which provided residence to the enrollee at the time of such admission.

(iii) SNF RESIDENCE OF SPOUSE AT TIME OF DISCHARGE.—The skilled nursing facility in which the spouse of the enrollee is residing at the time of discharge from such hospital.

(B) CONTINUING CARE RETIREMENT COMMUNITY.—The term "continuing care retirement community" means, with respect to an enrollee in a Medicare+Choice plan, an arrangement under which housing and health-related services are provided (or arranged) through an organization for the enrollee under an agreement that is effective for the life of the enrollee or for a specified period.

(m) PROVISION OF ADDITIONAL TELEHEALTH BENEFITS.—

(1) MA PLAN OPTION.—For plan year 2020 and subsequent plan years, subject to the requirements of paragraph (3), an MA plan may provide additional telehealth benefits (as defined in paragraph (2)) to individuals enrolled under this part.

(2) ADDITIONAL TELEHEALTH BENEFITS DEFINED.—

(A) IN GENERAL.—For purposes of this subsection and section 1854:

(i) DEFINITION.—The term "additional telehealth benefits" means services—

(I) for which benefits are available under part B, including services for which payment is not made under section 1834(m) due to the conditions for payment under such section; and

(II) that are identified for such year as clinically appropriate to furnish using electronic information and telecommunications technology when a physician (as defined in section 1861(r)) or practitioner (described in section 1842(b)(18)(C)) providing the service is not at the same location as the plan enrollee.

(ii) EXCLUSION OF CAPITAL AND INFRASTRUCTURE COSTS AND INVESTMENTS.—The term "additional telehealth benefits" does not include capital and infrastructure costs and investments relating to such benefits.

(B) PUBLIC COMMENT.—Not later than November 30, 2018, the Secretary shall solicit comments on—

(i) what types of items and services (including those provided through supplemental health care benefits, such as remote patient monitoring, secure messaging, store and forward technologies, and other non-face-to-face communication) should be considered to be additional telehealth benefits; and

(ii) the requirements for the provision or furnishing of such benefits (such as training and coordination requirements).

(3) REQUIREMENTS FOR ADDITIONAL TELEHEALTH BENEFITS.—The Secretary shall specify requirements for the provision or furnishing of additional telehealth benefits, including with respect to the following:

(A) Physician or practitioner qualifications (other than licensure) and other requirements such as specific training.

(B) Factors necessary for the coordination of such benefits with other items and services including those furnished in-person.

(C) Such other areas as determined by the Secretary.

(4) ENROLLEE CHOICE.—If an MA plan provides a service as an additional telehealth benefit (as defined in paragraph (2))—

(A) the MA plan shall also provide access to such benefit through an in-person visit (and not only as an additional telehealth benefit); and

(B) an individual enrollee shall have discretion as to whether to receive such service through the in-person visit or as an additional telehealth benefit.

(5) TREATMENT UNDER MA.—For purposes of this subsection and section 1854, if a plan provides additional telehealth benefits, such additional telehealth benefits shall be treated as if they were benefits under the original Medicare fee-for-service program option.

(6) CONSTRUCTION.—Nothing in this subsection shall be construed as affecting the requirement under subsection (a)(1) that MA plans provide enrollees with items and services (other than hospice care) for which benefits are available under parts A and B, including benefits available under section 1834(m).

*(n) PROVISION OF INFORMATION RELATING TO THE SAFE DISPOSAL OF CERTAIN PRESCRIPTION DRUGS.—*

*(1) IN GENERAL.—In the case of an individual enrolled under an MA or MA-PD plan who is furnished an in-home health risk assessment on or after January 1, 2021, such plan shall ensure that such assessment includes information on the safe disposal of prescription drugs that are controlled substances that meets the criteria established under paragraph (2). Such information shall include information on drug takeback programs that meet such requirements determined appropriate by the Secretary and information on in-home disposal.*

*(2) CRITERIA.—The Secretary shall, through rulemaking, establish criteria the Secretary determines appropriate with respect to information provided to an individual to ensure that such information sufficiently educates such individual on the safe disposal of prescription drugs that are controlled substances.*

* * * * * * *

CONTRACTS WITH MEDICARE+CHOICE ORGANIZATIONS

SEC. 1857. (a) IN GENERAL.—The Secretary shall not permit the election under section 1851 of a Medicare+Choice plan offered by a Medicare+Choice organization under this part, and no payment shall be made under section 1853 to an organization, unless the Secretary has entered into a contract under this section with the organization with respect to the offering of such plan. Such a contract with an organization may cover more than 1 Medicare+Choice plan. Such contract shall provide that the organization agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(b) MINIMUM ENROLLMENT REQUIREMENTS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may not enter into a contract under this section with a Medicare+Choice organization unless the organization has—

(A) at least 5,000 individuals (or 1,500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization, or

(B) at least 1,500 individuals (or 500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization if the organization primarily serves individuals residing outside of urbanized areas.

(2) APPLICATION TO MSA PLANS.—In applying paragraph (1) in the case of a Medicare+Choice organization that is offering an MSA plan, paragraph (1) shall be applied by substituting covered lives for individuals.

(3) ALLOWING TRANSITION.—The Secretary may waive the requirement of paragraph (1) during the first 3 contract years with respect to an organization.

(c) CONTRACT PERIOD AND EFFECTIVENESS.—

(1) PERIOD.—Each contract under this section shall be for a term of at least 1 year, as determined by the Secretary, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term.

(2) TERMINATION AUTHORITY.—In accordance with procedures established under subsection (h), the Secretary may at any time terminate any such contract if the Secretary determines that the organization—

(A) has failed substantially to carry out the contract;

(B) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part; or

(C) no longer substantially meets the applicable conditions of this part.

(3) EFFECTIVE DATE OF CONTRACTS.—The effective date of any contract executed pursuant to this section shall be specified in the contract, except that in no case shall a contract under this section which provides for coverage under an MSA plan be effective before January 1999 with respect to such coverage.

(4) PREVIOUS TERMINATIONS.—

(A) IN GENERAL.—The Secretary may not enter into a contract with a Medicare+Choice organization if a previous contract with that organization under this section was terminated at the request of the organization within the preceding 2-year period, except as provided in subparagraph (B) and except in such other circumstances which warrant special consideration, as determined by the Secretary.

(B) EARLIER RE-ENTRY PERMITTED WHERE CHANGE IN PAYMENT POLICY.—Subparagraph (A) shall not apply with respect to the offering by a Medicare+Choice organization of a Medicare+Choice plan in a Medicare+Choice payment area if during the 6-month period beginning on the date the organization notified the Secretary of the intention to terminate the most recent previous contract, there was a legislative change enacted (or a regulatory change adopted) that has the effect of increasing payment amounts under section 1853 for that Medicare+Choice payment area.

(5) CONTRACTING AUTHORITY.—The authority vested in the Secretary by this part may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this title.

(d) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—

(1) PERIODIC AUDITING.—The Secretary shall provide for the annual auditing of the financial records (including data relating to medicare utilization and costs, including allowable costs under section 1858(c)) of at least one-third of the Medicare+Choice organizations offering Medicare+Choice plans under this part. The Comptroller General shall monitor auditing activities conducted under this subsection.

(2) INSPECTION AND AUDIT.—Each contract under this section shall provide that the Secretary, or any person or organization designated by the Secretary—

(A) shall have the right to timely inspect or otherwise evaluate (i) the quality, appropriateness, and timeliness of services performed under the contract, and (ii) the facilities of the organization when there is reasonable evidence of some need for such inspection, and

(B) shall have the right to timely audit and inspect any books and records of the Medicare+Choice organization that pertain (i) to the ability of the organization to bear the risk of potential financial losses, or (ii) to services performed or determinations of amounts payable under the contract.

(3) ENROLLEE NOTICE AT TIME OF TERMINATION.—Each contract under this section shall require the organization to provide (and pay for) written notice in advance of the contract's termination, as well as a description of alternatives for obtaining benefits under this title, to each individual enrolled with the organization under this part.

(4) DISCLOSURE.—

(A) IN GENERAL.—Each Medicare+Choice organization shall, in accordance with regulations of the Secretary, report to the Secretary financial information which shall include the following:

(i) Such information as the Secretary may require demonstrating that the organization has a fiscally sound operation.

(ii) A copy of the report, if any, filed with the Secretary containing the information required to be reported under section 1124 by disclosing entities.

(iii) A description of transactions, as specified by the Secretary, between the organization and a party in interest. Such transactions shall include—

(I) any sale or exchange, or leasing of any property between the organization and a party in interest;

(II) any furnishing for consideration of goods, services (including management services), or facilities between the organization and a party in interest, but not including salaries paid to employees for services provided in the normal course of their employment and health services provided to members by hospitals and other providers and by staff, medical group (or groups), individual practice association (or associations), or any combination thereof; and

(III) any lending of money or other extension of credit between an organization and a party in interest.

The Secretary may require that information reported respecting an organization which controls, is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(B) PARTY IN INTEREST DEFINED.—For the purposes of this paragraph, the term "party in interest" means—

(i) any director, officer, partner, or employee responsible for management or administration of a Medicare+Choice organization, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the organization, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the organization, and, in the case of a Medicare+Choice organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

(ii) any entity in which a person described in clause (i)—

(I) is an officer or director;

(II) is a partner (if such entity is organized as a partnership);

(III) has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(IV) has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(iii) any person directly or indirectly controlling, controlled by, or under common control with an organization; and

(iv) any spouse, child, or parent of an individual described in clause (i).

(C) ACCESS TO INFORMATION.—Each Medicare+Choice organization shall make the information reported pursuant to subparagraph (A) available to its enrollees upon reasonable request.

(5) LOAN INFORMATION.—The contract shall require the organization to notify the Secretary of loans and other special financial arrangements which are made between the organization and subcontractors, affiliates, and related parties.

(6) REVIEW TO ENSURE COMPLIANCE WITH CARE MANAGEMENT REQUIREMENTS FOR SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS INDIVIDUALS.—In conjunction with the periodic audit of a specialized Medicare Advantage plan for special needs individuals under paragraph (1), the Secretary shall conduct a review to ensure that such organization offering the plan meets the requirements described in section 1859(f)(5).

(e) ADDITIONAL CONTRACT TERMS.—

(1) IN GENERAL.—The contract shall contain such other terms and conditions not inconsistent with this part (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.

(2) COST-SHARING IN ENROLLMENT-RELATED COSTS.—

(A) IN GENERAL.—A Medicare+Choice organization and a PDP sponsor under part D shall pay the fee established by the Secretary under subparagraph (B).

(B) AUTHORIZATION.—The Secretary is authorized to charge a fee to each Medicare+Choice organization with a contract under this part and each PDP sponsor with a contract under part D that is equal to the organization' or sponsor's pro rata share (as

determined by the Secretary) of the aggregate amount of fees which the Secretary is directed to collect in a fiscal year. Any amounts collected shall be available without further appropriation to the Secretary for the purpose of carrying out section 1851 (relating to enrollment and dissemination of information), section 1860D-1(c), and section 4360 of the Omnibus Budget Reconciliation Act of 1990 (relating to the health insurance counseling and assistance program).

(C) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the purposes described in subparagraph (B) for each fiscal year beginning with fiscal year 2001 and ending with fiscal year 2005 an amount equal to $100,000,000, and for each fiscal year beginning with fiscal year 2006 an amount equal to $200,000,000, reduced by the amount of fees authorized to be collected under this paragraph and section 1860D–12(b)(3)(D) for the fiscal year.

(D) LIMITATION.—In any fiscal year the fees collected by the Secretary under subparagraph (B) shall not exceed the lesser of—

(i) the estimated costs to be incurred by the Secretary in the fiscal year in carrying out the activities described in section 1851 and section 1860D–1(c) and section 4360 of the Omnibus Budget Reconciliation Act of 1990; or

(ii)(I) $200,000,000 in fiscal year 1998;

(II) $150,000,000 in fiscal year 1999;

(III) $100,000,000 in fiscal year 2000;

(IV) the Medicare+Choice portion (as defined in subparagraph (E)) of $100,000,000 in fiscal year 2001 and each succeeding fiscal year before fiscal year 2006; and

(V) the applicable portion (as defined in subparagraph (F)) of $200,000,000 in fiscal year 2006 and each succeeding fiscal year.

(E) MEDICARE+CHOICE PORTION DEFINED.—In this paragraph, the term "Medicare+Choice portion" means, for a fiscal year, the ratio, as estimated by the Secretary, of—

(i) the average number of individuals enrolled in Medicare+Choice plans during the fiscal year, to

(ii) the average number of individuals entitled to benefits under part A, and enrolled under part B, during the fiscal year.

(F) APPLICABLE PORTION DEFINED.—In this paragraph, the term "applicable portion" means, for a fiscal year—

(i) with respect to MA organizations, the Secretary's estimate of the total proportion of expenditures under this title that are attributable to expenditures made under this part (including payments under part D that are made to such organizations); or

(ii) with respect to PDP sponsors, the Secretary's estimate of the total proportion of expenditures under this title that are attributable to expenditures made to such sponsors under part D.

(3) AGREEMENTS WITH FEDERALLY QUALIFIED HEALTH CENTERS.—

(A) PAYMENT LEVELS AND AMOUNTS.—A contract under this section with an MA organization shall require the organization to provide, in any written agreement described in section 1853(a)(4) between the organization and a federally qualified health center, for a level and amount of payment to the federally qualified health center for services provided by such health center that is not less than the level and amount of payment that the plan would make for such services if the services had been furnished by a entity providing similar services that was not a federally qualified health center.

(B) COST-SHARING.—Under the written agreement referred to in subparagraph (A), a federally qualified health center must accept the payment amount referred to in such subparagraph plus the Federal payment provided for in section 1833(a)(3)(B) as payment in full for services covered by the agreement, except that such a health center may collect any amount of cost-sharing permitted under the contract under this section, so long as the amounts of any deductible, coinsurance, or copayment comply with the requirements under section 1854(e).

(4) REQUIREMENT FOR MINIMUM MEDICAL LOSS RATIO.—If the Secretary determines for a contract year (beginning with 2014) that an MA plan has failed to have a medical loss ratio of at least .85—

(A) the MA plan shall remit to the Secretary an amount equal to the product of—

(i) the total revenue of the MA plan under this part for the contract year; and

(ii) the difference between .85 and the medical loss ratio;

(B) for 3 consecutive contract years, the Secretary shall not permit the enrollment of new enrollees under the plan for coverage during the second succeeding contract year; and

(C) the Secretary shall terminate the plan contract if the plan fails to have such a medical loss ratio for 5 consecutive contract years.

*(5) COMMUNICATING PLAN CORRECTIVE ACTIONS AGAINST OPIOIDS OVER-PRESCRIBERS.—*

*(A) IN GENERAL.—Beginning with plan years beginning on or after January 1, 2021, a contract under this section with an MA organization shall require the organization to submit to the Secretary, through the process established under subparagraph (B), information on the investigations and other actions taken by such plans related to providers of services who prescribe a high volume of opioids.*

*(B) PROCESS.—Not later than January 1, 2021, the Secretary shall, in consultation with stakeholders, establish a process under which MA plans and prescription drug plans shall submit to the Secretary information described in subparagraph (A).*

*(C) REGULATIONS.—For purposes of this paragraph, including as applied under section 1860D–12(b)(3)(D), the Secretary shall, pursuant to rulemaking—*

*(i) specify a definition for the term "high volume of opioids" and a method for determining if a provider of services prescribes such a high volume; and*

*(ii) establish the process described in subparagraph (B) and the types of information that shall be submitted through such process.*

(f) PROMPT PAYMENT BY MEDICARE+CHOICE ORGANIZATION.—

(1) REQUIREMENT.—A contract under this part shall require a Medicare+Choice organization to provide prompt payment (consistent with the provisions of sections 1816(c)(2) and 1842(c)(2)) of claims submitted for services and supplies furnished to enrollees pursuant to the contract, if the services or supplies are not furnished under a contract between the organization and the provider or supplier (or in the case of a Medicare+Choice private fee-for-service plan, if a claim is submitted to such organization by an enrollee).

(2) SECRETARY'S OPTION TO BYPASS NONCOMPLYING ORGANIZATION.—In the case of a Medicare+Choice eligible organization which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with paragraph (1), the Secretary may provide for direct payment of the amounts owed to providers and suppliers (or, in the case of a Medicare+Choice private fee-for-service plan, amounts owed to the enrollees) for covered services and supplies furnished to individuals enrolled under this part under the contract. If the Secretary provides for the direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this part to reflect the amount of the Secretary's payments (and the Secretary's costs in making the payments).

(3) INCORPORATION OF CERTAIN PRESCRIPTION DRUG PLAN CONTRACT REQUIREMENTS.—The following provisions shall apply to contracts with a Medicare Advantage organization offering an MA–PD plan in the same manner as they apply to contracts with a PDP sponsor offering a prescription drug plan under part D:

(A) PROMPT PAYMENT.—Section 1860D–12(b)(4).

(B) SUBMISSION OF CLAIMS BY PHARMACIES LOCATED IN OR CONTRACTING WITH LONG-TERM CARE FACILITIES.—Section 1860D–12(b)(5).

(C) REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD.—Section 1860D–12(b)(6).

*(D) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.—Section 1860D–12(b)(7).*

(g) INTERMEDIATE SANCTIONS.—

(1) IN GENERAL.—If the Secretary determines that a Medicare+Choice organization with a contract under this section—

(A) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(B) imposes premiums on individuals enrolled under this part in excess of the amount of the Medicare+Choice monthly basic and supplemental beneficiary premiums permitted under section 1854;

(C) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this part;

(D) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(E) misrepresents or falsifies information that is furnished—

(i) to the Secretary under this part, or

(ii) to an individual or to any other entity under this part;

(F) fails to comply with the applicable requirements of section 1852(j)(3) or 1852(k)(2)(A)(ii);

(G) employs or contracts with any individual or entity that is excluded from participation under this title under section 1128 or 1128A for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services;

(H) except as provided under subparagraph (C) or (D) of section 1860D–1(b)(1), enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual;

(I) transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission;

(J) fails to comply with marketing restrictions described in subsections (h) and (j) of section 1851 or applicable implementing regulations or guidance; or

(K) employs or contracts with any individual or entity who engages in the conduct described in subparagraphs (A) through (J) of this paragraph;

the Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2). The Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2), if the Secretary determines that any employee or agent of such organization, or any provider or supplier who contracts with such organization, has engaged in any conduct described in subparagraphs (A) through (K) of this paragraph.

(2) REMEDIES.—The remedies described in this paragraph are—

(A) civil money penalties of not more than $25,000 for each determination under paragraph (1) or, with respect to a determination under subparagraph (D) or (E)(i) of such paragraph, of not more than $100,000 for each such determination, except with respect to a determination under subparagraph (E), an assessment of not more than the amount claimed by such plan or plan sponsor based upon the misrepresentation or falsified information involved, plus, with respect to a determination under paragraph (1)(B), double the excess amount charged in violation of such paragraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under paragraph (1)(D), $15,000 for each individual not enrolled as a result of the practice involved,

(B) suspension of enrollment of individuals under this part after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur, or

(C) suspension of payment to the organization under this part for individuals enrolled after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

(3) OTHER INTERMEDIATE SANCTIONS.—In the case of a Medicare+Choice organization for which the Secretary makes a determination under subsection (c)(2) the basis of which is not described in paragraph (1), the Secretary may apply the following intermediate sanctions:

(A) Civil money penalties of not more than $25,000 for each determination under subsection (c)(2) if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

(B) Civil money penalties of not more than $10,000 for each week beginning after the initiation of civil money penalty procedures by the Secretary during which the deficiency that is the basis of a determination under subsection (c)(2) exists.

(C) Suspension of enrollment of individuals under this part after the date the Secretary notifies the organization of a determination under subsection (c)(2) and until the Secretary is satisfied that the deficiency that is the basis for the determination has been corrected and is not likely to recur.

(D) Civil monetary penalties of not more than $100,000, or such higher amount as the Secretary may establish by regulation, where the finding under subsection (c)(2)(A) is based on the organization's termination of its contract under this section other than at a time and in a manner provided for under subsection (a).

(4) CIVIL MONEY PENALTIES.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under paragraph (2) or (3) in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).

(h) PROCEDURES FOR TERMINATION.—

(1) IN GENERAL.—The Secretary may terminate a contract with a Medicare+Choice organization under this section in accordance with formal investigation and compliance procedures established by the Secretary under which—

(A) the Secretary provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under subsection (c)(2); and

(B) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before terminating the contract.

(2) EXCEPTION FOR IMMINENT AND SERIOUS RISK TO HEALTH.—Paragraph (1) shall not apply if the Secretary determines that a delay in termination, resulting from compliance with the procedures specified in such paragraph prior to termination, would pose an imminent and serious risk to the health of individuals enrolled under this part with the organization.

(3) DELAY IN CONTRACT TERMINATION AUTHORITY FOR PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATING.—During the period beginning on the date of the enactment of this paragraph and through the end of plan year 2018, the Secretary may not terminate a contract under this section with respect to the offering of an MA plan by a Medicare Advantage organization solely because the MA plan has failed to achieve a minimum quality rating under the 5-star rating system under section 1853(o)(4).

(i) MEDICARE+CHOICE PROGRAM COMPATIBILITY WITH EMPLOYER OR UNION GROUP HEALTH PLANS.—

(1) CONTRACTS WITH MA ORGANIZATIONS.—To facilitate the offering of Medicare+Choice plans under contracts between Medicare+Choice organizations and employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such Medicare+Choice plans.

(2) EMPLOYER SPONSORED MA PLANS.—To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such MA plans. Notwithstanding section 1851(g), an MA plan described in the previous sentence may restrict the enrollment of individuals under this part to individuals who are beneficiaries and participants in such plan.

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DEFINITIONS; MISCELLANEOUS PROVISIONS

SEC. 1859. (a) DEFINITIONS RELATING TO MEDICARE+CHOICE ORGANIZATIONS.—In this part—

(1) MEDICARE+CHOICE ORGANIZATION.—The term "Medicare+Choice organization" means a public or private entity that is certified under section 1856 as meeting the requirements and standards of this part for such an organization.

(2) PROVIDER-SPONSORED ORGANIZATION.—The term "provider-sponsored organization" is defined in section 1855(d)(1).

(b) DEFINITIONS RELATING TO MEDICARE+CHOICE PLANS.—

(1) MEDICARE+CHOICE PLAN.—The term "Medicare+Choice plan" means health benefits coverage offered under a policy, contract, or plan by a Medicare+Choice organization pursuant to and in accordance with a contract under section 1857.

(2) MEDICARE+CHOICE PRIVATE FEE-FOR-SERVICE PLAN.—The term "Medicare+Choice private fee-for-service plan" means a Medicare+Choice plan that—

(A) reimburses hospitals, physicians, and other providers at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

(B) does not vary such rates for such a provider based on utilization relating to such provider; and

(C) does not restrict the selection of providers among those who are lawfully authorized to provide the covered services and agree to accept the terms and conditions of payment established by the plan.

Nothing in subparagraph (B) shall be construed to preclude a plan from varying rates for such a provider based on the specialty of the provider, the location of the provider, or other factors related to such provider that are not related to utilization, or to preclude a plan from increasing rates for such a provider based on increased utilization of specified preventive or screening services.

(3) MSA PLAN.—

(A) IN GENERAL.—The term "MSA plan" means a Medicare+Choice plan that—

(i) provides reimbursement for at least the items and services described in section 1852(a)(1) in a year but only after the enrollee incurs countable expenses (as specified under the plan) equal to the amount of an annual deductible (described in subparagraph (B));

(ii) counts as such expenses (for purposes of such deductible) at least all amounts that would have been payable under parts A and B, and that would have been payable by the enrollee as deductibles, coinsurance, or copayments, if the enrollee had elected to receive benefits through the provisions of such parts; and

(iii) provides, after such deductible is met for a year and for all subsequent expenses for items and services referred to in clause (i) in the year, for a level of reimbursement that is not less than—

(I) 100 percent of such expenses, or

(II) 100 percent of the amounts that would have been paid (without regard to any deductibles or coinsurance) under parts A and B with respect to such expenses,

whichever is less.

(B) DEDUCTIBLE.—The amount of annual deductible under an MSA plan—

(i) for contract year 1999 shall be not more than $6,000; and

(ii) for a subsequent contract year shall be not more than the maximum amount of such deductible for the previous contract year under this subparagraph increased by the national per capita Medicare+Choice growth percentage under section 1853(c)(6) for the year.

If the amount of the deductible under clause (ii) is not a multiple of $50, the amount shall be rounded to the nearest multiple of $50.

(4) MA REGIONAL PLAN.—The term "MA regional plan" means an MA plan described in section 1851(a)(2)(A)(i)—

(A) that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(B) that provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and

(C) the service area of which is one or more entire MA regions.

(5) MA LOCAL PLAN.—The term "MA local plan" means an MA plan that is not an MA regional plan.

(6) SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—

(A) IN GENERAL.—The term "specialized MA plan for special needs individuals" means an MA plan that exclusively serves special needs individuals (as defined in subparagraph

(B)) and that, as of January 1, 2010, meets the applicable requirements of paragraph (2), (3), or (4) of subsection (f), as the case may be.

(B) SPECIAL NEEDS INDIVIDUAL.—The term "special needs individual" means an MA eligible individual who—

(i) is institutionalized (as defined by the Secretary);

(ii) is entitled to medical assistance under a State plan under title XIX; or

(iii) meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized MA plan described in subparagraph (A) for individuals with severe or disabling chronic conditions who—

(I) before January 1, 2022, have one or more comorbid and medically complex chronic conditions that are substantially disabling or life threatening, have a high risk of hospitalization or other significant adverse health outcomes, and require specialized delivery systems across domains of care; and

(II) on or after January 1, 2022, have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits overall health or function, have a high risk of hospitalization or other adverse health outcomes, and require intensive care coordination and that is listed under subsection (f)(9)(A).

The Secretary may apply rules similar to the rules of section 1894(c)(4) for continued eligibility of special needs individuals.

(c) OTHER REFERENCES TO OTHER TERMS.—

(1) MEDICARE+CHOICE ELIGIBLE INDIVIDUAL.—The term "Medicare+Choice eligible individual" is defined in section 1851(a)(3).

(2) MEDICARE+CHOICE PAYMENT AREA.—The term "Medicare+Choice payment area" is defined in section 1853(d).

(3) NATIONAL PER CAPITA MEDICARE+CHOICE GROWTH PERCENTAGE.—The "national per capita Medicare+Choice growth percentage" is defined in section 1853(c)(6).

(4) MEDICARE+CHOICE MONTHLY BASIC BENEFICIARY PREMIUM; MEDICARE+CHOICE MONTHLY SUPPLEMENTAL BENEFICIARY PREMIUM.—The terms "Medicare+Choice monthly basic beneficiary premium" and "Medicare+Choice monthly supplemental beneficiary premium" are defined in section 1854(a)(2).

(5) MA LOCAL AREA.—The term "MA local area" is defined in section 1853(d)(2).

(d) COORDINATED ACUTE AND LONG-TERM CARE BENEFITS UNDER A MEDICARE+CHOICE PLAN.—Nothing in this part shall be construed as preventing a State from coordinating benefits under a medicaid plan under title XIX with those provided under a Medicare+Choice plan in a manner that assures continuity of a full-range of acute care and long-term care services to poor elderly or disabled individuals eligible for benefits under this title and under such plan.

(e) RESTRICTION ON ENROLLMENT FOR CERTAIN MEDICARE+CHOICE PLANS.—

(1) IN GENERAL.—In the case of a Medicare+Choice religious fraternal benefit society plan described in paragraph (2), notwithstanding any other provision of this part to the contrary and in accordance with regulations of the Secretary, the society offering the plan may restrict the enrollment of individuals under this part to individuals who are members of the church, convention, or group described in paragraph (3)(B) with which the society is affiliated.

(2) MEDICARE+CHOICE RELIGIOUS FRATERNAL BENEFIT SOCIETY PLAN DESCRIBED.—For purposes of this subsection, a Medicare+Choice religious fraternal benefit society plan described in this paragraph is a Medicare+Choice plan described in section 1851(a)(2) that—

(A) is offered by a religious fraternal benefit society described in paragraph (3) only to members of the church, convention, or group described in paragraph (3)(B); and

(B) permits all such members to enroll under the plan without regard to health status-related factors.

Nothing in this subsection shall be construed as waiving any plan requirements relating to financial solvency.

(3) RELIGIOUS FRATERNAL BENEFIT SOCIETY DEFINED.—For purposes of paragraph (2)(A), a "religious fraternal benefit society" described in this section is an organization that—

(A) is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of such Act;

(B) is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches;

(C) offers, in addition to a Medicare+Choice religious fraternal benefit society plan, health coverage to individuals not entitled to benefits under this title who are members of such church, convention, or group; and

(D) does not impose any limitation on membership in the society based on any health status-related factor.

(4) PAYMENT ADJUSTMENT.—Under regulations of the Secretary, in the case of individuals enrolled under this part under a Medicare+Choice religious fraternal benefit society plan described in paragraph (2), the Secretary shall provide for such adjustment to the payment amounts otherwise established under section 1854 as may be appropriate to assure an appropriate payment level, taking into account the actuarial characteristics and experience of such individuals.

(f) REQUIREMENTS REGARDING ENROLLMENT IN SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—

(1) REQUIREMENTS FOR ENROLLMENT.—In the case of a specialized MA plan for special needs individuals (as defined in subsection (b)(6)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs individuals.

(2) ADDITIONAL REQUIREMENTS FOR INSTITUTIONAL SNPS.—In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(i), the applicable requirements described in this paragraph are as follows:

(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individuals described in subsection (b)(6)(B)(i). In the case of an individual who is living in the community but requires an institutional level of care, such individual shall not be considered a special needs individual described in subsection (b)(6)(B)(i) unless the determination that the individual requires an institutional level of care was made—

(i) using a State assessment tool of the State in which the individual resides; and

(ii) by an entity other than the organization offering the plan.

(B) The plan meets the requirements described in paragraph (5).

(C) If applicable, the plan meets the requirement described in paragraph (7).

(3) ADDITIONAL REQUIREMENTS FOR DUAL SNPS.—In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii), the applicable requirements described in this paragraph are as follows:

(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individuals described in subsection (b)(6)(B)(ii).

(B) The plan meets the requirements described in paragraph (5).

(C) The plan provides each prospective enrollee, prior to enrollment, with a comprehensive written statement (using standardized content and format established by the Secretary) that describes—

(i) the benefits and cost-sharing protections that the individual is entitled to under the State Medicaid program under title XIX; and

(ii) which of such benefits and cost-sharing protections are covered under the plan. Such statement shall be included with any description of benefits offered by the plan.

(D) The plan has a contract with the State Medicaid agency to provide benefits, or arrange for benefits to be provided, for which such individual is entitled to receive as medical assistance under title XIX. Such benefits may include long-term care services consistent with State policy.

(E) If applicable, the plan meets the requirement described in paragraph (7).

(F) The plan meets the requirements applicable under paragraph (8).

(4) ADDITIONAL REQUIREMENTS FOR SEVERE OR DISABLING CHRONIC CONDITION SNPS.—In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(iii), the applicable requirements described in this paragraph are as follows:

(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individual described in subsection (b)(6)(B)(iii).

(B) The plan meets the requirements described in paragraph (5).

(C) If applicable, the plan meets the requirement described in paragraph (7).

(5) CARE MANAGEMENT REQUIREMENTS FOR ALL SNPS.—

(A) IN GENERAL.—Subject to subparagraph (B), the requirements described in this paragraph are that the organization offering a specialized MA plan for special needs individuals—

(i) have in place an evidenced-based model of care with appropriate networks of providers and specialists; and

(ii) with respect to each individual enrolled in the plan—

(I) conduct an initial assessment and an annual reassessment of the individual's physical, psychosocial, and functional needs;

(II) develop a plan, in consultation with the individual as feasible, that identifies goals and objectives, including measurable outcomes as well as specific services and benefits to be provided; and

(III) use an interdisciplinary team in the management of care.

(B) IMPROVEMENTS TO CARE MANAGEMENT REQUIREMENTS FOR SEVERE OR DISABLING CHRONIC CONDITION SNPS.—For 2020 and subsequent years, in the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(iii), the requirements described in this paragraph include the following:

(i) The interdisciplinary team under subparagraph (A)(ii)(III) includes a team of providers with demonstrated expertise, including training in an applicable specialty, in treating individuals similar to the targeted population of the plan.

(ii) Requirements developed by the Secretary to provide face-to-face encounters with individuals enrolled in the plan not less frequently than on an annual basis.

(III) As part of the model of care under clause (i) of subparagraph (A), the results of the initial assessment and annual reassessment under clause (ii)(I) of such subparagraph of each individual enrolled in the plan are addressed in the individual's individualized care plan under clause (ii)(II) of such subparagraph.

(iv) As part of the annual evaluation and approval of such model of care, the Secretary shall take into account whether the plan fulfilled the previous year's goals (as required under the model of care).

(v) The Secretary shall establish a minimum benchmark for each element of the model of care of a plan. The Secretary shall only approve a plan's model of care under this paragraph if each element of the model of care meets the minimum benchmark applicable under the preceding sentence.

(6) TRANSITION AND EXCEPTION REGARDING RESTRICTION ON ENROLLMENT.—

(A) IN GENERAL.—Subject to subparagraph (C), the Secretary shall establish procedures for the transition of applicable individuals to—

(i) a Medicare Advantage plan that is not a specialized MA plan for special needs individuals (as defined in subsection (b)(6)); or

(ii) the original medicare fee-for-service program under parts A and B.

(B) APPLICABLE INDIVIDUALS.—For purposes of clause (i), the term "applicable individual" means an individual who—

(i) is enrolled under a specialized MA plan for special needs individuals (as defined in subsection (b)(6)); and

(ii) is not within the 1 or more of the classes of special needs individuals to which enrollment under the plan is restricted to.

(C) EXCEPTION.—The Secretary shall provide for an exception to the transition described in subparagraph (A) for a limited period of time for individuals enrolled under a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii) who are no longer eligible for medical assistance under title XIX.

(D) TIMELINE FOR INITIAL TRANSITION.—The Secretary shall ensure that applicable individuals enrolled in a specialized MA plan for special needs individuals (as defined in subsection (b)(6)) prior to January 1, 2010, are transitioned to a plan or the program described in subparagraph (A) by not later than January 1, 2013.

(7) AUTHORITY TO REQUIRE SPECIAL NEEDS PLANS BE NCQA APPROVED.—For 2012 and subsequent years, the Secretary shall require that a Medicare Advantage organization offering a specialized MA plan for special needs individuals be approved by the National Committee for Quality Assurance (based on standards established by the Secretary).

(8) INCREASED INTEGRATION OF DUAL SNPS.—

(A) DESIGNATED CONTACT.—The Secretary, acting through the Federal Coordinated Health Care Office established under section 2602 of Public Law 111–148, shall serve as

a dedicated point of contact for States to address misalignments that arise with the integration of specialized MA plans for special needs individuals described in subsection (b)(6)(B)(ii) under this paragraph and, consistent with such role, shall establish—

(i) a uniform process for disseminating to State Medicaid agencies information under this title impacting contracts between such agencies and such plans under this subsection; and

(ii) basic resources for States interested in exploring such plans as a platform for integration, such as a model contract or other tools to achieve those goals.

(B) UNIFIED GRIEVANCES AND APPEALS PROCESS.—

(i) IN GENERAL.—Not later than April 1, 2020, the Secretary shall establish procedures, to the extent feasible as determined by the Secretary, unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) for items and services provided by specialized MA plans for special needs individuals described in subsection (b)(6)(B)(ii) under this title and title XIX. With respect to items and services described in the preceding sentence, procedures established under this clause shall apply in place of otherwise applicable grievances and appeals procedures. The Secretary shall solicit comment in developing such procedures from States, plans, beneficiaries and their representatives, and other relevant stakeholders.

(ii) PROCEDURES.—The procedures established under clause (i) shall be included in the plan contract under paragraph (3)(D) and shall—

(I) adopt the provisions for the enrollee that are most protective for the enrollee and, to the extent feasible as determined by the Secretary, are compatible with unified timeframes and consolidated access to external review under an integrated process;

(II) take into account differences in State plans under title XIX to the extent necessary;

(III) be easily navigable by an enrollee; and

(IV) include the elements described in clause (iii), as applicable.

(iii) ELEMENTS DESCRIBED.—Both unified appeals and unified grievance procedures shall include, as applicable, the following elements described in this clause:

(I) Single written notification of all applicable grievances and appeal rights under this title and title XIX. For purposes of this subparagraph, the Secretary may waive the requirements under section 1852(g)(1)(B) when the specialized MA plan covers items or services under this part or under title XIX.

(II) Single pathways for resolution of any grievance or appeal related to a particular item or service provided by specialized MA plans for special needs individuals described in subsection (b)(6)(B)(ii) under this title and title XIX.

(III) Notices written in plain language and available in a language and format that is accessible to the enrollee, including in non-English languages that are prevalent in the service area of the specialized MA plan.

(IV) Unified timeframes for grievances and appeals processes, such as an individual's filing of a grievance or appeal, a plan's acknowledgment and resolution of a grievance or appeal, and notification of decisions with respect to a grievance or appeal.

(V) Requirements for how the plan must process, track, and resolve grievances and appeals, to ensure beneficiaries are notified on a timely basis of decisions that are made throughout the grievance or appeals process and are able to easily determine the status of a grievance or appeal.

(iv) CONTINUATION OF BENEFITS PENDING APPEAL.—The unified procedures under clause (i) shall, with respect to all benefits under parts A and B and title XIX subject to appeal under such procedures, incorporate provisions under current law and implementing regulations that provide continuation of benefits pending appeal under this title and title XIX.

(C) REQUIREMENT FOR UNIFIED GRIEVANCES AND APPEALS.—For 2021 and subsequent years, the contract of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii) with a State Medicaid agency under paragraph (3)(D) shall require the use of unified grievances and appeals procedures as described in subparagraph (B).

(D) REQUIREMENTS FOR INTEGRATION.—

(i) IN GENERAL.—For 2021 and subsequent years, a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii) shall meet one or more of the following requirements, to the extent permitted under State law, for integration of benefits under this title and title XIX:

(I) The specialized MA plan must meet the requirements of contracting with the State Medicaid agency described in paragraph (3)(D) in addition to coordinating long-term services and supports or behavioral health services, or both, by meeting an additional minimum set of requirements determined by the Secretary through the Federal Coordinated Health Care Office established under section 2602 of the Patient Protection and Affordable Care Act based on input from stakeholders, such as notifying the State in a timely manner of hospitalizations, emergency room visits, and hospital or nursing home discharges of enrollees, assigning one primary care provider for each enrollee, or sharing data that would benefit the coordination of items and services under this title and the State plan under title XIX. Such minimum set of requirements must be included in the contract of the specialized MA plan with the State Medicaid agency under such paragraph.

(II) The specialized MA plan must meet the requirements of a fully integrated plan described in section 1853(a)(1)(B)(iv)(II) (other than the requirement that the plan have similar average levels of frailty, as determined by the Secretary, as the PACE program), or enter into a capitated contract with the State Medicaid agency to provide long-term services and supports or behavioral health services, or both.

(III) In the case of a specialized MA plan that is offered by a parent organization that is also the parent organization of a Medicaid managed care organization providing long term services and supports or behavioral services under a contract under section 1903(m), the parent organization must assume clinical and financial responsibility for benefits provided under this title and title XIX with respect to any individual who is enrolled in both the specialized MA plan and the Medicaid managed care organization.

(ii) SUSPENSION OF ENROLLMENT FOR FAILURE TO MEET REQUIREMENTS DURING INITIAL PERIOD.—During the period of plan years 2021 through 2025, if the Secretary determines that a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii) has failed to comply with clause (i), the Secretary may provide for the application against the Medicare Advantage organization offering the plan of the remedy described in section 1857(g)(2)(B) in the same manner as the Secretary may apply such remedy, and in accordance with the same procedures as would apply, in the case of an MA organization determined by the Secretary to have engaged in conduct described in section 1857(g)(1). If the Secretary applies such remedy to a Medicare Advantage organization under the preceding sentence, the organization shall submit to the Secretary (at a time, and in a form and manner, specified by the Secretary) information describing how the plan will come into compliance with clause (i).

(E) STUDY AND REPORT TO CONGRESS.—

(i) IN GENERAL.—Not later than March 15, 2022, and, subject to clause (iii), biennially thereafter through 2032, the Medicare Payment Advisory Commission established under section 1805, in consultation with the Medicaid and CHIP Payment and Access Commission established under section 1900, shall conduct (and submit to the Secretary and the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on) a study to determine how specialized MA plans for special needs individuals described in subsection (b)(6)(B)(ii) perform among each other based on data from Healthcare Effectiveness Data and Information Set (HEDIS) quality measures, reported on the plan level, as required under section 1852(e)(3) (or such other measures or data sources that are available and appropriate, such as encounter data and Consumer Assessment of Healthcare Providers and Systems data, as specified by such Commissions as enabling an accurate evaluation under this subparagraph). Such study shall include, as feasible, the following comparison groups of specialized MA plans for special needs individuals described in subsection (b)(6)(B)(ii):

(I) A comparison group of such plans that are described in subparagraph (D)(i)(I).

(II) A comparison group of such plans that are described in subparagraph (D)(i)(II).

(III) A comparison group of such plans operating within the Financial Alignment Initiative demonstration for the period for which such plan is so operating and the demonstration is in effect, and, in the case that an integration option that is not with respect to specialized MA plans for special needs individuals is established after the conclusion of the demonstration involved.

(IV) A comparison group of such plans that are described in subparagraph (D)(i)(III).

(V) A comparison group of MA plans, as feasible, not described in a previous subclause of this clause, with respect to the performance of such plans for enrollees who are special needs individuals described in subsection (b)(6)(B)(ii).

(ii) ADDITIONAL REPORTS.—Beginning with 2033 and every five years thereafter, the Medicare Payment Advisory Commission, in consultation with the Medicaid and CHIP Payment and Access Commission, shall conduct a study described in clause (i).

(9) LIST OF CONDITIONS FOR CLARIFICATION OF THE DEFINITION OF A SEVERE OR DISABLING CHRONIC CONDITIONS SPECIALIZED NEEDS INDIVIDUAL.—

(A) IN GENERAL.—Not later than December 31, 2020, and every 5 years thereafter, subject to subparagraphs (B) and (C), the Secretary shall convene a panel of clinical advisors to establish and update a list of conditions that meet each of the following criteria:

(i) Conditions that meet the definition of a severe or disabling chronic condition under subsection (b)(6)(B)(iii) on or after January 1, 2022.

(ii) Conditions that require prescription drugs, providers, and models of care that are unique to the specific population of enrollees in a specialized MA plan for special needs individuals described in such subsection on or after such date and—

(I) as a result of access to, and enrollment in, such a specialized MA plan for special needs individuals, individuals with such condition would have a reasonable expectation of slowing or halting the progression of the disease, improving health outcomes and decreasing overall costs for individuals diagnosed with such condition compared to available options of care other than through such a specialized MA plan for special needs individuals; or

(II) have a low prevalence in the general population of beneficiaries under this title or a disproportionally high per-beneficiary cost under this title.

(B) INCLUSION OF CERTAIN CONDITIONS.—The conditions listed under subparagraph (A) shall include HIV/AIDS, end stage renal disease, and chronic and disabling mental illness.

(C) REQUIREMENT.—In establishing and updating the list under subparagraph (A), the panel shall take into account the availability of varied benefits, cost-sharing, and supplemental benefits under the model described in paragraph (2) of section 1859(h), including the expansion under paragraph (1) of such section.

(g) SPECIAL RULES FOR SENIOR HOUSING FACILITY PLANS.—

(1) IN GENERAL.—In the case of a Medicare Advantage senior housing facility plan described in paragraph (2), notwithstanding any other provision of this part to the contrary and in accordance with regulations of the Secretary, the service area of such plan may be limited to a senior housing facility in a geographic area.

(2) MEDICARE ADVANTAGE SENIOR HOUSING FACILITY PLAN DESCRIBED.—For purposes of this subsection, a Medicare Advantage senior housing facility plan is a Medicare Advantage plan that—

(A) restricts enrollment of individuals under this part to individuals who reside in a continuing care retirement community (as defined in section 1852(l)(4)(B));

(B) provides primary care services onsite and has a ratio of accessible physicians to beneficiaries that the Secretary determines is adequate;

(C) provides transportation services for beneficiaries to specialty providers outside of the facility; and

(D) has participated (as of December 31, 2009) in a demonstration project established by the Secretary under which such a plan was offered for not less than 1 year.

(h) NATIONAL TESTING OF MEDICARE ADVANTAGE VALUE-BASED INSURANCE DESIGN MODEL.—

(1) IN GENERAL.—In implementing the Medicare Advantage Value-Based Insurance Design model that is being tested under section 1115A(b), the Secretary shall revise the testing of the model under such section to cover, effective not later than January 1, 2020, all States.

(2) TERMINATION AND MODIFICATION PROVISION NOT APPLICABLE UNTIL JANUARY 1, 2022.—The provisions of section 1115A(b)(3)(B) shall apply to the Medicare Advantage Value-Based Insurance Design model, including such model as revised under paragraph (1), beginning January 1, 2022, but shall not apply to such model, as so revised, prior to such date.

(3) FUNDING.—The Secretary shall allocate funds made available under section 1115A(f)(1) to design, implement, and evaluate the Medicare Advantage Value-Based Insurance Design model, as revised under paragraph (1).

*(i) PROGRAM INTEGRITY TRANSPARENCY MEASURES.—*

*(1) PROGRAM INTEGRITY PORTAL.—*

*(A) IN GENERAL.—Not later than two years after the date of the enactment of this subsection, the Secretary shall, after consultation with stakeholders, establish a secure Internet website portal (or other successor technology) that would allow a secure path for communication between the Secretary, MA plans under this part, prescription drug plans under part D, and an eligible entity with a contract under section 1893 (such as a Medicare drug integrity contractor or an entity responsible for carrying out program integrity activities under this part and part D) for the purpose of enabling through such portal (or other successor technology)—*

*(i) the referral by such plans of substantiated fraud, waste, and abuse for initiating or assisting investigations conducted by the eligible entity; and*

*(ii) data sharing among such MA plans, prescription drug plans, and the Secretary.*

*(B) REQUIRED USES OF PORTAL.—The Secretary shall disseminate the following information to MA plans under this part and prescription drug plans under part D through the secure Internet website portal (or other successor technology) established under subparagraph (A):*

*(i) Providers of services and suppliers that have been referred pursuant to subparagraph (A)(i) during the previous 12-month period.*

*(ii) Providers of services and suppliers who are the subject of an active exclusion under section 1128 or who are subject to a suspension of payment under this title pursuant to section 1862(o) or otherwise.*

*(iii) Providers of services and suppliers who are the subject of an active revocation of participation under this title, including for not satisfying conditions of participation.*

*(iv) In the case of such a plan that makes a referral under subparagraph (A)(i) through the portal (or other successor technology) with respect to activities of substantiated fraud, waste, or abuse of a provider of services or supplier, if such provider or supplier has been the subject of an administrative action under this title or title XI with respect to similar activities, a notification to such plan of such action so taken.*

*(C) RULEMAKING.—For purposes of this paragraph, the Secretary shall, through rulemaking, specify what constitutes substantiated fraud, waste, and abuse, using guidance such as what is provided in the Medicare Program Integrity Manual 4.7.1. In carrying out this subsection, a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for substantiated fraud, waste, or abuse*

*(D) HIPAA COMPLIANT INFORMATION ONLY.—For purposes of this subsection, communications may only occur if the communications are permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.*

*(2) QUARTERLY REPORTS.—Beginning two years after the date of enactment of this subsection, the Secretary shall make available to MA plans under this part and prescription drug plans under part D in a timely manner (but no less frequently than quarterly) and using information submitted to an entity described in paragraph (1) through the portal (or other successor technology) described in such paragraph or pursuant to section 1893, information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. Information included in each such report shall—*

*(A) include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders; and*

*(B) be anonymized information submitted by plans without identifying the source of such information.*

*(3) CLARIFICATION.—Nothing in this subsection shall be construed as precluding or otherwise affecting referrals described in subparagraph (A) that may otherwise be made to law enforcement entities or to the Secretary.*

PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

Subpart 1—Part D Eligible Individuals and Prescription Drug Benefits

* * * * * * *

BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

SEC. 1860D–4. (a) DISSEMINATION OF INFORMATION.—

(1) GENERAL INFORMATION.—

(A) APPLICATION OF MA INFORMATION.—A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan, insofar as the Secretary determines appropriate with respect to benefits provided under this part, and*, subject to subparagraph (C),* including the information described in subparagraph (B).

(B) DRUG SPECIFIC INFORMATION.—The information described in this subparagraph is information concerning the following:

(i) Access to specific covered part D drugs, including access through pharmacy networks.

(ii) How any formulary (including any tiered formulary structure) used by the sponsor functions, including a description of how a part D eligible individual may obtain information on the formulary consistent with paragraph (3).

(iii) Beneficiary cost-sharing requirements and how a part D eligible individual may obtain information on such requirements, including tiered or other copayment level applicable to each drug (or class of drugs), consistent with paragraph (3).

(iv) The medication therapy management program required under subsection (c).

(v) The drug management program for at-risk beneficiaries under subsection (c)(5).

*(vi) For plan year 2021 and each subsequent plan year, subject to subparagraph (C), with respect to the treatment of pain—*

*(I) the risks associated with prolonged opioid use; and*

*(II) coverage of nonpharmacological therapies, devices, and nonopioid medications—*

*(aa) in the case of an MA-PD plan under part C, under such plan; and*

*(bb) in the case of a prescription drug plan, under such plan and under parts A and B.*

*(C) TARGETED PROVISION OF INFORMATION.—A PDP sponsor of a prescription drug plan may, in lieu of disclosing the information described in subparagraph (B)(vi) to each enrollee under the plan, disclose such information through mail or electronic communications to a subset of enrollees under the plan, such as enrollees who have been prescribed an opioid in the previous two-year period.*

(2) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of a part D eligible individual who is eligible to enroll in a prescription drug plan, the PDP sponsor offering such plan shall provide information similar (as determined by the Secretary) to the information described in subparagraphs (A), (B), and (C) of section 1852(c)(2) to such individual.

(3) PROVISION OF SPECIFIC INFORMATION.—

(A) RESPONSE TO BENEFICIARY QUESTIONS.—Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information on a timely basis to enrollees upon request. Such mechanism shall include access to information through the use of a toll-free telephone number and, upon request, the provision of such information in writing.

(B) AVAILABILITY OF INFORMATION ON CHANGES IN FORMULARY THROUGH THE INTERNET.—A PDP sponsor offering a prescription drug plan shall make available on a timely

basis through an Internet website information on specific changes in the formulary under the plan (including changes to tiered or preferred status of covered part D drugs).

(4) CLAIMS INFORMATION.—A PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees—

(A) an explanation of benefits (in accordance with section 1806(a) or in a comparable manner); and

(B) when prescription drug benefits are provided under this part, a notice of the benefits in relation to—

(i) the initial coverage limit for the current year; and

(ii) the annual out-of-pocket threshold for the current year.

Notices under subparagraph (B) need not be provided more often than as specified by the Secretary and notices under subparagraph (B)(ii) shall take into account the application of section 1860D–2(b)(4)(C) to the extent practicable, as specified by the Secretary.

(b) ACCESS TO COVERED PART D DRUGS.—

(1) ASSURING PHARMACY ACCESS.—

(A) PARTICIPATION OF ANY WILLING PHARMACY.—A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.

(B) DISCOUNTS ALLOWED FOR NETWORK PHARMACIES.—For covered part D drugs dispensed through in-network pharmacies, a prescription drug plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required. In no case shall such a reduction result in an increase in payments made by the Secretary under section 1860D–15 to a plan.

(C) CONVENIENT ACCESS FOR NETWORK PHARMACIES.—

(i) IN GENERAL.—The PDP sponsor of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary).

(ii) APPLICATION OF TRICARE STANDARDS.—The Secretary shall establish rules for convenient access to in-network pharmacies under this subparagraph that are no less favorable to enrollees than the rules for convenient access to pharmacies included in the statement of work of solicitation (#MDA906–03–R–0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

(iii) ADEQUATE EMERGENCY ACCESS.—Such rules shall include adequate emergency access for enrollees.

(iv) CONVENIENT ACCESS IN LONG-TERM CARE FACILITIES.—Such rules may include standards with respect to access for enrollees who are residing in long-term care facilities and for pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 4 of the Indian Health Care Improvement Act).

(D) LEVEL PLAYING FIELD.—Such a sponsor shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail order pharmacy), with any differential in charge paid by such enrollees.

(E) NOT REQUIRED TO ACCEPT INSURANCE RISK.—The terms and conditions under subparagraph (A) may not require participating pharmacies to accept insurance risk as a condition of participation.

(2) USE OF STANDARDIZED TECHNOLOGY.—

(A) IN GENERAL.—The PDP sponsor of a prescription drug plan shall issue (and reissue, as appropriate) such a card (or other technology) that may be used by an enrollee to assure access to negotiated prices under section 1860D–2(d).

(B) STANDARDS.—

(i) IN GENERAL.—The Secretary shall provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology required under subparagraph (A). Such standards shall be compatible with part C of title XI and may be based on standards developed by an appropriate standard setting organization.

(ii) CONSULTATION.—In developing the standards under clause (i), the Secretary shall consult with the National Council for Prescription Drug Programs and other standard setting organizations determined appropriate by the Secretary.

(iii) IMPLEMENTATION.—The Secretary shall develop, adopt, or recognize the standards under clause (i) by such date as the Secretary determines shall be sufficient to ensure that PDP sponsors utilize such standards beginning January 1, 2006.

(3) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—If a PDP sponsor of a prescription drug plan uses a formulary (including the use of tiered cost-sharing), the following requirements must be met:

(A) DEVELOPMENT AND REVISION BY A PHARMACY AND THERAPEUTIC (P&T) COMMITTEE.—

(i) IN GENERAL.—The formulary must be developed and reviewed by a pharmacy and therapeutic committee. A majority of the members of such committee shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

(ii) INCLUSION OF INDEPENDENT EXPERTS.—Such committee shall include at least one practicing physician and at least one practicing pharmacist, each of whom—

(I) is independent and free of conflict with respect to the sponsor and plan; and

(II) has expertise in the care of elderly or disabled persons.

(B) FORMULARY DEVELOPMENT.—In developing and reviewing the formulary, the committee shall—

(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate; and

(ii) take into account whether including in the formulary (or in a tier in such formulary) particular covered part D drugs has therapeutic advantages in terms of safety and efficacy.

(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES AND CLASSES.—

(i) IN GENERAL.—Subject to subparagraph (G), the formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.

(ii) MODEL GUIDELINES.—The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.

(iii) LIMITATION ON CHANGES IN THERAPEUTIC CLASSIFICATION.—The PDP sponsor of a prescription drug plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as the Secretary may permit to take into account new therapeutic uses and newly approved covered part D drugs.

(D) PROVIDER AND PATIENT EDUCATION.—The PDP sponsor shall establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

(E) NOTICE BEFORE REMOVING DRUG FROM FORMULARY OR CHANGING PREFERRED OR TIER STATUS OF DRUG.—Any removal of a covered part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3)) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists.

(F) PERIODIC EVALUATION OF PROTOCOLS.—In connection with the formulary, the sponsor of a prescription drug plan shall provide for the periodic evaluation and analysis of treatment protocols and procedures.

(G) REQUIRED INCLUSION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

(i) FORMULARY REQUIREMENTS.—

(I) IN GENERAL.—Subject to subclause (II), a PDP sponsor offering a prescription drug plan shall be required to include all covered part D drugs in the categories and classes identified by the Secretary under clause (ii)(I).

(II) EXCEPTIONS.—The Secretary may establish exceptions that permit a PDP sponsor offering a prescription drug plan to exclude from its formulary a particular covered part D drug in a category or class that is otherwise required to

be included in the formulary under subclause (I) (or to otherwise limit access to such a drug, including through prior authorization or utilization management).

(ii) IDENTIFICATION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

(I) IN GENERAL.—Subject to clause (iv), the Secretary shall identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern.

(II) CRITERIA.—The Secretary shall use criteria established by the Secretary in making any determination under subclause (I).

(iii) IMPLEMENTATION.—The Secretary shall establish the criteria under clause (ii)(II) and any exceptions under clause (i)(II) through the promulgation of a regulation which includes a public notice and comment period.

(iv) REQUIREMENT FOR CERTAIN CATEGORIES AND CLASSES UNTIL CRITERIA ESTABLISHED.—Until such time as the Secretary establishes the criteria under clause (ii)(II) the following categories and classes of drugs shall be identified under clause (ii)(I):

(I) Anticonvulsants.
(II) Antidepressants.
(III) Antineoplastics.
(IV) Antipsychotics.
(V) Antiretrovirals.
(VI) Immunosuppressants for the treatment of transplant rejection.

(H) USE OF SINGLE, UNIFORM EXCEPTIONS AND APPEALS PROCESS.—Notwithstanding any other provision of this part, each PDP sponsor of a prescription drug plan shall—

(i) use a single, uniform exceptions and appeals process (including, to the extent the Secretary determines feasible, a single, uniform model form for use under such process) with respect to the determination of prescription drug coverage for an enrollee under the plan; and

(ii) provide instant access to such process by enrollees through a toll-free telephone number and an Internet website.

(c) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

(1) IN GENERAL.—The PDP sponsor shall have in place, directly or through appropriate arrangements, with respect to covered part D drugs, the following:

(A) A cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs (as defined in section 1927(k)(7)(A)(i)).

(B) Quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

(C) A medication therapy management program described in paragraph (2).

(D) A program to control fraud, abuse, and waste.

(E) A utilization management tool to prevent drug abuse (as described in paragraph (6)(A)).

*(F) With respect to plan years beginning on or after January 1, 2021, a drug management program for at-risk beneficiaries described in paragraph (5).*

Nothing in this section shall be construed as impairing a PDP sponsor from utilizing cost management tools (including differential payments) under all methods of operation.

(2) MEDICATION THERAPY MANAGEMENT PROGRAM.—

(A) DESCRIPTION.—

(i) IN GENERAL.—A medication therapy management program described in this paragraph is a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure, with respect to targeted beneficiaries described in clause (ii), that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Such a program may distinguish between services in ambulatory and institutional settings.

(ii) TARGETED BENEFICIARIES DESCRIBED.—Targeted beneficiaries described in this clause ⟦are part D eligible individuals who—⟧ *are the following:*

*(I) Part D eligible individuals who—*

[(I)] *(aa)* have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure);

[(II)] *(bb)* are taking multiple covered part D drugs; and

[(III)] *(cc)* are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by the Secretary.

*(II) Beginning January 1, 2021, at-risk beneficiaries for prescription drug abuse (as defined in paragraph (5)(C)).*

(B) ELEMENTS.—Such program [may include elements that promote]—

*(i) may include elements that promote—*

[(i)] *(I)* enhanced enrollee understanding to promote the appropriate use of medications by enrollees and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, and other appropriate means;

[(ii)] *(II)* increased enrollee adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs and other appropriate means; and

[(iii)] *(III)* detection of adverse drug events and patterns of overuse and underuse of prescription drugs[.]*; and*

*(ii) with respect to plan years beginning on or after January 1, 2021, shall provide for—*

*(I) the provision of information to the enrollee on the safe disposal of prescription drugs that are controlled substances that meets the criteria established under section 1852(n)(2), including information on drug takeback programs that meet such requirements determined appropriate by the Secretary and information on in-home disposal; and*

*(II) cost-effective means by which an enrollee may so safely dispose of such drugs.*

(C) REQUIRED INTERVENTIONS.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Patient Protection and Affordable Care Act, prescription drug plan sponsors shall offer medication therapy management services to targeted beneficiaries described in subparagraph (A)(ii) that include, at a minimum, the following to increase adherence to prescription medications or other goals deemed necessary by the Secretary:

(i) An annual comprehensive medication review furnished person-to-person or using telehealth technologies (as defined by the Secretary) by a licensed pharmacist or other qualified provider. The comprehensive medication review—

(I) shall include a review of the individual's medications and may result in the creation of a recommended medication action plan or other actions in consultation with the individual and with input from the prescriber to the extent necessary and practicable; and

(II) shall include providing the individual with a written or printed summary of the results of the review.

The Secretary, in consultation with relevant stakeholders, shall develop a standardized format for the action plan under subclause (I) and the summary under subclause (II).

(ii) Follow-up interventions as warranted based on the findings of the annual medication review or the targeted medication enrollment and which may be provided person-to-person or using telehealth technologies (as defined by the Secretary).

(D) ASSESSMENT.—The prescription drug plan sponsor shall have in place a process to assess, at least on a quarterly basis, the medication use of individuals who are at risk but not enrolled in the medication therapy management program, including individuals who have experienced a transition in care, if the prescription drug plan sponsor has access to that information.

(E) AUTOMATIC ENROLLMENT WITH ABILITY TO OPT-OUT.—The prescription drug plan sponsor shall have in place a process to—

(i) subject to clause (ii), automatically enroll targeted beneficiaries described in subparagraph (A)(ii), including beneficiaries identified under subparagraph (D), in the medication therapy management program required under this subsection; and

(ii) permit such beneficiaries to opt-out of enrollment in such program.

(E) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—Such program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

(F) COORDINATION WITH CARE MANAGEMENT PLANS.—The Secretary shall establish guidelines for the coordination of any medication therapy management program under this paragraph with respect to a targeted beneficiary with any care management plan established with respect to such beneficiary under a chronic care improvement program under section 1807.

(G) CONSIDERATIONS IN PHARMACY FEES.—The PDP sponsor of a prescription drug plan shall take into account, in establishing fees for pharmacists and others providing services under such plan, the resources used, and time required to, implement the medication therapy management program under this paragraph. Each such sponsor shall disclose to the Secretary upon request the amount of any such management or dispensing fees. The provisions of section 1927(b)(3)(D) apply to information disclosed under this subparagraph.

(3) REDUCING WASTEFUL DISPENSING OF OUTPATIENT PRESCRIPTION DRUGS IN LONG-TERM CARE FACILITIES.—The Secretary shall require PDP sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, as determined by the Secretary, in consultation with relevant stakeholders (including representatives of nursing facilities, residents of nursing facilities, pharmacists, the pharmacy industry (including retail and long-term care pharmacy), prescription drug plans, MA–PD plans, and any other stakeholders the Secretary determines appropriate), such as weekly, daily, or automated dose dispensing, when dispensing covered part D drugs to enrollees who reside in a long-term care facility in order to reduce waste associated with 30-day fills.

(4) REQUIRING VALID PRESCRIBER NATIONAL PROVIDER IDENTIFIERS ON PHARMACY CLAIMS.—

(A) IN GENERAL.—For plan year 2016 and subsequent plan years, the Secretary shall require a claim for a covered part D drug for a part D eligible individual enrolled in a prescription drug plan under this part or an MA–PD plan under part C to include a prescriber National Provider Identifier that is determined to be valid under the procedures established under subparagraph (B)(i).

(B) PROCEDURES.—

(i) VALIDITY OF PRESCRIBER NATIONAL PROVIDER IDENTIFIERS.—The Secretary, in consultation with appropriate stakeholders, shall establish procedures for determining the validity of prescriber National Provider Identifiers under subparagraph (A).

(ii) INFORMING BENEFICIARIES OF REASON FOR DENIAL.—The Secretary shall establish procedures to ensure that, in the case that a claim for a covered part D drug of an individual described in subparagraph (A) is denied because the claim does not meet the requirements of this paragraph, the individual is properly informed at the point of service of the reason for the denial.

(C) REPORT.—Not later than January 1, 2018, the Inspector General of the Department of Health and Human Services shall submit to Congress a report on the effectiveness of the procedures established under subparagraph (B)(i).

*(D) OUTLIER PRESCRIBER NOTIFICATION.—*

*(i) NOTIFICATION.—Beginning not later than two years after the date of the enactment of this subparagraph, the Secretary shall, in the case of a prescriber identified by the Secretary under clause (ii) to be an outlier prescriber of opioids, provide, subject to clause (iv), an annual notification to such prescriber that such prescriber has been so identified and that includes resources on proper prescribing methods and other information specified in accordance with clause (iii).*

*(ii) IDENTIFICATION OF OUTLIER PRESCRIBERS OF OPIOIDS.—*

*(I) IN GENERAL.—The Secretary shall, subject to subclause (III), using the valid prescriber National Provider Identifiers included pursuant to subparagraph (A) on claims for covered part D drugs for part D eligible individuals enrolled in prescription drug plans under this part or MA–PD plans under part C and based on the threshold established under subclause (II), conduct an analysis to identify prescribers that are outlier opioid prescribers for a period specified by the Secretary.*

*(II) ESTABLISHMENT OF THRESHOLD.—For purposes of subclause (I) and subject to subclause (III), the Secretary shall, after consultation with stakeholders, establish a threshold, based on prescriber specialty and geographic area, for identifying*

*whether a prescriber in a specialty and geographic area is an outlier prescriber of opioids as compared to other prescribers of opioids within such specialty and area.*

*(III) EXCLUSIONS.—The Secretary may exclude the following individuals and prescribers from the analysis under this clause:*

*(aa) Individuals receiving hospice services.*

*(bb) Individuals with a cancer diagnosis.*

*(cc) Prescribers who are the subject of an investigation by the Centers for Medicare & Medicaid Services or the Office of Inspector General of the Department of Health and Human Services.*

*(iii) CONTENTS OF NOTIFICATION.—The Secretary shall, based on input from stakeholders, specify the resources and other information to be included in notifications provided under clause (i).*

*(iv) MODIFICATIONS AND EXPANSIONS.—*

*(I) FREQUENCY.—Beginning 5 years after the date of the enactment of this subparagraph, the Secretary may change the frequency of the notifications described in clause (i) based on stakeholder input.*

*(II) EXPANSION TO OTHER PRESCRIPTIONS.—The Secretary may expand notifications under this subparagraph to include identifications and notifications with respect to concurrent prescriptions of covered Part D drugs used in combination with opioids that are considered to have adverse side effects when so used in such combination, as determined by the Secretary.*

*(v) OPIOIDS DEFINED.—For purposes of this subparagraph, the term "opioids" has such meaning as specified by the Secretary through program instruction or otherwise.*

(5) DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.—

(A) AUTHORITY TO ESTABLISH.—A PDP sponsor may *(and for plan years beginning on or after January 1, 2021, a PDP sponsor shall)* establish a drug management program for at-risk beneficiaries under which, subject to subparagraph (B), the PDP sponsor may, in the case of an at-risk beneficiary for prescription drug abuse who is an enrollee in a prescription drug plan of such PDP sponsor, limit such beneficiary's access to coverage for frequently abused drugs under such plan to frequently abused drugs that are prescribed for such beneficiary by one or more prescribers selected under subparagraph (D), and dispensed for such beneficiary by one or more pharmacies selected under such subparagraph.

(B) REQUIREMENT FOR NOTICES.—

(i) IN GENERAL.—A PDP sponsor may not limit the access of an at-risk beneficiary for prescription drug abuse to coverage for frequently abused drugs under a prescription drug plan until such sponsor—

(I) provides to the beneficiary an initial notice described in clause (ii) and a second notice described in clause (iii); and

(II) verifies with the providers of the beneficiary that the beneficiary is an at-risk beneficiary for prescription drug abuse.

(ii) INITIAL NOTICE.—An initial notice described in this clause is a notice that provides to the beneficiary—

(I) notice that the PDP sponsor has identified the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse;

(II) information describing all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health services and other counseling services;

(III) notice of, and information about, the right of the beneficiary to appeal such identification under subsection (h) and the option of an automatic escalation to external review;

(IV) a request for the beneficiary to submit to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor to select under subparagraph (D) in the case that the beneficiary is identified as an at-risk beneficiary for prescription drug abuse as described in clause (iii)(I);

(V) an explanation of the meaning and consequences of the identification of the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse, including an explanation of the drug management program established by the PDP sponsor pursuant to subparagraph (A);

(VI) clear instructions that explain how the beneficiary can contact the PDP sponsor in order to submit to the PDP sponsor the preferences described in subclause (IV) and any other communications relating to the drug management program for at-risk beneficiaries established by the PDP sponsor; and

(VII) contact information for other organizations that can provide the beneficiary with assistance regarding such drug management program (similar to the information provided by the Secretary in other standardized notices provided to part D eligible individuals enrolled in prescription drug plans under this part).

(iii) SECOND NOTICE.—A second notice described in this clause is a notice that provides to the beneficiary notice—

(I) that the PDP sponsor has identified the beneficiary as an at-risk beneficiary for prescription drug abuse;

(II) that such beneficiary is subject to the requirements of the drug management program for at-risk beneficiaries established by such PDP sponsor for such plan;

(III) of the prescriber (or prescribers) and pharmacy (or pharmacies) selected for such individual under subparagraph (D);

(IV) of, and information about, the beneficiary's right to appeal such identification under subsection (h) and the option of an automatic escalation to external review;

(V) that the beneficiary can, in the case that the beneficiary has not previously submitted to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor select under subparagraph (D), submit such preferences to the PDP sponsor; and

(VI) that includes clear instructions that explain how the beneficiary can contact the PDP sponsor.

(iv) TIMING OF NOTICES.—

(I) IN GENERAL.—Subject to subclause (II), a second notice described in clause (iii) shall be provided to the beneficiary on a date that is not less than 30 days after an initial notice described in clause (ii) is provided to the beneficiary.

(II) EXCEPTION.—In the case that the PDP sponsor, in conjunction with the Secretary, determines that concerns identified through rulemaking by the Secretary regarding the health or safety of the beneficiary or regarding significant drug diversion activities require the PDP sponsor to provide a second notice described in clause (iii) to the beneficiary on a date that is earlier than the date described in subclause (I), the PDP sponsor may provide such second notice on such earlier date.

(C) AT-RISK BENEFICIARY FOR PRESCRIPTION DRUG ABUSE.—

(i) IN GENERAL.—For purposes of this paragraph, the term "at-risk beneficiary for prescription drug abuse" means a part D eligible individual who is not an exempted individual described in clause (ii) and—

(I) who is identified as such an at-risk beneficiary through the use of clinical guidelines that indicate misuse or abuse of prescription drugs described in subparagraph (G) and that are developed by the Secretary in consultation with PDP sponsors and other stakeholders, including individuals entitled to benefits under part A or enrolled under part B, advocacy groups representing such individuals, physicians, pharmacists, and other clinicians, retail pharmacies, plan sponsors, entities delegated by plan sponsors, and biopharmaceutical manufacturers; or

(II) with respect to whom the PDP sponsor of a prescription drug plan, upon enrolling such individual in such plan, received notice from the Secretary that such individual was identified under this paragraph to be an at-risk beneficiary for prescription drug abuse under the prescription drug plan in which such individual was most recently previously enrolled and such identification has not been terminated under subparagraph (F).

(ii) EXEMPTED INDIVIDUAL DESCRIBED.—An exempted individual described in this clause is an individual who—

(I) receives hospice care under this title;

(II) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

(III) the Secretary elects to treat as an exempted individual for purposes of clause (i).

(iii) PROGRAM SIZE.—The Secretary shall establish policies, including the guidelines developed under clause (i)(I) and the exemptions under clause (ii)(III), to ensure that the population of enrollees in a drug management program for at-risk beneficiaries operated by a prescription drug plan can be effectively managed by such plans.

(iv) CLINICAL CONTACT.—With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by a PDP sponsor, the PDP sponsor shall contact the beneficiary's providers who have prescribed frequently abused drugs regarding whether prescribed medications are appropriate for such beneficiary's medical conditions.

(D) SELECTION OF PRESCRIBERS AND PHARMACIES.—

(i) IN GENERAL.—With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by such sponsor, a PDP sponsor shall, based on the preferences submitted to the PDP sponsor by the beneficiary pursuant to clauses (ii)(IV) and (iii)(V) of subparagraph (B) (except as otherwise provided in this subparagraph) select—

(I) one, or, if the PDP sponsor reasonably determines it necessary to provide the beneficiary with reasonable access under clause (ii), more than one, individual who is authorized to prescribe frequently abused drugs (referred to in this paragraph as a "prescriber") who may write prescriptions for such drugs for such beneficiary; and

(II) one, or, if the PDP sponsor reasonably determines it necessary to provide the beneficiary with reasonable access under clause (ii), more than one, pharmacy that may dispense such drugs to such beneficiary.

For purposes of subclause (II), in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy shall collectively be treated as one pharmacy.

(ii) REASONABLE ACCESS.—In making the selections under this subparagraph—

(I) a PDP sponsor shall ensure that the beneficiary continues to have reasonable access to frequently abused drugs (as defined in subparagraph (G)), taking into account geographic location, beneficiary preference, impact on costsharing, and reasonable travel time; and

(II) a PDP sponsor shall ensure such access (including access to prescribers and pharmacies with respect to frequently abused drugs) in the case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services.

(iii) BENEFICIARY PREFERENCES.—If an at-risk beneficiary for prescription drug abuse submits preferences for which in-network prescribers and pharmacies the beneficiary would prefer the PDP sponsor select in response to a notice under subparagraph (B), the PDP sponsor shall—

(I) review such preferences;

(II) select or change the selection of prescribers and pharmacies for the beneficiary based on such preferences; and

(III) inform the beneficiary of such selection or change of selection.

(iv) EXCEPTION REGARDING BENEFICIARY PREFERENCES.—In the case that the PDP sponsor determines that a change to the selection of prescriber or pharmacy under clause (iii)(II) by the PDP sponsor is contributing or would contribute to prescription drug abuse or drug diversion by the beneficiary, the PDP sponsor may change the selection of prescriber or pharmacy for the beneficiary without regard to the preferences of the beneficiary described in clause (iii). If the PDP sponsor changes the selection pursuant to the preceding sentence, the PDP sponsor shall provide the beneficiary with—

(I) at least 30 days written notice of the change of selection; and

(II) a rationale for the change.

(v) CONFIRMATION.—Before selecting a prescriber or pharmacy under this subparagraph, a PDP sponsor must notify the prescriber and pharmacy that the beneficiary involved has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber and pharmacy has been selected as the beneficiary's designated prescriber and pharmacy.

(E) TERMINATIONS AND APPEALS.—The identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph, a coverage determination made under a drug management program for at-risk beneficiaries, the selection of prescriber or pharmacy under subparagraph (D), and information to be shared under subparagraph (I), with respect to such individual, shall be subject to reconsideration and appeal under subsection (h) and the option of an automatic escalation to external review to the extent provided by the Secretary.

(F) TERMINATION OF IDENTIFICATION.—

(i) IN GENERAL.—The Secretary shall develop standards for the termination of identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph. Under such standards such identification shall terminate as of the earlier of—

(I) the date the individual demonstrates that the individual is no longer likely, in the absence of the restrictions under this paragraph, to be an at-risk beneficiary for prescription drug abuse described in subparagraph (C)(i); and

(II) the end of such maximum period of identification as the Secretary may specify.

(ii) RULE OF CONSTRUCTION.—Nothing in clause (i) shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary for prescription drug abuse under subparagraph (C)(i) after such termination on the basis of additional information on drug use occurring after the date of notice of such termination.

(G) FREQUENTLY ABUSED DRUG.—For purposes of this subsection, the term "frequently abused drug" means a drug that is a controlled substance that the Secretary determines to be frequently abused or diverted.

(H) DATA DISCLOSURE.—

(i) DATA ON DECISION TO IMPOSE LIMITATION.—In the case of an at-risk beneficiary for prescription drug abuse (or an individual who is a potentially at-risk beneficiary for prescription drug abuse) whose access to coverage for frequently abused drugs under a prescription drug plan has been limited by a PDP sponsor under this paragraph, the Secretary shall establish rules and procedures to require the PDP sponsor to disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to impose such limitations and the limitations imposed by the sponsor under this part.

(ii) DATA TO REDUCE FRAUD, ABUSE, AND WASTE.—The Secretary shall establish rules and procedures to require PDP sponsors operating a drug management program for at-risk beneficiaries under this paragraph to provide the Secretary with such data as the Secretary determines appropriate for purposes of identifying patterns of prescription drug utilization for plan enrollees that are outside normal patterns and that may indicate fraudulent, medically unnecessary, or unsafe use.

(I) SHARING OF INFORMATION FOR SUBSEQUENT PLAN ENROLLMENTS.—The Secretary shall establish procedures under which PDP sponsors who offer prescription drug plans shall share information with respect to individuals who are at-risk beneficiaries for prescription drug abuse (or individuals who are potentially at-risk beneficiaries for prescription drug abuse) and enrolled in a prescription drug plan and who subsequently disenroll from such plan and enroll in another prescription drug plan offered by another PDP sponsor.

(J) PRIVACY ISSUES.—Prior to the implementation of the rules and procedures under this paragraph, the Secretary shall clarify privacy requirements, including requirements under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), related to the sharing of data under subparagraphs (H) and (I) by PDP sponsors. Such clarification shall provide that the sharing of such data shall be considered to be protected health information in accordance with the requirements of the regulations promulgated pursuant to such section 264(c).

(K) EDUCATION.—The Secretary shall provide education to enrollees in prescription drug plans of PDP sponsors and providers regarding the drug management program for at-risk beneficiaries described in this paragraph, including education—

(i) provided by Medicare administrative contractors through the improper payment outreach and education program described in section 1874A(h); and

(ii) through current education efforts (such as State health insurance assistance programs described in subsection (a)(1)(A) of section 119 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395b–3 note)) and materials directed toward such enrollees.

(L) APPLICATION UNDER MA–PD PLANS.—Pursuant to section 1860D–21(c)(1), the provisions of this paragraph apply under part D to MA organizations offering MA–PD plans to MA eligible individuals in the same manner as such provisions apply under this part to a PDP sponsor offering a prescription drug plan to a part D eligible individual.

(M) CMS COMPLIANCE REVIEW.—The Secretary shall ensure that existing plan sponsor compliance reviews and audit processes include the drug management programs for at-risk beneficiaries under this paragraph, including appeals processes under such programs.

(6) UTILIZATION MANAGEMENT TOOL TO PREVENT DRUG ABUSE.—

(A) IN GENERAL.—A tool described in this paragraph is any of the following:

(i) A utilization tool designed to prevent the abuse of frequently abused drugs by individuals and to prevent the diversion of such drugs at pharmacies.

(ii) Retrospective utilization review to identify—

(I) individuals that receive frequently abused drugs at a frequency or in amounts that are not clinically appropriate; and

(II) providers of services or suppliers that may facilitate the abuse or diversion of frequently abused drugs by beneficiaries.

(iii) Consultation with the contractor described in subparagraph (B) to verify if an individual enrolling in a prescription drug plan offered by a PDP sponsor has been previously identified by another PDP sponsor as an individual described in clause (ii)(I).

(B) REPORTING.—A PDP sponsor offering a prescription drug plan (and an MA organization offering an MA–PD plan) in a State shall submit to the Secretary and the Medicare drug integrity contractor with which the Secretary has entered into a contract under section 1893 with respect to such State a report, on a monthly basis, containing information on—

(i) any provider of services or supplier described in subparagraph (A)(ii)(II) that is identified by such plan sponsor (or organization) during the 30-day period before such report is submitted; and

(ii) the name and prescription records of individuals described in paragraph (5)(C).

(C) CMS COMPLIANCE REVIEW.—The Secretary shall ensure that plan sponsor compliance reviews and program audits biennially include a certification that utilization management tools under this paragraph are in compliance with the requirements for such tools.

(6) PROVIDING PRESCRIPTION DRUG PLANS WITH PARTS A AND B CLAIMS DATA TO PROMOTE THE APPROPRIATE USE OF MEDICATIONS AND IMPROVE HEALTH OUTCOMES.—

(A) PROCESS.—Subject to subparagraph (B), the Secretary shall establish a process under which a PDP sponsor of a prescription drug plan may submit a request for the Secretary to provide the sponsor, on a periodic basis and in an electronic format, beginning in plan year 2020, data described in subparagraph (D) with respect to enrollees in such plan. Such data shall be provided without regard to whether such enrollees are described in clause (ii) of paragraph (2)(A).

(B) PURPOSES.—A PDP sponsor may use the data provided to the sponsor pursuant to subparagraph (A) for any of the following purposes:

(i) To optimize therapeutic outcomes through improved medication use, as such phrase is used in clause (i) of paragraph (2)(A).

(ii) To improving care coordination so as to prevent adverse health outcomes, such as preventable emergency department visits and hospital readmissions.

(iii) For any other purpose determined appropriate by the Secretary.

(C) LIMITATIONS ON DATA USE.—A PDP sponsor shall not use data provided to the sponsor pursuant to subparagraph (A) for any of the following purposes:

(i) To inform coverage determinations under this part.

(ii) To conduct retroactive reviews of medically accepted indications determinations.

(iii) To facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization.

(iv) To inform marketing of benefits.

(v) For any other purpose that the Secretary determines is necessary to include in order to protect the identity of individuals entitled to, or enrolled for, benefits under this title and to protect the security of personal health information.

(D) DATA DESCRIBED.—The data described in this clause are standardized extracts (as determined by the Secretary) of claims data under parts A and B for items and services furnished under such parts for time periods specified by the Secretary. Such data shall include data as current as practicable.

(d) CONSUMER SATISFACTION SURVEYS.—In order to provide for comparative information under section 1860D–1(c)(3)(A)(v), the Secretary shall conduct consumer satisfaction surveys with respect to PDP sponsors and prescription drug plans in a manner similar to the manner such surveys are conducted for MA organizations and MA plans under part C.

(e) ELECTRONIC PRESCRIPTION PROGRAM.—

(1) APPLICATION OF STANDARDS.—As of such date as the Secretary may specify, but not later than 1 year after the date of promulgation of final standards under paragraph (4)(D), prescriptions and other information described in paragraph (2)(A) for covered part D drugs prescribed for part D eligible individuals that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2).

(2) PROGRAM REQUIREMENTS.—Consistent with uniform standards established under paragraph (3)—

(A) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL AND DISPENSING PHARMACIES AND PHARMACISTS.—An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered part D drug:

(i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

(B) APPLICATION TO MEDICAL HISTORY INFORMATION.—Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to carry out this subparagraph, the program shall provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) of information that relates to the medical history concerning the individual and related to a covered part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

(C) LIMITATIONS.—Information shall only be disclosed under subparagraph (A) or (B) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

(D) TIMING.—To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis.

*(E) ELECTRONIC PRIOR AUTHORIZATION.—*

*(i) IN GENERAL.—Not later than January 1, 2021, the program shall provide for the secure electronic transmission of—*

*(I) a prior authorization request from the prescribing health care professional for coverage of a covered part D drug for a part D eligible individual enrolled in a part D plan (as defined in section 1860D–23(a)(5)) to the PDP sponsor or Medicare Advantage organization offering such plan; and*

*(II) a response, in accordance with this subparagraph, from such PDP sponsor or Medicare Advantage organization, respectively, to such professional.*

*(ii) ELECTRONIC TRANSMISSION.—*

*(I) EXCLUSIONS.—For purposes of this subparagraph, a facsimile, a proprietary payer portal that does not meet standards specified by the Secretary, or an electronic form shall not be treated as an electronic transmission described in clause (i).*

*(II) STANDARDS.—In order to be treated, for purposes of this subparagraph, as an electronic transmission described in clause (i), such transmission shall comply with technical standards adopted by the Secretary in consultation with the National Council for Prescription Drug Programs, other standard setting organizations determined appropriate by the Secretary, and stakeholders including PDP sponsors, Medicare Advantage organizations, health care professionals, and health information technology software vendors.*

*(III) APPLICATION.—Notwithstanding any other provision of law, for purposes of this subparagraph, the Secretary may require the use of such standards adopted under subclause (II) in lieu of any other applicable standards for an electronic transmission described in clause (i) for a covered part D drug for a part D eligible individual.*

(3) STANDARDS.—

(A) IN GENERAL.—The Secretary shall provide consistent with this subsection for the promulgation of uniform standards relating to the requirements for electronic prescription drug programs under paragraph (2).

(B) OBJECTIVES.—Such standards shall be consistent with the objectives of improving—

(i) patient safety;

(ii) the quality of care provided to patients; and

(iii) efficiencies, including cost savings, in the delivery of care.

(C) DESIGN CRITERIA.—Such standards shall—

(i) be designed so that, to the extent practicable, the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists;

(ii) be compatible with standards established under part C of title XI, standards established under subsection (b)(2)(B)(i), and with general health information technology standards; and

(iii) be designed so that they permit electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration and the National Library of Medicine.

(D) PERMITTING USE OF APPROPRIATE MESSAGING.—Such standards shall allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems referred to in subsection (c)(1)(B).

(E) PERMITTING PATIENT DESIGNATION OF DISPENSING PHARMACY.—

(i) IN GENERAL.—Consistent with clause (ii), such standards shall permit a part D eligible individual to designate a particular pharmacy to dispense a prescribed drug.

(ii) NO CHANGE IN BENEFITS.—Clause (i) shall not be construed as affecting—

(I) the access required to be provided to pharmacies by a prescription drug plan; or

(II) the application of any differences in benefits or payments under such a plan based on the pharmacy dispensing a covered part D drug.

(4) DEVELOPMENT, PROMULGATION, AND MODIFICATION OF STANDARDS.—

(A) INITIAL STANDARDS.—Not later than September 1, 2005, the Secretary shall develop, adopt, recognize, or modify initial uniform standards relating to the requirements for electronic prescription drug programs described in paragraph (2) taking into consideration the recommendations (if any) from the National Committee on Vital and Health Statistics (as established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k))) under subparagraph (B).

(B) ROLE OF NCVHS.—The National Committee on Vital and Health Statistics shall develop recommendations for uniform standards relating to such requirements in consultation with the following:

(i) Standard setting organizations (as defined in section 1171(8))

(ii) Practicing physicians.

(iii) Hospitals.

(iv) Pharmacies.
(v) Practicing pharmacists.
(vi) Pharmacy benefit managers.
(vii) State boards of pharmacy.
(viii) State boards of medicine.
(ix) Experts on electronic prescribing.
(x) Other appropriate Federal agencies.

(C) PILOT PROJECT TO TEST INITIAL STANDARDS.—

(i) IN GENERAL.—During the 1-year period that begins on January 1, 2006, the Secretary shall conduct a pilot project to test the initial standards developed under subparagraph (A) prior to the promulgation of the final uniform standards under subparagraph (D) in order to provide for the efficient implementation of the requirements described in paragraph (2).

(ii) EXCEPTION.—Pilot testing of standards is not required under clause (i) where there already is adequate industry experience with such standards, as determined by the Secretary after consultation with effected standard setting organizations and industry users.

(iii) VOLUNTARY PARTICIPATION OF PHYSICIANS AND PHARMACIES.—In order to conduct the pilot project under clause (i), the Secretary shall enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards.

(iv) EVALUATION AND REPORT.—

(I) EVALUATION.—The Secretary shall conduct an evaluation of the pilot project conducted under clause (i).

(II) REPORT TO CONGRESS.—Not later than April 1, 2007, the Secretary shall submit to Congress a report on the evaluation conducted under subclause (I).

(D) FINAL STANDARDS.—Based upon the evaluation of the pilot project under subparagraph (C)(iv)(I) and not later than April 1, 2008, the Secretary shall promulgate uniform standards relating to the requirements described in paragraph (2).

(5) RELATION TO STATE LAWS.—The standards promulgated under this subsection shall supersede any State law or regulation that—

(A) is contrary to the standards or restricts the ability to carry out this part; and

(B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

(6) ESTABLISHMENT OF SAFE HARBOR.—The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1128B(b) and an exception to the prohibition under subsection (a)(1) of section 1877 with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection—

(A) in the case of a hospital, by the hospital to members of its medical staff;

(B) in the case of a group practice (as defined in section 1877(h)(4)), by the practice to prescribing health care professionals who are members of such practice; and

(C) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization, and to prescribing health care professionals.

*(7) REQUIREMENT OF E-PRESCRIBING FOR CONTROLLED SUBSTANCES.—*

*(A) IN GENERAL.—Subject to subparagraph (B), a prescription for a covered part D drug under a prescription drug plan (or under an MA–PD plan) for a schedule II, III, IV, or V controlled substance shall be transmitted by a health care practitioner electronically in accordance with an electronic prescription drug program that meets the requirements of paragraph (2).*

*(B) EXCEPTION FOR CERTAIN CIRCUMSTANCES.—The Secretary shall, pursuant to rulemaking, specify circumstances with respect to which the Secretary may waive the requirement under subparagraph (A), with respect to a covered part D drug, including in the case of—*

*(i) a prescription issued when the practitioner and dispenser are the same entity;*

*(ii) a prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;*

*(iii) a prescription issued by a practitioner who has received a waiver or a renewal thereof for a specified period determined by the Secretary, not to exceed one year, from the requirement to use electronic prescribing, pursuant to a process established by regulation by the Secretary, due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;*

*(iv) a prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;*

*(v) a prescription issued by a practitioner allowing for the dispensing of a non-patient specific prescription pursuant to a standing order, approved protocol for drug therapy, collaborative drug management, or comprehensive medication management, in response to a public health emergency, or other circumstances where the practitioner may issue a non-patient specific prescription;*

*(vi) a prescription issued by a practitioner prescribing a drug under a research protocol;*

*(vii) a prescription issued by a practitioner for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use; and*

*(viii) a prescription issued by a practitioner for an individual who—*

*(I) receives hospice care under this title; or*

*(II) is a resident of a skilled nursing facility (as defined in section 1819(a)), or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B), for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, as determined by the Secretary in accordance with this paragraph.*

*(C) DISPENSING.—Nothing in this paragraph shall be construed as requiring a sponsor of a prescription drug plan under this part, MA organization offering an MA–PD plan under part C, or a pharmacist to verify that a practitioner, with respect to a prescription for a covered part D drug, has a waiver (or is otherwise exempt) under subparagraph (B) from the requirement under subparagraph (A). Nothing in this paragraph shall be construed as affecting the ability of the plan to cover or the pharmacists' ability to continue to dispense covered part D drugs from otherwise valid written, oral or fax prescriptions that are consistent with laws and regulations. Nothing in this paragraph shall be construed as affecting the ability of the beneficiary involved to designate a particular pharmacy to dispense a prescribed drug to the extent consistent with the requirements under subsection (b)(1) and under this paragraph.*

*(D) ENFORCEMENT.—The Secretary shall, pursuant to rulemaking, have authority to enforce and specify appropriate penalties for non-compliance with the requirement under subparagraph (A).*

(f) GRIEVANCE MECHANISM.—Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1852(f).

(g) COVERAGE DETERMINATIONS AND RECONSIDERATIONS.—

(1) APPLICATION OF COVERAGE DETERMINATION AND RECONSIDERATION PROVISIONS.—A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to an MA organization with respect to benefits it offers under an MA plan under part C.

(2) REQUEST FOR A DETERMINATION FOR THE TREATMENT OF TIERED FORMULARY DRUG.—In the case of a prescription drug plan offered by a PDP sponsor that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, a part D eligible individual who is enrolled in the plan may request an exception to the tiered cost-sharing structure. Under such an exception, a non-preferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both. A PDP sponsor shall have an exceptions process under this paragraph consistent with guidelines established by the Secretary for making a determination with respect to such a request. Denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h).

(h) APPEALS.—

(1) IN GENERAL.—Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1852(g) with respect to benefits (including a determination related to the application of tiered cost-sharing described in subsection (g)(2)) in a manner similar (as determined by the Secretary) to the manner such requirements apply to an MA organization with respect to benefits under the original medicare fee-for-service program option it offers under an MA plan under part C. In applying this paragraph only the part D eligible individual shall be entitled to bring such an appeal.

(2) LIMITATION IN CASES ON NONFORMULARY DETERMINATIONS.—A part D eligible individual who is enrolled in a prescription drug plan offered by a PDP sponsor may appeal under paragraph (1) a determination not to provide for coverage of a covered part D drug that is not on the formulary under the plan only if the prescribing physician determines that all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both.

(3) TREATMENT OF NONFORMULARY DETERMINATIONS.—If a PDP sponsor determines that a plan provides coverage for a covered part D drug that is not on the formulary of the plan, the drug shall be treated as being included on the formulary for purposes of section 1860D–2(b)(4)(C)(i).

(i) PRIVACY, CONFIDENTIALITY, AND ACCURACY OF ENROLLEE RECORDS.—The provisions of section 1852(h) shall apply to a PDP sponsor and prescription drug plan in the same manner as it applies to an MA organization and an MA plan.

(j) TREATMENT OF ACCREDITATION.—Subparagraph (A) of section 1852(e)(4) (relating to treatment of accreditation) shall apply to a PDP sponsor under this part with respect to the following requirements, in the same manner as it applies to an MA organization with respect to the requirements in subparagraph (B) (other than clause (vii) thereof) of such section:

(1) Subsection (b) of this section (relating to access to covered part D drugs).

(2) Subsection (c) of this section (including quality assurance and medication therapy management).

(3) Subsection (i) of this section (relating to confidentiality and accuracy of enrollee records).

(k) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—

(1) IN GENERAL.—A PDP sponsor offering a prescription drug plan shall provide that each pharmacy that dispenses a covered part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.

(2) TIMING OF NOTICE.—

(A) IN GENERAL.—Subject to subparagraph (B), the information under paragraph (1) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

(B) WAIVER.—The Secretary may waive subparagraph (A) in such circumstances as the Secretary may specify.

(l) REQUIREMENTS WITH RESPECT TO SALES AND MARKETING ACTIVITIES.—The following provisions shall apply to a PDP sponsor (and the agents, brokers, and other third parties representing such sponsor) in the same manner as such provisions apply to a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization):

(1) The prohibition under section 1851(h)(4)(C) on conducting activities described in section 1851(j)(1).

(2) The requirement under section 1851(h)(4)(D) to conduct activities described in section 1851(j)(2) in accordance with the limitations established under such subsection.

(3) The inclusion of the plan type in the plan name under section 1851(h)(6).

(4) The requirements regarding the appointment of agents and brokers and compliance with State information requests under subparagraphs (A) and (B), respectively, of section 1851(h)(7).

*(m) PROGRAM INTEGRITY TRANSPARENCY MEASURES.—For program integrity transparency measures applied with respect to prescription drug plan and MA plans, see section 1859(i).*

Subpart 2—Prescription Drug Plans; PDP Sponsors; Financing

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REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION DRUG PLAN (PDP) SPONSORS

SEC. 1860D–12. (a) GENERAL REQUIREMENTS.—Each PDP sponsor of a prescription drug plan shall meet the following requirements:

(1) LICENSURE.—Subject to subsection (c), the sponsor is organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan.

(2) ASSUMPTION OF FINANCIAL RISK FOR UNSUBSIDIZED COVERAGE.—

(A) IN GENERAL.—Subject to subparagraph (B), to the extent that the entity is at risk the entity assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D–15(b).

(B) REINSURANCE PERMITTED.—The plan sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing such coverage.

(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the case of a PDP sponsor that is not described in paragraph (1) and for which a waiver has been approved under subsection (c), such sponsor shall meet solvency standards established by the Secretary under subsection (d).

(b) CONTRACT REQUIREMENTS.—

(1) IN GENERAL.—The Secretary shall not permit the enrollment under section 1860D–1 in a prescription drug plan offered by a PDP sponsor under this part, and the sponsor shall not be eligible for payments under section 1860D–14 or 1860D–15, unless the Secretary has entered into a contract under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover more than one prescription drug plan. Such contract shall provide that the sponsor agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(2) LIMITATION ON ENTITIES OFFERING FALLBACK PRESCRIPTION DRUG PLANS.—The Secretary shall not enter into a contract with a PDP sponsor for the offering of a prescription drug plan (other than a fallback prescription drug plan) in a PDP region for a year if the sponsor—

(A) submitted a bid under section 1860D–11(g) for such year (as the first year of a contract period under such section) to offer a fallback prescription drug plan in any PDP region;

(B) offers a fallback prescription drug plan in any PDP region during the year; or

(C) offered a fallback prescription drug plan in that PDP region during the previous year.

For purposes of this paragraph, an entity shall be treated as submitting a bid with respect to a prescription drug plan or offering a fallback prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

(3) INCORPORATION OF CERTAIN MEDICARE ADVANTAGE CONTRACT REQUIREMENTS.—Except as otherwise provided, the following provisions of section 1857 shall apply to contracts under this section in the same manner as they apply to contracts under section 1857(a):

(A) MINIMUM ENROLLMENT.—Paragraphs (1) and (3) of section 1857(b), except that—

(i) the Secretary may increase the minimum number of enrollees required under such paragraph (1) as the Secretary determines appropriate; and

(ii) the requirement of such paragraph (1) shall be waived during the first contract year with respect to an organization in a region.

(B) CONTRACT PERIOD AND EFFECTIVENESS.—Section 1857(c), except that in applying paragraph (4)(B) of such section any reference to payment amounts under section 1853 shall be deemed payment amounts under section 1860D–15.

(C) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—Section 1857(d).

(D) ADDITIONAL CONTRACT TERMS.—Section 1857(e); except that section 1857(e)(2) shall apply as specified to PDP sponsors and payments under this part to an MA–PD plan shall be treated as expenditures made under part D. Notwithstanding any other provision of law, information provided to the Secretary under the application of section 1857(e)(1) to contracts under this section under the preceding sentence—

(i) may be used for the purposes of carrying out this part, improving public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services (as the Secretary determines appropriate); and

(ii) shall be made available to Congressional support agencies (in accordance with their obligations to support Congress as set out in their authorizing statutes) for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the program under this title.

(E) INTERMEDIATE SANCTIONS.—Section 1857(g) (other than paragraph (1)(F) of such section), except that in applying such section the reference in section 1857(g)(1)(B) to section 1854 is deemed a reference to this part.

(F) PROCEDURES FOR TERMINATION.—Section 1857(h).

(4) PROMPT PAYMENT OF CLEAN CLAIMS.—

(A) PROMPT PAYMENT.—

(i) IN GENERAL.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to all clean claims submitted by pharmacies (other than pharmacies that dispense drugs by mail order only or are located in, or contract with, a long-term care facility) under this part within the applicable number of calendar days after the date on which the claim is received.

(ii) CLEAN CLAIM DEFINED.—In this paragraph, the term "clean claim" means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.

(iii) DATE OF RECEIPT OF CLAIM.—In this paragraph, a claim is considered to have been received—

(I) with respect to claims submitted electronically, on the date on which the claim is transferred; and

(II) with respect to claims submitted otherwise, on the 5th day after the postmark date of the claim or the date specified in the time stamp of the transmission.

(B) APPLICABLE NUMBER OF CALENDAR DAYS DEFINED.—In this paragraph, the term "applicable number of calendar days" means—

(i) with respect to claims submitted electronically, 14 days; and

(ii) with respect to claims submitted otherwise, 30 days.

(C) INTEREST PAYMENT.—

(i) IN GENERAL.—Subject to clause (ii), if payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in subparagraph (B)) after a clean claim is received, the PDP sponsor shall pay interest to the pharmacy that submitted the claim at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which payment is made (as determined under subparagraph (D)(iv)). Interest amounts paid under this subparagraph shall not be counted against the administrative costs of a prescription drug plan or treated as allowable risk corridor costs under section 1860D–15(e).

(ii) AUTHORITY NOT TO CHARGE INTEREST.—The Secretary may provide that a PDP sponsor is not charged interest under clause (i) in the case where there are exigent circumstances, including natural disasters and other unique and unexpected events, that prevent the timely processing of claims.

(D) PROCEDURES INVOLVING CLAIMS.—

(i) CLAIM DEEMED TO BE CLEAN.—A claim is deemed to be a clean claim if the PDP sponsor involved does not provide notice to the claimant of any deficiency in the claim—

(I) with respect to claims submitted electronically, within 10 days after the date on which the claim is received; and

(II) with respect to claims submitted otherwise, within 15 days after the date on which the claim is received.

(ii) CLAIM DETERMINED TO NOT BE A CLEAN CLAIM.—

(I) IN GENERAL.—If a PDP sponsor determines that a submitted claim is not a clean claim, the PDP sponsor shall, not later than the end of the period described in clause (i), notify the claimant of such determination. Such notification shall specify all defects or improprieties in the claim and shall list all additional information or documents necessary for the proper processing and payment of the claim.

(II) DETERMINATION AFTER SUBMISSION OF ADDITIONAL INFORMATION.—A claim is deemed to be a clean claim under this paragraph if the PDP sponsor involved does not provide notice to the claimant of any defect or impropriety in the claim within 10 days of the date on which additional information is received under subclause (I).

(iii) OBLIGATION TO PAY.—A claim submitted to a PDP sponsor that is not paid or contested by the sponsor within the applicable number of days (as defined in subparagraph (B)) after the date on which the claim is received shall be deemed to be a clean claim and shall be paid by the PDP sponsor in accordance with subparagraph (A).

(iv) DATE OF PAYMENT OF CLAIM.—Payment of a clean claim under such subparagraph is considered to have been made on the date on which—

(I) with respect to claims paid electronically, the payment is transferred; and

(II) with respect to claims paid otherwise, the payment is submitted to the United States Postal Service or common carrier for delivery.

(E) ELECTRONIC TRANSFER OF FUNDS.—A PDP sponsor shall pay all clean claims submitted electronically by electronic transfer of funds if the pharmacy so requests or has so requested previously. In the case where such payment is made electronically, remittance may be made by the PDP sponsor electronically as well.

(F) PROTECTING THE RIGHTS OF CLAIMANTS.—

(i) IN GENERAL.—Nothing in this paragraph shall be construed to prohibit or limit a claim or action not covered by the subject matter of this section that any individual or organization has against a provider or a PDP sponsor.

(ii) ANTI-RETALIATION.—Consistent with applicable Federal or State law, a PDP sponsor shall not retaliate against an individual or provider for exercising a right of action under this subparagraph.

(G) RULE OF CONSTRUCTION.—A determination under this paragraph that a claim submitted by a pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under this title, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination shall not relieve any party of civil or criminal liability with respect to the claim, nor does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

(5) SUBMISSION OF CLAIMS BY PHARMACIES LOCATED IN OR CONTRACTING WITH LONG-TERM CARE FACILITIES.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that a pharmacy located in, or having a contract with, a long-term care facility shall have not less than 30 days (but not more than 90 days) to submit claims to the sponsor for reimbursement under the plan.

(6) REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD.—If the PDP sponsor of a prescription drug plan uses a standard for reimbursement of pharmacies based on the cost of a drug, each contract entered into with such sponsor under this part with respect to the plan

shall provide that the sponsor shall update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.

*(7) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.—*

*(A) IN GENERAL.—The provisions of section 1862(o) shall apply with respect to a PDP sponsor with a contract under this part, a pharmacy, and payments to such pharmacy under this part in the same manner as such provisions apply with respect to the Secretary, a provider of services or supplier, and payments to such provider of services or supplier under this title.*

*(B) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as limiting the authority of a PDP sponsor to conduct postpayment review.*

(c) WAIVER OF CERTAIN REQUIREMENTS TO EXPAND CHOICE.—

(1) AUTHORIZING WAIVER.—

(A) IN GENERAL.—In the case of an entity that seeks to offer a prescription drug plan in a State, the Secretary shall waive the requirement of subsection (a)(1) that the entity be licensed in that State if the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for approval of the application described in paragraph (2) have been met.

(B) APPLICATION OF REGIONAL PLAN WAIVER RULE.—In addition to the waiver available under subparagraph (A), the provisions of section 1858(d) shall apply to PDP sponsors under this part in a manner similar to the manner in which such provisions apply to MA organizations under part C, except that no application shall be required under paragraph (1)(B) of such section in the case of a State that does not provide a licensing process for such a sponsor.

(2) GROUNDS FOR APPROVAL.—

(A) IN GENERAL.—The grounds for approval under this paragraph are—

(i) subject to subparagraph (B), the grounds for approval described in subparagraphs (B), (C), and (D) of section 1855(a)(2); and

(ii) the application by a State of any grounds other than those required under Federal law.

(B) SPECIAL RULES.—In applying subparagraph (A)(i)—

(i) the ground of approval described in section 1855(a)(2)(B) is deemed to have been met if the State does not have a licensing process in effect with respect to the PDP sponsor; and

(ii) for plan years beginning before January 1, 2008, if the State does have such a licensing process in effect, such ground for approval described in such section is deemed to have been met upon submission of an application described in such section.

(3) APPLICATION OF WAIVER PROCEDURES.—With respect to an application for a waiver (or a waiver granted) under paragraph (1)(A) of this subsection, the provisions of subparagraphs (E), (F), and (G) of section 1855(a)(2) shall apply, except that clauses (i) and (ii) of such subparagraph (E) shall not apply in the case of a State that does not have a licensing process described in paragraph (2)(B)(i) in effect.

(4) REFERENCES TO CERTAIN PROVISIONS.—In applying provisions of section 1855(a)(2) under paragraphs (2) and (3) of this subsection to prescription drug plans and PDP sponsors—

(A) any reference to a waiver application under section 1855 shall be treated as a reference to a waiver application under paragraph (1)(A) of this subsection; and

(B) any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d) of this section.

(d) SOLVENCY STANDARDS FOR NON-LICENSED ENTITIES.—

(1) ESTABLISHMENT AND PUBLICATION.—The Secretary, in consultation with the National Association of Insurance Commissioners, shall establish and publish, by not later than January 1, 2005, financial solvency and capital adequacy standards for entities described in paragraph (2).

(2) COMPLIANCE WITH STANDARDS.—A PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Secretary shall establish certification procedures for such sponsors with respect to such solvency standards in the manner described in section 1855(c)(2).

(e) LICENSURE DOES NOT SUBSTITUTE FOR OR CONSTITUTE CERTIFICATION.—The fact that a PDP sponsor is licensed in accordance with subsection (a)(1) or has a waiver application approved under subsection (c) does not deem the sponsor to meet other requirements imposed under this part for a sponsor.

(f) PERIODIC REVIEW AND REVISION OF STANDARDS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may periodically review the standards established under this section and, based on such review, may revise such standards if the Secretary determines such revision to be appropriate.

(2) PROHIBITION OF MIDYEAR IMPLEMENTATION OF SIGNIFICANT NEW REGULATORY REQUIREMENTS.—The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

(g) PROHIBITION OF STATE IMPOSITION OF PREMIUM TAXES; RELATION TO STATE LAWS.—The provisions of sections 1854(g) and 1856(b)(3) shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C.

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## PART E—MISCELLANEOUS PROVISIONS

### DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. For purposes of this title—

### Spell of Illness

(a) The term "spell of illness" with respect to any individual means a period of consecutive days—

(1) beginning with the first day (not included in a previous spell of illness) (A) on which such individual is furnished inpatient hospital services, inpatient critical access hospital services or extended care services, and (B) which occurs in a month for which he is entitled to benefits under part A, and

(2) ending with the close of the first period of 60 consecutive days thereafter on each of which he is neither an inpatient of a hospital or critical access hospital nor an inpatient of a facility described in section 1819(a)(1) or subsection (y)(1).

### Inpatient Hospital Services

(b) The term "inpatient hospital services" means the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital—

(1) bed and board;

(2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and

(3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements;

excluding, however—

(4) medical or surgical services provided by a physician, resident, or intern, services described by subsection (s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist; and

(5) the services of a private-duty nurse or other private-duty attendant.

Paragraph (4) shall not apply to services provided in a hospital by—

(6) an intern or a resident-in-training under a teaching program approved by the Council on Medical Education of the American Medical Association or, in the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association, or, in the case of services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of dentistry, approved by the Council

on Dental Education of the American Dental Association, or in the case of services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of podiatry, approved by the Council on Podiatric Medical Education of the American Podiatric Medical Association; or

(7) a physician where the hospital has a teaching program approved as specified in paragraph (6), if (A) the hospital elects to receive any payment due under this title for reasonable costs of such services, and (B) all physicians in such hospital agree not to bill charges for professional services rendered in such hospital to individuals covered under the insurance program established by this title.

Inpatient Psychiatric Hospital Services

(c) The term "inpatient psychiatric hospital services" means inpatient hospital services furnished to an inpatient of a psychiatric hospital.

Supplier

(d) The term "supplier" means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.

Hospital

(e) The term "hospital" (except for purposes of sections 1814(d), 1814(f), and 1835(b), subsection (a)(2) of this section, paragraph (7) of this subsection, and subsection (i) of this section) means an institution which—

(1) is primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;

(2) maintains clinical records on all patients;

(3) has bylaws in effect with respect to its staff of physicians;

(4) has a requirement that every patient with respect to whom payment may be made under this title must be under the care of a physician, except that a patient receiving qualified psychologist services (as defined in subsection (ii)) may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law;

(5) provides 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed practical nurse or registered professional nurse on duty at all times; except that until January 1, 1979, the Secretary is authorized to waive the requirement of this paragraph for any one-year period with respect to any institution, insofar as such requirement relates to the provision of twenty-four-hour nursing service rendered or supervised by a registered professional nurse (except that in any event a registered professional nurse must be present on the premises to render or supervise the nursing service provided, during at least the regular daytime shift), where immediately preceding such one-year period he finds that—

(A) such institution is located in a rural area and the supply of hospital services in such area is not sufficient to meet the needs of individuals residing therein,

(B) the failure of such institution to qualify as a hospital would seriously reduce the availability of such services to such individuals, and

(C) such institution has made and continues to make a good faith effort to comply with this paragraph, but such compliance is impeded by the lack of qualified nursing personnel in such area;

(6)(A) has in effect a hospital utilization review plan which meets the requirements of subsection (k) and (B) has in place a discharge planning process that meets the requirements of subsection (ee);

(7) in the case of an institution in any State in which State or applicable local law provides for the licensing of hospitals, (A) is licensed pursuant to such law or (B) is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing;

(8) has in effect an overall plan and budget that meets the requirements of subsection (z); and

(9) meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.

For purposes of subsection (a)(2), such term includes any institution which meets the requirements of paragraph (1) of this subsection. For purposes of sections 1814(d) and 1835(b) (including determination of whether an individual received inpatient hospital services or diagnostic services for purposes of such sections), section 1814(f)(2), and subsection (i) of this section, such term includes any institution which (i) meets the requirements of paragraphs (5) and (7) of this subsection, (ii) is not primarily engaged in providing the services described in section 1861(j)(1)(A) and (iii) is primarily engaged in providing, by or under the supervision of individuals referred to in paragraph (1) of section 1861(r), to inpatients diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. For purposes of section 1814(f)(1), such term includes an institution which (i) is a hospital for purposes of sections 1814(d), 1814(f)(2), and 1835(b) and (ii) is accredited by a national accreditation body recognized by the Secretary under section 1865(a), or is accredited by or approved by a program of the country in which such institution is located if the Secretary finds the accreditation or comparable approval standards of such program to be essentially equivalent to those of such a national accreditation body.. Notwithstanding the preceding provisions of this subsection, such term shall not, except for purposes of subsection (a)(2), include any institution which is primarily for the care and treatment of mental diseases unless it is a psychiatric hospital (as defined in subsection (f)). The term "hospital" also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only with respect to items and services ordinarily furnished by such institution to inpatients, and payment may be made with respect to services provided by or in such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1821. For provisions deeming certain requirements of this subsection to be met in the case of accredited institutions, see section 1865. The term "hospital" also includes a facility of fifty beds or less which is located in an area determined by the Secretary to meet the definition relating to a rural area described in subparagraph (A) of paragraph (5) of this subsection and which meets the other requirements of this subsection, except that—

(A) with respect to the requirements for nursing services applicable after December 31, 1978, such requirements shall provide for temporary waiver of the requirements, for such period as the Secretary deems appropriate, where (i) the facility's failure to fully comply with the requirements is attributable to a temporary shortage of qualified nursing personnel in the area in which the facility is located, (ii) a registered professional nurse is present on the premises to render or supervise the nursing service provided during at least the regular daytime shift, and (iii) the Secretary determines that the employment of such nursing personnel as are available to the facility during such temporary period will not adversely affect the health and safety of patients;

(B) with respect to the health and safety requirements promulgated under paragraph (9), such requirements shall be applied by the Secretary to a facility herein defined in such manner as to assure that personnel requirements take into account the availability of technical personnel and the educational opportunities for technical personnel in the area in which such facility is located, and the scope of services rendered by such facility; and the Secretary, by regulations, shall provide for the continued participation of such a facility where such personnel requirements are not fully met, for such period as the Secretary determines that (i) the facility is making good faith efforts to fully comply with the personnel requirements, (ii) the employment by the facility of such personnel as are available to the facility will not adversely affect the health and safety of patients, and (iii) if the Secretary has determined that because of the facility's waiver under this subparagraph the facility should limit its scope of services in order not to adversely affect the health and safety of the facility's patients, the facility is so limiting the scope of services it provides; and

(C) with respect to the fire and safety requirements promulgated under paragraph (9), the Secretary (i) may waive, for such period as he deems appropriate, specific provisions of such requirements which if rigidly applied would result in unreasonable hardship for such a facility and which, if not applied, would not jeopardize the health and safety of patients, and (ii) may accept a facility's compliance with all applicable State codes relating to fire and safety in lieu of compliance with the fire and safety requirements promulgated under paragraph (9), if he

determines that such State has in effect fire and safety codes, imposed by State law, which adequately protect patients.

The term "hospital" does not include, unless the context otherwise requires, a critical access hospital (as defined in section 1861(mm)(1)).

Psychiatric Hospital

(f) The term "psychiatric hospital" means an institution which—

(1) is primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons;

(2) satisfies the requirements of paragraphs (3) through (9) of subsection (e);

(3) maintains clinical records on all patients and maintains such records as the Secretary finds to be necessary to determine the degree and intensity of the treatment provided to individuals entitled to hospital insurance benefits under part A; and

(4) meets such staffing requirements as the Secretary finds necessary for the institution to carry out an active program of treatment for individuals who are furnished services in the institution.

In the case of an institution which satisfies paragraphs (1) and (2) of the preceding sentence and which contains a distinct part which also satisfies paragraphs (3) and (4) of such sentence, such distinct part shall be considered to be a "psychiatric hospital".

Outpatient Occupational Therapy Services

(g) The term "outpatient occupational therapy services" has the meaning given the term "outpatient physical therapy services" in subsection (p), except that "occupational" shall be substituted for "physical" each place it appears therein.

Extended Care Services

(h) The term "extended care services" means the following items and services furnished to an inpatient of a skilled nursing facility and (except as provided in paragraphs (3), (6) and (7)) by such skilled nursing facility—

(1) nursing care provided by or under the supervision of a registered professional nurse;

(2) bed and board in connection with the furnishing of such nursing care;

(3) physical or occupational therapy or speech-language pathology services furnished by the skilled nursing facility or by others under arrangements with them made by the facility;

(4) medical social services;

(5) such drugs, biologicals, supplies, appliances, and equipment, furnished for use in the skilled nursing facility, as are ordinarily furnished by such facility for the care and treatment of inpatients;

(6) medical services provided by an intern or resident-in- training of a hospital with which the facility has in effect a transfer agreement (meeting the requirements of subsection (l)), under a teaching program of such hospital approved as provided in the last sentence of subsection (b), and other diagnostic or therapeutic services provided by a hospital with which the facility has such an agreement in effect; and

(7) such other services necessary to the health of the patients as are generally provided by skilled nursing facilities, or by others under arrangements with them made by the facility;

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital.

Post-Hospital Extended Care Services

(i) The term "post-hospital extended care services" means extended care services furnished an individual after transfer from a hospital in which he was an inpatient for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer. For purposes of the preceding sentence, items and services shall be deemed to have been furnished to an individual after transfer from a hospital, and he shall be deemed to have been an inpatient in the hospital immediately before transfer therefrom, if he is admitted to the skilled nursing facility (A) within 30 days after discharge from such hospital, or (B) within such time as it would be medically appropriate to begin an active course of treatment, in the case of an individual whose condition is such that skilled nursing facility care would not be medically appropriate within 30 days after discharge

from a hospital; and an individual shall be deemed not to have been discharged from a skilled nursing facility if, within 30 days after discharge therefrom, he is admitted to such facility or any other skilled nursing facility.

Skilled Nursing Facility

(j) The term "skilled nursing facility" has the meaning given such term in section 1819(a).

Utilization Review

(k) A utilization review plan of a hospital or skilled nursing facility shall be considered sufficient if it is applicable to services furnished by the institution to individuals entitled to insurance benefits under this title and if it provides—

(1) for the review, on a sample or other basis, of admissions to the institution, the duration of stays therein, and the professional services (including drugs and biologicals) furnished, (A) with respect to the medical necessity of the services, and (B) for the purpose of promoting the most efficient use of available health facilities and services;

(2) for such review to be made by either (A) a staff committee of the institution composed of two or more physicians (of which at least two must be physicians described in subsection (r)(1) of this section), with or without participation of other professional personnel, or (B) a group outside the institution which is similarly composed and (i) which is established by the local medical society and some or all of the hospitals and skilled nursing facilities in the locality, or (ii) if (and for as long as) there has not been established such a group which serves such institution, which is established in such other manner as may be approved by the Secretary;

(3) for such review, in each case of inpatient hospital services or extended care services furnished to such an individual during a continuous period of extended duration, as of such days of such period (which may differ for different classes of cases) as may be specified in regulations, with such review to be made as promptly as possible, after each day so specified, and in no event later than one week following such day; and

(4) for prompt notification to the institution, the individual, and his attending physician of any finding (made after opportunity for consultation to such attending physician) by the physician members of such committee or group that any further stay in the institution is not medically necessary.

The review committee must be composed as provided in clause (B) of paragraph (2) rather than as provided in clause (A) of such paragraph in the case of any hospital or skilled nursing facility where, because of the small size of the institution, or (in the case of a skilled nursing facility) because of lack of an organized medical staff, or for such other reason or reasons as may be included in regulations, it is impracticable for the institution to have a properly functioning staff committee for the purposes of this subsection. If the Secretary determines that the utilization review procedures established pursuant to title XIX are superior in their effectiveness to the procedures required under this section, he may, to the extent that he deems it appropriate, require for purposes of this title that the procedures established pursuant to title XIX be utilized instead of the procedures required by this section.

Agreements for Transfer Between Skilled Nursing Facilities and Hospitals

(l) A hospital and a skilled nursing facility shall be considered to have a transfer agreement in effect if, by reason of a written agreement between them or (in case the two institutions are under common control) by reason of a written undertaking by the person or body which controls them, there is reasonable assurance that—

(1) transfer of patients will be effected between the hospital and the skilled nursing facility whenever such transfer is medically appropriate as determined by the attending physician; and

(2) there will be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between the institutions, or in determining whether such individuals can be adequately cared for otherwise than in either of such institutions.

Any skilled nursing facility which does not have such an agreement in effect, but which is found by a State agency (of the State in which such facility is situated) with which an agreement under section 1864 is in effect (or, in the case of a State in which no such agency has an agreement under

section 1864, by the Secretary) to have attempted in good faith to enter into such an agreement with a hospital sufficiently close to the facility to make feasible the transfer between them of patients and the information referred to in paragraph (2), shall be considered to have such an agreement in effect if and for so long as such agency (or the Secretary, as the case may be) finds that to do so is in the public interest and essential to assuring extended care services for persons in the community who are eligible for payments with respect to such services under this title.

Home Health Services

(m) The term "home health services" means the following items and services furnished to an individual, who is under the care of a physician, by a home health agency or by others under arrangements with them made by such agency, under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician, which items and services are, except as provided in paragraph (7), provided on a visiting basis in a place of residence used as such individual's home—

(1) part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse;

(2) physical or occupational therapy or speech-language pathology services;

(3) medical social services under the direction of a physician;

(4) to the extent permitted in regulations, part-time or intermittent services of a home health aide who has successfully completed a training program approved by the Secretary;

(5) medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and a covered osteoporosis drug (as defined in subsection (kk)), but excluding other drugs and biologicals) and durable medical equipment and applicable disposable devices (as defined in section 1834(s)(2)) while under such a plan;

(6) in the case of a home health agency which is affiliated or under common control with a hospital, medical services provided by an intern or resident-in-training of such hospital, under a teaching program of such hospital approved as provided in the last sentence of subsection (b); and

(7) any of the foregoing items and services which are provided on an outpatient basis, under arrangements made by the home health agency, at a hospital or skilled nursing facility, or at a rehabilitation center which meets such standards as may be prescribed in regulations, and—

(A) the furnishing of which involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual in such place of residence, or

(B) which are furnished at such facility while he is there to receive any such item or service described in clause (A),

but not including transportation of the individual in connection with any such item or service; excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital and home infusion therapy (as defined in subsection (iii)(i)). For purposes of paragraphs (1) and (4), the term "part-time or intermittent services" means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week). For purposes of sections 1814(a)(2)(C) and 1835(a)(2)(A), "intermittent" means skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).

Durable Medical Equipment

(n) The term "durable medical equipment" includes iron lungs, oxygen tents, hospital beds, and wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient's home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1819(a)(1)), whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the indi-

vidual has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations) and eye tracking and gaze interaction accessories for speech generating devices furnished to individuals with a demonstrated medical need for such accessories; except that such term does not include such equipment furnished by a supplier who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment. With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.

Home Health Agency

(o) The term "home health agency" means a public agency or private organization, or a subdivision of such an agency or organization, which—

(1) is primarily engaged in providing skilled nursing services and other therapeutic services;

(2) has policies, established by a group of professional personnel (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services (referred to in paragraph (1)) which it provides, and provides for supervision of such services by a physician or registered professional nurse;

(3) maintains clinical records on all patients;

(4) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing;

(5) has in effect an overall plan and budget that meets the requirements of subsection (z);

(6) meets the conditions of participation specified in section 1891(a) and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization;

(7) provides the Secretary with a surety bond—

(A) in a form specified by the Secretary and in an amount that is not less than the minimum of $50,000; and

(B) that the Secretary determines is commensurate with the volume of payments to the home health agency; and

(8) meets such additional requirements (including conditions relating to bonding or establishing of escrow accounts as the Secretary finds necessary for the financial security of the program) as the Secretary finds necessary for the effective and efficient operation of the program;

except that for purposes of part A such term shall not include any agency or organization which is primarily for the care and treatment of mental diseases. The Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law.

Outpatient Physical Therapy Services

(p) The term "outpatient physical therapy services" means physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient—

(1) who is under the care of a physician (as defined in paragraph (1), (3), or (4) of section 1861(r)), and

(2) with respect to whom a plan prescribing the type, amount, and duration of physical therapy services that are to be furnished such individual has been established by a physician (as so defined) or by a qualified physical therapist and is periodically reviewed by a physician (as so defined);

excluding, however—

(3) any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital; and

(4) any such service—

(A) if furnished by a clinic or rehabilitation agency, or by others under arrangements with such clinic or agency, unless such clinic or rehabilitation agency—

(i) provides an adequate program of physical therapy services for outpatients and has the facilities and personnel required for such program or required for the supervision of such a program, in accordance with such requirements as the Secretary may specify,

(ii) has policies, established by a group of professional personnel, including one or more physicians (associated with the clinic or rehabilitation agency) and one or more qualified physical therapists, to govern the services (referred to in clause (i)) it provides,

(iii) maintains clinical records on all patients,

(iv) if such clinic or agency is situated in a State in which State or applicable local law provides for the licensing of institutions of this nature, (I) is licensed pursuant to such law, or (II) is approved by the agency of such State or locality responsible for licensing institutions of this nature, as meeting the standards established for such licensing; and

(v) meets such other conditions relating to the health and safety of individuals who are furnished services by such clinic or agency on an outpatient basis, as the Secretary may find necessary, and provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000, or

(B) if furnished by a public health agency, unless such agency meets such other conditions relating to health and safety of individuals who are furnished services by such agency on an outpatient basis, as the Secretary may find necessary.

The term "outpatient physical therapy services" also includes physical therapy services furnished an individual by a physical therapist (in his office or in such individual's home) who meets licensing and other standards prescribed by the Secretary in regulations, otherwise than under an arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary. In addition, such term includes physical therapy services which meet the requirements of the first sentence of this subsection except that they are furnished to an individual as an inpatient of a hospital or extended care facility. Nothing in this subsection shall be construed as requiring, with respect to outpatients who are not entitled to benefits under this title, a physical therapist to provide outpatient physical therapy services only to outpatients who are under the care of a physician or pursuant to a plan of care established by a physician. The Secretary may waive the requirement of a surety bond under paragraph (4)(A)(v) in the case of a clinic or agency that provides a comparable surety bond under State law.

Physicians' Services

(q) The term "physicians' services" means professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls (but not including services described in subsection (b)(6)).

Physician

(r) The term "physician", when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7)), (2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (3) a doctor of podiatric medicine for the purposes of subsections (k), (m), (p)(1), and (s) of this section and sections 1814(a), 1832(a)(2)(F)(ii), and 1835 but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them, (4) a doctor of optometry, but only for purposes of subsection (p)(1) and with respect to the provision of items or services described in subsection (s) which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or (5) a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of sections 1861(s)(1) and 1861(s)(2)(A) and only with respect to treatment by means of manual manipulation of the spine

(to correct a subluxation) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided. For the purposes of section 1862(a)(4) and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to practice such art in the country in which the inpatient hospital services (referred to in such section 1862(a)(4)) are furnished.

Medical and Other Health Services

(s) The term "medical and other health services" means any of the following items or services:

(1) physicians' services;

(2)(A) services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills (or would have been so included but for the application of section 1847B);

(B) hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services;

(C) diagnostic services which are—

(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and

(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;

(D) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services;

(E) rural health clinic services and Federally qualified health center services;

(F) home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies, and, for items and services furnished on or after January 1, 2011, renal dialysis services (as defined in section 1881(b)(14)(B)), including such renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or provider of services paid under section 1881(b)(14) to an individual with acute kidney injury (as defined in section 1834(r)(2));

(G) antigens (subject to quantity limitations prescribed in regulations by the Secretary) prepared by a physician, as defined in section 1861(r)(1), for a particular patient, including antigens so prepared which are forwarded to another qualified person (including a rural health clinic) for administration to such patient, from time to time, by or under the supervision of another such physician;

(H)(i) services furnished pursuant to a contract under section 1876 to a member of an eligible organization by a physician assistant or by a nurse practitioner (as defined in subsection (aa)(5)) and such services and supplies furnished as an incident to his service to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service; and

(ii) services furnished pursuant to a risk-sharing contract under section 1876(g) to a member of an eligible organization by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(2)), and such services and supplies furnished as an incident to such clinical psychologist's services or clinical social worker's services to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service;

(I) blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors, subject to utilization controls deemed necessary by the Secretary for the efficient use of such factors;

(J) prescription drugs used in immunosuppressive therapy furnished, to an individual who receives an organ transplant for which payment is made under this title;

(K)(i) services which would be physicians' services and services described in subsections (ww)(1) and (hhh) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a physician assistant (as defined in subsection (aa)(5)) under the supervision of a physician (as so defined) and which the physician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished

as incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services,

(ii) services which would be physicians' services and services described in subsections (ww)(1) and (hhh) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in subsection (aa)(5)) working in collaboration (as defined in subsection (aa)(6)) with a physician (as defined in subsection (r)(1)) which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;

(L) certified nurse-midwife services;

(M) qualified psychologist services;

(N) clinical social worker services (as defined in subsection (hh)(2));

(O) erythropoietin for dialysis patients competent to use such drug without medical or other supervision with respect to the administration of such drug, subject to methods and standards established by the Secretary by regulation for the safe and effective use of such drug, and items related to the administration of such drug;

(P) prostate cancer screening tests (as defined in subsection (oo));

(Q) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an anticancer chemotherapeutic agent for a given indication, and containing an active ingredient (or ingredients), which is the same indication and active ingredient (or ingredients) as a drug which the carrier determines would be covered pursuant to subparagraph (A) or (B) if the drug could not be self-administered;

(R) colorectal cancer screening tests (as defined in subsection (pp));

(S) diabetes outpatient self-management training services (as defined in subsection (qq));

(T) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an acute anti-emetic used as part of an anticancer chemotherapeutic regimen if the drug is administered by a physician (or as prescribed by a physician)—

(i) for use immediately before, at, or within 48 hours after the time of the administration of the anticancer chemotherapeutic agent; and

(ii) as a full replacement for the anti-emetic therapy which would otherwise be administered intravenously;

(U) screening for glaucoma (as defined in subsection (uu)) for individuals determined to be at high risk for glaucoma, individuals with a family history of glaucoma and individuals with diabetes;

(V) medical nutrition therapy services (as defined in subsection (vv)(1)) in the case of a beneficiary with diabetes or a renal disease who—

(i) has not received diabetes outpatient self-management training services within a time period determined by the Secretary;

(ii) is not receiving maintenance dialysis for which payment is made under section 1881; and

(iii) meets such other criteria determined by the Secretary after consideration of protocols established by dietitian or nutrition professional organizations;

(W) an initial preventive physical examination (as defined in subsection (ww));

(X) cardiovascular screening blood tests (as defined in subsection (xx)(1));

(Y) diabetes screening tests (as defined in subsection (yy));

(Z) intravenous immune globulin for the treatment of primary immune deficiency diseases in the home (as defined in subsection (zz));

(AA) ultrasound screening for abdominal aortic aneurysm (as defined in subsection (bbb)) for an individual—

(i) who receives a referral for such an ultrasound screening as a result of an initial preventive physical examination (as defined in section 1861(ww)(1));

(ii) who has not been previously furnished such an ultrasound screening under this title; and

(iii) who—

(I) has a family history of abdominal aortic aneurysm; or

(II) manifests risk factors included in a beneficiary category recommended for screening by the United States Preventive Services Task Force regarding abdominal aortic aneurysms;

(BB) additional preventive services (described in subsection (ddd)(1));

(CC) items and services furnished under a cardiac rehabilitation program (as defined in subsection (eee)(1)) or under a pulmonary rehabilitation program (as defined in subsection (fff)(1));

(DD) items and services furnished under an intensive cardiac rehabilitation program (as defined in subsection (eee)(4));

(EE) kidney disease education services (as defined in subsection (ggg));

(FF) personalized prevention plan services (as defined in subsection (hhh)); [and]

(GG) home infusion therapy (as defined in subsection (iii)(1));*; and*

*(HH) opioid use disorder treatment services (as defined in subsection (jjj))*.

(3) diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act), diagnostic laboratory tests, and other diagnostic tests;

(4) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;

(5) surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;

(6) durable medical equipment;

(7) ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but, subject to section 1834(l)(14), only to the extent provided in regulations;

(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens;

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;

(10)(A) pneumococcal vaccine and its administration and, subject to section 4071(b) of the Omnibus Budget Reconciliation Act of 1987, influenza vaccine and its administration; and

(B) hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations);

(11) services of a certified registered nurse anesthetist (as defined in subsection (bb));

(12) subject to section 4072(e) of the Omnibus Budget Reconciliation Act of 1987, extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes, if—

(A) the physician who is managing the individual's diabetic condition (i) documents that the individual has peripheral neuropathy with evidence of callus formation, a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor circulation, and (ii) certifies that the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition;

(B) the particular type of shoes are prescribed by a podiatrist or other qualified physician (as established by the Secretary); and

(C) the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary) who is not the physician described in subparagraph (A) (unless the Secretary finds that the physician is the only such qualified individual in the area);

(13) screening mammography (as defined in subsection (jj));

(14) screening pap smear and screening pelvic exam; and

(15) bone mass measurement (as defined in subsection (rr)).

No diagnostic tests performed in any laboratory, including a laboratory that is part of a rural health clinic, or a hospital (which, for purposes of this sentence, means an institution considered

a hospital for purposes of section 1814(d)) shall be included within paragraph (3) unless such laboratory—

(16) if situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing; and

(17)(A) meets the certification requirements under section 353 of the Public Health Service Act; and

(B) meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.

There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which would not be included under subsection (b) if it were furnished to an inpatient of a hospital. None of the items and services referred to in the preceding paragraphs (other than paragraphs (1) and (2)(A)) of this subsection which are furnished to a patient of an institution which meets the definition of a hospital for purposes of section 1814(d) shall be included unless such other conditions are met as the Secretary may find necessary relating to health and safety of individuals with respect to whom such items and services are furnished.

Drugs and Biologicals

(t)(1) The term "drugs" and the term "biologicals", except for purposes of subsection (m)(5) and paragraph (2), include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.

(2)(A) For purposes of paragraph (1), the term "drugs" also includes any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication (as described in subparagraph (B)).

(B) In subparagraph (A), the term "medically accepted indication", with respect to the use of a drug, includes any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if—

(i) the drug has been approved by the Food and Drug Administration; and

(ii)(I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information (or its successor publications), and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or

(II) the carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary.

The Secretary may revise the list of compendia in clause (ii)(I) as is appropriate for identifying medically accepted indications for drugs. On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.

Provider of Services

(u) The term "provider of services" means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1814(g) and section 1835(e), a fund.

Reasonable Cost

(v)(1)(A) The reasonable cost of any services shall be the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs for various types or classes of institutions, agencies, and services; except that in any case to which paragraph (2) or (3) applies, the amount of the payment determined under such paragraph with respect to the services involved shall be considered the reasonable cost of such services. In prescribing the regulations referred to in the preceding sentence, the Secretary shall consider, among other things, the principles generally applied by national organizations or established prepayment organizations (which have developed such principles) in computing the amount of payment, to be made by persons other than the recipients of services, to providers of services on account of services furnished to such recipients by such providers. Such regulations may provide for determination of the costs of services on a per diem, per unit, per capita, or other basis, may provide for using different methods in different circumstances, may provide for the use of estimates of costs of particular items or services, may provide for the establishment of limits on the direct or indirect overall incurred costs or incurred costs of specific items or services or groups of items or services to be recognized as reasonable based on estimates of the costs necessary in the efficient delivery of needed health services to individuals covered by the insurance programs established under this title, and may provide for the use of charges or a percentage of charges where this method reasonably reflects the costs. Such regulations shall (i) take into account both direct and indirect costs of providers of services (excluding therefrom any such costs, including standby costs, which are determined in accordance with regulations to be unnecessary in the efficient delivery of services covered by the insurance programs established under this title) in order that, under the methods of determining costs, the necessary costs of efficiently delivering covered services to individuals covered by the insurance programs established by this title will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by such insurance programs, and (ii) provide for the making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive.

(B) In the case of extended care services, the regulations under subparagraph (A) shall not include provision for specific recognition of a return on equity capital.

(C) Where a hospital has an arrangement with a medical school under which the faculty of such school provides services at such hospital, an amount not in excess of the reasonable cost of such services to the medical school shall be included in determining the reasonable cost to the hospital of furnishing services—

(i) for which payment may be made under part A, but only if—

(I) payment for such services as furnished under such arrangement would be made under part A to the hospital had such services been furnished by the hospital, and

(II) such hospital pays to the medical school at least the reasonable cost of such services to the medical school, or

(ii) for which payment may be made under part B, but only if such hospital pays to the medical school at least the reasonable cost of such services to the medical school.

(D) Where (i) physicians furnish services which are either inpatient hospital services (including services in conjunction with the teaching programs of such hospital) by reason of paragraph (7) of subsection (b) or for which entitlement exists by reason of clause (II) of section 1832(a)(2)(B)(i), and (ii) such hospital (or medical school under arrangement with such hospital) incurs no actual cost in the furnishing of such services, the reasonable cost of such services shall (under regulations of the Secretary) be deemed to be the cost such hospital or medical school would have incurred had it paid a salary to such physicians rendering such services approximately equivalent to the average salary paid to all physicians employed by such hospital (or if such employment does not exist, or is minimal in such hospital, by similar hospitals in a geographic area of sufficient size to assure reasonable inclusion of sufficient physicians in development of such average salary).

(E) Such regulations may, in the case of skilled nursing facilities in any State, provide for the use of rates, developed by the State in which such facilities are located, for the payment of the cost of skilled nursing facility services furnished under the State's plan approved under title XIX (and such rates may be increased by the Secretary on a class or size of institution or on a geographical basis by a percentage factor not in excess of 10 percent to take into account determinable

items or services or other requirements under this title not otherwise included in the computation of such State rates), if the Secretary finds that such rates are reasonably related to (but not necessarily limited to) analyses undertaken by such State of costs of care in comparable facilities in such State. Notwithstanding the previous sentence, such regulations with respect to skilled nursing facilities shall take into account (in a manner consistent with subparagraph (A) and based on patient-days of services furnished) the costs (including the costs of services required to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident eligible for benefits under this title) of such facilities complying with the requirements of subsections (b), (c), and (d) of section 1819 (including the costs of conducting nurse aide training and competency evaluation programs and competency evaluation programs).

(F) Such regulations shall require each provider of services (other than a fund) to make reports to the Secretary of information described in section 1121(a) in accordance with the uniform reporting system (established under such section) for that type of provider.

(G)(i) In any case in which a hospital provides inpatient services to an individual that would constitute post-hospital extended care services if provided by a skilled nursing facility and a quality improvement organization (or, in the absence of such a qualified organization, the Secretary or such agent as the Secretary may designate) determines that inpatient hospital services for the individual are not medically necessary but post-hospital extended care services for the individual are medically necessary and such extended care services are not otherwise available to the individual (as determined in accordance with criteria established by the Secretary) at the time of such determination, payment for such services provided to the individual shall continue to be made under this title at the payment rate described in clause (ii) during the period in which—

(I) such post-hospital extended care services for the individual are medically necessary and not otherwise available to the individual (as so determined),

(II) inpatient hospital services for the individual are not medically necessary, and

(III) the individual is entitled to have payment made for post-hospital extended care services under this title,

except that if the Secretary determines that there is not an excess of hospital beds in such hospital and (subject to clause (iv)) there is not an excess of hospital beds in the area of such hospital, such payment shall be made (during such period) on the basis of the amount otherwise payable under part A with respect to inpatient hospital services.

(ii)(I) Except as provided in subclause (II), the payment rate referred to in clause (i) is a rate equal to the estimated adjusted State-wide average rate per patient-day paid for services provided in skilled nursing facilities under the State plan approved under title XIX for the State in which such hospital is located, or, if the State in which the hospital is located does not have a State plan approved under title XIX, the estimated adjusted State-wide average allowable costs per patient-day for extended care services under this title in that State.

(II) If a hospital has a unit which is a skilled nursing facility, the payment rate referred to in clause (i) for the hospital is a rate equal to the lesser of the rate described in subclause (I) or the allowable costs in effect under this title for extended care services provided to patients of such unit.

(iii) Any day on which an individual receives inpatient services for which payment is made under this subparagraph shall, for purposes of this Act (other than this subparagraph), be deemed to be a day on which the individual received inpatient hospital services.

(iv) In determining under clause (i), in the case of a public hospital, whether or not there is an excess of hospital beds in the area of such hospital, such determination shall be made on the basis of only the public hospitals (including the hospital) which are in the area of the hospital and which are under common ownership with that hospital.

(H) In determining such reasonable cost with respect to home health agencies, the Secretary may not include—

(i) any costs incurred in connection with bonding or establishing an escrow account by any such agency as a result of the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8);

(ii) in the case of home health agencies to which the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8) apply, any costs attributed to interest charged such an agency in connection with amounts borrowed by the agency to repay overpayments made under this title to the agency, except that such costs may be included in reasonable cost if the Secretary determines that the agency was acting in good faith in borrowing the amounts;

(iii) in the case of contracts entered into by a home health agency after the date of the enactment of this subparagraph for the purpose of having services furnished for or on behalf of such agency, any cost incurred by such agency pursuant to any such contract which is entered into for a period exceeding five years; and

(iv) in the case of contracts entered into by a home health agency before the date of the enactment of this subparagraph for the purpose of having services furnished for or on behalf of such agency, any cost incurred by such agency pursuant to any such contract, which determines the amount payable by the home health agency on the basis of a percentage of the agency's reimbursement or claim for reimbursement for services furnished by the agency, to the extent that such cost exceeds the reasonable value of the services furnished on behalf of such agency.

(I) In determining such reasonable cost, the Secretary may not include any costs incurred by a provider with respect to any services furnished in connection with matters for which payment may be made under this title and furnished pursuant to a contract between the provider and any of its subcontractors which is entered into after the date of the enactment of this subparagraph and the value or cost of which is $10,000 or more over a twelve-month period unless the contract contains a clause to the effect that—

(i) until the expiration of four years after the furnishing of such services pursuant to such contract, the subcontractor shall make available, upon written request by the Secretary, or upon request by the Comptroller General, or any of their duly authorized representatives, the contract, and books, documents and records of such subcontractor that are necessary to certify the nature and extent of such costs, and

(ii) if the subcontractor carries out any of the duties of the contract through a subcontract, with a value or cost of $10,000 or more over a twelve-month period, with a related organization, such subcontract shall contain a clause to the effect that until the expiration of four years after the furnishing of such services pursuant to such subcontract, the related organization shall make available, upon written request by the Secretary, or upon request by the Comptroller General, or any of their duly authorized representatives, the subcontract, and books, documents and records of such organization that are necessary to verify the nature and extent of such costs.

The Secretary shall prescribe in regulation criteria and procedures which the Secretary shall use in obtaining access to books, documents, and records under clauses required in contracts and subcontracts under this subparagraph.

(J) Such regulations may not provide for any inpatient routine salary cost differential as a reimbursable cost for hospitals and skilled nursing facilities.

(K)(i) The Secretary shall issue regulations that provide, to the extent feasible, for the establishment of limitations on the amount of any costs or charges that shall be considered reasonable with respect to services provided on an outpatient basis by hospitals (other than bona fide emergency services as defined in clause (ii)) or clinics (other than rural health clinics), which are reimbursed on a cost basis or on the basis of cost related charges, and by physicians utilizing such outpatient facilities. Such limitations shall be reasonably related to the charges in the same area for similar services provided in physicians' offices. Such regulations shall provide for exceptions to such limitations in cases where similar services are not generally available in physicians' offices in the area to individuals entitled to benefits under this title.

(ii) For purposes of clause (i), the term "bona fide emergency services" means services provided in a hospital emergency room after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(I) placing the patient's health in serious jeopardy;

(II) serious impairment to bodily functions; or

(III) serious dysfunction of any bodily organ or part.

(L)(i) The Secretary, in determining the amount of the payments that may be made under this title with respect to services furnished by home health agencies, may not recognize as reasonable (in the efficient delivery of such services) costs for the provision of such services by an agency to the extent these costs exceed (on the aggregate for the agency) for cost reporting periods beginning on or after—

(I) July 1, 1985, and before July 1, 1986, 120 percent of the mean of the labor-related and nonlabor per visit costs for freestanding home health agencies,

(II) July 1, 1986, and before July 1, 1987, 115 percent of such mean,

(III) July 1, 1987, and before October 1, 1997, 112 percent of such mean,

(IV) October 1, 1997, and before October 1, 1998, 105 percent of the median of the labor-related and nonlabor per visit costs for freestanding home health agencies, or

(V) October 1, 1998, 106 percent of such median.

(ii) Effective for cost reporting periods beginning on or after July 1, 1986, such limitations shall be applied on an aggregate basis for the agency, rather than on a discipline specific basis. The Secretary may provide for such exemptions and exceptions to such limitation as he deems appropriate.

(iii) Not later than July 1, 1991, and annually thereafter (but not for cost reporting periods beginning on or after July 1, 1994, and before July 1, 1996, or on or after July 1, 1997, and before October 1, 1997), the Secretary shall establish limits under this subparagraph for cost reporting periods beginning on or after such date by utilizing the area wage index applicable under section 1886(d)(3)(E) and determined using the survey of the most recent available wages and wage-related costs of hospitals located in the geographic area in which the home health service is furnished (determined without regard to whether such hospitals have been reclassified to a new geographic area pursuant to section 1886(d)(8)(B), a decision of the Medicare Geographic Classification Review Board under section 1886(d)(10), or a decision of the Secretary).

(iv) In establishing limits under this subparagraph for cost reporting periods beginning after September 30, 1997, the Secretary shall not take into account any changes in the home health market basket, as determined by the Secretary, with respect to cost reporting periods which began on or after July 1, 1994, and before July 1, 1996.

(v) For services furnished by home health agencies for cost reporting periods beginning on or after October 1, 1997, subject to clause (viii)(I), the Secretary shall provide for an interim system of limits. Payment shall not exceed the costs determined under the preceding provisions of this subparagraph or, if lower, the product of—

(I) an agency-specific per beneficiary annual limitation calculated based 75 percent on 98 percent of the reasonable costs (including nonroutine medical supplies) for the agency's 12-month cost reporting period ending during fiscal year 1994, and based 25 percent on 98 percent of the standardized regional average of such costs for the agency's census division, as applied to such agency, for cost reporting periods ending during fiscal year 1994, such costs updated by the home health market basket index; and

(II) the agency's unduplicated census count of patients (entitled to benefits under this title) for the cost reporting period subject to the limitation.

(vi) For services furnished by home health agencies for cost reporting periods beginning on or after October 1, 1997, the following rules apply:

(I) For new providers and those providers without a 12-month cost reporting period ending in fiscal year 1994 subject to clauses (viii)(II) and (viii)(III), the per beneficiary limitation shall be equal to the median of these limits (or the Secretary's best estimates thereof) applied to other home health agencies as determined by the Secretary. A home health agency that has altered its corporate structure or name shall not be considered a new provider for this purpose.

(II) For beneficiaries who use services furnished by more than one home health agency, the per beneficiary limitations shall be prorated among the agencies.

(vii)(I) Not later than January 1, 1998, the Secretary shall establish per visit limits applicable for fiscal year 1998, and not later than April 1, 1998, the Secretary shall establish per beneficiary limits under clause (v)(I) for fiscal year 1998.

(II) Not later than August 1 of each year (beginning in 1998) the Secretary shall establish the limits applicable under this subparagraph for services furnished during the fiscal year beginning October 1 of the year.

(viii)(I) In the case of a provider with a 12-month cost reporting period ending in fiscal year 1994, if the limit imposed under clause (v) (determined without regard to this subclause) for a cost reporting period beginning during or after fiscal year 1999 is less than the median described in clause (vi)(I) (but determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent"), the limit otherwise imposed under clause (v) for such provider and period shall be increased by ⅓ of such difference.

(II) Subject to subclause (IV), for new providers and those providers without a 12-month cost reporting period ending in fiscal year 1994, but for which the first cost reporting period begins before fiscal year 1999, for cost reporting periods beginning during or after fiscal year 1999, the per beneficiary limitation described in clause (vi)(I) shall be equal to the median described in such clause (determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent").

(III) Subject to subclause (IV), in the case of a new provider for which the first cost reporting period begins during or after fiscal year 1999, the limitation applied under clause (vi)(I) (but only with respect to such provider) shall be equal to 75 percent of the median described in clause (vi)(I).

(IV) In the case of a new provider or a provider without a 12-month cost reporting period ending in fiscal year 1994, subclause (II) shall apply, instead of subclause (III), to a home health agency which filed an application for home health agency provider status under this title before September 15, 1998, or which was approved as a branch of its parent agency before such date and becomes a subunit of the parent agency or a separate agency on or after such date.

(V) Each of the amounts specified in subclauses (I) through (III) are such amounts as adjusted under clause (iii) to reflect variations in wages among different areas.

(ix) Notwithstanding the per beneficiary limit under clause (viii), if the limit imposed under clause (v) (determined without regard to this clause) for a cost reporting period beginning during or after fiscal year 2000 is less than the median described in clause (vi)(I) (but determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent"), the limit otherwise imposed under clause (v) for such provider and period shall be increased by 2 percent.

(x) Notwithstanding any other provision of this subparagraph, in updating any limit under this subparagraph by a home health market basket index for cost reporting periods beginning during each of fiscal years 2000, 2002, and 2003, the update otherwise provided shall be reduced by 1.1 percentage points. With respect to cost reporting periods beginning during fiscal year 2001, the update to any limit under this subparagraph shall be the home health market basket index.

(M) Such regulations shall provide that costs respecting care provided by a provider of services, pursuant to an assurance under title VI or XVI of the Public Health Service Act that the provider will make available a reasonable volume of services to persons unable to pay therefor, shall not be allowable as reasonable costs.

(N) In determining such reasonable costs, costs incurred for activities directly related to influencing employees respecting unionization may not be included.

(O)(i) In establishing an appropriate allowance for depreciation and for interest on capital indebtedness with respect to an asset of a provider of services which has undergone a change of ownership, such regulations shall provide, except as provided in clause (iii), that the valuation of the asset after such change of ownership shall be the historical cost of the asset, as recognized under this title, less depreciation allowed, to the owner of record as of the date of enactment of the Balanced Budget Act of 1997 (or, in the case of an asset not in existence as of that date, the first owner of record of the asset after that date).

(ii) Such regulations shall not recognize, as reasonable in the provision of health care services, costs (including legal fees, accounting and administrative costs, travel costs, and the costs of feasibility studies) attributable to the negotiation or settlement of the sale or purchase of any capital asset (by acquisition or merger) for which any payment has previously been made under this title.

(iii) In the case of the transfer of a hospital from ownership by a State to ownership by a nonprofit corporation without monetary consideration, the basis for capital allowances to the new owner shall be the book value of the hospital to the State at the time of the transfer.

(P) If such regulations provide for the payment for a return on equity capital (other than with respect to costs of inpatient hospital services), the rate of return to be recognized, for determining the reasonable cost of services furnished in a cost reporting period, shall be equal to the average of the rates of interest, for each of the months any part of which is included in the period, on obligations issued for purchase by the Federal Hospital Insurance Trust Fund.

(Q) Except as otherwise explicitly authorized, the Secretary is not authorized to limit the rate of increase on allowable costs of approved medical educational activities.

(R) In determining such reasonable cost, costs incurred by a provider of services representing a beneficiary in an unsuccessful appeal of a determination described in section 1869(b) shall not be allowable as reasonable costs.

(S)(i) Such regulations shall not include provision for specific recognition of any return on equity capital with respect to hospital outpatient departments.

(ii)(I) Such regulations shall provide that, in determining the amount of the payments that may be made under this title with respect to all the capital-related costs of outpatient hospital services, the Secretary shall reduce the amounts of such payments otherwise established under this title by 15 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1990, by 15 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1991, and by 10 percent for payments attributable to portions of cost report-

ing periods occurring during fiscal years 1992 through 1999 and until the first date that the prospective payment system under section 1833(t) is implemented.

(II) The Secretary shall reduce the reasonable cost of outpatient hospital services (other than the capital-related costs of such services) otherwise determined pursuant to section 1833(a)(2)(B)(i)(I) by 5.8 percent for payments attributable to portions of cost reporting periods occurring during fiscal years 1991 through 1999 and until the first date that the prospective payment system under section 1833(t) is implemented.

(III) Subclauses (I) and (II) shall not apply to payments with respect to the costs of hospital outpatient services provided by any hospital that is a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) or a critical access hospital (as defined in section 1861(mm)(1)).

(IV) In applying subclauses (I) and (II) to services for which payment is made on the basis of a blend amount under section 1833(i)(3)(A)(ii) or 1833(n)(1)(A)(ii), the costs reflected in the amounts described in sections 1833(i)(3)(B)(i)(I) and 1833(n)(1)(B)(i)(I), respectively, shall be reduced in accordance with such subclause.

(T) In determining such reasonable costs for hospitals, no reduction in copayments under section 1833(t)(8)(B) shall be treated as a bad debt and the amount of bad debts otherwise treated as allowable costs which are attributable to the deductibles and coinsurance amounts under this title shall be reduced—

(i) for cost reporting periods beginning during fiscal year 1998, by 25 percent of such amount otherwise allowable,

(ii) for cost reporting periods beginning during fiscal year 1999, by 40 percent of such amount otherwise allowable,

(iii) for cost reporting periods beginning during fiscal year 2000, by 45 percent of such amount otherwise allowable,

(iv) for cost reporting periods beginning during fiscal years 2001 through 2012, by 30 percent of such amount otherwise allowable, and

(v) for cost reporting periods beginning during fiscal year 2013 or a subsequent fiscal year, by 35 percent of such amount otherwise allowable.

(U) In determining the reasonable cost of ambulance services (as described in subsection (s)(7)) provided during fiscal year 1998, during fiscal year 1999, and during so much of fiscal year 2000 as precedes January 1, 2000, the Secretary shall not recognize the costs per trip in excess of costs recognized as reasonable for ambulance services provided on a per trip basis during the previous fiscal year (after application of this subparagraph), increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the fiscal year involved reduced by 1.0 percentage point. For ambulance services provided after June 30, 1998, the Secretary may provide that claims for such services must include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(V) In determining such reasonable costs for skilled nursing facilities and (beginning with respect to cost reporting periods beginning during fiscal year 2013) for covered skilled nursing services described in section 1888(e)(2)(A) furnished by hospital providers of extended care services (as described in section 1883), the amount of bad debts otherwise treated as allowed costs which are attributable to the coinsurance amounts under this title for individuals who are entitled to benefits under part A and—

(i) are not described in section 1935(c)(6)(A)(ii) shall be reduced by—

(I) for cost reporting periods beginning on or after October 1, 2005, but before fiscal year 2013, 30 percent of such amount otherwise allowable; and

(II) for cost reporting periods beginning during fiscal year 2013 or a subsequent fiscal year, by 35 percent of such amount otherwise allowable.

(ii) are described in such section—

(I) for cost reporting periods beginning on or after October 1, 2005, but before fiscal year 2013, shall not be reduced;

(II) for cost reporting periods beginning during fiscal year 2013, shall be reduced by 12 percent of such amount otherwise allowable;

(III) for cost reporting periods beginning during fiscal year 2014, shall be reduced by 24 percent of such amount otherwise allowable; and

(IV) for cost reporting periods beginning during a subsequent fiscal year, shall be reduced by 35 percent of such amount otherwise allowable.

(W)(i) In determining such reasonable costs for providers described in clause (ii), the amount of bad debts otherwise treated as allowable costs which are attributable to deductibles and coinsurance amounts under this title shall be reduced—

(I) for cost reporting periods beginning during fiscal year 2013, by 12 percent of such amount otherwise allowable;

(II) for cost reporting periods beginning during fiscal year 2014, by 24 percent of such amount otherwise allowable; and

(III) for cost reporting periods beginning during a subsequent fiscal year, by 35 percent of such amount otherwise allowable.

(ii) A provider described in this clause is a provider of services not described in subparagraph (T) or (V), a supplier, or any other type of entity that receives payment for bad debts under the authority under subparagraph (A).

(2)(A) If the bed and board furnished as part of inpatient hospital services (including inpatient tuberculosis hospital services and inpatient psychiatric hospital services) or post-hospital extended care services is in accommodations more expensive than semi-private accommodations, the amount taken into account for purposes of payment under this title with respect to such services may not exceed the amount that would be taken into account with respect to such services if furnished in such semi-private accommodations unless the more expensive accommodations were required for medical reasons.

(B) Where a provider of services which has an agreement in effect under this title furnishes to an individual items or services which are in excess of or more expensive than the items or services with respect to which payment may be made under part A or part B, as the case may be, the Secretary shall take into account for purposes of payment to such provider of services only the items or services with respect to which such payment may be made.

(3) If the bed and board furnished as part of inpatient hospital services (including inpatient tuberculosis hospital services and inpatient psychiatric hospital services) or post-hospital extended care services is in accommodations other than, but not more expensive than, semi-private accommodations and the use of such other accommodations rather than semi-private accommodations was neither at the request of the patient nor for a reason which the Secretary determines is consistent with the purposes of this title, the amount of the payment with respect to such bed and board under part A shall be the amount otherwise payable under this title for such bed and board furnished in semi-private accommodations minus the difference between the charge customarily made by the hospital or skilled nursing facility for bed and board in semi-private accommodations and the charge customarily made by it for bed and board in the accommodations furnished.

(4) If a provider of services furnishes items or services to an individual which are in excess of or more expensive than the items or services determined to be necessary in the efficient delivery of needed health services and charges are imposed for such more expensive items or services under the authority granted in section 1866(a)(2)(B)(ii), the amount of payment with respect to such items or services otherwise due such provider in any fiscal period shall be reduced to the extent that such payment plus such charges exceed the cost actually incurred for such items or services in the fiscal period in which such charges are imposed.

(5)(A) Where physical therapy services, occupational therapy services, speech therapy services, or other therapy services or services of other health-related personnel (other than physicians) are furnished under an arrangement with a provider of services or other organization, specified in the first sentence of subsection (p) (including through the operation of subsection (g)) the amount included in any payment to such provider or other organization under this title as the reasonable cost of such services (as furnished under such arrangements) shall not exceed an amount equal to the salary which would reasonably have been paid for such services (together with any additional costs that would have been incurred by the provider or other organization) to the person performing them if they had been performed in an employment relationship with such provider or other organization (rather than under such arrangement) plus the cost of such other expenses (including a reasonable allowance for traveltime and other reasonable types of expense related to any differences in acceptable methods of organization for the provision of such therapy) incurred by such person, as the Secretary may in regulations determine to be appropriate.

(B) Notwithstanding the provisions of subparagraph (A), if a provider of services or other organization specified in the first sentence of section 1861(p) requires the services of a therapist on a limited part-time basis, or only to perform intermittent services, the Secretary may make payment on the basis of a reasonable rate per unit of service, even though such rate is greater per unit of time than salary related amounts, where he finds that such greater payment is, in the ag-

gregate, less than the amount that would have been paid if such organization had employed a therapist on a full- or part-time salary basis.

(6) For purposes of this subsection, the term "semi-private accommodations" means two-bed, three-bed, or four-bed accommodations.

(7)(A) For limitation on Federal participation for capital expenditures which are out of conformity with a comprehensive plan of a State or areawide planning agency, see section 1122.

(B) For further limitations on reasonable cost and determination of payment amounts for operating costs of inpatient hospital services and waivers for certain States, see section 1886.

(C) For provisions restricting payment for provider-based physicians' services and for payments under certain percentage arrangements, see section 1887.

(D) For further limitations on reasonable cost and determination of payment amounts for routine service costs of skilled nursing facilities, see subsections (a) through (c) of section 1888.

(8) ITEMS UNRELATED TO PATIENT CARE.—Reasonable costs do not include costs for the following—

(i) entertainment, including tickets to sporting and other entertainment events;

(ii) gifts or donations;

(iii) personal use of motor vehicles;

(iv) costs for fines and penalties resulting from violations of Federal, State, or local laws; and

(v) education expenses for spouses or other dependents of providers of services, their employees or contractors.

Arrangements for Certain Services

(w)(1) The term "arrangements" is limited to arrangements under which receipt of payment by the hospital, critical access hospital, skilled nursing facility, home health agency, or hospice program (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services.

(2) Utilization review activities conducted, in accordance with the requirements of the program established under part B of title XI of the Social Security Act with respect to services furnished by a hospital or critical access hospital to patients insured under part A of this title or entitled to have payment made for such services under part B of this title or under a State plan approved under title XIX, by a quality improvement organization designated for the area in which such hospital or critical access hospital is located shall be deemed to have been conducted pursuant to arrangements between such hospital or critical access hospital and such organization under which such hospital or critical access hospital is obligated to pay to such organization, as a condition of receiving payment for hospital or critical access hospital services so furnished under this part or under such a State plan, such amount as is reasonably incurred and requested (as determined under regulations of the Secretary) by such organization in conducting such review activities with respect to services furnished by such hospital or critical access hospital to such patients.

State and United States

(x) The terms "State" and "United States" have the meaning given to them by subsections (h) and (i), respectively, of section 210.

Extended Care in Religious Nonmedical Health Care Institutions

(y)(1) The term "skilled nursing facility" also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only (except for purposes of subsection (a)(2)) with respect to items and services ordinarily furnished by such an institution to inpatients, and payment may be made with respect to services provided by or in such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1821.

(2) Notwithstanding any other provision of this title, payment under part A may not be made for services furnished an individual in a skilled nursing facility to which paragraph (1) applies unless such individual elects, in accordance with regulations, for a spell of illness to have such serv-

ices treated as post-hospital extended care services for purposes of such part; and payment under part A may not be made for post-hospital extended care services—

(A) furnished an individual during such spell of illness in a skilled nursing facility to which paragraph (1) applies after—

(i) such services have been furnished to him in such a facility for 30 days during such spell, or

(ii) such services have been furnished to him during such spell in a skilled nursing facility to which such paragraph does not apply; or

(B) furnished an individual during such spell of illness in a skilled nursing facility to which paragraph (1) does not apply after such services have been furnished to him during such spell in a skilled nursing facility to which such paragraph applies.

(3) The amount payable under part A for post-hospital extended care services furnished an individual during any spell of illness in a skilled nursing facility to which paragraph (1) applies shall be reduced by a coinsurance amount equal to one-eighth of the inpatient hospital deductible for each day before the 31st day on which he is furnished such services in such a facility during such spell (and the reduction under this paragraph shall be in lieu of any reduction under section 1813(a)(3)).

(4) For purposes of subsection (i), the determination of whether services furnished by or in an institution described in paragraph (1) constitute post-hospital extended care services shall be made in accordance with and subject to such conditions, limitations, and requirements as may be provided in regulations.

Institutional Planning

(z) An overall plan and budget of a hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, or home health agency shall be considered sufficient if it—

(1) provides for an annual operating budget which includes all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items (except that nothing in this paragraph shall require that there be prepared, in connection with any budget, an item-by-item identification of the components of each type of anticipated expenditure or income);

(2)(A) provides for a capital expenditures plan for at least a 3-year period (including the year to which the operating budget described in paragraph (1) is applicable) which includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure in excess of $600,000 (or such lesser amount as may be established by the State under section 1122(g)(1) in which the hospital is located) related to the acquisition of land, the improvement of land, buildings, and equipment, and the replacement, modernization, and expansion of the buildings and equipment which would, under generally accepted accounting principles, be considered capital items;

(B) provides that such plan is submitted to the agency designated under section 1122(b), or if no such agency is designated, to the appropriate health planning agency in the State (but this subparagraph shall not apply in the case of a facility exempt from review under section 1122 by reason of section 1122(j));

(3) provides for review and updating at least annually; and

(4) is prepared, under the direction of the governing body of the institution or agency, by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the institution or agency.

Rural Health Clinic Services and Federally Qualified Health Center Services

(aa)(1) The term "rural health clinic services" means —

(A) physicians' services and such services and supplies as are covered under section 1861(s)(2)(A) if furnished as an incident to a physician's professional service and items and services described in section 1861(s)(10),

(B) such services furnished by a physician assistant or a nurse practitioner (as defined in paragraph (5)), by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(1)), and such services and supplies furnished as an incident to his service as would otherwise be covered if furnished by a physician or as an incident to a physician's service, and

(C) in the case of a rural health clinic located in an area in which there exists a shortage of home health agencies, part-time or intermittent nursing care and related medical supplies (other than drugs and biologicals) furnished by a registered professional nurse or licensed practical nurse to a homebound individual under a written plan of treatment (i) established and periodically reviewed by a physician described in paragraph (2)(B), or (ii) established by a nurse practitioner or physician assistant and periodically reviewed and approved by a physician described in paragraph (2)(B),

when furnished to an individual as an outpatient of a rural health clinic.

(2) The term "rural health clinic" means a facility which —

(A) is primarily engaged in furnishing to outpatients services described in subparagraphs (A) and (B) of paragraph (1);

(B) in the case of a facility which is not a physician-directed clinic, has an arrangement (consistent with the provisions of State and local law relative to the practice, performance, and delivery of health services) with one or more physicians (as defined in subsection (r)(1)) under which provision is made for the periodic review by such physicians of covered services furnished by physician assistants and nurse practitioners, the supervision and guidance by such physicians of physician assistants and nurse practitioners, the preparation by such physicians of such medical orders for care and treatment of clinic patients as may be necessary, and the availability of such physicians for such referral of and consultation for patients as is necessary and for advice and assistance in the management of medical emergencies; and, in the case of a physician-directed clinic, has one or more of its staff physicians perform the activities accomplished through such an arrangement;

(C) maintains clinical records on all patients;

(D) has arrangements with one or more hospitals, having agreements in effect under section 1866, for the referral and admission of patients requiring inpatient services or such diagnostic or other specialized services as are not available at the clinic;

(E) has written policies, which are developed with the advice of (and with provision for review of such policies from time to time by) a group of professional personnel, including one or more physicians and one or more physician assistants or nurse practitioners, to govern those services described in paragraph (1) which it furnishes;

(F) has a physician, physician assistant, or nurse practitioner responsible for the execution of policies described in subparagraph (E) and relating to the provision of the clinic's services;

(G) directly provides routine diagnostic services, including clinical laboratory services, as prescribed in regulations by the Secretary, and has prompt access to additional diagnostic services from facilities meeting requirements under this title;

(H) in compliance with State and Federal law, has available for administering to patients of the clinic at least such drugs and biologicals as are determined by the Secretary to be necessary for the treatment of emergency cases (as defined in regulations) and has appropriate procedures or arrangements for storing, administering, and dispensing any drugs and biologicals;

(I) has a quality assessment and performance improvement program, and appropriate procedures for review of utilization of clinic services, as the Secretary may specify;

(J) has a nurse practitioner, a physician assistant, or a certified nurse-midwife (as defined in subsection (gg)) available to furnish patient care services not less than 50 percent of the time the clinic operates; and

(K) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services by the clinic.

For the purposes of this title, such term includes only a facility which (i) is located in an area that is not an urbanized area (as defined by the Bureau of the Census) and in which there are insufficient numbers of needed health care practitioners (as determined by the Secretary), and that, within the previous 4-year period, has been designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services or designated by the Secretary either (I) as an area with a shortage of personal health services under section 330(b)(3) or 1302(7) of the Public Health Service Act, (II) as a health professional shortage area described in section 332(a)(1)(A) of that Act because of its shortage of primary medical care manpower, (III) as a high impact area described in section 329(a)(5) of that Act, of (IV) as an area which includes a population group which the Secretary determines has a health manpower shortage under section 332(a)(1)(B) of that Act, (ii) has filed an agreement with the Secretary by which it agrees not to charge any individual or other person for items or services for which such indi-

vidual is entitled to have payment made under this title, except for the amount of any deductible or coinsurance amount imposed with respect to such items or services (not in excess of the amount customarily charged for such items and services by such clinic), pursuant to subsections (a) and (b) of section 1833, (iii) employs a physician assistant or nurse practitioner, and (iv) is not a rehabilitation agency or a facility which is primarily for the care and treatment of mental diseases. A facility that is in operation and qualifies as a rural health clinic under this title or title XIX and that subsequently fails to satisfy the requirement of clause (i) shall be considered, for purposes of this title and title XIX, as still satisfying the requirement of such clause if it is determined, in accordance with criteria established by the Secretary in regulations, to be essential to the delivery of primary care services that would otherwise be unavailable in the geographic area served by the clinic. If a State agency has determined under section 1864(a) that a facility is a rural health clinic and the facility has applied to the Secretary for approval as such a clinic, the Secretary shall notify the facility of the Secretary's approval or disapproval not later than 60 days after the date of the State agency determination or the application (whichever is later).

(3) The term "Federally qualified health center services" means—

(A) services of the type described in subparagraphs (A) through (C) of paragraph (1) and preventive services (as defined in section 1861(ddd)(3)); and

(B) preventive primary health services that a center is required to provide under section 330 of the Public Health Service Act,

when furnished to an individual as an outpatient of a Federally qualified health center by the center or by a health care professional under contract with the center and, for this purpose, any reference to a rural health clinic or a physician described in paragraph (2)(B) is deemed a reference to a Federally qualified health center or a physician at the center, respectively.

(4) The term "Federally qualified health center" means an entity which—

(A)(i) is receiving a grant under section 330 of the Public Health Service Act, or

(ii)(I) is receiving funding from such a grant under a contract with the recipient of such a grant, and (II) meets the requirements to receive a grant under section 330 of such Act;

(B) based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant;

(C) was treated by the Secretary, for purposes of part B, as a comprehensive Federally funded health center as of January 1, 1990; or

(D) is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(5)(A) The term "physician assistant" and the term "nurse practitioner" mean, for purposes of this title, a physician assistant or nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

(B) The term "clinical nurse specialist" means, for purposes of this title, an individual who—

(i) is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and

(ii) holds a master's degree in a defined clinical area of nursing from an accredited educational institution.

(6) The term "collaboration" means a process in which a nurse practitioner works with a physician to deliver health care services within the scope of the practitioner's professional expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as defined by the law of the State in which the services are performed.

(7)(A) The Secretary shall waive for a 1-year period the requirements of paragraph (2) that a rural health clinic employ a physician assistant, nurse practitioner or certified nurse midwife or that such clinic require such providers to furnish services at least 50 percent of the time that the clinic operates for any facility that requests such waiver if the facility demonstrates that the facility has been unable, despite reasonable efforts, to hire a physician assistant, nurse practitioner, or certified nurse-midwife in the previous 90-day period.

(B) The Secretary may not grant such a waiver under subparagraph (A) to a facility if the request for the waiver is made less than 6 months after the date of the expiration of any previous

such waiver for the facility, or if the facility has not yet been determined to meet the requirements (including subparagraph (J) of the first sentence of paragraph (2)) of a rural health clinic.

(C) A waiver which is requested under this paragraph shall be deemed granted unless such request is denied by the Secretary within 60 days after the date such request is received.

Services of a Certified Registered Nurse Anesthetist

(bb)(1) The term "services of a certified registered nurse anesthetist" means anesthesia services and related care furnished by a certified registered nurse anesthetist (as defined in paragraph (2)) which the nurse anesthetist is legally authorized to perform as such by the State in which the services are furnished.

(2) The term "certified registered nurse anesthetist" means a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists. Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant.

Comprehensive Outpatient Rehabilitation Facility Services

(cc)(1) The term "comprehensive outpatient rehabilitation facility services" means the following items and services furnished by a physician or other qualified professional personnel (as defined in regulations by the Secretary) to an individual who is an outpatient of a comprehensive outpatient rehabilitation facility under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician—

(A) physicians' services;

(B) physical therapy, occupational therapy, speech-language pathology services, and respiratory therapy;

(C) prosthetic and orthotic devices, including testing, fitting, or training in the use of prosthetic and orthotic devices;

(D) social and psychological services;

(E) nursing care provided by or under the supervision of a registered professional nurse;

(F) drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered;

(G) supplies and durable medical equipment; and

(H) such other items and services as are medically necessary for the rehabilitation of the patient and are ordinarily furnished by comprehensive outpatient rehabilitation facilities,

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital. In the case of physical therapy, occupational therapy, and speech pathology services, there shall be no requirement that the item or service be furnished at any single fixed location if the item or service is furnished pursuant to such plan and payments are not otherwise made for the item or service under this title.

(2) The term "comprehensive outpatient rehabilitation facility" means a facility which—

(A) is primarily engaged in providing (by or under the supervision of physicians) diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons;

(B) provides at least the following comprehensive outpatient rehabilitation services: (i) physicians' services (rendered by physicians, as defined in section 1861(r)(1), who are available at the facility on a full- or part-time basis); (ii) physical therapy; and (iii) social or psychological services;

(C) maintains clinical records on all patients;

(D) has policies established by a group of professional personnel (associated with the facility), including one or more physicians defined in subsection (r)(1) to govern the comprehensive outpatient rehabilitation services it furnishes, and provides for the carrying out of such policies by a full- or part-time physician referred to in subparagraph (B)(i);

(E) has a requirement that every patient must be under the care of a physician;

(F) in the case of a facility in any State in which State or applicable local law provides for the licensing of facilities of this nature (i) is licensed pursuant to such law, or (ii) is approved by the agency of such State or locality, responsible for licensing facilities of this nature, as meeting the standards established for such licensing;

(G) has in effect a utilization review plan in accordance with regulations prescribed by the Secretary;

(H) has in effect an overall plan and budget that meets the requirements of subsection (z);

(I) provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000; and

(J) meets such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such facility, including conditions concerning qualifications of personnel in these facilities.

The Secretary may waive the requirement of a surety bond under subparagraph (I) in the case of a facility that provides a comparable surety bond under State law.

Hospice Care; Hospice Program

(dd)(1) The term "hospice care" means the following items and services provided to a terminally ill individual by, or by others under arrangements made by, a hospice program under a written plan (for providing such care to such individual) established and periodically reviewed by the individual's attending physician and by the medical director (and by the interdisciplinary group described in paragraph (2)(B)) of the program—

(A) nursing care provided by or under the supervision of a registered professional nurse,

(B) physical or occupational therapy, or speech-language pathology services,

(C) medical social services under the direction of a physician,

(D)(i) services of a home health aide who has successfully completed a training program approved by the Secretary and (ii) homemaker services,

(E) medical supplies (including drugs and biologicals) and the use of medical appliances, while under such a plan,

(F) physicians' services,

(G) short-term inpatient care (including both respite care and procedures necessary for pain control and acute and chronic symptom management) in an inpatient facility meeting such conditions as the Secretary determines to be appropriate to provide such care, but such respite care may be provided only on an intermittent, nonroutine, and occasional basis and may not be provided consecutively over longer than five days,

(H) counseling (including dietary counseling) with respect to care of the terminally ill individual and adjustment to his death, and

(I) any other item or service which is specified in the plan and for which payment may otherwise be made under this title.

The care and services described in subparagraphs (A) and (D) may be provided on a 24-hour, continuous basis only during periods of crisis (meeting criteria established by the Secretary) and only as necessary to maintain the terminally ill individual at home.

(2) The term "hospice program" means a public agency or private organization (or a subdivision thereof) which—

(A)(i) is primarily engaged in providing the care and services described in paragraph (1) and makes such services available (as needed) on a 24-hour basis and which also provides bereavement counseling for the immediate family of terminally ill individuals and services described in section 1812(a)(5),

(ii) provides for such care and services in individuals' homes, on an outpatient basis, and on a short-term inpatient basis, directly or under arrangements made by the agency or organization, except that—

(I) the agency or organization must routinely provide directly substantially all of each of the services described in subparagraphs (A), (C), and (H) of paragraph (1), except as otherwise provided in paragraph (5), and

(II) in the case of other services described in paragraph (1) which are not provided directly by the agency or organization, the agency or organization must maintain professional management responsibility for all such services furnished to an individual, regardless of the location or facility in which such services are furnished; and

(iii) provides assurances satisfactory to the Secretary that the aggregate number of days of inpatient care described in paragraph (1)(G) provided in any 12-month period to individuals who have an election in effect under section 1812(d) with respect to that agency or organiza-

tion does not exceed 20 percent of the aggregate number of days during that period on which such elections for such individuals are in effect;

(B) has an interdisciplinary group of personnel which—

(i) includes at least—

(I) one physician (as defined in subsection (r)(1)),

(II) one registered professional nurse, and

(III) one social worker,

employed by or, in the case of a physician described in subclause (I), under contract with the agency or organization, and also includes at least one pastoral or other counselor,

(ii) provides (or supervises the provision of) the care and services described in paragraph (1), and

(iii) establishes the policies governing the provision of such care and services;

(C) maintains central clinical records on all patients;

(D) does not discontinue the hospice care it provides with respect to a patient because of the inability of the patient to pay for such care;

(E)(i) utilizes volunteers in its provision of care and services in accordance with standards set by the Secretary, which standards shall ensure a continuing level of effort to utilize such volunteers, and (ii) maintains records on the use of these volunteers and the cost savings and expansion of care and services achieved through the use of these volunteers;

(F) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, is licensed pursuant to such law; and

(G) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization.

(3)(A) An individual is considered to be "terminally ill" if the individual has a medical prognosis that the individual's life expectancy is 6 months or less.

(B) The term "attending physician" means, with respect to an individual, the physician (as defined in subsection (r)(1)), the nurse practitioner (as defined in subsection (aa)(5)), or the physician assistant (as defined in such subsection), who may be employed by a hospice program, whom the individual identifies as having the most significant role in the determination and delivery of medical care to the individual at the time the individual makes an election to receive hospice care.

(4)(A) An entity which is certified as a provider of services other than a hospice program shall be considered, for purposes of certification as a hospice program, to have met any requirements under paragraph (2) which are also the same requirements for certification as such other type of provider. The Secretary shall coordinate surveys for determining certification under this title so as to provide, to the extent feasible, for simultaneous surveys of an entity which seeks to be certified as a hospice program and as a provider of services of another type.

(B) Any entity which is certified as a hospice program and as a provider of another type shall have separate provider agreements under section 1866 and shall file separate cost reports with respect to costs incurred in providing hospice care and in providing other services and items under this title.

(C) Any entity that is certified as a hospice program shall be subject to a standard survey by an appropriate State or local survey agency, or an approved accreditation agency, as determined by the Secretary, not less frequently than once every 36 months beginning 6 months after the date of the enactment of this subparagraph and ending September 30, 2025.

(5)(A) The Secretary may waive the requirements of paragraph (2)(A)(ii)(I) for an agency or organization with respect to all or part of the nursing care described in paragraph (1)(A) if such agency or organization—

(i) is located in an area which is not an urbanized area (as defined by the Bureau of the Census);

(ii) was in operation on or before January 1, 1983; and

(iii) has demonstrated a good faith effort (as determined by the Secretary) to hire a sufficient number of nurses to provide such nursing care directly.

(B) Any waiver, which is in such form and containing such information as the Secretary may require and which is requested by an agency or organization under subparagraph (A) or (C), shall be deemed to be granted unless such request is denied by the Secretary within 60 days after the date such request is received by the Secretary. The granting of a waiver under subparagraph (A)

or (C) shall not preclude the granting of any subsequent waiver request should such a waiver again become necessary.

(C) The Secretary may waive the requirements of paragraph (2)(A)(i) and (2)(A)(ii) for an agency or organization with respect to the services described in paragraph (1)(B) and, with respect to dietary counseling, paragraph (1)(H), if such agency or organization—

(i) is located in an area which is not an urbanized area (as defined by the Bureau of Census), and

(ii) demonstrates to the satisfaction of the Secretary that the agency or organization has been unable, despite diligent efforts, to recruit appropriate personnel.

(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a registered professional nurse and are provided non-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.

Discharge Planning Process

(ee)(1) A discharge planning process of a hospital shall be considered sufficient if it is applicable to services furnished by the hospital to individuals entitled to benefits under this title and if it meets the guidelines and standards established by the Secretary under paragraph (2).

(2) The Secretary shall develop guidelines and standards for the discharge planning process in order to ensure a timely and smooth transition to the most appropriate type of and setting for post-hospital or rehabilitative care. The guidelines and standards shall include the following:

(A) The hospital must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning.

(B) Hospitals must provide a discharge planning evaluation for patients identified under subparagraph (A) and for other patients upon the request of the patient, patient's representative, or patient's physician.

(C) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

(D) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including hospice care and post-hospital extended care services, and the availability of those services, including the availability of home health services through individuals and entities that participate in the program under this title and that serve the area in which the patient resides and that request to be listed by the hospital as available and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this title and that serve the area in which the patient resides.

(E) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(F) Upon the request of a patient's physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.

(G) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered professional nurse, social worker, or other appropriately qualified personnel.

(H) Consistent with section 1802, the discharge plan shall—

(i) not specify or otherwise limit the qualified provider which may provide post-hospital home health services, and

(ii) identify (in a form and manner specified by the Secretary) any entity to whom the individual is referred in which the hospital has a disclosable financial interest (as specified

by the Secretary consistent with section 1866(a)(1)(S)) or which has such an interest in the hospital.

(3) With respect to a discharge plan for an individual who is enrolled with a Medicare+Choice organization under a Medicare+Choice plan and is furnished inpatient hospital services by a hospital under a contract with the organization—

(A) the discharge planning evaluation under paragraph (2)(D) is not required to include information on the availability of home health services through individuals and entities which do not have a contract with the organization; and

(B) notwithstanding subparagraph (H)(i), the plan may specify or limit the provider (or providers) of post-hospital home health services or other post-hospital services under the plan.

Partial Hospitalization Services

(ff)(1) The term "partial hospitalization services" means the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which plan sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan.

(2) The items and services described in this paragraph are—

(A) individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law),

(B) occupational therapy requiring the skills of a qualified occupational therapist,

(C) services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients,

(D) drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered),

(E) individualized activity therapies that are not primarily recreational or diversionary,

(F) family counseling (the primary purpose of which is treatment of the individual's condition),

(G) patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment),

(H) diagnostic services, and

(I) such other items and services as the Secretary may provide (but in no event to include meals and transportation);

that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish (taking into account accepted norms of medical practice and the reasonable expectation of patient improvement).

(3)(A) A program described in this paragraph is a program which is furnished by a hospital to its outpatients or by a community mental health center (as defined in subparagraph (B)), and which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care other than in an individual's home or in an inpatient or residential setting.

(B) For purposes of subparagraph (A), the term "community mental health center" means an entity that—

(i)(I) provides the mental health services described in section 1913(c)(1) of the Public Health Service Act; or

(II) in the case of an entity operating in a State that by law precludes the entity from providing itself the service described in subparagraph (E) of such section, provides for such service by contract with an approved organization or entity (as determined by the Secretary);

(ii) meets applicable licensing or certification requirements for community mental health centers in the State in which it is located;

(iii) provides at least 40 percent of its services to individuals who are not eligible for benefits under this title; and

(iv) meets such additional conditions as the Secretary shall specify to ensure (I) the health and safety of individuals being furnished such services, (II) the effective and efficient fur-

nishing of such services, and (III) the compliance of such entity with the criteria described in section 1931(c)(1) of the Public Health Service Act.

Certified Nurse-Midwife Services

(gg)(1) The term "certified nurse-midwife services" means such services furnished by a certified nurse-midwife (as defined in paragraph (2)) and such services and supplies furnished as an incident to the nurse-midwife's service which the certified nurse-midwife is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician or as an incident to a physicians' service.

(2) The term "certified nurse-midwife" means a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary, or has been certified by an organization recognized by the Secretary.

Clinical Social Worker; Clinical Social Worker Services

(hh)(1) The term "clinical social worker" means an individual who—

(A) possesses a master's or doctor's degree in social work;

(B) after obtaining such degree has performed at least 2 years of supervised clinical social work; and

(C)(i) is licensed or certified as a clinical social worker by the State in which the services are performed, or

(ii) in the case of an individual in a State which does not provide for licensure or certification—

(I) has completed at least 2 years or 3,000 hours of post-master's degree supervised clinical social work practice under the supervision of a master's level social worker in an appropriate setting (as determined by the Secretary), and

(II) meets such other criteria as the Secretary establishes.

(2) The term "clinical social worker services" means services performed by a clinical social worker (as defined in paragraph (1)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital and other than services furnished to an inpatient of a skilled nursing facility which the facility is required to provide as a requirement for participation) which the clinical social worker is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service.

Qualified Psychologist Services

(ii) The term "qualified psychologist services" means such services and such services and supplies furnished as an incident to his service furnished by a clinical psychologist (as defined by the Secretary) which the psychologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician or as an incident to a physician's service.

Screening Mammography

(jj) The term "screening mammography" means a radiologic procedure provided to a woman for the purpose of early detection of breast cancer and includes a physician's interpretation of the results of the procedure.

Covered Osteoporosis Drug

(kk) The term "covered osteoporosis drug" means an injectable drug approved for the treatment of post-menopausal osteoporosis provided to an individual by a home health agency if, in accordance with regulations promulgated by the Secretary—

(1) the individual's attending physician certifies that the individual has suffered a bone fracture related to post-menopausal osteoporosis and that the individual is unable to learn the skills needed to self-administer such drug or is otherwise physically or mentally incapable of self-administering such drug; and

(2) the individual is confined to the individual's home (except when receiving items and services referred to in subsection (m)(7)).

Speech-Language Pathology Services; Audiology Services

(ll)(1) The term "speech-language pathology services" means such speech, language, and related function assessment and rehabilitation services furnished by a qualified speech-language pathologist as the speech-language pathologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician.

(2) The term "outpatient speech-language pathology services" has the meaning given the term "outpatient physical therapy services" in subsection (p), except that in applying such subsection—

(A) "speech-language pathology" shall be substituted for "physical therapy" each place it appears; and

(B) "speech-language pathologist" shall be substituted for "physical therapist" each place it appears.

(3) The term "audiology services" means such hearing and balance assessment services furnished by a qualified audiologist as the audiologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), as would otherwise be covered if furnished by a physician.

(4) In this subsection:

(A) The term "qualified speech-language pathologist" means an individual with a master's or doctoral degree in speech-language pathology who—

(i) is licensed as a speech-language pathologist by the State in which the individual furnishes such services, or

(ii) in the case of an individual who furnishes services in a State which does not license speech-language pathologists, has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field, and successfully completed a national examination in speech-language pathology approved by the Secretary.

(B) The term "qualified audiologist" means an individual with a master's or doctoral degree in audiology who—

(i) is licensed as an audiologist by the State in which the individual furnishes such services, or

(ii) in the case of an individual who furnishes services in a State which does not license audiologists, has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), performed not less than 9 months of supervised full-time audiology services after obtaining a master's or doctoral degree in audiology or a related field, and successfully completed a national examination in audiology approved by the Secretary.

Critical Access Hospital; Critical Access Hospital Services

(mm)(1) The term "critical access hospital" means a facility certified by the Secretary as a critical access hospital under section 1820(e).

(2) The term "inpatient critical access hospital services" means items and services, furnished to an inpatient of a critical access hospital by such facility, that would be inpatient hospital services if furnished to an inpatient of a hospital by a hospital.

(3) The term "outpatient critical access hospital services" means medical and other health services furnished by a critical access hospital on an outpatient basis.

Screening Pap Smear; Screening Pelvic Exam

(nn)(1) The term "screening pap smear" means a diagnostic laboratory test consisting of a routine exfoliative cytology test (Papanicolaou test) provided to a woman for the purpose of early detection of cervical or vaginal cancer and includes a physician's interpretation of the results of the test, if the individual involved has not had such a test during the preceding 2 years, or during the preceding year in the case of a woman described in paragraph (3).

(2) The term "screening pelvic exam" means a pelvic examination provided to a woman if the woman involved has not had such an examination during the preceding 2 years, or during the pre-

ceding year in the case of a woman described in paragraph (3), and includes a clinical breast examination.

(3) A woman described in this paragraph is a woman who—

(A) is of childbearing age and has had a test described in this subsection during any of the preceding 3 years that indicated the presence of cervical or vaginal cancer or other abnormality; or

(B) is at high risk of developing cervical or vaginal cancer (as determined pursuant to factors identified by the Secretary).

Prostate Cancer Screening Tests

(oo)(1) The term "prostate cancer screening test" means a test that consists of any (or all) of the procedures described in paragraph (2) provided for the purpose of early detection of prostate cancer to a man over 50 years of age who has not had such a test during the preceding year.

(2) The procedures described in this paragraph are as follows:

(A) A digital rectal examination.

(B) A prostate-specific antigen blood test.

(C) For years beginning after 2002, such other procedures as the Secretary finds appropriate for the purpose of early detection of prostate cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and such other factors as the Secretary considers appropriate.

Colorectal Cancer Screening Tests

(pp)(1) The term "colorectal cancer screening test" means any of the following procedures furnished to an individual for the purpose of early detection of colorectal cancer:

(A) Screening fecal-occult blood test.

(B) Screening flexible sigmoidoscopy.

(C) Screening colonoscopy.

(D) Such other tests or procedures, and modifications to tests and procedures under this subsection, with such frequency and payment limits, as the Secretary determines appropriate, in consultation with appropriate organizations.

(2) An "individual at high risk for colorectal cancer" is an individual who, because of family history, prior experience of cancer or precursor neoplastic polyps, a history of chronic digestive disease condition (including inflammatory bowel disease, Crohn's Disease, or ulcerative colitis), the presence of any appropriate recognized gene markers for colorectal cancer, or other predisposing factors, faces a high risk for colorectal cancer.

Diabetes Outpatient Self-Management Training Services

(qq)(1) The term "diabetes outpatient self-management training services" means educational and training services furnished (at such times as the Secretary determines appropriate) to an individual with diabetes by a certified provider (as described in paragraph (2)(A)) in an outpatient setting by an individual or entity who meets the quality standards described in paragraph (2)(B), but only if the physician who is managing the individual's diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual's diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual's condition.

(2) In paragraph (1)—

(A) a "certified provider" is a physician, or other individual or entity designated by the Secretary, that, in addition to providing diabetes outpatient self-management training services, provides other items or services for which payment may be made under this title; and

(B) a physician, or such other individual or entity, meets the quality standards described in this paragraph if the physician, or individual or entity, meets quality standards established by the Secretary, except that the physician or other individual or entity shall be deemed to have met such standards if the physician or other individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards by such Board, or is recog-

nized by an organization that represents individuals (including individuals under this title) with diabetes as meeting standards for furnishing the services.

Bone Mass Measurement

(rr)(1) The term "bone mass measurement" means a radiologic or radioisotopic procedure or other procedure approved by the Food and Drug Administration performed on a qualified individual (as defined in paragraph (2)) for the purpose of identifying bone mass or detecting bone loss or determining bone quality, and includes a physician's interpretation of the results of the procedure.

(2) For purposes of this subsection, the term "qualified individual" means an individual who is (in accordance with regulations prescribed by the Secretary)—

(A) an estrogen-deficient woman at clinical risk for osteoporosis;

(B) an individual with vertebral abnormalities;

(C) an individual receiving long-term glucocorticoid steroid therapy;

(D) an individual with primary hyperparathyroidism; or

(E) an individual being monitored to assess the response to or efficacy of an approved osteoporosis drug therapy.

(3) The Secretary shall establish such standards regarding the frequency with which a qualified individual shall be eligible to be provided benefits for bone mass measurement under this title.

Religious Nonmedical Health Care Institution

(ss)(1) The term "religious nonmedical health care institution" means an institution that—

(A) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986 and is exempt from taxes under subsection (a) of such section;

(B) is lawfully operated under all applicable Federal, State, and local laws and regulations;

(C) provides only nonmedical nursing items and services exclusively to patients who choose to rely solely upon a religious method of healing and for whom the acceptance of medical health services would be inconsistent with their religious beliefs;

(D) provides such nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of such patients;

(E) provides such nonmedical items and services to inpatients on a 24-hour basis;

(F) on the basis of its religious beliefs, does not provide through its personnel or otherwise medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients;

(G)(i) is not owned by, under common ownership with, or has an ownership interest in, a provider of medical treatment or services;

(ii) is not affiliated with—

(I) a provider of medical treatment or services, or

(II) an individual who has an ownership interest in a provider of medical treatment or services;

(H) has in effect a utilization review plan which—

(i) provides for the review of admissions to the institution, of the duration of stays therein, of cases of continuous extended duration, and of the items and services furnished by the institution,

(ii) requires that such reviews be made by an appropriate committee of the institution that includes the individuals responsible for overall administration and for supervision of nursing personnel at the institution,

(iii) provides that records be maintained of the meetings, decisions, and actions of such committee, and

(iv) meets such other requirements as the Secretary finds necessary to establish an effective utilization review plan;

(I) provides the Secretary with such information as the Secretary may require to implement section 1821, including information relating to quality of care and coverage determinations; and

(J) meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.

(2) To the extent that the Secretary finds that the accreditation of an institution by a State, regional, or national agency or association provides reasonable assurances that any or all of the requirements of paragraph (1) are met or exceeded, the Secretary may treat such institution as meeting the condition or conditions with respect to which the Secretary made such finding.

(3)(A)(i) In administering this subsection and section 1821, the Secretary shall not require any patient of a religious nonmedical health care institution to undergo medical screening, examination, diagnosis, prognosis, or treatment or to accept any other medical health care service, if such patient (or legal representative of the patient) objects thereto on religious grounds.

(ii) Clause (i) shall not be construed as preventing the Secretary from requiring under section 1821(a)(2) the provision of sufficient information regarding an individual's condition as a condition for receipt of benefits under part A for services provided in such an institution.

(B)(i) In administering this subsection and section 1821, the Secretary shall not subject a religious nonmedical health care institution or its personnel to any medical supervision, regulation, or control, insofar as such supervision, regulation, or control would be contrary to the religious beliefs observed by the institution or such personnel.

(ii) Clause (i) shall not be construed as preventing the Secretary from reviewing items and services billed by the institution to the extent the Secretary determines such review to be necessary to determine whether such items and services were not covered under part A, are excessive, or are fraudulent.

(4)(A) For purposes of paragraph (1)(G)(i), an ownership interest of less than 5 percent shall not be taken into account.

(B) For purposes of paragraph (1)(G)(ii), none of the following shall be considered to create an affiliation:

(i) An individual serving as an uncompensated director, trustee, officer, or other member of the governing body of a religious nonmedical health care institution.

(ii) An individual who is a director, trustee, officer, employee, or staff member of a religious nonmedical health care institution having a family relationship with an individual who is affiliated with (or has an ownership interest in) a provider of medical treatment or services.

(iii) An individual or entity furnishing goods or services as a vendor to both providers of medical treatment or services and religious nonmedical health care institutions.

Post-Institutional Home Health Services; Home Health Spell of Illness

(tt)(1) The term "post-institutional home health services" means home health services furnished to an individual—

(A) after discharge from a hospital or critical access hospital in which the individual was an inpatient for not less than 3 consecutive days before such discharge if such home health services were initiated within 14 days after the date of such discharge; or

(B) after discharge from a skilled nursing facility in which the individual was provided post-hospital extended care services if such home health services were initiated within 14 days after the date of such discharge.

(2) The term "home health spell of illness" with respect to any individual means a period of consecutive days—

(A) beginning with the first day (not included in a previous home health spell of illness) (i) on which such individual is furnished post-institutional home health services, and (ii) which occurs in a month for which the individual is entitled to benefits under part A, and

(B) ending with the close of the first period of 60 consecutive days thereafter on each of which the individual is neither an inpatient of a hospital or critical access hospital nor an inpatient of a facility described in section 1819(a)(1) or subsection (y)(1) nor provided home health services.

Screening for Glaucoma

(uu) The term "screening for glaucoma" means a dilated eye examination with an intraocular pressure measurement, and a direct ophthalmoscopy or a slit-lamp biomicroscopic examination for the early detection of glaucoma which is furnished by or under the direct supervision of an optometrist or ophthalmologist who is legally authorized to furnish such services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished, as would otherwise be covered if furnished by a physician or as an incident to a physician's

professional service, if the individual involved has not had such an examination in the preceding year.

Medical Nutrition Therapy Services; Registered Dietitian or Nutrition Professional

(vv)(1) The term "medical nutrition therapy services" means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional (as defined in paragraph (2)) pursuant to a referral by a physician (as defined in subsection (r)(1)).

(2) Subject to paragraph (3), the term "registered dietitian or nutrition professional" means an individual who—

(A) holds a baccalaureate or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics, as accredited by an appropriate national accreditation organization recognized by the Secretary for this purpose;

(B) has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and

(C)(i) is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed; or

(ii) in the case of an individual in a State that does not provide for such licensure or certification, meets such other criteria as the Secretary establishes.

(3) Subparagraphs (A) and (B) of paragraph (2) shall not apply in the case of an individual who, as of the date of the enactment of this subsection, is licensed or certified as a dietitian or nutrition professional by the State in which medical nutrition therapy services are performed.

Initial Preventive Physical Examination

(ww)(1) The term "initial preventive physical examination" means physicians' services consisting of a physical examination (including measurement of height, weight body mass index,, and blood pressure) with the goal of health promotion and disease detection and includes education, counseling, and referral with respect to screening and other preventive services described in paragraph (2) and end-of-life planning (as defined in paragraph (3)) upon the agreement with the individual, *and a review of current opioid prescriptions and screening for opioid use disorder (as defined in paragraph (4)),* but does not include clinical laboratory tests.

(2) The screening and other preventive services described in this paragraph include the following:

(A) Pneumococcal, influenza, and hepatitis B vaccine and administration under subsection (s)(10).

(B) Screening mammography as defined in subsection (jj).

(C) Screening pap smear and screening pelvic exam as defined in subsection (nn).

(D) Prostate cancer screening tests as defined in subsection (oo).

(E) Colorectal cancer screening tests as defined in subsection (pp).

(F) Diabetes outpatient self-management training services as defined in subsection (qq)(1).

(G) Bone mass measurement as defined in subsection (rr).

(H) Screening for glaucoma as defined in subsection (uu).

(I) Medical nutrition therapy services as defined in subsection (vv).

(J) Cardiovascular screening blood tests as defined in subsection (xx)(1).

(K) Diabetes screening tests as defined in subsection (yy).

(L) Ultrasound screening for abdominal aortic aneurysm as defined in section 1861(bbb).

(M) An electrocardiogram.

(N) Additional preventive services (as defined in subsection (ddd)(1)).

(3) For purposes of paragraph (1), the term "end-of-life planning" means verbal or written information regarding—

(A) an individual's ability to prepare an advance directive in the case that an injury or illness causes the individual to be unable to make health care decisions; and

(B) whether or not the physician is willing to follow the individual's wishes as expressed in an advance directive.

*(4)(A) For purposes of paragraph (1), the term "a review of current opioid prescriptions and screening for opioid use disorder" means, with respect to an individual—*

*(i) a review by a physician or qualified non-physician practitioner of all current prescriptions of the individual; and*

*(ii) in the case of an individual determined by the review of a physician or qualified non-physician practitioner under subparagraph (A) to have a current prescription for opioids for chronic pain that has been prescribed for a minimum period of time (as specified by the Secretary)—*

*(I) a review by the physician or practitioner of the potential risk factors to the individual for opioid use disorder;*

*(II) an evaluation by the physician or practitioner of pain of the individual;*

*(III) the provision of information regarding non-opioid treatment options for the treatment and management of any chronic pain of the individual; and*

*(IV) if determined necessary by the physician or practitioner based on the results of the review and evaluation conducted as described in this paragraph, an appropriate referral by the physician or practitioner for additional treatment.*

*(B) For purposes of this paragraph, the term "qualified non-physician practitioner" means a physician assistant, nurse practitioner, or certified clinical nurse specialist.*

Cardiovascular Screening Blood Test

(xx)(1) The term "cardiovascular screening blood test" means a blood test for the early detection of cardiovascular disease (or abnormalities associated with an elevated risk of cardiovascular disease) that tests for the following:

(A) Cholesterol levels and other lipid or triglyceride levels.

(B) Such other indications associated with the presence of, or an elevated risk for, cardiovascular disease as the Secretary may approve for all individuals (or for some individuals determined by the Secretary to be at risk for cardiovascular disease), including indications measured by noninvasive testing.

The Secretary may not approve an indication under subparagraph (B) for any individual unless a blood test for such is recommended by the United States Preventive Services Task Force.

(2) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency for each type of cardiovascular screening blood tests, except that such frequency may not be more often than once every 2 years.

Diabetes Screening Tests

(yy)(1) The term "diabetes screening tests" means testing furnished to an individual at risk for diabetes (as defined in paragraph (2)) for the purpose of early detection of diabetes, including—

(A) a fasting plasma glucose test; and

(B) such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations.

(2) For purposes of paragraph (1), the term "individual at risk for diabetes" means an individual who has any of the following risk factors for diabetes:

(A) Hypertension.

(B) Dyslipidemia.

(C) Obesity, defined as a body mass index greater than or equal to 30 $kg/m^2$.

(D) Previous identification of an elevated impaired fasting glucose.

(E) Previous identification of impaired glucose tolerance.

(F) A risk factor consisting of at least 2 of the following characteristics:

(i) Overweight, defined as a body mass index greater than 25, but less than 30, $kg/m^2$.

(ii) A family history of diabetes.

(iii) A history of gestational diabetes mellitus or delivery of a baby weighing greater than 9 pounds.

(iv) 65 years of age or older.

(3) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency of diabetes screening tests, except that such frequency may not be more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.

Intravenous Immune Globulin

(zz) The term "intravenous immune globulin" means an approved pooled plasma derivative for the treatment in the patient's home of a patient with a diagnosed primary immune deficiency disease, but not including items or services related to the administration of the derivative, if a physician determines administration of the derivative in the patient's home is medically appropriate.

Extended Care in Religious Nonmedical Health Care Institutions

(aaa)(1) The term "home health agency" also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only with respect to items and services ordinarily furnished by such an institution to individuals in their homes, and that are comparable to items and services furnished to individuals by a home health agency that is not religious nonmedical health care institution.

(2)(A) Subject to subparagraphs (B), payment may be made with respect to services provided by such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1821.

(B) Notwithstanding any other provision of this title, payment may not be made under subparagraph (A)—

(i) in a year insofar as such payments exceed $700,000; and

(ii) after December 31, 2006.

Ultrasound Screening for Abdominal Aortic Aneurysm

(bbb) The term "ultrasound screening for abdominal aortic aneurysm" means—

(1) a procedure using sound waves (or such other procedures using alternative technologies, of commensurate accuracy and cost, that the Secretary may specify) provided for the early detection of abdominal aortic aneurysm; and

(2) includes a physician's interpretation of the results of the procedure.

Long-Term Care Hospital

(ccc) The term "long-term care hospital" means a hospital which—

(1) is primarily engaged in providing inpatient services, by or under the supervision of a physician, to Medicare beneficiaries whose medically complex conditions require a long hospital stay and programs of care provided by a long-term care hospital;

(2) has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days, or meets the requirements of clause (II) of section 1886(d)(1)(B)(iv);

(3) satisfies the requirements of subsection (e); and

(4) meets the following facility criteria:

(A) the institution has a patient review process, documented in the patient medical record, that screens patients prior to admission for appropriateness of admission to a long-term care hospital, validates within 48 hours of admission that patients meet admission criteria for long-term care hospitals, regularly evaluates patients throughout their stay for continuation of care in a long-term care hospital, and assesses the available discharge options when patients no longer meet such continued stay criteria;

(B) the institution has active physician involvement with patients during their treatment through an organized medical staff, physician-directed treatment with physician onsite availability on a daily basis to review patient progress, and consulting physicians on call and capable of being at the patient's side within a moderate period of time, as determined by the Secretary; and

(C) the institution has interdisciplinary team treatment for patients, requiring interdisciplinary teams of health care professionals, including physicians, to prepare and carry out an individualized treatment plan for each patient.

Additional Preventive Services; Preventive Services

(ddd)(1) The term "additional preventive services" means services not described in subparagraph (A) or (C) of paragraph (3) that identify medical conditions or risk factors and that the Secretary determines are—

(A) reasonable and necessary for the prevention or early detection of an illness or disability;

(B) recommended with a grade of A or B by the United States Preventive Services Task Force; and

(C) appropriate for individuals entitled to benefits under part A or enrolled under part B.

(2) In making determinations under paragraph (1) regarding the coverage of a new service, the Secretary shall use the process for making national coverage determinations (as defined in section 1869(f)(1)(B)) under this title. As part of the use of such process, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such service and may take into account the results of such assessment in making such determination.

(3) The term "preventive services" means the following:

(A) The screening and preventive services described in subsection (ww)(2) (other than the service described in subparagraph (M) of such subsection).

(B) An initial preventive physical examination (as defined in subsection (ww)).

(C) Personalized prevention plan services (as defined in subsection (hhh)(1)).

Cardiac Rehabilitation Program; Intensive Cardiac Rehabilitation Program

(eee)(1) The term "cardiac rehabilitation program" means a program (as described in paragraph (2)) that furnishes the items and services described in paragraph (3) under the supervision of a physician (as defined in subsection (r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)).

(2) A program described in this paragraph is a program under which—

(A) items and services under the program are delivered—

(i) in a physician's office;

(ii) in a hospital on an outpatient basis; or

(iii) in other settings determined appropriate by the Secretary;

(B) a physician (as defined in subsection (r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)) is immediately available and accessible for medical consultation and medical emergencies at all times items and services are being furnished under the program, except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed; and

(C) individualized treatment is furnished under a written plan established, reviewed, and signed by a physician every 30 days that describes—

(i) the individual's diagnosis;

(ii) the type, amount, frequency, and duration of the items and services furnished under the plan; and

(iii) the goals set for the individual under the plan.

(3) The items and services described in this paragraph are—

(A) physician-prescribed exercise;

(B) cardiac risk factor modification, including education, counseling, and behavioral intervention (to the extent such education, counseling, and behavioral intervention is closely related to the individual's care and treatment and is tailored to the individual's needs);

(C) psychosocial assessment;

(D) outcomes assessment; and

(E) such other items and services as the Secretary may determine, but only if such items and services are—

(i) reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(ii) reasonably expected to improve or maintain the individual's condition and functional level; and

(iii) furnished under such guidelines relating to the frequency and duration of such items and services as the Secretary shall establish, taking into account accepted norms of medical practice and the reasonable expectation of improvement of the individual.

(4)(A) The term "intensive cardiac rehabilitation program" means a program (as described in paragraph (2)) that furnishes the items and services described in paragraph (3) under the supervision of a physician (as defined in subsection (r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)) and has shown, in peer-reviewed published research, that it accomplished—

(i) one or more of the following:

(I) positively affected the progression of coronary heart disease; or

(II) reduced the need for coronary bypass surgery; or

(III) reduced the need for percutaneous coronary interventions; and

(ii) a statistically significant reduction in 5 or more of the following measures from their level before receipt of cardiac rehabilitation services to their level after receipt of such services:

(I) low density lipoprotein;

(II) triglycerides;

(III) body mass index;

(IV) systolic blood pressure;

(V) diastolic blood pressure; or

(VI) the need for cholesterol, blood pressure, and diabetes medications.

(B) To be eligible for an intensive cardiac rehabilitation program, an individual must have—

(i) had an acute myocardial infarction within the preceding 12 months;

(ii) had coronary bypass surgery;

(iii) stable angina pectoris;

(iv) had heart valve repair or replacement;

(v) had percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting;

(vi) had a heart or heart-lung transplant;

(vii) stable, chronic heart failure (defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks); or

(viii) any additional condition for which the Secretary has determined that a cardiac rehabilitation program shall be covered, unless the Secretary determines, using the same process used to determine that the condition is covered for a cardiac rehabilitation program, that such coverage is not supported by the clinical evidence.

(C) An intensive cardiac rehabilitation program may be provided in a series of 72 one-hour sessions (as defined in section 1848(b)(5)), up to 6 sessions per day, over a period of up to 18 weeks.

(5) The Secretary shall establish standards to ensure that a physician with expertise in the management of individuals with cardiac pathophysiology who is licensed to practice medicine in the State in which a cardiac rehabilitation program (or the intensive cardiac rehabilitation program, as the case may be) is offered—

(A) is responsible for such program; and

(B) in consultation with appropriate staff, is involved substantially in directing the progress of individual in the program.

Pulmonary Rehabilitation Program

(fff)(1) The term "pulmonary rehabilitation program" means a program (as described in subsection (eee)(2) with respect to a program under this subsection) that furnishes the items and services described in paragraph (2) under the supervision of a physician (as defined in subsection (r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)).

(2) The items and services described in this paragraph are—

(A) physician-prescribed exercise;

(B) education or training (to the extent the education or training is closely and clearly related to the individual's care and treatment and is tailored to such individual's needs);

(C) psychosocial assessment;

(D) outcomes assessment; and

(E) such other items and services as the Secretary may determine, but only if such items and services are—

(i) reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(ii) reasonably expected to improve or maintain the individual's condition and functional level; and

(iii) furnished under such guidelines relating to the frequency and duration of such items and services as the Secretary shall establish, taking into account accepted norms of medical practice and the reasonable expectation of improvement of the individual.

(3) The Secretary shall establish standards to ensure that a physician with expertise in the management of individuals with respiratory pathophysiology who is licensed to practice medicine in the State in which a pulmonary rehabilitation program is offered—

(A) is responsible for such program; and

(B) in consultation with appropriate staff, is involved substantially in directing the progress of individual in the program.

Kidney Disease Education Services

(ggg)(1) The term "kidney disease education services" means educational services that are—

(A) furnished to an individual with stage IV chronic kidney disease who, according to accepted clinical guidelines identified by the Secretary, will require dialysis or a kidney transplant;

(B) furnished, upon the referral of the physician managing the individual's kidney condition, by a qualified person (as defined in paragraph (2)); and

(C) designed—

(i) to provide comprehensive information (consistent with the standards set under paragraph (3)) regarding—

(I) the management of comorbidities, including for purposes of delaying the need for dialysis;

(II) the prevention of uremic complications; and

(III) each option for renal replacement therapy (including hemodialysis and peritoneal dialysis at home and in-center as well as vascular access options and transplantation);

(ii) to ensure that the individual has the opportunity to actively participate in the choice of therapy; and

(iii) to be tailored to meet the needs of the individual involved.

(2)(A) The term "qualified person" means—

(i) a physician (as defined in section 1861(r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5)), who furnishes services for which payment may be made under the fee schedule established under section 1848; and

(ii) a provider of services located in a rural area (as defined in section 1886(d)(2)(D)).

(B) Such term does not include a provider of services (other than a provider of services described in subparagraph (A)(ii)) or a renal dialysis facility.

(3) The Secretary shall set standards for the content of such information to be provided under paragraph (1)(C)(i) after consulting with physicians, other health professionals, health educators, professional organizations, accrediting organizations, kidney patient organizations, dialysis facilities, transplant centers, network organizations described in section 1881(c)(2), and other knowledgeable persons. To the extent possible the Secretary shall consult with persons or entities described in the previous sentence, other than a dialysis facility, that has not received industry funding from a drug or biological manufacturer or dialysis facility.

(4) No individual shall be furnished more than 6 sessions of kidney disease education services under this title.

Annual Wellness Visit

(hhh)(1) The term "personalized prevention plan services" means the creation of a plan for an individual—

(A) that includes a health risk assessment (that meets the guidelines established by the Secretary under paragraph (4)(A)) of the individual that is completed prior to or as part of the same visit with a health professional described in paragraph (3); and

(B) that—

(i) takes into account the results of the health risk assessment; and

(ii) may contain the elements described in paragraph (2).

(2) Subject to paragraph (4)(H), the elements described in this paragraph are the following:

(A) The establishment of, or an update to, the individual's medical and family history.

(B) A list of current providers and suppliers that are regularly involved in providing medical care to the individual (including a list of all prescribed medications).

(C) A measurement of height, weight, body mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements.

(D) Detection of any cognitive impairment.

(E) The establishment of, or an update to, the following:

(i) A screening schedule for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force and the Advisory Committee on Immunization Practices, and the individual's health status, screening history, and age-appropriate preventive services covered under this title.

(ii) A list of risk factors and conditions for which primary, secondary, or tertiary prevention interventions are recommended or are underway, including any mental health conditions or any such risk factors or conditions that have been identified through an initial preventive physical examination (as described under subsection (ww)(1)), and a list of treatment options and their associated risks and benefits.

(F) The furnishing of personalized health advice and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

(G) Any other element determined appropriate by the Secretary.

(3) A health professional described in this paragraph is—

(A) a physician;

(B) a practitioner described in clause (i) of section 1842(b)(18)(C); or

(C) a medical professional (including a health educator, registered dietitian, or nutrition professional) or a team of medical professionals, as determined appropriate by the Secretary, under the supervision of a physician.

(4)(A) For purposes of paragraph (1)(A), the Secretary, not later than 1 year after the date of enactment of this subsection, shall establish publicly available guidelines for health risk assessments. Such guidelines shall be developed in consultation with relevant groups and entities and shall provide that a health risk assessment—

(i) identify chronic diseases, injury risks, modifiable risk factors, and urgent health needs of the individual; and

(ii) may be furnished—

(I) through an interactive telephonic or web-based program that meets the standards established under subparagraph (B);

(II) during an encounter with a health care professional;

(III) through community-based prevention programs; or

(IV) through any other means the Secretary determines appropriate to maximize accessibility and ease of use by beneficiaries, while ensuring the privacy of such beneficiaries.

(B) Not later than 1 year after the date of enactment of this subsection, the Secretary shall establish standards for interactive telephonic or web-based programs used to furnish health risk assessments under subparagraph (A)(ii)(I). The Secretary may utilize any health risk assessment developed under section 4004(f) of the Patient Protection and Affordable Care Act as part of the requirement to develop a personalized prevention plan to comply with this subparagraph.

(C)(i) Not later than 18 months after the date of enactment of this subsection, the Secretary shall develop and make available to the public a health risk assessment model. Such model shall meet the guidelines under subparagraph (A) and may be used to meet the requirement under paragraph (1)(A).

(ii) Any health risk assessment that meets the guidelines under subparagraph (A) and is approved by the Secretary may be used to meet the requirement under paragraph (1)(A).

(D) The Secretary may coordinate with community-based entities (including State Health Insurance Programs, Area Agencies on Aging, Aging and Disability Resource Centers, and the Administration on Aging) to—

(i) ensure that health risk assessments are accessible to beneficiaries; and

(ii) provide appropriate support for the completion of health risk assessments by beneficiaries.

(E) The Secretary shall establish procedures to make beneficiaries and providers aware of the requirement that a beneficiary complete a health risk assessment prior to or at the same time as receiving personalized prevention plan services.

(F) To the extent practicable, the Secretary shall encourage the use of, integration with, and coordination of health information technology (including use of technology that is compatible with

electronic medical records and personal health records) and may experiment with the use of personalized technology to aid in the development of self-management skills and management of and adherence to provider recommendations in order to improve the health status of beneficiaries.

(G) A beneficiary shall be eligible to receive only an initial preventive physical examination (as defined under subsection (ww)(1)) during the 12-month period after the date that the beneficiary's coverage begins under part B and shall be eligible to receive personalized prevention plan services under this subsection each year thereafter provided that the beneficiary has not received either an initial preventive physical examination or personalized prevention plan services within the preceding 12-month period.

(H) The Secretary shall issue guidance that—

(i) identifies elements under paragraph (2) that are required to be provided to a beneficiary as part of their first visit for personalized prevention plan services; and

(ii) establishes a yearly schedule for appropriate provision of such elements thereafter.

(iii) HOME INFUSION THERAPY.—(1) The term "home infusion therapy" means the items and services described in paragraph (2) furnished by a qualified home infusion therapy supplier (as defined in paragraph (3)(D)) which are furnished in the individual's home (as defined in paragraph (3)(B)) to an individual—

(A) who is under the care of an applicable provider (as defined in paragraph (3)(A)); and

(B) with respect to whom a plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished such individual has been established by a physician (as defined in subsection (r)(1)) and is periodically reviewed by a physician (as so defined) in coordination with the furnishing of home infusion drugs (as defined in paragraph (3)(C)) under part B.

(2) The items and services described in this paragraph are the following:

(A) Professional services, including nursing services, furnished in accordance with the plan.

(B) Training and education (not otherwise paid for as durable medical equipment (as defined in subsection (n)), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier.

(3) For purposes of this subsection:

(A) The term "applicable provider" means—

(i) a physician;

(ii) a nurse practitioner; and

(iii) a physician assistant.

(B) The term "home" means a place of residence used as the home of an individual (as defined for purposes of subsection (n)).

(C) The term "home infusion drug" means a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in subsection (n)). Such term does not include the following:

(i) Insulin pump systems.

(ii) A self-administered drug or biological on a self-administered drug exclusion list.

(D)(i) The term "qualified home infusion therapy supplier" means a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider or services or supplier furnishes items or services and that—

(I) furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;

(II) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;

(III) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and

(IV) meets such other requirements as the Secretary determines appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector.

(ii) A qualified home infusion therapy supplier may subcontract with a pharmacy, physician, provider of services, or supplier to meet the requirements of this subparagraph.

*(jjj) OPIOID USE DISORDER TREATMENT SERVICES; OPIOID TREATMENT PROGRAM.—*

*(1) OPIOID USE DISORDER TREATMENT SERVICES.—The term "opioid use disorder treatment services" means items and services that are furnished by an opioid treatment program for the treatment of opioid use disorder, including—*

*(A) opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug and Cosmetic Act for use in the treatment of opioid use disorder;*

*(B) dispensing and administration of such medications, if applicable;*

*(C) substance use counseling by a professional to the extent authorized under State law to furnish such services;*

*(D) individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law);*

*(E) toxicology testing, and*

*(F) other items and services that the Secretary determines are appropriate (but in no event to include meals or transportation).*

*(2) OPIOID TREATMENT PROGRAM.—The term "opioid treatment program" means an entity that is opioid treatment program (as defined in section 8.2 of title 42 of the Code of Federal Regulations, or any successor regulation) that—*

*(A) is enrolled under section 1866(j);*

*(B) has in effect a certification by the Substance Abuse and Mental Health Services Administration for such a program;*

*(C) is accredited by an accrediting body approved by the Substance Abuse and Mental Health Services Administration; and*

*(D) meets such additional conditions as the Secretary may find necessary to ensure—*

*(i) the health and safety of individuals being furnished services under such program; and*

*(ii) the effective and efficient furnishing of such services.*

EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER

SEC. 1862. (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1861(ddd)(1)), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section 1861(s)(10), which are not reasonable and necessary for the prevention of illness,

(C) in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness,

(D) in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1886(e)(6),

(E) in the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section,

(F) in the case of screening mammography, which is performed more frequently than is covered under section 1834(c)(2) or which is not conducted by a facility described in section 1834(c)(1)(B), in the case of screening pap smear and screening pelvic exam, which is performed more frequently than is provided under section 1861(nn), and, in the case of screening for glaucoma, which is performed more frequently than is provided under section 1861(uu),

(G) in the case of prostate cancer screening tests (as defined in section 1861(oo)), which are performed more frequently than is covered under such section,

(H) in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1834(d),

(I) the frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation,

(J) in the case of a drug or biological specified in section 1847A(c)(6)(C) for which payment is made under part B that is furnished in a competitive area under section 1847B, that is not furnished by an entity under a contract under such section,

(K) in the case of an initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under part B,

(L) in the case of cardiovascular screening blood tests (as defined in section 1861(xx)(1)), which are performed more frequently than is covered under section 1861(xx)(2),

(M) in the case of a diabetes screening test (as defined in section 1861(yy)(1)), which is performed more frequently than is covered under section 1861(yy)(3),

(N) in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1861(s)(2)(AA),

(O) in the case of kidney disease education services (as defined in paragraph (1) of section 1861(ggg)), which are furnished in excess of the number of sessions covered under paragraph (4) of such section, and

(P) in the case of personalized prevention plan services (as defined in section 1861(hhh)(1)), which are performed more frequently than is covered under such section;

(2) for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services;

(3) which are paid for directly or indirectly by a governmental entity (other than under this Act and other than under a health benefits or insurance plan established for employees of such an entity), except in the case of rural health clinic services, as defined in section 1861(aa)(1), in the case of Federally qualified health center services, as defined in section 1861(aa)(3), in the case of services for which payment may be made under section 1880(e), and in such other cases as the Secretary may specify;

(4) which are not provided within the United States (except for inpatient hospital services furnished outside the United States under the conditions described in section 1814(f) and, subject to such conditions, limitations, and requirements as are provided under or pursuant to this title, physicians' services and ambulance services furnished an individual in conjunction with such inpatient hospital services but only for the period during which such inpatient hospital services were furnished);

(5) which are required as a result of war, or of an act of war, occurring after the effective date of such individual's current coverage under such part;

(6) which constitute personal comfort items (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(7) where such expenses are for routine physical checkups, eyeglasses (other than eyewear described in section 1861(s)(8)) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefor, or immunizations (except as otherwise allowed under section 1861(s)(10) and subparagraph (B), (F), (G), (H), (K), or (P) of paragraph (1));

(8) where such expenses are for orthopedic shoes or other supportive devices for the feet, other than shoes furnished pursuant to section 1861(s)(12);

(9) where such expenses are for custodial care (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(10) where such expenses are for cosmetic surgery or are incurred in connection therewith, except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member;

(11) where such expenses constitute charges imposed by immediate relatives of such individual or members of his household;

(12) where such expenses are for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

(13) where such expenses are for—

(A) the treatment of flat foot conditions and the prescription of supportive devices therefor,

(B) the treatment of subluxations of the foot, or

(C) routine foot care (including the cutting or removal of corns or calluses, the trimming of nails, and other routine hygienic care);

(14) which are other than physicians' services (as defined in regulations promulgated specifically for purposes of this paragraph), services described by section 1861(s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist, and which are furnished to an individual who is a patient of a hospital or critical access hospital by an entity other than the hospital or critical access hospital, unless the services are furnished under arrangements (as defined in section 1861(w)(1)) with the entity made by the hospital or critical access hospital;

(15)(A) which are for services of an assistant at surgery in a cataract operation (including subsequent insertion of an intraocular lens) unless, before the surgery is performed, the appropriate quality improvement organization (under part B of title XI) or a carrier under section 1842 has approved of the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition, or

(B) which are for services of an assistant at surgery to which section 1848(i)(2)(B) applies;

(16) in the case in which funds may not be used for such items and services under the Assisted Suicide Funding Restriction Act of 1997;

(17) where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1847(a)) by an entity other than an entity with which the Secretary has entered into a contract under section 1847(b) for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary;

(18) which are covered skilled nursing facility services described in section 1888(e)(2)(A)(i) and which are furnished to an individual who is a resident of a skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1861(s)(2)(D), which are furnished to such an individual without regard to such period), by an entity other than the skilled nursing facility, unless the services are furnished under arrangements (as defined in section 1861(w)(1)) with the entity made by the skilled nursing facility;

(19) which are for items or services which are furnished pursuant to a private contract described in section 1802(b);

(20) in the case of outpatient physical therapy services, outpatient speech-language pathology services, or outpatient occupational therapy services furnished as an incident to a physician's professional services (as described in section 1861(s)(2)(A)), that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1861(p) (or under such sentence through the operation of subsection (g) or (ll)(2) of section 1861) as such standards and conditions would apply to such therapy services if furnished by a therapist;

(21) where such expenses are for home health services (including medical supplies described in section 1861(m)(5), but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who is under a plan of care of the home health agency if the claim for payment for such services is not submitted by the agency;

(22) subject to subsection (h), for which a claim is submitted other than in an electronic form specified by the Secretary;

(23) which are the technical component of advanced diagnostic imaging services described in section 1834(e)(1)(B) for which payment is made under the fee schedule established under section 1848(b) and that are furnished by a supplier (as defined in section 1861(d)), if such supplier is not accredited by an accreditation organization designated by the Secretary under section 1834(e)(2)(B);

(24) where such expenses are for renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14)) for which payment is made under such section unless such payment is made under such section to a provider of services or a renal dialysis facility for such services; or

(25) not later than January 1, 2014, for which the payment is other than by electronic funds transfer (EFT) or an electronic remittance in a form as specified in ASC X12 835 Health Care Payment and Remittance Advice or subsequent standard.

Paragraph (7) shall not apply to Federally qualified health center services described in section 1861(aa)(3)(B). In making a national coverage determination (as defined in paragraph (1)(B) of section 1869(f)) the Secretary shall ensure consistent with subsection (l) that the public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

(b) MEDICARE AS SECONDARY PAYER.—

(1) REQUIREMENTS OF GROUP HEALTH PLANS.—

(A) WORKING AGED UNDER GROUP HEALTH PLANS.—

(i) IN GENERAL.—A group health plan—

(I) may not take into account that an individual (or the individual's spouse) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this title under section 226(a), and

(II) shall provide that any individual age 65 or older (and the spouse age 65 or older of any individual) who has current employment status with an employer shall be entitled to the same benefits under the plan under the same conditions as any such individual (or spouse) under age 65.

(ii) EXCLUSION OF GROUP HEALTH PLAN OF A SMALL EMPLOYER.—Clause (i) shall not apply to a group health plan unless the plan is a plan of, or contributed to by, an employer that has 20 or more employees for each working day in each of 20 or more calendar weeks in the current calendar year or the preceding calendar year.

(iii) EXCEPTION FOR SMALL EMPLOYERS IN MULTIEMPLOYER OR MULTIPLE EMPLOYER GROUP HEALTH PLANS.—Clause (i) also shall not apply with respect to individuals enrolled in a multiemployer or multiple employer group health plan if the coverage of the individuals under the plan is by virtue of current employment status with an employer that does not have 20 or more individuals in current employment status for each working day in each of 20 or more calendar weeks in the current calendar year and the preceding calendar year; except that the exception provided in this clause shall only apply if the plan elects treatment under this clause.

(iv) EXCEPTION FOR INDIVIDUALS WITH END STAGE RENAL DISEASE.—Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 226) would upon application be, entitled to benefits under section 226A.

(v) GROUP HEALTH PLAN DEFINED.—In this subparagraph, and subparagraph (C), the term "group health plan" has the meaning given such term in section 5000(b)(1) of the Internal Revenue Code of 1986, without regard to section 5000(d) of such Code

(B) DISABLED INDIVIDUALS IN LARGE GROUP HEALTH PLANS.—

(i) IN GENERAL.—A large group health plan (as defined in clause (iii)) may not take into account that an individual (or a member of the individual's family) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this title under section 226(b).

(ii) EXCEPTION FOR INDIVIDUALS WITH END STAGE RENAL DISEASE.—Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 226) would upon application be, entitled to benefits under section 226A.

(iii) LARGE GROUP HEALTH PLAN DEFINED.—In this subparagraph, the term "large group health plan" has the meaning given such term in section 5000(b)(2) of the Internal Revenue Code of 1986, without regard to section 5000(d) of such Code.

(C) INDIVIDUALS WITH END STAGE RENAL DISEASE.—A group health plan (as defined in subparagraph (A)(v))—

(i) may not take into account that an individual is entitled to or eligible for benefits under this title under section 226A during the 12-month period which begins with the first month in which the individual becomes entitled to benefits under part A

under the provisions of section 226A, or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 226A if the individual had filed an application for such benefits; and

(ii) may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner;

except that clause (ii) shall not prohibit a plan from paying benefits secondary to this title when an individual is entitled to or eligible for benefits under this title under section 226A after the end of the 12-month period described in clause (i). Effective for items and services furnished on or after February 1, 1991, and before the date of enactment of the Balanced Budget Act of 1997 (with respect to periods beginning on or after February 1, 1990), this subparagraph shall be applied by substituting "18- month" for "12-month" each place it appears. Effective for items and services furnished on or after the date of enactment of the Balanced Budget Act of 1997 *and before January 1, 2020*, (with respect to periods beginning on or after the date that is 18 months prior to such date), clauses (i) and (ii) shall be applied by substituting "30-month" for "12-month" each place it appears. *Effective for items and services furnished on or after January 1, 2020 (with respect to periods beginning on or after July 1, 2018), clauses (i) and (ii) shall be applied by substituting "33-month" for "12-month" each place it appears.*

(D) TREATMENT OF CERTAIN MEMBERS OF RELIGIOUS ORDERS.—In this subsection, an individual shall not be considered to be employed, or an employee, with respect to the performance of services as a member of a religious order which are considered employment only by virtue of an election made by the religious order under section 3121(r) of the Internal Revenue Code of 1986.

(E) GENERAL PROVISIONS.—For purposes of this subsection:

(i) AGGREGATION RULES.—

(I) All employers treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as a single employer.

(II) All employees of the members of an affiliated service group (as defined in section 414(m) of such Code) shall be treated as employed by a single employer.

(III) Leased employees (as defined in section 414(n)(2) of such Code) shall be treated as employees of the person for whom they perform services to the extent they are so treated under section 414(n) of such Code.

In applying sections of the Internal Revenue Code of 1986 under this clause, the Secretary shall rely upon regulations and decisions of the Secretary of the Treasury respecting such sections.

(ii) CURRENT EMPLOYMENT STATUS DEFINED.—An individual has "current employment status" with an employer if the individual is an employee, is the employer, or is associated with the employer in a business relationship.

(iii) TREATMENT OF SELF-EMPLOYED PERSONS AS EMPLOYERS.—The term "employer" includes a self-employed person.

(F) LIMITATION ON BENEFICIARY LIABILITY.—An individual who is entitled to benefits under this title and is furnished an item or service for which such benefits are incorrectly paid is not liable for repayment of such benefits under this paragraph unless payment of such benefits was made to the individual.

(2) MEDICARE SECONDARY PAYER.—

(A) IN GENERAL.—Payment under this title may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that—

(i) payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under paragraph (1), or

(ii) payment has been made or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance.

In the subsection, the term "primary plan" means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or

no fault insurance, to the extent that clause (ii) applies. An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

(B) CONDITIONAL PAYMENT.—

(i) AUTHORITY TO MAKE CONDITIONAL PAYMENT.—The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.

(ii) REPAYMENT REQUIRED.—Subject to paragraph (9), a primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means. If reimbursement is not made to the appropriate Trust Fund before the expiration of the 60-day period that begins on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received, the Secretary may charge interest (beginning with the date on which the notice or other information is received) on the amount of the reimbursement until reimbursement is made (at a rate determined by the Secretary in accordance with regulations of the Secretary of the Treasury applicable to charges for late payments).

(iii) ACTION BY UNITED STATES.—In order to recover payment made under this title for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity. The United States may not recover from a third-party administrator under this clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and is not employed by or under contract with the employer or group health plan at the time the action for recovery is initiated by the United States or for whom it provides administrative services due to the insolvency or bankruptcy of the employer or plan. An action may not be brought by the United States under this clause with respect to payment owed unless the complaint is filed not later than 3 years after the date of the receipt of notice of a settlement, judgment, award, or other payment made pursuant to paragraph (8) relating to such payment owed.

(iv) SUBROGATION RIGHTS.—The United States shall be subrogated (to the extent of payment made under this title for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

(v) WAIVER OF RIGHTS.—The Secretary may waive (in whole or in part) the provisions of this subparagraph in the case of an individual claim if the Secretary determines that the waiver is in the best interests of the program established under this title.

(vi) CLAIMS-FILING PERIOD.—Notwithstanding any other time limits that may exist for filing a claim under an employer group health plan, the United States may seek to recover conditional payments in accordance with this subparagraph where the request for payment is submitted to the entity required or responsible under this subsection to pay with respect to the item or service (or any portion thereof) under a pri-

mary plan within the 3-year period beginning on the date on which the item or service was furnished.

(vii) USE OF WEBSITE TO DETERMINE FINAL CONDITIONAL REIMBURSEMENT AMOUNT.—

(I) NOTICE TO SECRETARY OF EXPECTED DATE OF A SETTLEMENT, JUDGMENT, ETC.—In the case of a payment made by the Secretary pursuant to clause (i) for items and services provided to the claimant, the claimant or applicable plan (as defined in paragraph (8)(F)) may at any time beginning 120 days before the reasonably expected date of a settlement, judgment, award, or other payment, notify the Secretary that a payment is reasonably expected and the expected date of such payment.

(II) SECRETARIAL PROVIDING ACCESS TO CLAIMS INFORMATION THROUGH A WEBSITE.—The Secretary shall maintain and make available to individuals to whom items and services are furnished under this title (and to authorized family or other representatives recognized under regulations and to an applicable plan which has obtained the consent of the individual) access to information on the claims for such items and services (including payment amounts for such claims), including those claims that relate to a potential settlement, judgment, award, or other payment. Such access shall be provided to an individual, representative, or plan through a website that requires a password to gain access to the information. The Secretary shall update the information on claims and payments on such website in as timely a manner as possible but not later than 15 days after the date that payment is made. Information related to claims and payments subject to the notice under subclause (I) shall be maintained and made available consistent with the following:

(aa) The information shall be as complete as possible and shall include provider or supplier name, diagnosis codes (if any), dates of service, and conditional payment amounts.

(bb) The information accurately identifies those claims and payments that are related to a potential settlement, judgment, award, or other payment to which the provisions of this subsection apply.

(cc) The website provides a method for the receipt of secure electronic communications with the individual, representative, or plan involved.

(dd) The website provides that information is transmitted from the website in a form that includes an official time and date that the information is transmitted.

(ee) The website shall permit the individual, representative, or plan to download a statement of reimbursement amounts (in this clause referred to as a "statement of reimbursement amount") on payments for claims under this title relating to a potential settlement, judgment, award, or other payment.

(III) USE OF TIMELY WEB DOWNLOAD AS BASIS FOR FINAL CONDITIONAL AMOUNT.—If an individual (or other claimant or applicable plan with the consent of the individual) obtains a statement of reimbursement amount from the website during the protected period as defined in subclause (V) and the related settlement, judgment, award or other payment is made during such period, then the last statement of reimbursement amount that is downloaded during such period and within 3 business days before the date of the settlement, judgment, award, or other payment shall constitute the final conditional amount subject to recovery under clause (ii) related to such settlement, judgment, award, or other payment.

(IV) RESOLUTION OF DISCREPANCIES.—If the individual (or authorized representative) believes there is a discrepancy with the statement of reimbursement amount, the Secretary shall provide a timely process to resolve the discrepancy. Under such process the individual (or representative) must provide documentation explaining the discrepancy and a proposal to resolve such discrepancy. Within 11 business days after the date of receipt of such documentation, the Secretary shall determine whether there is a reasonable basis to include or remove claims on the statement of reimbursement. If the Secretary does not make such determination within the 11 business-day period, then the proposal to resolve the discrepancy

shall be accepted. If the Secretary determines within such period that there is not a reasonable basis to include or remove claims on the statement of reimbursement, the proposal shall be rejected. If the Secretary determines within such period that there is a reasonable basis to conclude there is a discrepancy, the Secretary must respond in a timely manner by agreeing to the proposal to resolve the discrepancy or by providing documentation showing with good cause why the Secretary is not agreeing to such proposal and establishing an alternate discrepancy resolution. In no case shall the process under this subclause be treated as an appeals process or as establishing a right of appeal for a statement of reimbursement amount and there shall be no administrative or judicial review of the Secretary's determinations under this subclause.

(V) PROTECTED PERIOD.—In subclause (III), the term "protected period" means, with respect to a settlement, judgment, award or other payment relating to an injury or incident, the portion (if any) of the period beginning on the date of notice under subclause (I) with respect to such settlement, judgment, award, or other payment that is after the end of a Secretarial response period beginning on the date of such notice to the Secretary. Such Secretarial response period shall be a period of 65 days, except that such period may be extended by the Secretary for a period of an additional 30 days if the Secretary determines that additional time is required to address claims for which payment has been made. Such Secretarial response period shall be extended and shall not include any days for any part of which the Secretary determines (in accordance with regulations) that there was a failure in the claims and payment posting system and the failure was justified due to exceptional circumstances (as defined in such regulations). Such regulations shall define exceptional circumstances in a manner so that not more than 1 percent of the repayment obligations under this subclause would qualify as exceptional circumstances.

(VI) EFFECTIVE DATE.—The Secretary shall promulgate final regulations to carry out this clause not later than 9 months after the date of the enactment of this clause.

(VII) WEBSITE INCLUDING SUCCESSOR TECHNOLOGY.—In this clause, the term "website" includes any successor technology.

(viii) RIGHT OF APPEAL FOR SECONDARY PAYER DETERMINATIONS RELATING TO LIABILITY INSURANCE (INCLUDING SELF-INSURANCE), NO FAULT INSURANCE, AND WORKERS' COMPENSATION LAWS AND PLANS.—The Secretary shall promulgate regulations establishing a right of appeal and appeals process, with respect to any determination under this subsection for a payment made under this title for an item or service for which the Secretary is seeking to recover conditional payments from an applicable plan (as defined in paragraph (8)(F)) that is a primary plan under subsection (A)(ii), under which the applicable plan involved, or an attorney, agent, or third party administrator on behalf of such plan, may appeal such determination. The individual furnished such an item or service shall be notified of the plan's intent to appeal such determination

(C) TREATMENT OF QUESTIONNAIRES.—The Secretary may not fail to make payment under subparagraph (A) solely on the ground that an individual failed to complete a questionnaire concerning the existence of a primary plan.

(3) ENFORCEMENT.—

(A) PRIVATE CAUSE OF ACTION.—There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A).

(B) REFERENCE TO EXCISE TAX WITH RESPECT TO NONCONFORMING GROUP HEALTH PLANS.—For provision imposing an excise tax with respect to nonconforming group health plans, see section 5000 of the Internal Revenue Code of 1986.

(C) PROHIBITION OF FINANCIAL INCENTIVES NOT TO ENROLL IN A GROUP HEALTH PLAN OR A LARGE GROUP HEALTH PLAN.—It is unlawful for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits under this title not to enroll (or to terminate enrollment) under a group health plan or a large group health plan which would (in the case of such enrollment) be a primary plan (as defined in paragraph (2)(A)). Any entity that violates the previous sentence is subject to a civil money

penalty of not to exceed $5,000 for each such violation. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(4) COORDINATION OF BENEFITS.—Where payment for an item or service by a primary plan is less than the amount of the charge for such item or service and is not payment in full, payment may be made under this title (without regard to deductibles and coinsurance under this title) for the remainder of such charge, but—

(A) payment under this title may not exceed an amount which would be payable under this title for such item or service if paragraph (2)(A) did not apply; and

(B) payment under this title, when combined with the amount payable under the primary plan, may not exceed—

(i) in the case of an item or service payment for which is determined under this title on the basis of reasonable cost (or other cost-related basis) or under section 1886, the amount which would be payable under this title on such basis, and

(ii) in the case of an item or service for which payment is authorized under this title on another basis—

(I) the amount which would be payable under the primary plan (without regard to deductibles and coinsurance under such plan), or

(II) the reasonable charge or other amount which would be payable under this title (without regard to deductibles and coinsurance under this title),

whichever is greater.

(5) IDENTIFICATION OF SECONDARY PAYER SITUATIONS.—

(A) REQUESTING MATCHING INFORMATION.—

(i) COMMISSIONER OF SOCIAL SECURITY.—The Commissioner of Social Security shall, not less often that annually, transmit to the Secretary of the Treasury a list of the names and TINs of medicare beneficiaries (as defined in section 6103(l)(12) of the Internal Revenue Code of 1986) and request that the Secretary disclose to the Commissioner the information described in subparagraph (A) of such section.

(ii) ADMINISTRATOR.—The Administrator of the Centers for Medicare & Medicaid Services shall request, not less often than annually, the Commissioner of the Social Security Administration to disclose to the Administrator the information described in subparagraph (B) of section 6103(l)(12) of the Internal Revenue Code of 1986.

(B) DISCLOSURE TO FISCAL INTERMEDIARIES AND CARRIERS.—In addition to any other information provided under this title to fiscal intermediaries and carriers, the Administrator shall disclose to such intermediaries and carriers (or to such a single intermediary or carrier as the Secretary may designate) the information received under subparagraph (A) for purposes of carrying out this subsection.

(C) CONTACTING EMPLOYERS.—

(i) IN GENERAL.—With respect to each individual (in this subparagraph referred to as an "employee") who was furnished a written statement under section 6051 of the Internal Revenue Code of 1986 by a qualified employer (as defined in section 6103(l)(12)(E)(iii) of such Code), as disclosed under subparagraph (B), the appropriate fiscal intermediary or carrier shall contact the employer in order to determine during what period the employee or employee's spouse may be (or have been) covered under a group health plan of the employer and the nature of the coverage that is or was provided under the plan (including the name, address, and identifying number of the plan).

(ii) EMPLOYER RESPONSE.—Within 30 days of the date of receipt of the inquiry, the employer shall notify the intermediary or carrier making the inquiry as to the determinations described in clause (i). An employer (other than a Federal or other governmental entity) who willfully or repeatedly fails to provide timely and accurate notice in accordance with the previous sentence shall be subject to a civil money penalty of not to exceed $1,000 for each individual with respect to which such an inquiry is made. The provision of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(D) OBTAINING INFORMATION FROM BENEFICIARIES.—Before an individual applies for benefits under part A or enrolls under part B, the Administrator shall mail the individual

a questionnaire to obtain information on whether the individual is covered under a primary plan and the nature of the coverage provided under the plan, including the name, address, and identifying number of the plan.

(E) END DATE.—The provisions of this paragraph shall not apply to information required to be provided on or after July 1, 2016.

(6) SCREENING REQUIREMENTS FOR PROVIDERS AND SUPPLIERS.—

(A) IN GENERAL.—Notwithstanding any other provision of this title, no payment may be made for any item or service furnished under part B unless the entity furnishing such item or service completes (to the best of its knowledge and on the basis of information obtained from the individual to whom the item or service is furnished) the portion of the claim form relating to the availability of other health benefit plans.

(B) PENALTIES.—An entity that knowingly, willfully, and repeatedly fails to complete a claim form in accordance with subparagraph (A) or provides inaccurate information relating to the availability of other health benefit plans on a claim form under such subparagraph shall be subject to a civil money penalty of not to exceed $2,000 for each such incident. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(7) REQUIRED SUBMISSION OF INFORMATION BY GROUP HEALTH PLANS.—

(A) REQUIREMENT.—On and after the first day of the first calendar quarter beginning after the date that is 1 year after the date of the enactment of this paragraph, an entity serving as an insurer or third party administrator for a group health plan, as defined in paragraph (1)(A)(v), and, in the case of a group health plan that is self-insured and self-administered, a plan administrator or fiduciary, shall—

**[**(i) secure from the plan sponsor and plan participants such information as the Secretary shall specify for the purpose of identifying situations where the group health plan is or has been a primary plan to the program under this title; and**]**

*(i) secure from the plan sponsor and plan participants such information as the Secretary shall specify for the purpose of identifying situations where the group health plan is or has been—*

*(I) a primary plan to the program under this title; or*

*(II) for calendar quarters beginning on or after January 1, 2020, a primary payer with respect to benefits relating to prescription drug coverage under part D; and*

(ii) submit such information to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) ENFORCEMENT.—

(i) IN GENERAL.—An entity, a plan administrator, or a fiduciary described in subparagraph (A) that fails to comply with the requirements under such subparagraph shall be subject to a civil money penalty of $1,000 for each day of noncompliance for each individual for which the information under such subparagraph should have been submitted. The provisions of subsections (e) and (k) of section 1128A shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this title with respect to an individual.

(ii) DEPOSIT OF AMOUNTS COLLECTED.—Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund under section 1817.

(C) SHARING OF INFORMATION.—Notwithstanding any other provision of law, under terms and conditions established by the Secretary, the Secretary—

(i) shall share information on entitlement under Part A and enrollment under Part B under this title with entities, plan administrators, and fiduciaries described in subparagraph (A);

(ii) may share the entitlement and enrollment information described in clause (i) with entities and persons not described in such clause; and

(iii) may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

(D) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(8) REQUIRED SUBMISSION OF INFORMATION BY OR ON BEHALF OF LIABILITY INSURANCE (INCLUDING SELF-INSURANCE), NO FAULT INSURANCE, AND WORKERS' COMPENSATION LAWS AND PLANS.—

(A) REQUIREMENT.—On and after the first day of the first calendar quarter beginning after the date that is 18 months after the date of the enactment of this paragraph, an applicable plan shall—

(i) determine whether a claimant (including an individual whose claim is unresolved) is entitled to benefits under the program under this title on any basis; and

(ii) if the claimant is determined to be so entitled, submit the information described in subparagraph (B) with respect to the claimant to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) REQUIRED INFORMATION.—The information described in this subparagraph is—

(i) the identity of the claimant for which the determination under subparagraph (A) was made; and

(ii) such other information as the Secretary shall specify in order to enable the Secretary to make an appropriate determination concerning coordination of benefits, including any applicable recovery claim.

Not later than 18 months after the date of enactment of this sentence, the Secretary shall modify the reporting requirements under this paragraph so that an applicable plan in complying with such requirements is permitted but not required to access or report to the Secretary beneficiary social security account numbers or health identification claim numbers, except that the deadline for such modification shall be extended by one or more periods (specified by the Secretary) of up to 1 year each if the Secretary notifies the committees of jurisdiction of the House of Representatives and of the Senate that the prior deadline for such modification, without such extension, threatens patient privacy or the integrity of the secondary payer program under this subsection. Any such deadline extension notice shall include information on the progress being made in implementing such modification and the anticipated implementation date for such modification.

(C) TIMING.—Information shall be submitted under subparagraph (A)(ii) within a time specified by the Secretary after the claim is resolved through a settlement, judgment, award, or other payment (regardless of whether or not there is a determination or admission of liability).

(D) CLAIMANT.—For purposes of subparagraph (A), the term "claimant" includes—

(i) an individual filing a claim directly against the applicable plan; and

(ii) an individual filing a claim against an individual or entity insured or covered by the applicable plan.

(E) ENFORCEMENT.—

(i) IN GENERAL.—An applicable plan that fails to comply with the requirements under subparagraph (A) with respect to any claimant may be subject to a civil money penalty of up to $1,000 for each day of noncompliance with respect to each claimant. The provisions of subsections (e) and (k) of section 1128A shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this title with respect to an individual.

(ii) DEPOSIT OF AMOUNTS COLLECTED.—Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund.

(F) APPLICABLE PLAN.—In this paragraph, the term "applicable plan" means the following laws, plans, or other arrangements, including the fiduciary or administrator for such law, plan, or arrangement:

(i) Liability insurance (including self-insurance).

(ii) No fault insurance.

(iii) Workers' compensation laws or plans.

(G) SHARING OF INFORMATION.—The Secretary may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

(H) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(I) REGULATIONS.—Not later than 60 days after the date of the enactment of this subparagraph, the Secretary shall publish a notice in the Federal Register soliciting proposals, which will be accepted during a 60-day period, for the specification of practices for which sanctions will and will not be imposed under subparagraph (E), including not imposing sanctions for good faith efforts to identify a beneficiary pursuant to this paragraph under an applicable entity responsible for reporting information. After considering the proposals so submitted, the Secretary, in consultation with the Attorney General, shall publish in the Federal Register, including a 60-day period for comment, proposed specified practices for which such sanctions will and will not be imposed. After considering any public comments received during such period, the Secretary shall issue final rules specifying such practices.

(9) EXCEPTION.—

(A) IN GENERAL.—Clause (ii) of paragraph (2)(B) and any reporting required by paragraph (8) shall not apply with respect to any settlement, judgment, award, or other payment by an applicable plan arising from liability insurance (including self-insurance) and from alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) constituting a total payment obligation to a claimant of not more than the single threshold amount calculated by the Secretary under subparagraph (B) for the year involved.

(B) ANNUAL COMPUTATION OF THRESHOLD.—

(i) IN GENERAL.—Not later than November 15 before each year, the Secretary shall calculate and publish a single threshold amount for settlements, judgments, awards, or other payments for obligations arising from liability insurance (including self-insurance) and for alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) subject to this section for that year. The annual single threshold amount for a year shall be set such that the estimated average amount to be credited to the Medicare trust funds of collections of conditional payments from such settlements, judgments, awards, or other payments arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section shall equal the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section for the year. At the time of calculating, but before publishing, the single threshold amount for 2014, the Secretary shall inform, and seek review of, the Comptroller General of the United States with regard to such amount.

(ii) PUBLICATION.—The Secretary shall include, as part of such publication for a year—

(I) the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents; and

(II) a summary of the methodology and data used by the Secretary in computing such threshold amount and such cost of collection.

(C) EXCLUSION OF ONGOING EXPENSES.—For purposes of this paragraph and with respect to a settlement, judgment, award, or other payment not otherwise addressed in clause (ii) of paragraph (2)(B) that includes ongoing responsibility for medical payments (excluding settlements, judgments, awards, or other payments made by a workers' compensation law or plan or no fault insurance), the amount utilized for calculation of the threshold described in subparagraph (A) shall include only the cumulative value of the medical payments made under this title.

(D) REPORT TO CONGRESS.—Not later than November 15 before each year, the Secretary shall submit to the Congress a report on the single threshold amount for settlements, judgments, awards, or other payments for conditional payment obligations arising from liability insurance (including self-insurance) and alleged incidents described in subparagraph (A) for that year and on the establishment and application of similar thresholds for such payments for conditional payment obligations arising from worker compensation cases and from no fault insurance cases subject to this section for the year. For each such report, the Secretary shall—

(i) calculate the threshold amount by using the methodology applicable to certain liability claims described in subparagraph (B); and

(ii) include a summary of the methodology and data used in calculating each threshold amount and the amount of estimated savings under this title achieved by the Secretary implementing each such threshold.

(c) No payment may be made under part B for any expenses incurred for—

(1) a drug product—

(A) which is described in section 107(c)(3) of the Drug Amendments of 1962,

(B) which may be dispensed only upon prescription,

(C) for which the Secretary has issued a notice of an opportunity for a hearing under subsection (e) of section 505 of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug product under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling, and

(D) for which the Secretary has not determined there is a compelling justification for its medical need; and

(2) any other drug product—

(A) which is identical, related, or similar (as determined in accordance with section 310.6 of title 21 of the Code of Federal Regulations) to a drug product described in paragraph (1), and

(B) for which the Secretary has not determined there is a compelling justification for its medical need,

until such time as the Secretary withdraws such proposed order.

(d) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.

(e)(1) No payment may be made under this title with respect to any item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished—

(A) by an individual or entity during the period when such individual or entity is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) from participation in the program under this title; or

(B) at the medical direction or on the prescription of a physician during the period when he is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) from participation in the program under this title and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after reasonable notice has been furnished to the person).

(2) Where an individual eligible for benefits under this title submits a claim for payment for items or services furnished by an individual or entity excluded from participation in the programs under this title, pursuant to section 1128, 1128A, 1156, 1160 (as in effect on September 2, 1982), 1842(j)(2), 1862(d) (as in effect on the date of the enactment of the Medicare and Medicaid Patient and Program Protection Act of 1987), or l866, and such beneficiary did not know or have reason to know that such individual or entity was so excluded, then, to the extent permitted by this title, and notwithstanding such exclusion, payment shall be made for such items or services. In each such case the Secretary shall notify the beneficiary of the exclusion of the individual or entity furnishing the items or services. Payment shall not be made for items or services furnished by an excluded individual or entity to a beneficiary after a reasonable time (as determined by the Secretary in regulations) after the Secretary has notified the beneficiary of the exclusion of that individual or entity.

(f) The Secretary shall establish utilization guidelines for the determination of whether or not payment may be made, consistent with paragraph (1)(A) of subsection (a), under part A or part B for expenses incurred with respect to the provision of home health services, and shall provide for the implementation of such guidelines through a process of selective postpayment coverage review by intermediaries or otherwise.

(g) The Secretary shall, in making the determinations under paragraphs (1) and (9) of subsection (a), and for the purposes of promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services of the type for which payment may be made under this title, enter into contracts with quality improvement organizations pursuant to part B of title XI of this Act.

(h)(1) The Secretary—

(A) shall waive the application of subsection (a)(22) in cases in which—

(i) there is no method available for the submission of claims in an electronic form; or

(ii) the entity submitting the claim is a small provider of services or supplier; and

(B) may waive the application of such subsection in such unusual cases as the Secretary finds appropriate.

(2) For purposes of this subsection, the term "small provider of services or supplier" means—

(A) a provider of services with fewer than 25 full-time equivalent employees; or

(B) a physician, practitioner, facility, or supplier (other than provider of services) with fewer than 10 full-time equivalent employees.

(i) In order to supplement the activities of the Medicare Payment Advisory Commission under section 1886(e) in assessing the safety, efficacy, and cost-effectiveness of new and existing medical procedures, the Secretary may carry out, or award grants or contracts for, original research and experimentation of the type described in clause (ii) of section 1886(e)(6)(E) with respect to such a procedure if the Secretary finds that—

(1) such procedure is not of sufficient commercial value to justify research and experimentation by a commercial organization;

(2) research and experimentation with respect to such procedure is not of a type that may appropriately be carried out by an institute, division, or bureau of the National Institutes of Health; and

(3) such procedure has the potential to be more cost-effective in the treatment of a condition than procedures currently in use with respect to such condition.

(j)(1) Any advisory committee appointed to advise the Secretary on matters relating to the interpretation, application, or implementation of subsection (a)(1) shall assure the full participation of a nonvoting member in the deliberations of the advisory committee, and shall provide such nonvoting member access to all information and data made available to voting members of the advisory committee, other than information that—

(A) is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section (relating to trade secrets); or

(B) the Secretary determines would present a conflict of interest relating to such nonvoting member.

(2) If an advisory committee described in paragraph (1) organizes into panels of experts according to types of items or services considered by the advisory committee, any such panel of experts may report any recommendation with respect to such items or services directly to the Secretary without the prior approval of the advisory committee or an executive committee thereof.

(k)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.

(l) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

(1) FACTORS AND EVIDENCE USED IN MAKING NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph in a manner similar to the development of guidance documents under section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)).

(2) TIMEFRAME FOR DECISIONS ON REQUESTS FOR NATIONAL COVERAGE DETERMINATIONS.—In the case of a request for a national coverage determination that—

(A) does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or

(B) requires such an assessment or deliberation and in which a clinical trial is not requested, the decision on the request shall be made not later than 9 months after the date of the request.

(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL COVERAGE DETERMINATIONS.—

(A) PERIOD FOR PROPOSED DECISION.—Not later than the end of the 6-month period (or 9-month period for requests described in paragraph (2)(B)) that begins on the date a request for a national coverage determination is made, the Secretary shall make a draft of proposed decision on the request available to the public through the Internet website of the Centers for Medicare & Medicaid Services or other appropriate means.

(B) 30-DAY PERIOD FOR PUBLIC COMMENT.—Beginning on the date the Secretary makes a draft of the proposed decision available under subparagraph (A), the Secretary shall provide a 30-day period for public comment on such draft.

(C) 60-DAY PERIOD FOR FINAL DECISION.—Not later than 60 days after the conclusion of the 30-day period referred to under subparagraph (B), the Secretary shall—

(i) make a final decision on the request;

(ii) include in such final decision summaries of the public comments received and responses to such comments;

(iii) make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

(iv) in the case of a final decision under clause (i) to grant the request for the national coverage determination, the Secretary shall assign a temporary or permanent code (whether existing or unclassified) and implement the coding change.

(4) CONSULTATION WITH OUTSIDE EXPERTS IN CERTAIN NATIONAL COVERAGE DETERMINATIONS.—With respect to a request for a national coverage determination for which there is not a review by the Medicare Coverage Advisory Committee, the Secretary shall consult with appropriate outside clinical experts.

(5) LOCAL COVERAGE DETERMINATION PROCESS.—

(A) PLAN TO PROMOTE CONSISTENCY OF COVERAGE DETERMINATIONS.—The Secretary shall develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations.

(B) CONSULTATION.—The Secretary shall require the fiscal intermediaries or carriers providing services within the same area to consult on all new local coverage determinations within the area.

(C) DISSEMINATION OF INFORMATION.—The Secretary should serve as a center to disseminate information on local coverage determinations among fiscal intermediaries and carriers to reduce duplication of effort.

(D) LOCAL COVERAGE DETERMINATIONS.—The Secretary shall require each Medicare administrative contractor that develops a local coverage determination to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination, the following information:

(i) Such determination in its entirety.

(ii) Where and when the proposed determination was first made public.

(iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

(iv) A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.

(v) An explanation of the rationale that supports such determination.

(6) NATIONAL AND LOCAL COVERAGE DETERMINATION DEFINED.—For purposes of this subsection—

(A) NATIONAL COVERAGE DETERMINATION.—The term "national coverage determination" means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title.

(B) LOCAL COVERAGE DETERMINATION.—The term "local coverage determination" has the meaning given that in section 1869(f)(2)(B).

(m) COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS OF CATEGORY A DEVICES.—

(1) IN GENERAL.—In the case of an individual entitled to benefits under part A, or enrolled under part B, or both who participates in a category A clinical trial, the Secretary shall not exclude under subsection (a)(1) payment for coverage of routine costs of care (as defined by the Secretary) furnished to such individual in the trial.

(2) CATEGORY A CLINICAL TRIAL.—For purposes of paragraph (1), a "category A clinical trial" means a trial of a medical device if—

(A) the trial is of an experimental/investigational (category A) medical device (as defined in regulations under section 405.201(b) of title 42, Code of Federal Regulations (as in effect as of September 1, 2003));

(B) the trial meets criteria established by the Secretary to ensure that the trial conforms to appropriate scientific and ethical standards; and

(C) in the case of a trial initiated before January 1, 2010, the device involved in the trial has been determined by the Secretary to be intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.

(n) REQUIREMENT OF A SURETY BOND FOR CERTAIN PROVIDERS OF SERVICES AND SUPPLIERS.—

(1) IN GENERAL.—The Secretary may require a provider of services or supplier described in paragraph (2) to provide the Secretary on a continuing basis with a surety bond in a form specified by the Secretary in an amount (not less than $50,000) that the Secretary determines is commensurate with the volume of the billing of the provider of services or supplier. The Secretary may waive the requirement of a bond under the preceding sentence in the case of a provider of services or supplier that provides a comparable surety bond under State law.

(2) PROVIDER OF SERVICES OR SUPPLIER DESCRIBED.—A provider of services or supplier described in this paragraph is a provider of services or supplier the Secretary determines appropriate based on the level of risk involved with respect to the provider of services or supplier, and consistent with the surety bond requirements under sections 1834(a)(16)(B) and 1861(o)(7)(C).

(o) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD.—

(1) IN GENERAL.—The Secretary may suspend payments to a provider of services or supplier under this title pending an investigation of a credible allegation of fraud against the provider of services or supplier, unless the Secretary determines there is good cause not to suspend such payments.

(2) CONSULTATION.—The Secretary shall consult with the Inspector General of the Department of Health and Human Services in determining whether there is a credible allegation of fraud against a provider of services or supplier.

(3) PROMULGATION OF REGULATIONS.—The Secretary shall promulgate regulations to carry out this subsection*, section 1860D–12(b)(7) (including as applied pursuant to section 1857(f)(3)(D)),* and section 1903(i)(2)(C).

*(4) CREDIBLE ALLEGATION OF FRAUD.—In carrying out this subsection, section 1860D–12(b)(7) (including as applied pursuant to section 1857(f)(3)(D)), and section 1903(i)(2)(C), a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for a credible allegation of fraud.*

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AGREEMENTS WITH PROVIDERS OF SERVICES; ENROLLMENT PROCESSES

SEC. 1866. (a)(1) Any provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e)) shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement—

(A)(i) not to charge, except as provided in paragraph (2), any individual or any other person for items or services for which such individual is entitled to have payment made under this title (or for which he would be so entitled if such provider of services had complied with the procedural and other requirements under or pursuant to this title or for which such provider is paid pursuant to the provisions of section 1814(e)), and (ii) not to impose any charge that is prohibited under section 1902(n)(3),

(B) not to charge any individual or any other person for items or services for which such individual is not entitled to have payment made under this title because payment for expenses incurred for such items or services may not be made by reason of the provisions of paragraph

(1) or (9) of section 1862(a), but only if (i) such individual was without fault in incurring such expenses and (ii) the Secretary's determination that such payment may not be made for such items and services was made after the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title,

(C) to make adequate provision for return (or other disposition, in accordance with regulations) of any moneys incorrectly collected from such individual or other person,

(D) to promptly notify the Secretary of its employment of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity (as determined by the Secretary by regulation) by an agency or organization which serves as a fiscal intermediary or carrier (for purposes of part A or part B, or both, of this title) with respect to the provider,

(E) to release data with respect to patients of such provider upon request to an organization having a contract with the Secretary under part B of title XI as may be necessary (i) to allow such organization to carry out its functions under such contract, or (ii) to allow such organization to carry out similar review functions under any contract the organization may have with a private or public agency paying for health care in the same area with respect to patients who authorize release of such data for such purposes,

(F)(i) in the case of hospitals which provide inpatient hospital services for which payment may be made under subsection (b), (c), or (d) of section 1886, to maintain an agreement with a professional standards review organization (if there is such an organization in existence in the area in which the hospital is located) or with a quality improvement organization which has a contract with the Secretary under part B of title XI for the area in which the hospital is located, under which the organization will perform functions under that part with respect to the review of the validity of diagnostic information provided by such hospital, the completeness, adequacy, and quality of care provided, the appropriateness of admissions and discharges, and the appropriateness of care provided for which additional payments are sought under section 1886(d)(5), with respect to inpatient hospital services for which payment may be made under part A of this title (and for purposes of payment under this title, the cost of such agreement to the hospital shall be considered a cost incurred by such hospital in providing inpatient services under part A, and (I) shall be paid directly by the Secretary to such organization on behalf of such hospital in accordance with a rate per review established by the Secretary, (II) shall be transferred from the Federal Hospital Insurance Trust Fund, without regard to amounts appropriated in advance in appropriation Acts, in the same manner as transfers are made for payment for services provided directly to beneficiaries, and (III) shall not be less in the aggregate for a fiscal year than the aggregate amount expended in fiscal year 1988 for direct and administrative costs (adjusted for inflation and for any direct or administrative costs incurred as a result of review functions added with respect to a subsequent fiscal year) of such reviews),

(ii) in the case of hospitals, critical access hospitals, skilled nursing facilities, and home health agencies, to maintain an agreement with a quality improvement organization (which has a contract with the Secretary under part B of title XI for the area in which the hospital, facility, or agency is located) to perform the functions described in paragraph (3)(A),

(G) in the case of hospitals which provide inpatient hospital services for which payment may be made under subsection (b) or (d) of section 1886, not to charge any individual or any other person for inpatient hospital services for which such individual would be entitled to have payment made under part A but for a denial or reduction of payments under section 1886(f)(2),

(H)(i) in the case of hospitals which provide services for which payment may be made under this title and in the case of critical access hospitals which provide critical access hospital services, to have all items and services (other than physicians' services as defined in regulations for purposes of section 1862(a)(14), and other than services described by section 1861(s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist) (I) that are furnished to an individual who is a patient of the hospital, and (II) for which the individual is entitled to have payment made under this title, furnished by the hospital or otherwise under arrangements (as defined in section 1861(w)(1)) made by the hospital,

(ii) in the case of skilled nursing facilities which provide covered skilled nursing facility services—

(I) that are furnished to an individual who is a resident of the skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1861(s)(2)(D), that are furnished to such an individual without regard to such period), and

(II) for which the individual is entitled to have payment made under this title,

to have items and services (other than services described in section 1888(e)(2)(A)(ii)) furnished by the skilled nursing facility or otherwise under arrangements (as defined in section 1861(w)(1)) made by the skilled nursing facility,

(I) in the case of a hospital or critical access hospital—

(i) to adopt and enforce a policy to ensure compliance with the requirements of section 1867 and to meet the requirements of such section,

(ii) to maintain medical and other records related to individuals transferred to or from the hospital for a period of five years from the date of the transfer, and

(iii) to maintain a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition,

(J) in the case of hospitals which provide inpatient hospital services for which payment may be made under this title, to be a participating provider of medical care under any health plan contracted for under section 1079 or 1086 of title 10, or under section 613 of title 38, United States Code, in accordance with admission practices, payment methodology, and amounts as prescribed under joint regulations issued by the Secretary and by the Secretaries of Defense and Transportation, in implementation of sections 1079 and 1086 of title 10, United States Code,

(K) not to charge any individual or any other person for items or services for which payment under this title is denied under section 1154(a)(2) by reason of a determination under section 1154(a)(1)(B),

(L) in the case of hospitals which provide inpatient hospital services for which payment may be made under this title, to be a participating provider of medical care under section 603 of title 38, United States Code, in accordance with such admission practices, and such payment methodology and amounts, as are prescribed under joint regulations issued by the Secretary and by the Secretary of Veterans Affairs in implementation of such section,

Section 144(a)(2) of Public Law 115–182 provides for an amendment to strike "under section 603" and insert "under chapter 17". Subsection (b) of such section 144 provides "[t]he amendments made by subsection (a) shall take effect on the date described in section 101(b).". Paragraphs (1) and (2) of section 101(b) of such Public Law provides: "(1) the date that is 30 days after the date on which the Secretary of Veterans Affairs submits the report required under section 101(q)(2) of the Veterans Access, Choice, and Accountability Act of 2014 (Public Law 113–146; 38 U.S.C. 1701 note); or (2) the date on which the Secretary promulgates regulations pursuant to subsection (c).".

(M) in the case of hospitals, to provide to each individual who is entitled to benefits under part A (or to a person acting on the individual's behalf), at or about the time of the individual's admission as an inpatient to the hospital, a written statement (containing such language as the Secretary prescribes consistent with this paragraph) which explains—

(i) the individual's rights to benefits for inpatient hospital services and for post-hospital services under this title,

(ii) the circumstances under which such an individual will and will not be liable for charges for continued stay in the hospital,

(iii) the individual's right to appeal denials of benefits for continued inpatient hospital services, including the practical steps to initiate such an appeal, and

(iv) the individual's liability for payment for services if such a denial of benefits is upheld on appeal,—and which provides such additional information as the Secretary may specify,

(N) in the case of hospitals and critical access hospitals—

(i) to make available to its patients the directory or directories of participating physicians (published under section 1842(h)(4)) for the area served by the hospital or critical access hospital,

(ii) if hospital personnel (including staff of any emergency or outpatient department) refer a patient to a nonparticipating physician for further medical care on an outpatient basis, the personnel must inform the patient that the physician is a nonparticipating physician and, whenever practicable, must identify at least one qualified participating physi-

cian who is listed in such a directory and from whom the patient may receive the necessary services,

(iii) to post conspicuously in any emergency department a sign (in a form specified by the Secretary) specifying rights of individuals under section 1867 with respect to examination and treatment for emergency medical conditions and women in labor, and

(iv) to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital participates in the medicaid program under a State plan approved under title XIX,

(O) to accept as payment in full for services that are covered under this title and are furnished to any individual enrolled with a Medicare+Choice organization under part C, with a PACE provider under section 1894 or 1934, or with an eligible organization with a risk-sharing contract under section 1876, under section 1876(i)(2)(A) (as in effect before February 1, 1985), under section 402(a) of the Social Security Amendments of 1967, or under section 222(a) of the Social Security Amendments of 1972, which does not have a contract (or, in the case of a PACE provider, contract or other agreement) establishing payment amounts for services furnished to members of the organization or PACE program eligible individuals enrolled with the PACE provider, the amounts that would be made as a payment in full under this title (less any payments under sections 1886(d)(11) and 1886(h)(3)(D)) if the individuals were not so enrolled,

(P) in the case of home health agencies which provide home health services to individuals entitled to benefits under this title who require catheters, catheter supplies, ostomy bags, and supplies related to ostomy car (described in section 1861(m)(5)), to offer to furnish such supplies to such an individual as part of their furnishing of home health services,

(Q) in the case of hospitals, skilled nursing facilities, home health agencies, and hospice programs, to comply with the requirement of subsection (f) (relating to maintaining written policies and procedures respecting advance directives),

(R) to contract only with a health care clearinghouse (as defined in section 1171) that meets each standard and implementation specification adopted or established under part C of title XI on or after the date on which the health care clearinghouse is required to comply with the standard or specification,

(S) in the case of a hospital that has a financial interest (as specified by the Secretary in regulations) in an entity to which individuals are referred as described in section 1861(ee)(2)(H)(ii), or in which such an entity has such a financial interest, or in which another entity has such a financial interest (directly or indirectly) with such hospital and such an entity, to maintain and disclose to the Secretary (in a form and manner specified by the Secretary) information on—

(i) the nature of such financial interest,

(ii) the number of individuals who were discharged from the hospital and who were identified as requiring home health services, and

(iii) the percentage of such individuals who received such services from such provider (or another such provider),

(T) in the case of hospitals and critical access hospitals, to furnish to the Secretary such data as the Secretary determines appropriate pursuant to subparagraph (E) of section 1886(d)(12) to carry out such section,

(U) in the case of hospitals which furnish inpatient hospital services for which payment may be made under this title, to be a participating provider of medical care both—

(i) under the contract health services program funded by the Indian Health Service and operated by the Indian Health Service, an Indian tribe, or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act), with respect to items and services that are covered under such program and furnished to an individual eligible for such items and services under such program; and

(ii) under any program funded by the Indian Health Service and operated by an urban Indian organization with respect to the purchase of items and services for an eligible urban Indian (as those terms are defined in such section 4),

in accordance with regulations promulgated by the Secretary regarding admission practices, payment methodology, and rates of payment (including the acceptance of no more than such payment rate as payment in full for such items and services,

(V) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 (or a State occupational safety and health plan that is approved under

18(b) of such Act), to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated),

(W) in the case of a hospital described in section 1886(d)(1)(B)(v), to report quality data to the Secretary in accordance with subsection (k),

(X) maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider under this title, as specified by the Secretary, and

(Y) beginning 12 months after the date of the enactment of this subparagraph, in the case of a hospital or critical access hospital, with respect to each individual who receives observation services as an outpatient at such hospital or critical access hospital for more than 24 hours, to provide to such individual not later than 36 hours after the time such individual begins receiving such services (or, if sooner, upon release)—

(i) such oral explanation of the written notification described in clause (ii), and such documentation of the provision of such explanation, as the Secretary determines to be appropriate;

(ii) a written notification (as specified by the Secretary pursuant to rulemaking and containing such language as the Secretary prescribes consistent with this paragraph) which—

(I) explains the status of the individual as an outpatient receiving observation services and not as an inpatient of the hospital or critical access hospital and the reasons for such status of such individual;

(II) explains the implications of such status on services furnished by the hospital or critical access hospital (including services furnished on an inpatient basis), such as implications for cost-sharing requirements under this title and for subsequent eligibility for coverage under this title for services furnished by a skilled nursing facility;

(III) includes such additional information as the Secretary determines appropriate;

(IV) either—

(aa) is signed by such individual or a person acting on such individual's behalf to acknowledge receipt of such notification; or

(bb) if such individual or person refuses to provide the signature described in item (aa), is signed by the staff member of the hospital or critical access hospital who presented the written notification and includes the name and title of such staff member, a certification that the notification was presented, and the date and time the notification was presented; and

(V) is written and formatted using plain language and is made available in appropriate languages as determined by the Secretary.

In the case of a hospital which has an agreement in effect with an organization described in subparagraph (F), which organization's contract with the Secretary under part B of title XI is terminated on or after October 1, 1984, the hospital shall not be determined to be out of compliance with the requirement of such subparagraph during the six month period beginning on the date of the termination of that contract.

(2)(A) A provider of services may charge such individual or other person (i) the amount of any deduction or coinsurance amount imposed pursuant to section 1813(a)(1), (a)(3), or (a)(4), section 1833(b), or section 1861(y)(3) with respect to such items and services (not in excess of the amount customarily charged for such items and services by such provider), and (ii) an amount equal to 20 per centum of the reasonable charges for such items and services (not in excess of 20 per centum of the amount customarily charged for such items and services by such provider) for which payment is made under part B or which are durable medical equipment furnished as home health services (but in the case of items and services furnished to individuals with end-stage renal disease, an amount equal to 20 percent of the estimated amounts for such items and services calculated on the basis established by the Secretary). In the case of items and services described in section 1833(c), clause (ii) of the preceding sentence shall be applied by substituting for 20 percent the proportion which is appropriate under such section. A provider of services may not impose a charge under clause (ii) of the first sentence of this subparagraph with respect to items and services described in section 1861(s)(10)(A) and with respect to clinical diagnostic laboratory tests for which payment is made under part B. Notwithstanding the first sentence of this subparagraph, a home health agency may charge such an individual or person, with respect to covered items sub-

ject to payment under section 1834(a), the amount of any deduction imposed under section 1833(b) and 20 percent of the payment basis described in section 1834(a)(1)(B). In the case of items and services for which payment is made under part B under the prospective payment system established under section 1833(t), clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge, the applicable copayment amount established under section 1833(t)(5). In the case of services described in section 1833(a)(8) or section 1833(a)(9) for which payment is made under part B under section 1834(k), clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge for such services 20 percent of the lesser of the actual charge or the applicable fee schedule amount (as defined in such section) for such services.

(B) Where a provider of services has furnished, at the request of such individual, items or services which are in excess of or more expensive than the items or services with respect to which payment may be made under this title, such provider of services may also charge such individual or other person for such more expensive items or services to the extent that the amount customarily charged by it for the items or services furnished at such request exceeds the amount customarily charged by it for the items or services with respect to which payment may be made under this title.

(C) A provider of services may in accordance with its customary practice also appropriately charge any such individual for any whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished him with respect to which a deductible is imposed under section 1813(a)(2), except that (i) any excess of such charge over the cost to such provider for the blood (or equivalent quantities of packed red blood cells, as so defined) shall be deducted from any payment to such provider under this title, (ii) no such charge may be imposed for the cost of administration of such blood (or equivalent quantities of packed red blood cells, as so defined), and (iii) such charge may not be made to the extent such blood (or equivalent quantities of packed red blood cells, as so defined) has been replaced on behalf of such individual or arrangements have been made for its replacement on his behalf. For purposes of subparagraph (C), whole blood (or equivalent quantities of packed red blood cells, as so defined) furnished an individual shall be deemed replaced when the provider of services is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is imposed under section 1813(a)(2).

(D) Where a provider of services customarily furnishes items or services which are in excess of or more expensive than the items or services with respect to which payment may be made under this title, such provider, notwithstanding the preceding provisions of this paragraph, may not, under the authority of section 1866(a)(2)(B)(ii), charge any individual or other person any amount for such items or services in excess of the amount of the payment which may otherwise be made for such items or services under this title if the admitting physician has a direct or indirect financial interest in such provider.

(3)(A) Under the agreement required under paragraph (1)(F)(ii), the quality improvement organization must perform functions (other than those covered under an agreement under paragraph (1)(F)(i)) under the third sentence of section 1154(a)(4)(A) and under section 1154(a)(14) with respect to services, furnished by the hospital, critical access hospital, facility, or agency involved, for which payment may be made under this title.

(B) For purposes of payment under this title, the cost of such an agreement to the hospital, critical access hospital, facility, or agency shall be considered a cost incurred by such hospital, critical access hospital, facility, or agency in providing covered services under this title and shall be paid directly by the Secretary to the quality improvement organization on behalf of such hospital, critical access hospital, facility, or agency in accordance with a schedule established by the Secretary.

(C) Such payments—

(i) shall be transferred in appropriate proportions from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund, without regard to amounts appropriated in advance in appropriation Acts, in the same manner as transfers are made for payment for services provided directly to beneficiaries, and

(ii) shall not be less in the aggregate for a fiscal year—

(I) in the case of hospitals, than the amount specified in paragraph (1)(F)(i)(III), and

(II) in the case of facilities, critical access hospitals, and agencies, than the amounts the Secretary determines to be sufficient to cover the costs of such organizations' con-

ducting the activities described in subparagraph (A) with respect to such facilities, critical access hospitals, or agencies under part B of title XI.

(b)(1) A provider of services may terminate an agreement with the Secretary under this section at such time and upon such notice to the Secretary and the public as may be provided in regulations, except that notice of more than six months shall not be required.

(2) The Secretary may refuse to enter into an agreement under this section or, upon such reasonable notice to the provider and the public as may be specified in regulations, may refuse to renew or may terminate such an agreement after the Secretary—

(A) has determined that the provider fails to comply substantially with the provisions of the agreement, with the provisions of this title and regulations thereunder, or with a corrective action required under section 1886(f)(2)(B),

(B) has determined that the provider fails substantially to meet the applicable provisions of section 1861,

(C) has excluded the provider from participation in a program under this title pursuant to section 1128 or section 1128A, or

(D) has ascertained that the provider has been convicted of a felony under Federal or State law for an offense which the Secretary determines is detrimental to the best interests of the program or program beneficiaries.

(3) A termination of an agreement or a refusal to renew an agreement under this subsection shall become effective on the same date and in the same manner as an exclusion from participation under the programs under this title becomes effective under section 1128(c).

(4)(A) A hospital that fails to comply with the requirement of subsection (a)(1)(V) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(U) by a hospital that is subject to the provisions of such Act.

(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

(c)(1) Where the Secretary has terminated or has refused to renew an agreement under this title with a provider of services, such provider may not file another agreement under this title unless the Secretary finds that the reason for the termination or nonrenewal has been removed and that there is reasonable assurance that it will not recur.

(2) Where the Secretary has terminated or has refused to renew an agreement under this title with a provider of services, the Secretary shall promptly notify each State agency which administers or supervises the administration of a State plan approved under title XIX of such termination or nonrenewal.

(d) If the Secretary finds that there is a substantial failure to make timely review in accordance with section 1861(k) of long-stay cases in a hospital, he may, in lieu of terminating his agreement with such hospital, decide that, with respect to any individual admitted to such hospital after a subsequent date specified by him, no payment shall be made under this title for inpatient hospital services (including inpatient psychiatric hospital services) after the 20th day of a continuous period of such services. Such decision may be made effective only after such notice to the hospital and to the public, as may be prescribed by regulations, and its effectiveness shall terminate when the Secretary finds that the reason therefor has been removed and that there is reasonable assurance that it will not recur. The Secretary shall not make any such decision except after reasonable notice and opportunity for hearing to the institution or agency affected thereby.

(e) For purposes of this section, the term "provider of services" shall include—

(1) a clinic, rehabilitation agency, or public health agency if, in the case of a clinic or rehabilitation agency, such clinic or agency meets the requirements of section 1861(p)(4)(A) (or meets the requirements of such section through the operation of subsection (g) or (ll)(2) of section 1861), or if, in the case of a public health agency, such agency meets the requirements of section 1861(p)(4)(B) (or meets the requirements of such section through the operation of subsection (g) or (ll)(2) of section 1861), but only with respect to the furnishing of outpatient physical therapy services (as therein defined), (through the operation of section 1861(g)) with respect to the furnishing of outpatient occupational therapy services, or (through the operation

of section 1861(ll)(2)) with respect to the furnishing of outpatient speech-language pathology; [and]

(2) a community mental health center (as defined in section 1861(ff)(3)(B)), but only with respect to the furnishing of partial hospitalization services (as described in section 1861(ff)(1))[.]*; and*

*(3) opioid treatment programs (as defined in paragraph (2) of section 1861(jjj)), but only with respect to the furnishing of opioid use disorder treatment services (as defined in paragraph (1) of such section).*

(f)(1) For purposes of subsection (a)(1)(Q) and sections 1819(c)(2)(E), 1833(s), 1855(i), 1876(c)(8), and 1891(a)(6), the requirement of this subsection is that a provider of services, Medicare+Choice organization, or prepaid or eligible organization (as the case may be) maintain written policies and procedures with respect to all adult individuals receiving medical care by or through the provider or organization—

(A) to provide written information to each such individual concerning—

(i) an individual's rights under State law (whether statutory or as recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives (as defined in paragraph (3)), and

(ii) the written policies of the provider or organization respecting the implementation of such rights;

(B) to document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive;

(C) not to condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(D) to ensure compliance with requirements of State law (whether statutory or as recognized by the courts of the State) respecting advance directives at facilities of the provider or organization; and

(E) to provide (individually or with others) for education for staff and the community on issues concerning advance directives.

Subparagraph (C) shall not be construed as requiring the provision of care which conflicts with an advance directive.

(2) The written information described in paragraph (1)(A) shall be provided to an adult individual—

(A) in the case of a hospital, at the time of the individual's admission as an inpatient,

(B) in the case of a skilled nursing facility, at the time of the individual's admission as a resident,

(C) in the case of a home health agency, in advance of the individual coming under the care of the agency,

(D) in the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program, and

(E) in the case of an eligible organization (as defined in section 1876(b)) or an organization provided payments under section 1833(a)(1)(A) or a Medicare+Choice organization, at the time of enrollment of the individual with the organization.

(3) In this subsection, the term "advance directive" means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State) and relating to the provision of such care when the individual is incapacitated.

(4) For construction relating to this subsection, see section 7 of the Assisted Suicide Funding Restriction Act of 1997 (relating to clarification respecting assisted suicide, euthanasia, and mercy killing).

(g) Except as permitted under subsection (a)(2), any person who knowingly and willfully presents, or causes to be presented, a bill or request for payment inconsistent with an arrangement under subsection (a)(1)(H) or in violation of the requirement for such an arrangement, is subject to a civil money penalty of not to exceed $2,000. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(h)(1)(A) Except as provided in paragraph (2), an institution or agency dissatisfied with a determination by the Secretary that it is not a provider of services or with a determination described in subsection (b)(2) shall be entitled to a hearing thereon by the Secretary (after reasonable notice)

to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g), except that, in so applying such sections and in applying section 205(l) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, may obtain expedited access to judicial review under the process established under section 1869(b)(2). Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.

(C)(i) The Secretary shall develop and implement a process to expedite proceedings under this subsection in which—

(I) the remedy of termination of participation has been imposed;

(II) a remedy described in clause (i) or (iii) of section 1819(h)(2)(B) has been imposed, but only if such remedy has been imposed on an immediate basis; or

(III) a determination has been made as to a finding of substandard quality of care that results in the loss of approval of a skilled nursing facility's nurse aide training program.

(ii) Under such process under clause (i), priority shall be provided in cases of termination described in clause (i)(I).

(iii) Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.

(2) An institution or agency is not entitled to separate notice and opportunity for a hearing under both section 1128 and this section with respect to a determination or determinations based on the same underlying facts and issues.

(i)(1) If the Secretary determines that a psychiatric hospital which has an agreement in effect under this section no longer meets the requirements for a psychiatric hospital under this title and further finds that the hospital's deficiencies—

(A) immediately jeopardize the health and safety of its patients, the Secretary shall terminate such agreement; or

(B) do not immediately jeopardize the health and safety of its patients, the Secretary may terminate such agreement, or provide that no payment will be made under this title with respect to any individual admitted to such hospital after the effective date of the finding, or both.

(2) If a psychiatric hospital, found to have deficiencies described in paragraph (1)(B), has not complied with the requirements of this title—

(A) within 3 months after the date the hospital is found to be out of compliance with such requirements, the Secretary shall provide that no payment will be made under this title with respect to any individual admitted to such hospital after the end of such 3-month period, or

(B) within 6 months after the date the hospital is found to be out of compliance with such requirements, no payment may be made under this title with respect to any individual in the hospital until the Secretary finds that the hospital is in compliance with the requirements of this title.

(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

(1) ENROLLMENT PROCESS.—

(A) IN GENERAL.—The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title. Such process shall include screening of providers and suppliers in accordance with paragraph (2), a provisional period of enhanced oversight in accordance with paragraph (3), disclosure requirements in accordance with paragraph (5), the imposition of temporary enrollment moratoria in accordance with paragraph (7), and the establishment of compliance programs in accordance with paragraph (9).

(B) DEADLINES.—The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of medicare administrative contractors in meeting the deadlines established under this subparagraph.

(C) CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.—The Secretary shall consult with providers of services and suppliers before making changes in the pro-

vider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may be made under this title.

(2) PROVIDER SCREENING.—

(A) PROCEDURES.—Not later than 180 days after the date of enactment of this paragraph, the Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish procedures under which screening is conducted with respect to providers of medical or other items or services and suppliers under the program under this title, the Medicaid program under title XIX, and the CHIP program under title XXI.

(B) LEVEL OF SCREENING.—The Secretary shall determine the level of screening conducted under this paragraph according to the risk of fraud, waste, and abuse, as determined by the Secretary, with respect to the category of provider of medical or other items or services or supplier. Such screening—

(i) shall include a licensure check, which may include such checks across States; and

(ii) may, as the Secretary determines appropriate based on the risk of fraud, waste, and abuse described in the preceding sentence, include—

(I) a criminal background check;

(II) fingerprinting;

(III) unscheduled and unannounced site visits, including preenrollment site visits;

(IV) database checks (including such checks across States); and

(V) such other screening as the Secretary determines appropriate.

(C) APPLICATION FEES.—

(i) INSTITUTIONAL PROVIDERS.—Except as provided in clause (ii), the Secretary shall impose a fee on each institutional provider of medical or other items or services or supplier (such as a hospital or skilled nursing facility) with respect to which screening is conducted under this paragraph in an amount equal to—

(I) for 2010, $500; and

(II) for 2011 and each subsequent year, the amount determined under this clause for the preceding year, adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year.

(ii) HARDSHIP EXCEPTION; WAIVER FOR CERTAIN MEDICAID PROVIDERS.—The Secretary may, on a case-by-case basis, exempt a provider of medical or other items or services or supplier from the imposition of an application fee under this subparagraph if the Secretary determines that the imposition of the application fee would result in a hardship. The Secretary may waive the application fee under this subparagraph for providers enrolled in a State Medicaid program for whom the State demonstrates that imposition of the fee would impede beneficiary access to care.

(iii) USE OF FUNDS.—Amounts collected as a result of the imposition of a fee under this subparagraph shall be used by the Secretary for program integrity efforts, including to cover the costs of conducting screening under this paragraph and to carry out this subsection and section 1128J.

(D) APPLICATION AND ENFORCEMENT.—

(i) NEW PROVIDERS OF SERVICES AND SUPPLIERS.—The screening under this paragraph shall apply, in the case of a provider of medical or other items or services or supplier who is not enrolled in the program under this title, title XIX, or title XXI as of the date of enactment of this paragraph, on or after the date that is 1 year after such date of enactment.

(ii) CURRENT PROVIDERS OF SERVICES AND SUPPLIERS.—The screening under this paragraph shall apply, in the case of a provider of medical or other items or services or supplier who is enrolled in the program under this title, title XIX, or title XXI as of such date of enactment, on or after the date that is 2 years after such date of enactment.

(iii) REVALIDATION OF ENROLLMENT.—Effective beginning on the date that is 180 days after such date of enactment, the screening under this paragraph shall apply with respect to the revalidation of enrollment of a provider of medical or other items or services or supplier in the program under this title, title XIX, or title XXI.

(iv) LIMITATION ON ENROLLMENT AND REVALIDATION OF ENROLLMENT.—In no case may a provider of medical or other items or services or supplier who has not been screened under this paragraph be initially enrolled or reenrolled in the program under this title, title XIX, or title XXI on or after the date that is 3 years after such date of enactment.

(E) USE OF INFORMATION FROM THE DEPARTMENT OF TREASURY CONCERNING TAX DEBTS.—In reviewing the application of a provider of services or supplier to enroll or reenroll under the program under this title, the Secretary shall take into account the information supplied by the Secretary of the Treasury pursuant to section 6103(l)(22) of the Internal Revenue Code of 1986, in determining whether to deny such application or to apply enhanced oversight to such provider of services or supplier pursuant to paragraph (3) if the Secretary determines such provider of services or supplier owes such a debt.

(F) EXPEDITED RULEMAKING.—The Secretary may promulgate an interim final rule to carry out this paragraph.

(3) PROVISIONAL PERIOD OF ENHANCED OVERSIGHT FOR NEW PROVIDERS OF SERVICES AND SUPPLIERS.—

(A) IN GENERAL.—The Secretary shall establish procedures to provide for a provisional period of not less than 30 days and not more than 1 year during which new providers of medical or other items or services and suppliers, as the Secretary determines appropriate, including categories of providers or suppliers, would be subject to enhanced oversight, such as prepayment review and payment caps, under the program under this title, the Medicaid program under title XIX. and the CHIP program under title XXI.

(B) IMPLEMENTATION.—The Secretary may establish by program instruction or otherwise the procedures under this paragraph.

(4) 90-DAY PERIOD OF ENHANCED OVERSIGHT FOR INITIAL CLAIMS OF DME SUPPLIERS.—For periods beginning after January 1, 2011, if the Secretary determines that there is a significant risk of fraudulent activity among suppliers of durable medical equipment, in the case of a supplier of durable medical equipment who is within a category or geographic area under title XVIII identified pursuant to such determination and who is initially enrolling under such title, the Secretary shall, notwithstanding sections 1816(c), 1842(c), and 1869(a)(2), withhold payment under such title with respect to durable medical equipment furnished by such supplier during the 90-day period beginning on the date of the first submission of a claim under such title for durable medical equipment furnished by such supplier.

(5) INCREASED DISCLOSURE REQUIREMENTS.—

(A) DISCLOSURE.—A provider of medical or other items or services or supplier who submits an application for enrollment or revalidation of enrollment in the program under this title, title XIX, or title XXI on or after the date that is 1 year after the date of enactment of this paragraph shall disclose (in a form and manner and at such time as determined by the Secretary) any current or previous affiliation (directly or indirectly) with a provider of medical or other items or services or supplier that has uncollected debt, has been or is subject to a payment suspension under a Federal health care program (as defined in section 1128B(f)), has been excluded from participation under the program under this title, the Medicaid program under title XIX, or the CHIP program under title XXI, or has had its billing privileges denied or revoked.

(B) AUTHORITY TO DENY ENROLLMENT.—If the Secretary determines that such previous affiliation poses an undue risk of fraud, waste, or abuse, the Secretary may deny such application. Such a denial shall be subject to appeal in accordance with paragraph (7).

(6) AUTHORITY TO ADJUST PAYMENTS OF PROVIDERS OF SERVICES AND SUPPLIERS WITH THE SAME TAX IDENTIFICATION NUMBER FOR MEDICARE OBLIGATIONS.—

(A) IN GENERAL.—Notwithstanding any other provision of this title, in the case of an applicable provider of services or supplier, the Secretary may make any necessary adjustments to payments to the applicable provider of services or supplier under the program under this title in order to satisfy any amount described in subparagraph (B)(ii) due from such obligated provider of services or supplier.

(B) DEFINITIONS.—In this paragraph:

(i) IN GENERAL.—The term "applicable provider of services or supplier" means a provider of services or supplier that has the same taxpayer identification number assigned under section 6109 of the Internal Revenue Code of 1986 as is assigned to the obligated provider of services or supplier under such section, regardless of whether the

applicable provider of services or supplier is assigned a different billing number or national provider identification number under the program under this title than is assigned to the obligated provider of services or supplier.

(ii) OBLIGATED PROVIDER OF SERVICES OR SUPPLIER.—The term "obligated provider of services or supplier" means a provider of services or supplier that owes an amount that is more than the amount required to be paid under the program under this title (as determined by the Secretary).

(7) TEMPORARY MORATORIUM ON ENROLLMENT OF NEW PROVIDERS; NONPAYMENT.—

(A) IN GENERAL.—The Secretary may impose a temporary moratorium on the enrollment of new providers of services and suppliers, including categories of providers of services and suppliers, in the program under this title, under the Medicaid program under title XIX, or under the CHIP program under title XXI if the Secretary determines such moratorium is necessary to prevent or combat fraud, waste, or abuse under either such program.

(B) LIMITATION ON REVIEW.—There shall be no judicial review under section 1869, section 1878, or otherwise, of a temporary moratorium imposed under subparagraph (A).

(C) NONPAYMENT.—

(i) IN GENERAL.—No payment may be made under this title or under a program described in subparagraph (A) with respect to an item or service described in clause (ii) furnished on or after October 1, 2017.

(ii) ITEM OR SERVICE DESCRIBED.—An item or service described in this clause is an item or service furnished—

(I) within a geographic area with respect to which a temporary moratorium imposed under subparagraph (A) is in effect; and

(II) by a provider of services or supplier that meets the requirements of clause (iii).

(iii) REQUIREMENTS.—For purposes of clause (ii), the requirements of this clause are that a provider of services or supplier—

(I) enrolls under this title on or after the effective date of such temporary moratorium; and

(II) is within a category of providers of services and suppliers (as described in subparagraph (A)) subject to such temporary moratorium.

(iv) PROHIBITION ON CHARGES FOR SPECIFIED ITEMS OR SERVICES.—In no case shall a provider of services or supplier described in clause (ii)(II) charge an individual or other person for an item or service described in clause (ii) furnished on or after October 1, 2017, to an individual entitled to benefits under part A or enrolled under part B or an individual under a program specified in subparagraph (A).

(8) COMPLIANCE PROGRAMS.—

(A) IN GENERAL.—On or after the date of implementation determined by the Secretary under subparagraph (C), a provider of medical or other items or services or supplier within a particular industry sector or category shall, as a condition of enrollment in the program under this title, title XIX, or title XXI, establish a compliance program that contains the core elements established under subparagraph (B) with respect to that provider or supplier and industry or category.

(B) ESTABLISHMENT OF CORE ELEMENTS.—The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish core elements for a compliance program under subparagraph (A) for providers or suppliers within a particular industry or category.

(C) TIMELINE FOR IMPLEMENTATION.—The Secretary shall determine the timeline for the establishment of the core elements under subparagraph (B) and the date of the implementation of subparagraph (A) for providers or suppliers within a particular industry or category. The Secretary shall, in determining such date of implementation, consider the extent to which the adoption of compliance programs by a provider of medical or other items or services or supplier is widespread in a particular industry sector or with respect to a particular provider or supplier category.

(9) HEARING RIGHTS IN CASES OF DENIAL OR NON-RENEWAL.—A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.

(k) QUALITY REPORTING BY CANCER HOSPITALS.—

(1) IN GENERAL.—For purposes of fiscal year 2014 and each subsequent fiscal year, a hospital described in section 1886(d)(1)(B)(v) shall submit data to the Secretary in accordance with paragraph (2) with respect to such a fiscal year.

(2) SUBMISSION OF QUALITY DATA.—For fiscal year 2014 and each subsequent fiscal year, each hospital described in such section shall submit to the Secretary data on quality measures specified under paragraph (3). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(3) QUALITY MEASURES.—

(A) IN GENERAL.—Subject to subparagraph (B), any measure specified by the Secretary under this paragraph must have been endorsed by the entity with a contract under section 1890(a).

(B) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(C) TIME FRAME.—Not later than October 1, 2012, the Secretary shall publish the measures selected under this paragraph that will be applicable with respect to fiscal year 2014.

(4) PUBLIC AVAILABILITY OF DATA SUBMITTED.—The Secretary shall establish procedures for making data submitted under paragraph (4) available to the public. Such procedures shall ensure that a hospital described in section 1886(d)(1)(B)(v) has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

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***SEC. 1866F. OPIOID USE DISORDER TREATMENT DEMONSTRATION PROGRAM.***

*(a) IMPLEMENTATION OF 4-YEAR DEMONSTRATION PROGRAM.—*

*(1) IN GENERAL.—Not later than January 1, 2021, the Secretary shall implement a 4-year demonstration program under this title (in this section referred to as the "Program") to increase access of applicable beneficiaries to opioid use disorder treatment services, improve physical and mental health outcomes for such beneficiaries, and to the extent possible, reduce expenditures under this title. Under the Program, the Secretary shall make payments under subsection (e) to participants (as defined in subsection (c)(1)(A)) for furnishing opioid use disorder treatment services delivered through opioid use disorder care teams, or arranging for such services to be furnished, to applicable beneficiaries participating in the Program.*

*(2) OPIOID USE DISORDER TREATMENT SERVICES.—For purposes of this section, the term "opioid use disorder treatment services"—*

*(A) means, with respect to an applicable beneficiary, services that are furnished for the treatment of opioid use disorders and that utilize drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act for the treatment of opioid use disorders in an outpatient setting; and*

*(B) includes—*

*(i) medication assisted treatment;*

*(ii) treatment planning;*

*(iii) psychiatric, psychological, or counseling services (or any combination of such services), as appropriate;*

*(iv) social support services, as appropriate; and*

*(v) care management and care coordination services, including coordination with other providers of services and suppliers not on an opioid use disorder care team.*

*(b) PROGRAM DESIGN.—*

*(1) IN GENERAL.—The Secretary shall design the Program in such a manner to allow for the evaluation of the extent to which the Program accomplishes the following purposes:*

*(A) Reduces hospitalizations and emergency department visits.*

*(B) Increases use of medication-assisted treatment for opioid use disorders.*

*(C) Improves health outcomes of individuals with opioid use disorders, including by reducing the incidence of infectious diseases (such as hepatitis C and HIV).*

*(D) Does not increase the total spending on items and services under this title.*

*(E) Reduces deaths from opioid overdose.*

*(F) Reduces the utilization of inpatient residential treatment.*

*(2) CONSULTATION.—In designing the Program, including the criteria under subsection (e)(2)(A), the Secretary shall, not later than 3 months after the date of the enactment of this section, consult with specialists in the field of addiction, clinicians in the primary care community, and beneficiary groups.*

*(c) PARTICIPANTS; OPIOID USE DISORDER CARE TEAMS.—*

*(1) PARTICIPANTS.—*

*(A) DEFINITION.—In this section, the term "participant" means an entity or individual—*

*(i) that is otherwise enrolled under this title and that is—*

*(I) a physician (as defined in section 1861(r)(1));*

*(II) a group practice comprised of at least one physician described in subclause (I);*

*(III) a hospital outpatient department;*

*(IV) a federally qualified health center (as defined in section 1861(aa)(4));*

*(V) a rural health clinic (as defined in section 1861(aa)(2));*

*(VI) a community mental health center (as defined in section 1861(ff)(3)(B));*

*(VII) a clinic certified as a certified community behavioral health clinic pursuant to section 223 of the Protecting Access to Medicare Act of 2014; or*

*(VIII) any other individual or entity specified by the Secretary;*

*(ii) that applied for and was selected to participate in the Program pursuant to an application and selection process established by the Secretary; and*

*(iii) that establishes an opioid use disorder care team (as defined in paragraph (2)) through employing or contracting with health care practitioners described in paragraph (2)(A), and uses such team to furnish or arrange for opioid use disorder treatment services in the outpatient setting under the Program.*

*(B) PREFERENCE.—In selecting participants for the Program, the Secretary shall give preference to individuals and entities that are located in areas with a prevalence of opioid use disorders that is higher than the national average prevalence.*

*(2) OPIOID USE DISORDER CARE TEAMS.—*

*(A) IN GENERAL.—For purposes of this section, the term "opioid use disorder care team" means a team of health care practitioners established by a participant described in paragraph (1)(A) that—*

*(i) shall include—*

*(I) at least one physician (as defined in section 1861(r)(1)) furnishing primary care services or addiction treatment services to an applicable beneficiary; and*

*(II) at least one eligible practitioner (as defined in paragraph (3)(A)), who may be a physician who meets the criterion in subclause (I); and*

*(ii) may include other practitioners licensed under State law to furnish psychiatric, psychological, counseling, and social services to applicable beneficiaries.*

*(B) REQUIREMENTS FOR RECEIPT OF PAYMENT UNDER PROGRAM.—In order to receive payments under subsection (e), each participant in the Program shall—*

*(i) furnish opioid use disorder treatment services through opioid use disorder care teams to applicable beneficiaries who agree to receive the services;*

*(ii) meet minimum criteria, as established by the Secretary; and*

*(iii) submit to the Secretary, in such form, manner, and frequency as specified by the Secretary, with respect to each applicable beneficiary for whom opioid use disorder treatment services are furnished by the opioid use disorder care team, data and such other information as the Secretary determines appropriate to—*

*(I) monitor and evaluate the Program;*

*(II) determine if minimum criteria are met under clause (ii); and*

*(III) determine the incentive payment under subsection (e).*

*(3) ELIGIBLE PRACTITIONERS; OTHER PROVIDER-RELATED DEFINITIONS AND APPLICATION PROVISIONS.—*

*(A) ELIGIBLE PRACTITIONERS.—For purposes of this section, the term "eligible practitioner" means a physician or other health care practitioner, such as a nurse practitioner, that—*

*(i) is enrolled under section 1866(j)(1);*

*(ii) is authorized to prescribe or dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment; and*

*(iii) has in effect a waiver in accordance with section 303(g) of the Controlled Substances Act for such purpose and is otherwise in compliance with regulations promulgated by the Substance Abuse and Mental Health Services Administration to carry out such section.*

*(B) ADDICTION SPECIALISTS.—For purposes of subsection (e)(1)(B)(iv), the term "addiction specialist" means a physician that possesses expert knowledge and skills in addiction medicine, as evidenced by appropriate certification from a specialty body, a certificate of advanced qualification in addiction medicine, or completion of an accredited residency or fellowship in addiction medicine or addiction psychiatry, as determined by the Secretary.*

*(d) PARTICIPATION OF APPLICABLE BENEFICIARIES.—*

*(1) APPLICABLE BENEFICIARY DEFINED.—In this section, the term "applicable beneficiary" means an individual who—*

*(A) is entitled to, or enrolled for, benefits under part A and enrolled for benefits under part B;*

*(B) is not enrolled in a Medicare Advantage plan under part C;*

*(C) has a current diagnosis for an opioid use disorder; and*

*(D) meets such other criteria as the Secretary determines appropriate.*

*Such term shall include an individual who is dually eligible for benefits under this title and title XIX if such individual satisfies the criteria described in subparagraphs (A) through (D).*

*(2) VOLUNTARY BENEFICIARY PARTICIPATION; LIMITATION ON NUMBER OF BENEFICIARIES.—An applicable beneficiary may participate in the Program on a voluntary basis and may terminate participation in the Program at any time. Not more than 20,000 applicable beneficiaries may participate in the Program at any time.*

*(3) SERVICES.—In order to participate in the Program, an applicable beneficiary shall agree to receive opioid use disorder treatment services from a participant. Participation under the Program shall not affect coverage of or payment for any other item or service under this title for the applicable beneficiary.*

*(4) BENEFICIARY ACCESS TO SERVICES.—Nothing in this section shall be construed as encouraging providers to limit applicable beneficiary access to services covered under this title and applicable beneficiaries shall not be required to relinquish access to any benefit under this title as a condition of receiving services from a participant in the Program.*

*(e) PAYMENTS.—*

*(1) PER APPLICABLE BENEFICIARY PER MONTH CARE MANAGEMENT FEE.—*

*(A) IN GENERAL.—The Secretary shall establish a schedule of per applicable beneficiary per month care management fees. Such a per applicable beneficiary per month care management fee shall be paid to a participant in addition to any other amount otherwise payable under this title to the health care practitioners in the participant's opioid use disorder care team or, if applicable, to the participant. A participant may use such per applicable beneficiary per month care management fee to deliver additional services to applicable beneficiaries, including services not otherwise eligible for payment under this title.*

*(B) PAYMENT AMOUNTS.—In carrying out subparagraph (A), the Secretary shall—*

*(i) consider payments otherwise payable under this title for opioid use disorder treatment services and the needs of applicable beneficiaries;*

*(ii) pay a higher per applicable beneficiary per month care management fee for an applicable beneficiary who receives more intensive treatment services from a participant and for whom those services are appropriate based on clinical guidelines for opioid use disorder care;*

*(iii) pay a higher per applicable beneficiary per month care management fee for the month in which the applicable beneficiary begins treatment with a participant than in subsequent months, to reflect the greater time and costs required for the planning and initiation of treatment, as compared to maintenance of treatment;*

*(iv) pay higher per applicable beneficiary per month care management fees for participants that have established opioid use disorder care teams that include an addiction specialist (as defined in subsection (c)(3)(B)); and*

*(v) take into account whether a participant's opioid use disorder care team refers applicable beneficiaries to other suppliers or providers for any opioid use disorder treatment services.*

*(C) NO DUPLICATE PAYMENT.—The Secretary shall make payments under this paragraph to only one participant for services furnished to an applicable beneficiary during a calendar month.*

*(2) INCENTIVE PAYMENTS.—*

*(A) IN GENERAL.—Under the Program, the Secretary shall establish a performance-based incentive payment, which shall be paid (using a methodology established and at a time determined appropriate by the Secretary) to participants based on the performance of participants with respect to criteria, as determined appropriate by the Secretary, in accordance with subparagraph (B).*

*(B) CRITERIA.—*

*(i) IN GENERAL.—Criteria described in subparagraph (A) may include consideration of the following:*

*(I) Patient engagement and retention in treatment.*

*(II) Evidence-based medication-assisted treatment.*

*(III) Other criteria established by the Secretary.*

*(ii) REQUIRED CONSULTATION AND CONSIDERATION.—In determining criteria described in subparagraph (A), the Secretary shall—*

*(I) consult with stakeholders, including clinicians in the primary care community and in the field of addiction medicine; and*

*(II) consider existing clinical guidelines for the treatment of opioid use disorders.*

*(C) NO DUPLICATE PAYMENT.—The Secretary shall ensure that no duplicate payments under this paragraph are made with respect to an applicable beneficiary.*

*(f) MULTIPAYER STRATEGY.—In carrying out the Program, the Secretary shall encourage other payers to provide similar payments and to use similar criteria as applied under the Program under subsection (e)(2)(C). The Secretary may enter into a memorandum of understanding with other payers to align the methodology for payment provided by such a payer related to opioid use disorder treatment services with such methodology for payment under the Program.*

*(g) EVALUATION.—*

*(1) IN GENERAL.—The Secretary shall conduct an intermediate and final evaluation of the program. Each such evaluation shall determine the extent to which each of the purposes described in subsection (b) have been accomplished under the Program.*

*(2) REPORTS.—The Secretary shall submit to the Secretary and Congress—*

*(A) a report with respect to the intermediate evaluation under paragraph (1) not later than 3 years after the date of the implementation of the Program; and*

*(B) a report with respect to the final evaluation under paragraph (1) not later than 6 years after such date.*

*(h) FUNDING.—*

*(1) ADMINISTRATIVE FUNDING For the purposes of implementing, administering, and carrying out the Program (other than for purposes described in paragraph (2)), $5,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841.*

*(2) CARE MANAGEMENT FEES AND INCENTIVES For the purposes of making payments under subsection (e), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841 for each of fiscal years 2021 through 2024.*

*(3) AVAILABILITY.—Amounts transferred under this subsection for a fiscal year shall be available until expended.*

*(i) WAIVERS.—The Secretary may waive any provision of this title as may be necessary to carry out the Program under this section.*

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PAYMENT TO HOSPITALS FOR INPATIENT HOSPITAL SERVICES

SEC. 1886. (a)(1)(A)(i) The Secretary, in determining the amount of the payments that may be made under this title with respect to operating costs of inpatient hospital services (as defined in paragraph (4)) shall not recognize as reasonable (in the efficient delivery of health services) costs for the provision of such services by a hospital for a cost reporting period to the extent such costs exceed the applicable percentage (as determined under clause (ii)) of the average of such costs for all hospitals in the same grouping as such hospital for comparable time periods.

(ii) For purposes of clause (i), the applicable percentage for hospital cost reporting periods beginning—

(I) on or after October 1, 1982, and before October 1, 1983, is 120 percent;

(II) on or after October 1, 1983, and before October 1, 1984, is 115 percent; and

(III) on or after October 1, 1984, is 110 percent.

(B)(i) For purposes of subparagraph (A) the Secretary shall establish case mix indexes for all short- term hospitals, and shall set limits for each hospital based upon the general mix of types of medical cases with respect to which such hospital provides services for which payment may be made under this title.

(ii) The Secretary shall set such limits for a cost reporting period of a hospital—

(I) by updating available data for a previous period to the immediate preceding cost reporting period by the estimated average rate of change of hospital costs industry-wide, and

(II) by projecting for the cost reporting period by the applicable percentage increase (as defined in subsection (b)(3)(B)).

(C) The limitation established under subparagraph (A) for any hospital shall in no event be lower than the allowable operating costs of inpatient hospital services (as defined in paragraph (4)) recognized under this title for such hospital for such hospital's last cost reporting period prior to the hospital's first cost reporting period for which this section is in effect.

(D) Subparagraph (A) shall not apply to cost reporting periods beginning on or after October 1, 1983.

(2) The Secretary shall provide for such exemptions from, and exceptions and adjustments to, the limitation established under paragraph (1)(A) as he deems appropriate, including those which he deems necessary to take into account—

(A) the special needs of sole community hospitals, of new hospitals, of risk based health maintenance organizations, and of hospitals which provide atypical services or essential community services, and to take into account extraordinary circumstances beyond the hospital's control, medical and paramedical education costs, significantly fluctuating population in the service area of the hospital, and unusual labor costs,

(B) the special needs of psychiatric hospitals and of public or other hospitals that serve a significantly disproportionate number of patients who have low income or are entitled to benefits under part A of this title, and

(C) a decrease in the inpatient hospital services that a hospital provides and that are customarily provided directly by similar hospitals which results in a significant distortion in the operating costs of inpatient hospital services.

(3) The limitation established under paragraph (1)(A) shall not apply with respect to any hospital which—

(A) is located outside of a standard metropolitan statistical area, and

(B)(i) has less than 50 beds, and

(ii) was in operation and had less than 50 beds on the date of the enactment of this section.

(4) For purposes of this section, the term "operating costs of inpatient hospital services" includes all routine operating costs, ancillary service operating costs, and special care unit operating costs with respect to inpatient hospital services as such costs are determined on an average per admission or per discharge basis (as determined by the Secretary), and includes the costs of all services for which payment may be made under this title that are provided by the hospital (or by an entity wholly owned or operated by the hospital) to the patient during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) immediately preceding the date of the patient's admission if such services are diagnostic services (including clinical diagnostic laboratory tests) or are other services related to the admission (as defined by the Secretary). Such term does not include costs of approved educational activities, a return on equity capital, other capital-related costs (as defined by the Secretary for periods before October 1, 1987), or costs

with respect to administering blood clotting factors to individuals with hemophilia. In applying the first sentence of this paragraph, the term "other services related to the admission" includes all services that are not diagnostic services (other than ambulance and maintenance renal dialysis services) for which payment may be made under this title that are provided by a hospital (or an entity wholly owned or operated by the hospital) to a patient—

(A) on the date of the patient's inpatient admission; or

(B) during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) immediately preceding the date of such admission unless the hospital demonstrates (in a form and manner, and at a time, specified by the Secretary) that such services are not related (as determined by the Secretary) to such admission.

(b)(1) Notwithstanding section 1814(b) but subject to the provisions of section 1813, if the operating costs of inpatient hospital services (as defined in subsection (a)(4)) of a hospital (other than a subsection (d) hospital, as defined in subsection (d)(1)(B) and other than a rehabilitation facility described in subsection (j)(1)) for a cost reporting period subject to this paragraph—

(A) are less than or equal to the target amount (as defined in paragraph (3)) for that hospital for that period, the amount of the payment with respect to such operating costs payable under part A on a per discharge or per admission basis (as the case may be) shall be equal to the amount of such operating costs, plus—

(i) 15 percent of the amount by which the target amount exceeds the amount of the operating costs, or

(ii) 2 percent of the target amount,

whichever is less;

(B) are greater than the target amount but do not exceed 110 percent of the target amount, the amount of the payment with respect to those operating costs payable under part A on a per discharge basis shall equal the target amount; or

(C) are greater than 110 percent of the target amount, the amount of the payment with respect to such operating costs payable under part A on a per discharge or per admission basis (as the case may be) shall be equal to (i) the target amount, plus (ii) in the case of cost reporting periods beginning on or after October 1, 1991, an additional amount equal to 50 percent of the amount by which the operating costs exceed 110 percent of the target amount (except that such additional amount may not exceed 10 percent of the target amount) after any exceptions or adjustments are made to such target amount for the cost reporting period;

plus the amount, if any, provided under paragraph (2), except that in no case may the amount payable under this title (other than on the basis of a DRG prospective payment rate determined under subsection (d)) with respect to operating costs of inpatient hospital services exceed the maximum amount payable with respect to such costs pursuant to subsection (a).

(2)(A) Except as provided in subparagraph (E), in addition to the payment computed under paragraph (1), in the case of an eligible hospital (described in subparagraph (B)) for a cost reporting period beginning on or after October 1, 1997, the amount of payment on a per discharge basis under paragraph (1) shall be increased by the lesser of—

(i) 50 percent of the amount by which the operating costs are less than the expected costs (as defined in subparagraph (D)) for the period; or

(ii) 1 percent of the target amount for the period.

(B) For purposes of this paragraph, an "eligible hospital" means with respect to a cost reporting period, a hospital—

(i) that has received payments under this subsection for at least 3 full cost reporting periods before that cost reporting period, and

(ii) whose operating costs for the period are less than the least of its target amount, its trended costs (as defined in subparagraph (C)), or its expected costs (as defined in subparagraph (D)) for the period.

(C) For purposes of subparagraph (B)(ii), the term "trended costs" means for a hospital cost reporting period ending in a fiscal year—

(i) in the case of a hospital for which its cost reporting period ending in fiscal year 1996 was its third or subsequent full cost reporting period for which it receives payments under this subsection, the lesser of the operating costs or target amount for that hospital for its cost reporting period ending in fiscal year 1996, or

(ii) in the case of any other hospital, the operating costs for that hospital for its third full cost reporting period for which it receives payments under this subsection,

increased (in a compounded manner) for each succeeding fiscal year (through the fiscal year involved) by the market basket percentage increase for the fiscal year.

(D) For purposes of this paragraph, the term "expected costs", with respect to the cost reporting period ending in a fiscal year, means the lesser of the operating costs of inpatient hospital services or target amount per discharge for the previous cost reporting period updated by the market basket percentage increase (as defined in paragraph (3)(B)(iii)) for the fiscal year.

(E)(i) In the case of an eligible hospital that is a hospital or unit that is within a class of hospital described in clause (ii) with a 12-month cost reporting period beginning before the enactment of this subparagraph, in determining the amount of the increase under subparagraph (A), the Secretary shall substitute for the percentage of the target amount applicable under subparagraph (A)(ii)—

(I) for a cost reporting period beginning on or after October 1, 2000, and before September 30, 2001, 1.5 percent; and

(II) for a cost reporting period beginning on or after October 1, 2001, and before September 30, 2002, 2 percent.

(ii) For purposes of clause (i), each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (iv) of such subsection.

(3)(A) Except as provided in subparagraph (C) and succeeding subparagraphs and in paragraph (7)(A)(ii), for purposes of this subsection, the term "target amount" means, with respect to a hospital for a particular 12-month cost reporting period—

(i) in the case of the first such reporting period for which this subsection is in effect, the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this title for such hospital for the preceding 12-month cost reporting period, and

(ii) in the case of a later reporting period, the target amount for the preceding 12-month cost reporting period,

increased by the applicable percentage increase under subparagraph (B) for that particular cost reporting period.

(B)(i) For purposes of subsection (d) and subsection (j) for discharges occurring during a fiscal year, the "applicable percentage increase" shall be—

(I) for fiscal year 1986, ½ percent,

(II) for fiscal year 1987, 1.15 percent,

(III) for fiscal year 1988, 3.0 percent for hospitals located in a rural area, 1.5 percent for hospitals located in a large urban area (as defined in subsection (d)(2)(D)), and 1.0 percent for hospitals located in other urban areas,

(IV) for fiscal year 1989, the market basket percentage increase minus 1.5 percentage points for hospitals located in a rural area, the market basket percentage increase minus 2.0 percentage points for hospitals located in a large urban area, and the market basket percentage increase minus 2.5 percentage points for hospitals located in other urban areas,

(V) for fiscal year 1990, the market basket percentage increase plus 4.22 percentage points for hospitals located in a rural area, the market basket percentage increase plus 0.12 percentage points for hospitals located in a large urban area, and the market basket percentage increase minus 0.53 percentage points for hospitals located in other urban areas,

(VI) for fiscal year 1991, the market basket percentage increase minus 2.0 percentage points for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.7 percentage point for hospitals located in a rural area,

(VII) for fiscal year 1992, the market basket percentage increase minus 1.6 percentage points for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.6 percentage point for hospitals located in a rural area,

(VIII) for fiscal year 1993, the market basket percentage increase minus 1.55 percentage point for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.55 for hospitals located in a rural area,

(IX) for fiscal year 1994, the market basket percentage increase minus 2.5 percentage points for hospitals located in a large urban or other urban area, and the market basket percentage increase minus 1.0 percentage point for hospitals located in a rural area,

(X) for fiscal year 1995, the market basket percentage increase minus 2.5 percentage points for hospitals located in a large urban or other urban area, and such percentage increase

for hospitals located in a rural area as will provide for the average standardized amount determined under subsection (d)(3)(A) for hospitals located in a rural area being equal to such average standardized amount for hospitals located in an urban area (other than a large urban area),

(XI) for fiscal year 1996, the market basket percentage increase minus 2.0 percentage points for hospitals in all areas,

(XII) for fiscal year 1997, the market basket percentage increase minus 0.5 percentage point for hospitals in all areas,

(XIII) for fiscal year 1998, 0 percent,

(XIV) for fiscal year 1999, the market basket percentage increase minus 1.9 percentage points for hospitals in all areas,

(XV) for fiscal year 2000, the market basket percentage increase minus 1.8 percentage points for hospitals in all areas,

(XVI) for fiscal year 2001, the market basket percentage increase for hospitals in all areas,

(XVII) for fiscal year 2002, the market basket percentage increase minus 0.55 percentage points for hospitals in all areas,

(XVIII) for fiscal year 2003, the market basket percentage increase minus 0.55 percentage points for hospitals in all areas,

(XIX) for each of fiscal years 2004 through 2006, subject to clause (vii), the market basket percentage increase for hospitals in all areas; and

(XX) for each subsequent fiscal year, subject to clauses (viii), (ix), (xi), and (xii), the market basket percentage increase for hospitals in all areas.

(ii) For purposes of subparagraphs (A) and (E), the "applicable percentage increase" for 12-month cost reporting periods beginning during—

(I) fiscal year 1986, is 0.5 percent,

(II) fiscal year 1987, is 1.15 percent,

(III) fiscal year 1988, is the market basket percentage increase minus 2.0 percentage points,

(IV) a subsequent fiscal year ending on or before September 30, 1993, is the market basket percentage increase,

(V) fiscal years 1994 through 1997, is the market basket percentage increase minus the applicable reduction (as defined in clause (v)(II)), or in the case of a hospital for a fiscal year for which the hospital's update adjustment percentage (as defined in clause (v)(I)) is at least 10 percent, the market basket percentage increase,

(VI) for fiscal year 1998, is 0 percent,

(VII) for fiscal years 1999 through 2002, is the applicable update factor specified under clause (vi) for the fiscal year, and

(VIII) subsequent fiscal years is the market basket percentage increase.

(iii) For purposes of this subparagraph, the term "market basket percentage increase" means, with respect to cost reporting periods and discharges occurring in a fiscal year, the percentage, estimated by the Secretary before the beginning of the period or fiscal year, by which the cost of the mix of goods and services (including personnel costs but excluding nonoperating costs) comprising routine, ancillary, and special care unit inpatient hospital services, based on an index of appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services included in such inpatient hospital services, for the period or fiscal year will exceed the cost of such mix of goods and services for the preceding 12-month cost reporting period or fiscal year.

(iv) For purposes of subparagraphs (C) and (D), the "applicable percentage increase" is—

(I) for 12-month cost reporting periods beginning during fiscal years 1986 through 1993, the applicable percentage increase specified in clause (ii),

(II) for fiscal year 1994, the market basket percentage increase minus 2.3 percentage points (adjusted to exclude any portion of a cost reporting period beginning during fiscal year 1993 for which the applicable percentage increase is determined under subparagraph (I)),

(III) for fiscal year 1995, the market basket percentage increase minus 2.2 percentage points, and

(IV) for fiscal year 1996 and each subsequent fiscal year, the applicable percentage increase under clause (i).

(v) For purposes of clause (ii)(V)—

(I) a hospital's "update adjustment percentage" for a fiscal year is the percentage by which the hospital's allowable operating costs of inpatient hospital services recognized under this title for the cost reporting period beginning in fiscal year 1990 exceeds the hospital's target amount (as determined under subparagraph (A)) for such cost reporting period, increased for each fiscal year (beginning with fiscal year 1994) by the sum of any of the hospital's applicable reductions under subclause (V) for previous fiscal years; and

(II) the "applicable reduction" with respect to a hospital for a fiscal year is the lesser of 1 percentage point or the percentage point difference between 10 percent and the hospital's update adjustment percentage for the fiscal year.

(vi) For purposes of clause (ii)(VII) for a fiscal year, if a hospital's allowable operating costs of inpatient hospital services recognized under this title for the most recent cost reporting period for which information is available—

(I) is equal to, or exceeds, 110 percent of the hospital's target amount (as determined under subparagraph (A)) for such cost reporting period, the applicable update factor specified under this clause is the market basket percentage;

(II) exceeds 100 percent, but is less than 110 percent, of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent or, if greater, the market basket percentage minus 0.25 percentage points for each percentage point by which such allowable operating costs (expressed as a percentage of such target amount) is less than 110 percent of such target amount;

(III) is equal to, or less than 100 percent, but exceeds ⅔ of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent or, if greater, the market basket percentage minus 2.5 percentage points; or

(IV) does not exceed ⅔ of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent.

(vii)(I) For purposes of clause (i)(XIX) for fiscal years 2005 and 2006, in a case of a subsection (d) hospital that does not submit data to the Secretary in accordance with subclause (II) with respect to such a fiscal year, the applicable percentage increase under such clause for such fiscal year shall be reduced by 0.4 percentage points. Such reduction shall apply only with respect to the fiscal year involved, and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i)(XIX) for a subsequent fiscal year.

(II) For fiscal years 2005 and 2006, each subsection (d) hospital shall submit to the Secretary quality data (for a set of 10 indicators established by the Secretary as of November 1, 2003) that relate to the quality of care furnished by the hospital in inpatient settings in a form and manner, and at a time, specified by the Secretary for purposes of this clause, but with respect to fiscal year 2005, the Secretary shall provide for a 30-day grace period for the submission of data by a hospital.

(viii)(I) For purposes of clause (i) for fiscal year 2007 and each subsequent fiscal year, in the case of a subsection (d) hospital that does not submit, to the Secretary in accordance with this clause, data required to be submitted on measures selected under this clause with respect to such a fiscal year, the applicable percentage increase under clause (i) for such fiscal year shall be reduced by 2.0 percentage points (or, beginning with fiscal year 2015, by one-quarter of such applicable percentage increase (determined without regard to clause (ix), (xi), or (xii))). Such reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i) for a subsequent fiscal year, and the Secretary and the Medicare Payment Advisory Commission shall carry out the requirements under section 5001(b) of the Deficit Reduction Act of 2005.

(II) Each subsection (d) hospital shall submit data on measures selected under this clause to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this clause. The Secretary may require hospitals to submit data on measures that are not used for the determination of value-based incentive payments under subsection (o).

(III) The Secretary shall expand, beyond the measures specified under clause (vii)(II) and consistent with the succeeding subclauses, the set of measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in inpatient settings.

(IV) Effective for payments beginning with fiscal year 2007, in expanding the number of measures under subclause (III), the Secretary shall begin to adopt the baseline set of performance measures as set forth in the November 2005 report by the Institute of Medicine of the National Academy of Sciences under section 238(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(V) Effective for payments for fiscal years 2008 through 2012, the Secretary shall add other measures that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(VI) For purposes of this clause and clause (vii), the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(VII) The Secretary shall establish procedures for making information regarding measures submitted under this clause available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(VIII) Effective for payments beginning with fiscal year 2013, with respect to quality measures for outcomes of care, the Secretary shall provide for such risk adjustment as the Secretary determines to be appropriate to maintain incentives for hospitals to treat patients with severe illnesses or conditions.

(IX)(aa) Subject to item (bb), effective for payments beginning with fiscal year 2013, each measure specified by the Secretary under this clause shall be endorsed by the entity with a contract under section 1890(a).

(bb) In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(X) To the extent practicable, the Secretary shall, with input from consensus organizations and other stakeholders, take steps to ensure that the measures specified by the Secretary under this clause are coordinated and aligned with quality measures applicable to—

(aa) physicians under section 1848(k); and

(bb) other providers of services and suppliers under this title.

(XI) The Secretary shall establish a process to validate measures specified under this clause as appropriate. Such process shall include the auditing of a number of randomly selected hospitals sufficient to ensure validity of the reporting program under this clause as a whole and shall provide a hospital with an opportunity to appeal the validation of measures reported by such hospital.

*(XII)(aa) With respect to a Hospital Consumer Assessment of Healthcare Providers and Systems survey (or a successor survey) conducted on or after January 1, 2019, such survey may not include questions about communication by hospital staff with an individual about such individual's pain unless such questions take into account, as applicable, whether an individual experiencing pain was informed about risks associated with the use of opioids and about non-opioid alternatives for the treatment of pain.*

*(bb) The Secretary shall not include on the Hospital Compare Internet website any measures based on the questions appearing on the Hospital Consumer Assessment of Healthcare Providers and Systems survey in 2018 about communication by hospital staff with an individual about such individual's pain.*

(ix)(I) For purposes of clause (i) for fiscal year 2015 and each subsequent fiscal year, in the case of an eligible hospital (as defined in subsection (n)(6)(B)) that is not a meaningful EHR user (as defined in subsection (n)(3)) for an EHR reporting period for such fiscal year, three-quarters of the applicable percentage increase otherwise applicable under clause (i) (determined without regard to clause (viii), (xi), or (xii)) for such fiscal year shall be reduced by 33⅓ percent for fiscal year 2015, 66⅔ percent for fiscal year 2016, and 100 percent for fiscal year 2017 and each subsequent fiscal year. Such reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i) for a subsequent fiscal year.

(II) The Secretary may, on a case-by-case basis (and, with respect to the application of subclause (I) for fiscal year 2017, for categories of subsection (d) hospitals, as established by the Secretary and posted on the Internet website of the Centers for Medicare & Medicaid Services prior to December 15, 2015, an application for which must be submitted to the Secretary by not later than April 1, 2016), exempt an eligible hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines, subject to annual renewal, that requiring such hospital

to be a meaningful EHR user during such fiscal year would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access. The Secretary shall exempt an eligible hospital from the application of the payment adjustment under subclause (I) with respect to a fiscal year, subject to annual renewal, if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by such hospital is decertified under a program kept or recognized pursuant to section 3001(c)(5) of the Public Health Service Act. In no case may a hospital be granted an exemption under this subclause for more than 5 years.

(III) For fiscal year 2015 and each subsequent fiscal year, a State in which hospitals are paid for services under section 1814(b)(3) shall adjust the payments to each subsection (d) hospital in the State that is not a meaningful EHR user (as defined in subsection (n)(3)) in a manner that is designed to result in an aggregate reduction in payments to hospitals in the State that is equivalent to the aggregate reduction that would have occurred if payments had been reduced to each subsection (d) hospital in the State in a manner comparable to the reduction under the previous provisions of this clause. The State shall report to the Secretary the methodology it will use to make the payment adjustment under the previous sentence.

(IV) For purposes of this clause, the term "EHR reporting period" means, with respect to a fiscal year, any period (or periods) as specified by the Secretary.

(x)(I) The Secretary shall develop standard Internet website reports tailored to meet the needs of various stakeholders such as hospitals, patients, researchers, and policymakers. The Secretary shall seek input from such stakeholders in determining the type of information that is useful and the formats that best facilitate the use of the information.

(II) The Secretary shall modify the Hospital Compare Internet website to make the use and navigation of that website readily available to individuals accessing it.

(xi)(I) For 2012 and each subsequent fiscal year, after determining the applicable percentage increase described in clause (i) and after application of clauses (viii) and (ix), such percentage increase shall be reduced by the productivity adjustment described in subclause (II).

(II) The productivity adjustment described in this subclause, with respect to a percentage, factor, or update for a fiscal year, year, cost reporting period, or other annual period, is a productivity adjustment equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

(III) The application of subclause (I) may result in the applicable percentage increase described in clause (i) being less than 0.0 for a fiscal year, and may result in payment rates under this section for a fiscal year being less than such payment rates for the preceding fiscal year.

(xii) After determining the applicable percentage increase described in clause (i), and after application of clauses (viii), (ix), and (xi), the Secretary shall reduce such applicable percentage increase—

(I) for each of fiscal years 2010 and 2011, by 0.25 percentage point;
(II) for each of fiscal years 2012 and 2013, by 0.1 percentage point;
(III) for fiscal year 2014, by 0.3 percentage point;
(IV) for each of fiscal years 2015 and 2016, by 0.2 percentage point; and
(V) for each of fiscal years 2017, 2018, and 2019, by 0.75 percentage point.

The application of this clause may result in the applicable percentage increase described in clause (i) being less than 0.0 for a fiscal year, and may result in payment rates under this section for a fiscal year being less than such payment rates for the preceding fiscal year.

(C) In the case of a hospital that is a sole community hospital (as defined in subsection (d)(5)(D)(iii)), subject to subparagraphs (I) and (L), the term "target amount" means—

(i) with respect to the first 12-month cost reporting period in which this subparagraph is applied to the hospital—

(I) the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this title for the hospital for the 12-month cost reporting period (in this subparagraph referred to as the "base cost reporting period") preceding the first cost reporting period for which this subsection was in effect with respect to such hospital, increased (in a compounded manner) by—

(II) the applicable percentage increases applied to such hospital under this paragraph for cost reporting periods after the base cost reporting period and up to and including such first 12-month cost reporting period,

(ii) with respect to a later cost reporting period beginning before fiscal year 1994, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(iv) for discharges occurring in the fiscal year in which that later cost reporting period begins,

(iii) with respect to discharges occurring in fiscal year 1994, the target amount for the cost reporting period beginning in fiscal year 1993 increased by the applicable percentage increase under subparagraph (B)(iv), or

(iv) with respect to discharges occurring in fiscal year 1995 and each subsequent fiscal year, the target amount for the preceding year increased by the applicable percentage increase under subparagraph (B)(iv).

There shall be substituted for the base cost reporting period described in clause (i) a hospital's cost reporting period (if any) beginning during fiscal year 1987 if such substitution results in an increase in the target amount for the hospital.

(D) For cost reporting periods ending on or before September 30, 1994, and for cost reporting periods occurring on or after October 1, 1997, and before October 1, 2022, in the case of a hospital that is a medicare-dependent, small rural hospital (as defined in subsection (d)(5)(G)), subject to subparagraph (K), the term "target amount" means—

(i) with respect to the first 12-month cost reporting period in which this subparagraph is applied to the hospital—

(I) the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this title for the hospital for the 12-month cost reporting period (in this subparagraph referred to as the "base cost reporting period") preceding the first cost reporting period for which this subsection was in effect with respect to such hospital, increased (in a compounded manner) by—

(II) the applicable percentage increases applied to such hospital under this paragraph for cost reporting periods after the base cost reporting period and up to and including such first 12-month cost reporting period, or

(ii) with respect to a later cost reporting period beginning before fiscal year 1994, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(iv) for discharges occurring in the fiscal year in which that later cost reporting period begins,

(iii) with respect to discharges occurring in fiscal year 1994, the target amount for the cost reporting period beginning in fiscal year 1993 increased by the applicable percentage increase under subparagraph (B)(iv), and

(iv) with respect to discharges occurring during fiscal year 1998 through fiscal year 2022, the target amount for the preceding year increased by the applicable percentage increase under subparagraph (B)(iv).

There shall be substituted for the base cost reporting period described in clause (i) a hospital's cost reporting period (if any) beginning during fiscal year 1987 if such substitution results in an increase in the target amount for the hospital.

(E) In the case of a hospital described in clause (v) of subsection (d)(1)(B), the term "target amount" means—

(i) with respect to the first 12-month cost reporting period in which this subparagraph is applied to the hospital—

(I) the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this title for the hospital for the 12-month cost reporting period (in this subparagraph referred to as the "base cost reporting period") preceding the first cost reporting period for which this subsection was in effect with respect to such hospital, increased (in a compounded manner) by—

(II) the sum of the applicable percentage increases applied to such hospital under this paragraph for cost reporting periods after the base cost reporting period and up to and including such first 12-month cost reporting period, or

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.

There shall be substituted for the base cost reporting period described in clause (i) a hospital's cost reporting period (if any) beginning during fiscal year 1987 if such substitution results in an increase in the target amount for the hospital.

(F)(i) In the case of a hospital (or unit described in the matter following clause (v) of subsection (d)(1)(B)) that received payment under this subsection for inpatient hospital services furnished during cost reporting periods beginning before October 1, 1990, that is within a class of hospital described in clause (iii), and that elects (in a form and manner determined by the Secretary) this subparagraph to apply to the hospital, the target amount for the hospital's 12-month cost reporting period beginning during fiscal year 1998 is equal to the average described in clause (ii).

(ii) The average described in this clause for a hospital or unit shall be determined by the Secretary as follows:

(I) The Secretary shall determine the allowable operating costs for inpatient hospital services for the hospital or unit for each of the 5 cost reporting periods for which the Secretary has the most recent settled cost reports as of the date of the enactment of this subparagraph.

(II) The Secretary shall increase the amount determined under subclause (I) for each cost reporting period by the applicable percentage increase under subparagraph (B)(ii) for each subsequent cost reporting period up to the cost reporting period described in clause (i).

(III) The Secretary shall identify among such 5 cost reporting periods the cost reporting periods for which the amount determined under subclause (II) is the highest, and the lowest.

(IV) The Secretary shall compute the averages of the amounts determined under subclause (II) for the 3 cost reporting periods not identified under subclause (III).

(iii) For purposes of this subparagraph, each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(III) Hospitals described in clause (iii) of such subsection.

(IV) Hospitals described in clause (iv) of such subsection.

(V) Hospitals described in clause (v) of such subsection.

(G)(i) In the case of a qualified long-term care hospital (as defined in clause (ii)) that elects (in a form and manner determined by the Secretary) this subparagraph to apply to the hospital, the target amount for the hospital's 12-month cost reporting period beginning during fiscal year 1998 is equal to the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4)) recognized under this title for the hospital for the 12-month cost reporting period beginning during fiscal year 1996, increased by the applicable percentage increase for the cost reporting period beginning during fiscal year 1997.

(ii) In clause (i), a "qualified long-term care hospital" means, with respect to a cost reporting period, a hospital described in clause (iv) of subsection (d)(1)(B) during each of the 2 cost reporting periods for which the Secretary has the most recent settled cost reports as of the date of the enactment of this subparagraph for each of which—

(I) the hospital's allowable operating costs of inpatient hospital services recognized under this title exceeded 115 percent of the hospital's target amount, and

(II) the hospital would have a disproportionate patient percentage of at least 70 percent (as determined by the Secretary under subsection (d)(5)(F)(vi)) if the hospital were a subsection (d) hospital.

(H)(i) In the case of a hospital or unit that is within a class of hospital described in clause (iv), for a cost reporting period beginning during fiscal years 1998 through 2002, the target amount for such a hospital or unit may not exceed the amount as updated up to or for such cost reporting period under clause (ii).

(ii)(I) In the case of a hospital or unit that is within a class of hospital described in clause (iv), the Secretary shall estimate the 75th percentile of the target amounts for such hospitals within such class for cost reporting periods ending during fiscal year 1996, as adjusted under clause (iii).

(II) The Secretary shall update the amount determined under subclause (I), for each cost reporting period after the cost reporting period described in such subclause and up to the first cost reporting period beginning on or after October 1, 1997, by a factor equal to the market basket percentage increase.

(III) For cost reporting periods beginning during each of fiscal years 1999 through 2002, subject to subparagraph (J), the Secretary shall update such amount by a factor equal to the market basket percentage increase.

(iii) In applying clause (ii)(I) in the case of a hospital or unit, the Secretary shall provide for an appropriate adjustment to the labor-related portion of the amount determined under such subparagraph to take into account differences between average wage-related costs in the area of the hospital and the national average of such costs within the same class of hospital.

(iv) For purposes of this subparagraph, each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(III) Hospitals described in clause (iv) of such subsection.

(I)(i) Subject to subparagraph (L), for cost reporting periods beginning on or after October 1, 2000, in the case of a sole community hospital there shall be substituted for the amount otherwise determined under subsection (d)(5)(D)(i), if such substitution results in a greater amount of payment under this section for the hospital—

(I) with respect to discharges occurring in fiscal year 2001, 75 percent of the amount otherwise applicable to the hospital under subsection (d)(5)(D)(i) (referred to in this clause as the "subsection (d)(5)(D)(i) amount") and 25 percent of the rebased target amount (as defined in clause (ii));

(II) with respect to discharges occurring in fiscal year 2002, 50 percent of the subsection (d)(5)(D)(i) amount and 50 percent of the rebased target amount;

(III) with respect to discharges occurring in fiscal year 2003, 25 percent of the subsection (d)(5)(D)(i) amount and 75 percent of the rebased target amount; and

(IV) with respect to discharges occurring after fiscal year 2003, 100 percent of the rebased target amount.

(ii) For purposes of this subparagraph, the "rebased target amount" has the meaning given the term "target amount" in subparagraph (C) except that—

(I) there shall be substituted for the base cost reporting period the 12-month cost reporting period beginning during fiscal year 1996;

(II) any reference in subparagraph (C)(i) to the "first cost reporting period" described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after October 1, 2000; and

(III) applicable increase percentage shall only be applied under subparagraph (C)(iv) for discharges occurring in fiscal years beginning with fiscal year 2002.

(iii) In no case shall a hospital be denied treatment as a sole community hospital or payment (on the basis of a target rate as such as a hospital) because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data for at least one applicable base cost reporting period is available.

(J) For cost reporting periods beginning during fiscal year 2001, for a hospital described in subsection (d)(1)(B)(iv)—

(i) the limiting or cap amount otherwise determined under subparagraph (H) shall be increased by 2 percent; and

(ii) the target amount otherwise determined under subparagraph (A) shall be increased by 25 percent (subject to the limiting or cap amount determined under subparagraph (H), as increased by clause (i)).

(K)(i) With respect to discharges occurring on or after October 1, 2006, in the case of a medicare-dependent, small rural hospital, for purposes of applying subparagraph (D)—

(I) there shall be substituted for the base cost reporting period described in subparagraph (D)(i) the 12-month cost reporting period beginning during fiscal year 2002; and

(II) any reference in such subparagraph to the "first cost reporting period" described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after October 1, 2006.

(ii) This subparagraph shall only apply to a hospital if the substitution described in clause (i)(I) results in an increase in the target amount under subparagraph (D) for the hospital.

(L)(i) For cost reporting periods beginning on or after January 1, 2009, in the case of a sole community hospital there shall be substituted for the amount otherwise determined under subsection (d)(5)(D)(i) of this section, if such substitution results in a greater amount of payment under this section for the hospital, the subparagraph (L) rebased target amount.

(ii) For purposes of this subparagraph, the term "subparagraph (L) rebased target amount" has the meaning given the term "target amount" in subparagraph (C), except that—

(I) there shall be substituted for the base cost reporting period the 12-month cost reporting period beginning during fiscal year 2006;

(II) any reference in subparagraph (C)(i) to the "first cost reporting period" described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after January 1, 2009; and

(III) the applicable percentage increase shall only be applied under subparagraph (C)(iv) for discharges occurring on or after January 1, 2009.

(4)(A)(i) The Secretary shall provide for an exception and adjustment to (and in the case of a hospital described in subsection (d)(1)(B)(iii), may provide an exemption from) the method under this subsection for determining the amount of payment to a hospital where events beyond the hospital's control or extraordinary circumstances, including changes in the case mix of such hospital, create a distortion in the increase in costs for a cost reporting period (including any distortion in the costs for the base period against which such increase is measured). The Secretary may provide for such other exemptions from, and exceptions and adjustments to, such method as the Secretary deems appropriate, including the assignment of a new base period which is more representative, as determined by the Secretary, of the reasonable and necessary cost of inpatient services and including those which he deems necessary to take into account a decrease in the inpatient hospital services that a hospital provides and that are customarily provided directly by similar hospitals which results in a significant distortion in the operating costs of inpatient hospital services. The Secretary shall announce a decision on any request for an exemption, exception, or adjustment under this paragraph not later than 180 days after receiving a completed application from the intermediary for such exemption, exception, or adjustment, and shall include in such decision a detailed explanation of the grounds on which such request was approved or denied.

(ii) The payment reductions under paragraph (3)(B)(ii)(V) shall not be considered by the Secretary in making adjustments pursuant to clause (i). In making such reductions, the Secretary shall treat the applicable update factor described in paragraph (3)(B)(vi) for a fiscal year as being equal to the market basket percentage for that year.

(B) In determining under subparagraph (A) whether to assign a new base period which is more representative of the reasonable and necessary cost to a hospital of providing inpatient services, the Secretary shall take into consideration—

(i) changes in applicable technologies and medical practices, or differences in the severity of illness among patients, that increase the hospital's costs;

(ii) whether increases in wages and wage-related costs for hospitals located in the geographic area in which the hospital is located exceed the average of the increases in such costs paid by hospitals in the United States; and

(iii) such other factors as the Secretary considers appropriate in determining increases in the hospital's costs of providing inpatient services.

(C) Paragraph (1) shall not apply to payment of hospitals which is otherwise determined under paragraph (3) of section 1814(b).

(5) In the case of any hospital having any cost reporting period of other than a 12-month period, the Secretary shall determine the 12-month period which shall be used for purposes of this section.

(6) In the case of any hospital which becomes subject to the taxes under section 3111 of the Internal Revenue Code of 1954, with respect to any or all of its employees, for part or all of a cost reporting period, and was not subject to such taxes with respect to any or all of its employees for all or part of the 12-month base cost reporting period referred to in subsection (b)(3)(A)(i), the Secretary shall provide for an adjustment by increasing the base period amount described in such subsection for such hospital by an amount equal to the amount of such taxes which would have been paid or accrued by such hospital for such base period if such hospital had been subject to such taxes for all of such base period with respect to all its employees, minus the amount of any such taxes actually paid or accrued for such base period.

(7)(A) Notwithstanding paragraph (1), in the case of a hospital or unit that is within a class of hospital described in subparagraph (B) which first receives payments under this section on or after October 1, 1997—

(i) for each of the first 2 cost reporting periods for which the hospital has a settled cost report, the amount of the payment with respect to operating costs described in paragraph (1)

under part A on a per discharge or per admission basis (as the case may be) is equal to the lesser of—

(I) the amount of operating costs for such respective period, or

(II) 110 percent of the national median (as estimated by the Secretary) of the target amount for hospitals in the same class as the hospital for cost reporting periods ending during fiscal year 1996, updated by the hospital market basket increase percentage to the fiscal year in which the hospital first received payments under this section, as adjusted under subparagraph (C); and

(ii) for purposes of computing the target amount for the subsequent cost reporting period, the target amount for the preceding cost reporting period is equal to the amount determined under clause (i) for such preceding period.

(B) For purposes of this paragraph, each of the following shall be treated as a separate class of hospital:

(i) Hospitals described in clause (i) of subsection (d)(1)(B) and psychiatric units described in the matter following clause (v) of such subsection.

(ii) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(iii) Hospitals described in clause (iv) of such subsection.

(C) In applying subparagraph (A)(i)(II) in the case of a hospital or unit, the Secretary shall provide for an appropriate adjustment to the labor-related portion of the amount determined under such subparagraph to take into account differences between average wage-related costs in the area of the hospital and the national average of such costs within the same class of hospital.

(c)(1) The Secretary may provide, in his discretion, that payment with respect to services provided by a hospital in a State may be made in accordance with a hospital reimbursement control system in a State, rather than in accordance with the other provisions of this title, if the chief executive officer of the State requests such treatment and if—

(A) the Secretary determines that the system, if approved under this subsection, will apply (i) to substantially all non- Federal acute care hospitals (as defined by the Secretary) in the State and (ii) to the review of at least 75 percent of all revenues or expenses in the State for inpatient hospital services and of revenues or expenses for inpatient hospital services provided under the State's plan approved under title XIX;

(B) the Secretary has been provided satisfactory assurances as to the equitable treatment under the system of all entities (including Federal and State programs) that pay hospitals for inpatient hospital services, of hospital employees, and of hospital patients;

(C) the Secretary has been provided satisfactory assurances that under the system, over 36-month periods (the first such period beginning with the first month in which this subsection applies to that system in the State), the amount of payments made under this title under such system will not exceed the amount of payments which would otherwise have been made under this title not using such system;

(D) the Secretary determines that the system will not preclude an eligible organization (as defined in section 1876(b)) from negotiating directly with hospitals with respect to the organization's rate of payment for inpatient hospital services; and

(E) the Secretary determines that the system requires hospitals to meet the requirement of section 1866(a)(1)(G) and the system provides for the exclusion of certain costs in accordance with section 1862(a)(14) (except for such waivers thereof as the Secretary provides by regulation).

The Secretary cannot deny the application of a State under this subsection on the ground that the State's hospital reimbursement control system is based on a payment methodology other than on the basis of a diagnosis-related group or on the ground that the amount of payments made under this title under such system must be less than the amount of payments which would otherwise have been made under this title not using such system. If the Secretary determines that the conditions described in subparagraph (C) are based on maintaining payment amounts at no more than a specified percentage increase above the payment amounts in a base period, the State has the option of applying such test (for inpatient hospital services under part A) on an aggregate payment basis or on the basis of the amount of payment per inpatient discharge or admission. If the Secretary determines that the conditions described in subparagraph (C) are based on maintaining aggregate payment amounts below a national average percentage increase in total payments under part A for inpatient hospital services, the Secretary cannot deny the application of a State under

this subsection on the ground that the State's rate of increase in such payments for such services must be less than such national average rate of increase.

(2) In determining under paragraph (1)(C) the amount of payment which would otherwise have been made under this title for a State, the Secretary may provide for appropriate adjustment of such amount to take into account previous reductions effected in the amount of payments made under this title in the State due to the operation of the hospital reimbursement control system in the State if the system has resulted in an aggregate rate of increase in operating costs of inpatient hospital services (as defined in subsection (a)(4)) under this title for hospitals in the State which is less than the aggregate rate of increase in such costs under this title for hospitals in the United States.

(3) The Secretary shall discontinue payments under a system described in paragraph (1) if the Secretary—

(A) determines that the system no longer meets the requirements of subparagraphs (A), (D), and (E) of paragraph (1) and, if applicable, the requirements of paragraph (5), or

(B) has reason to believe that the assurances described in subparagraph (B) or (C) of paragraph (1) (or, if applicable, in paragraph (5)) are not being (or will not be) met.

(4) The Secretary shall approve the request of a State under paragraph (1) with respect to a hospital reimbursement control system if—

(A) the requirements of subparagraphs (A), (B), (C), (D), and (E) of paragraph (1) have been met with respect to the system, and

(B) with respect to that system a waiver of certain requirements of title XVIII of the Social Security Act has been approved on or before (and which is in effect as of) the date of the enactment of the Social Security Amendments of 1983, pursuant to section 402(a) of the Social Security Amendments of 1967 or section 222(a) of the Social Security Amendments of 1972.

With respect to a State system described in this paragraph, the Secretary shall judge the effectiveness of such system on the basis of its rate of increase or inflation in inpatient hospital payments for individuals under this title, as compared to the national rate of increase or inflation for such payments, with the State retaining the option to have the test applied on the basis of the aggregate payments under the State system as compared to aggregate payments which would have been made under the national system since October 1, 1984, to the most recent date for which annual data are available.

(5) The Secretary shall approve the request of a State under paragraph (1) with respect to a hospital reimbursement control system if—

(A) the requirements of subparagraphs (A), (B), (C), (D), and (E) of paragraph (1) have been met with respect to the system;

(B) the Secretary determines that the system—

(i) is operated directly by the State or by an entity designated pursuant to State law,

(ii) provides for payment of hospitals covered under the system under a methodology (which sets forth exceptions and adjustments, as well as any method for changes in the methodology) by which rates or amounts to be paid for hospital services during a specified period are established under the system prior to the defined rate period, and

(iii) hospitals covered under the system will make such reports (in lieu of cost and other reports, identified by the Secretary, otherwise required under this title) as the Secretary may require in order to properly monitor assurances provided under this subsection;

(C) the State has provided the Secretary with satisfactory assurances that operation of the system will not result in any change in hospital admission practices which result in—

(i) a significant reduction in the proportion of patients (receiving hospital services covered under the system) who have no third-party coverage and who are unable to pay for hospital services,

(ii) a significant reduction in the proportion of individuals admitted to hospitals for inpatient hospital services for which payment is (or is likely to be) less than the anticipated charges for or costs of such services,

(iii) the refusal to admit patients who would be expected to require unusually costly or prolonged treatment for reasons other than those related to the appropriateness of the care available at the hospital, or

(iv) the refusal to provide emergency services to any person who is in need of emergency services if the hospital provides such services;

(D) any change by the State in the system which has the effect of materially reducing payments to hospitals can only take effect upon 60 days notice to the Secretary and to the hospitals the payment to which is likely to be materially affected by the change; and

(E) the State has provided the Secretary with satisfactory assurances that in the development of the system the State has consulted with local governmental officials concerning the impact of the system on public hospitals.

The Secretary shall respond to requests of States under this paragraph within 60 days of the date the request is submitted to the Secretary.

(6) If the Secretary determines that the assurances described in paragraph (1)(C) have not been met with respect to any 36-month period, the Secretary may reduce payments under this title to hospitals under the system in an amount equal to the amount by which the payment under this title under such system for such period exceeded the amount of payments which would otherwise have been made under this title not using such system.

(7) In the case of a State which made a request under paragraph (5) before December 31, 1984, for the approval of a State hospital reimbursement control system and which request was approved—

(A) in applying paragraphs (1)(C) and (6), a reference to a "36-month period" is deemed a reference to a "48-month period", and

(B) in order to allow the State the opportunity to provide the assurances described in paragraph (1)(C) for a 48-month period, the Secretary may not discontinue payments under the system, under the authority of paragraph (3)(A) because the Secretary has reason to believe that such assurances are not being (or will not be) met, before July 1, 1986.

(d)(1)(A) Notwithstanding section 1814(b) but subject to the provisions of section 1813, the amount of the payment with respect to the operating costs of inpatient hospital services (as defined in subsection (a)(4)) of a subsection (d) hospital (as defined in subparagraph (B)) for inpatient hospital discharges in a cost reporting period or in a fiscal year—

(i) beginning on or after October 1, 1983, and before October 1, 1984, is equal to the sum of—

(I) the target percentage (as defined in subparagraph (C)) of the hospital's target amount for the cost reporting period (as defined in subsection (b)(3)(A), but determined without the application of subsection (a)), and

(II) the DRG percentage (as defined in subparagraph (C)) of the regional adjusted DRG prospective payment rate determined under paragraph (2) for such discharges;

(ii) beginning on or after October 1, 1984, and before October 1, 1987, is equal to the sum of—

(I) the target percentage (as defined in subparagraph (C)) of the hospital's target amount for the cost reporting period (as defined in subsection (b)(3)(A), but determined without the application of subsection (a)), and

(II) the DRG percentage (as defined in subparagraph (C)) of the applicable combined adjusted DRG prospective payment rate determined under subparagraph (D) for such discharges; or

(iii) beginning on or after April 1, 1988, is equal to

(I) the national adjusted DRG prospective payment rate determined under paragraph (3) for such discharges, or

(II) for discharges occurring during a fiscal year ending on or before September 30, 1996, the sum of 85 percent of the national adjusted DRG prospective payment rate determined under paragraph (3) for such discharges and 15 percent of the regional adjusted DRG prospective payment rate determined under such paragraph, but only if the average standardized amount (described in clause (i)(I) or clause (ii)(I) of paragraph (3)(D)) for hospitals within the region of, and in the same large urban or other area (or, for discharges occurring during a fiscal year ending on or before September 30, 1994, the same rural, large urban, or other urban area) as, the hospital is greater than the average standardized amount (described in the respective clause) for hospitals within the United States in that type of area for discharges occurring during such fiscal year.

(B) As used in this section, the term "subsection (d) hospital" means a hospital located in one of the fifty States or the District of Columbia other than—

(i) a psychiatric hospital (as defined in section 1861(f)),

(ii) a rehabilitation hospital (as defined by the Secretary),

(iii) a hospital whose inpatients are predominantly individuals under 18 years of age,

(iv) a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days,

(v)(I) a hospital that the Secretary has classified, at any time on or before December 31, 1990, (or, in the case of a hospital that, as of the date of the enactment of this clause, is located in a State operating a demonstration project under section 1814(b), on or before December 31, 1991) for purposes of applying exceptions and adjustments to payment amounts under this subsection, as a hospital involved extensively in treatment for or research on cancer,

(II) a hospital that was recognized as a comprehensive cancer center or clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of April 20, 1983, that is located in a State which, as of December 19, 1989, was not operating a demonstration project under section 1814(b), that applied and was denied, on or before December 31, 1990, for classification as a hospital involved extensively in treatment for or research on cancer under this clause (as in effect on the day before the date of the enactment of this subclause), that as of the date of the enactment of this subclause, is licensed for less than 50 acute care beds, and that demonstrates for the 4–year period ending on December 31, 1996, that at least 50 percent of its total discharges have a principal finding of neoplastic disease, as defined in subparagraph (E), or

(III) a hospital that was recognized as a clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of February 18, 1998, that has never been reimbursed for inpatient hospital services pursuant to a reimbursement system under a demonstration project under section 1814(b), that is a freestanding facility organized primarily for treatment of and research on cancer and is not a unit of another hospital, that as of the date of the enactment of this subclause, is licensed for 162 acute care beds, and that demonstrates for the 4-year period ending on June 30, 1999, that at least 50 percent of its total discharges have a principal finding of neoplastic disease, as defined in subparagraph (E), or

(vi) a hospital that first received payment under this subsection in 1986 which has an average inpatient length of stay (as determined by the Secretary) of greater than 20 days and that has 80 percent or more of its annual medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in fiscal year 1997;

and, in accordance with regulations of the Secretary, does not include a psychiatric or rehabilitation unit of the hospital which is a distinct part of the hospital (as defined by the Secretary). A hospital that was classified by the Secretary on or before September 30, 1995, as a hospital described in clause (iv) (as in effect as of such date) shall continue to be so classified (or, in the case of a hospital described in clause (iv)(II), as so in effect, shall be classified under clause (vi) on and after the effective date of such clause (vi) and for cost reporting periods beginning on or after January 1, 2015, shall not be subject to subsection (m) as of the date of such classification) notwithstanding that it is located in the same building as, or on the same campus as, another hospital.

(C) For purposes of this subsection, for cost reporting periods beginning—

(i) on or after October 1, 1983, and before October 1, 1984, the "target percentage" is 75 percent and the "DRG percentage" is 25 percent;

(ii) on or after October 1, 1984, and before October 1, 1985, the "target percentage" is 50 percent and the "DRG percentage" is 50 percent;

(iii) on or after October 1, 1985, and before October 1, 1986, the "target percentage" is 45 percent and the "DRG percentage" is 55 percent; and

(iv) on or after October 1, 1986, and before October 1, 1987, the "target percentage" is 25 percent and the "DRG percentage" is 75 percent.

(D) For purposes of subparagraph (A)(ii)(II), the "applicable combined adjusted DRG prospective payment rate" for discharges occurring—

(i) on or after October 1, 1984, and before October 1, 1986, is a combined rate consisting of 25 percent of the national adjusted DRG prospective payment rate, and 75 percent of the regional adjusted DRG prospective payment rate, determined under paragraph (3) for such discharges; and

(ii) on or after October 1, 1986, and before October 1, 1987, is a combined rate consisting of 50 percent of the national adjusted DRG prospective payment rate, and 50 percent of the regional adjusted DRG prospective payment rate, determined under paragraph (3) for such discharges.

(E) For purposes of subclauses (II) and (III) of subparagraph (B)(v) only, the term "principal finding of neoplastic disease" means the condition established after study to be chiefly responsible

for occasioning the admission of a patient to a hospital, except that only discharges with ICD–9–CM principal diagnosis codes of 140 through 239, V58.0, V58.1, V66.1, V66.2, or 990 will be considered to reflect such a principal diagnosis.

(2) The Secretary shall determine a national adjusted DRG prospective payment rate, for each inpatient hospital discharge in fiscal year 1984 involving inpatient hospital services of a subsection (d) hospital in the United States, and shall determine a regional adjusted DRG prospective payment rate for such discharges in each region, for which payment may be made under part A of this title. Each such rate shall be determined for hospitals located in urban or rural areas within the United States or within each such region, respectively, as follows:

(A) DETERMINING ALLOWABLE INDIVIDUAL HOSPITAL COSTS FOR BASE PERIOD.—The Secretary shall determine the allowable operating costs per discharge of inpatient hospital services for the hospital for the most recent cost reporting period for which data are available.

(B) UPDATING FOR FISCAL YEAR 1984.—The Secretary shall update each amount determined under subparagraph (A) for fiscal year 1984 by—

(i) updating for fiscal year 1983 by the estimated average rate of change of hospital costs industry-wide between the cost reporting period used under such subparagraph and fiscal year 1983 and the most recent case-mix data available, and

(ii) projecting for fiscal year 1984 by the applicable percentage increase (as defined in subsection (b)(3)(B)) for fiscal year 1984.

(C) STANDARDIZING AMOUNTS.—The Secretary shall standardize the amount updated under subparagraph (B) for each hospital by—

(i) excluding an estimate of indirect medical education costs (taking into account, for discharges occurring after September 30, 1986, the amendments made by section 9104(a) of the Medicare and Medicaid Budget Reconciliation Amendments of 1985), except that the Secretary shall not take into account any reduction in the amount of additional payments under paragraph (5)(B)(ii) resulting from the amendment made by section 4621(a)(1) of the Balanced Budget Act of 1997 or any additional payments under such paragraph resulting from the application of section 111 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, of section 302 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, or the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,

(ii) adjusting for variations among hospitals by area in the average hospital wage level,

(iii) adjusting for variations in case mix among hospitals, and

(iv) for discharges occurring on or after October 1, 1986, excluding an estimate of the additional payments to certain hospitals to be made under paragraph (5)(F), except that the Secretary shall not exclude additional payments under such paragraph made as a result of the enactment of section 6003(c) of the Omnibus Budget Reconciliation Act of 1989, the enactment of section 4002(b) of the Omnibus Budget Reconciliation Act of 1990, the enactment of section 303 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, or the enactment of section 402(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(D) COMPUTING URBAN AND RURAL AVERAGES.—The Secretary shall compute an average of the standardized amounts determined under subparagraph (C) for the United States and for each region—

(i) for all subsection (d) hospitals located in an urban area within the United States or that region, respectively, and

(ii) for all subsection (d) hospitals located in a rural area within the United States or that region, respectively.

For purposes of this subsection, the term "region" means one of the nine census divisions, comprising the fifty States and the District of Columbia, established by the Bureau of the Census for statistical and reporting purposes; the term "urban area" means an area within a Metropolitan Statistical Area (as defined by the Office of Management and Budget) or within such similar area as the Secretary has recognized under subsection (a) by regulation; the term "large urban area" means, with respect to a fiscal year, such an urban area which the Secretary determines (in the publications described in subsection (e)(5) before the fiscal year) has a population of more than 1,000,000 (as determined by the Secretary based on the most recent available population data published by the Bureau of the Census); and the term "rural area" means any area outside such an area or similar area. A hospital located in a Metropolitan Sta-

tistical Area shall be deemed to be located in the region in which the largest number of the hospitals in the same Metropolitan Statistical Area are located, or, at the option of the Secretary, the region in which the majority of the inpatient discharges (with respect to which payments are made under this title) from hospitals in the same Metropolitan Statistical Area are made.

(E) REDUCING FOR VALUE OF OUTLIER PAYMENTS.—The Secretary shall reduce each of the average standardized amounts determined under subparagraph (D) by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this subsection based on DRG prospective payment rates which are additional payments described in paragraph (5)(A) (relating to outlier payments).

(F) MAINTAINING BUDGET NEUTRALITY.—The Secretary shall adjust each of such average standardized amounts as may be required under subsection (e)(1)(B) for that fiscal year.

(G) COMPUTING DRG-SPECIFIC RATES FOR URBAN AND RURAL HOSPITALS IN THE UNITED STATES AND IN EACH REGION.—For each discharge classified within a diagnosis-related group, the Secretary shall establish a national DRG prospective payment rate and shall establish a regional DRG prospective payment rate for each region, each of which is equal—

(i) for hospitals located in an urban area in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (D), reduced under subparagraph (E), and adjusted under subparagraph (F)) for hospitals located in an urban area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group; and

(ii) for hospitals located in a rural area in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (D), reduced under subparagraph (E), and adjusted under subparagraph (F)) for hospitals located in a rural area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(H) ADJUSTING FOR DIFFERENT AREA WAGE LEVELS.—The Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the national and regional DRG prospective payment rates computed under subparagraph (G) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.

(3) The Secretary shall determine a national adjusted DRG prospective payment rate, for each inpatient hospital discharge in a fiscal year after fiscal year 1984 involving inpatient hospital services of a subsection (d) hospital in the United States, and shall determine, for fiscal years before fiscal year 1997, a regional adjusted DRG prospective payment rate for such discharges in each region for which payment may be made under part A of this title. Each such rate shall be determined for hospitals located in large urban, other urban, or rural areas within the United States and within each such region, respectively, as follows:

(A) UPDATING PREVIOUS STANDARDIZED AMOUNTS.—(i) For discharges occurring in a fiscal year beginning before October 1, 1987, the Secretary shall compute an average standardized amount for hospitals located in an urban area and for hospitals located in a rural area within the United States and for hospitals located in an urban area and for hospitals located in a rural area within each region, equal to the respective average standardized amount computed for the previous fiscal year under paragraph (2)(D) or under this subparagraph, increased for the fiscal year involved by the applicable percentage increase under subsection (b)(3)(B). With respect to discharges occurring on or after October 1, 1987, the Secretary shall compute urban and rural averages on the basis of discharge weighting rather than hospital weighting, making appropriate adjustments to ensure that computation on such basis does not result in total payments under this section that are greater or less than the total payments that would have been made under this section but for this sentence, and making appropriate changes in the manner of determining the reductions under subparagraph (C)(ii).

(ii) For discharges occurring in a fiscal year beginning on or after October 1, 1987, and ending on or before September 30, 1994, the Secretary shall compute an average standardized amount for hospitals located in a large urban area, for hospitals located in a rural area, and

for hospitals located in other urban areas, within the United States and within each region, equal to the respective average standardized amount computed for the previous fiscal year under this subparagraph increased by the applicable percentage increase under subsection (b)(3)(B)(i) with respect to hospitals located in the respective areas for the fiscal year involved.

(iii) For discharges occurring in the fiscal year beginning on October 1, 1994, the average standardized amount for hospitals located in a rural area shall be equal to the average standardized amount for hospitals located in an urban area. For discharges occurring on or after October 1, 1994, the Secretary shall adjust the ratio of the labor portion to non-labor portion of each average standardized amount to equal such ratio for the national average of all standardized amounts.

(iv)(I) Subject to subclause (II), for discharges occurring in a fiscal year beginning on or after October 1, 1995, the Secretary shall compute an average standardized amount for hospitals located in a large urban area and for hospitals located in other areas within the United States and within each region equal to the respective average standardized amount computed for the previous fiscal year under this subparagraph increased by the applicable percentage increase under subsection (b)(3)(B)(i) with respect to hospitals located in the respective areas for the fiscal year involved.

(II) For discharges occurring in a fiscal year (beginning with fiscal year 2004), the Secretary shall compute a standardized amount for hospitals located in any area within the United States and within each region equal to the standardized amount computed for the previous fiscal year under this subparagraph for hospitals located in a large urban area (or, beginning with fiscal year 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B)(i) for the fiscal year involved.

(v) Average standardized amounts computed under this paragraph shall be adjusted to reflect the most recent case-mix data available.

(vi) Insofar as the Secretary determines that the adjustments under paragraph (4)(C)(i) for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under this subsection during the fiscal year that are a result of changes in the coding or classification of discharges that do not reflect real changes in case mix, the Secretary may adjust the average standardized amounts computed under this paragraph for subsequent fiscal years so as to eliminate the effect of such coding or classification changes.

(B) REDUCING FOR VALUE OF OUTLIER PAYMENTS.—The Secretary shall reduce each of the average standardized amounts determined under subparagraph (A) by a factor equal to the proportion of payments under this subsection (as estimated by the Secretary) based on DRG prospective payment amounts which are additional payments described in paragraph (5)(A) (relating to outlier payments).

(C)(i) MAINTAINING BUDGET NEUTRALITY FOR FISCAL YEAR 1985.—For discharges occurring in fiscal year 1985, the Secretary shall adjust each of such average standardized amounts as may be required under subsection (e)(1)(B) for that fiscal year.

(ii) REDUCING FOR SAVINGS FROM AMENDMENT TO INDIRECT TEACHING ADJUSTMENT FOR DISCHARGES AFTER SEPTEMBER 30, 1986.—For discharges occurring after September 30, 1986, the Secretary shall further reduce each of the average standardized amounts (in a proportion which takes into account the differing effects of the standardization effected under paragraph (2)(C)(i)) so as to provide for a reduction in the total of the payments (attributable to this paragraph) made for discharges occurring on or after October 1, 1986, of an amount equal to the estimated reduction in the payment amounts under paragraph (5)(B) that would have resulted from the enactment of the amendments made by section 9104 of the Medicare and Medicaid Budget Reconciliation Amendments of 1985 and by section 4003(a)(1) of the Omnibus Budget Reconciliation Act of 1987 if the factor described in clause (ii)(II) of paragraph (5)(B) (determined without regard to amendments made by the Omnibus Budget Reconciliation Act of 1990) were applied for discharges occurring on or after such date instead of the factor described in clause (ii) of that paragraph.

(D) COMPUTING DRG-SPECIFIC RATES FOR HOSPITALS.—For each discharge classified within a diagnosis-related group, the Secretary shall establish for the fiscal year a national DRG prospective payment rate and shall establish, for fiscal years before fiscal year 1997, a regional DRG prospective payment rate for each region which is equal—

(i) for fiscal years before fiscal year 2004, for hospitals located in a large urban area in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (A), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C)) for the fiscal year for hospitals located in such a large urban area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group;

(ii) for fiscal years before fiscal year 2004, for hospitals located in other areas in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (A), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C)) for the fiscal year for hospitals located in other areas in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group; and

(iii) for a fiscal year beginning after fiscal year 2003, for hospitals located in all areas, to the product of—

(I) the applicable standardized amount (computed under subparagraph (A)), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C) for the fiscal year; and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(E) ADJUSTING FOR DIFFERENT AREA WAGE LEVELS.—

(i) IN GENERAL.—Except as provided in clause (ii) or (iii), the Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates computed under subparagraph (D) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. Not later than October 1, 1990, and October 1, 1993 (and at least every 12 months thereafter), the Secretary shall update the factor under the preceding sentence on the basis of a survey conducted by the Secretary (and updated as appropriate) of the wages and wage-related costs of subsection (d) hospitals in the United States. Not less often than once every 3 years the Secretary (through such survey or otherwise) shall measure the earnings and paid hours of employment by occupational category and shall exclude data with respect to the wages and wage-related costs incurred in furnishing skilled nursing facility services. Any adjustments or updates made under this subparagraph for a fiscal year (beginning with fiscal year 1991) shall be made in a manner that assures that the aggregate payments under this subsection in the fiscal year are not greater or less than those that would have been made in the year without such adjustment. The Secretary shall apply the previous sentence for any period as if the amendments made by section 403(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the amendments made by section 10324(a)(1) of the Patient Protection and Affordable Care Act had not been enacted.

(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED BEGINNING IN FISCAL YEAR 2005.—For discharges occurring on or after October 1, 2004, the Secretary shall substitute "62 percent" for the proportion described in the first sentence of clause (i), unless the application of this clause would result in lower payments to a hospital than would otherwise be made.

(iii) FLOOR ON AREA WAGE INDEX FOR HOSPITALS IN FRONTIER STATES.—

(I) IN GENERAL.—Subject to subclause (IV), for discharges occurring on or after October 1, 2010, the area wage index applicable under this subparagraph to any hospital which is located in a frontier State (as defined in subclause (II)) may not be less than 1.00.

(II) FRONTIER STATE DEFINED.—In this clause, the term "frontier State" means a State in which at least 50 percent of the counties in the State are frontier counties.

(III) FRONTIER COUNTY DEFINED.—In this clause, the term "frontier county" means a county in which the population per square mile is less than 6.

(IV) LIMITATION.—This clause shall not apply to any hospital located in a State that receives a non-labor related share adjustment under paragraph (5)(H).

(4)(A) The Secretary shall establish a classification of inpatient hospital discharges by diagnosis-related groups and a methodology for classifying specific hospital discharges within these groups.

(B) For each such diagnosis-related group the Secretary shall assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups.

(C)(i) The Secretary shall adjust the classifications and weighting factors established under subparagraphs (A) and (B), for discharges in fiscal year 1988 and at least annually thereafter, to reflect changes in treatment patterns, technology (including a new medical service or technology under paragraph (5)(K)), and other factors which may change the relative use of hospital resources.

(ii) For discharges in fiscal year 1990, the Secretary shall reduce the weighting factor for each diagnosis-related group by 1.22 percent.

(iii) Any such adjustment under clause (i) for discharges in a fiscal year (beginning with fiscal year 1991) shall be made in a manner that assures that the aggregate payments under this subsection for discharges in the fiscal year are not greater or less than those that would have been made for discharges in the year without such adjustment.

(D)(i) For discharges occurring on or after October 1, 2008, the diagnosis-related group to be assigned under this paragraph for a discharge described in clause (ii) shall be a diagnosis-related group that does not result in higher payment based on the presence of a secondary diagnosis code described in clause (iv).

(ii) A discharge described in this clause is a discharge which meets the following requirements:

(I) The discharge includes a condition identified by a diagnosis code selected under clause (iv) as a secondary diagnosis.

(II) But for clause (i), the discharge would have been classified to a diagnosis-related group that results in a higher payment based on the presence of a secondary diagnosis code selected under clause (iv).

(III) At the time of admission, no code selected under clause (iv) was present.

(iii) As part of the information required to be reported by a hospital with respect to a discharge of an individual in order for payment to be made under this subsection, for discharges occurring on or after October 1, 2007, the information shall include the secondary diagnosis of the individual at admission.

(iv) By not later than October 1, 2007, the Secretary shall select diagnosis codes associated with at least two conditions, each of which codes meets all of the following requirements (as determined by the Secretary):

(I) Cases described by such code have a high cost or high volume, or both, under this title.

(II) The code results in the assignment of a case to a diagnosis-related group that has a higher payment when the code is present as a secondary diagnosis.

(III) The code describes such conditions that could reasonably have been prevented through the application of evidence-based guidelines.

The Secretary may from time to time revise (through addition or deletion of codes) the diagnosis codes selected under this clause so long as there are diagnosis codes associated with at least two conditions selected for discharges occurring during any fiscal year.

(v) In selecting and revising diagnosis codes under clause (iv), the Secretary shall consult with the Centers for Disease Control and Prevention and other appropriate entities.

(vi) Any change resulting from the application of this subparagraph shall not be taken into account in adjusting the weighting factors under subparagraph (C)(i) or in applying budget neutrality under subparagraph (C)(iii).

(5)(A)(i) For discharges occurring during fiscal years ending on or before September 30, 1997, the Secretary shall provide for an additional payment for a subsection (d) hospital for any discharge in a diagnosis-related group, the length of stay of which exceeds the mean length of stay for discharges within that group by a fixed number of days, or exceeds such mean length of stay by some fixed number of standard deviations, whichever is the fewer number of days.

(ii) For cases which are not included in clause (i), a subsection (d) hospital may request additional payments in any case where charges, adjusted to cost, exceed a fixed multiple of the applicable DRG prospective payment rate, or exceed such other fixed dollar amount, whichever is greater, or for discharges in fiscal years beginning on or after October 1, 1994, exceed the sum of the applicable DRG prospective payment rate plus any amounts payable under subparagraphs (B) and (F) plus a fixed dollar amount determined by the Secretary.

(iii) The amount of such additional payment under clauses (i) and (ii) shall be determined by the Secretary and shall (except as payments under clause (i) are required to be reduced to take into account the requirements of clause (v)) approximate the marginal cost of care beyond the cut-off point applicable under clause (i) or (ii).

(iv) The total amount of the additional payments made under this subparagraph for discharges in a fiscal year may not be less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on DRG prospective payment rates for discharges in that year.

(v) The Secretary shall provide that—

(I) the day outlier percentage for fiscal year 1995 shall be 75 percent of the day outlier percentage for fiscal year 1994;

(II) the day outlier percentage for fiscal year 1996 shall be 50 percent of the day outlier percentage for fiscal year 1994; and

(III) the day outlier percentage for fiscal year 1997 shall be 25 percent of the day outlier percentage for fiscal year 1994.

(vi) For purposes of this subparagraph the term "day outlier percentage" means, for a fiscal year, the percentage of the total additional payments made by the Secretary under this subparagraph for discharges in that fiscal year which are additional payments under clause (i).

(B) The Secretary shall provide for an additional payment amount for subsection (d) hospitals with indirect costs of medical education, in an amount computed in the same manner as the adjustment for such costs under regulations (in effect as of January 1, 1983) under subsection (a)(2), except as follows:

(i) The amount of such additional payment shall be determined by multiplying (I) the sum of the amount determined under paragraph (1)(A)(ii)(II) (or, if applicable, the amount determined under paragraph (1)(A)(iii)) and, for cases qualifying for additional payment under subparagraph (A)(i), the amount paid to the hospital under subparagraph (A), by (II) the indirect teaching adjustment factor described in clause (ii).

(ii) For purposes of clause (i)(II), the indirect teaching adjustment factor is equal to c × (((1+r) to the nth power) − 1), where "r" is the ratio of the hospital's full-time equivalent interns and residents to beds and "n" equals .405. Subject to clause (ix), for discharges occurring—

(I) on or after October 1, 1988, and before October 1, 1997, "c" is equal to 1.89;
(II) during fiscal year 1998, "c" is equal to 1.72;
(III) during fiscal year 1999, "c" is equal to 1.6;
(IV) during fiscal year 2000, "c" is equal to 1.47;
(V) during fiscal year 2001, "c" is equal to 1.54;
(VI) during fiscal year 2002, "c" is equal to 1.6;
(VII) on or after October 1, 2002, and before April 1, 2004, "c" is equal to 1.35;
(VIII) on or after April 1, 2004, and before October 1, 2004, "c" is equal to 1.47;
(IX) during fiscal year 2005, "c" is equal to 1.42;
(X) during fiscal year 2006, "c" is equal to 1.37;
(XI) during fiscal year 2007, "c" is equal to 1.32; and
(XII) on or after October 1, 2007, "c" is equal to 1.35.

(iii) In determining such adjustment the Secretary shall not distinguish between those interns and residents who are employees of a hospital and those interns and residents who furnish services to a hospital but are not employees of such hospital.

(iv)(I) Effective for discharges occurring on or after October 1, 1997, and before July 1, 2010, all the time spent by an intern or resident in patient care activities under an approved medical residency training program at an entity in a nonhospital setting shall be counted towards the determination of full-time equivalency if the hospital incurs all, or substantially all, of the costs for the training program in that setting.

(II) Effective for discharges occurring on or after July 1, 2010, all the time spent by an intern or resident in patient care activities in a nonprovider setting shall be counted towards the determination of full-time equivalency if a hospital incurs the costs of the stipends and fringe benefits of the intern or resident during the time the intern or resident spends in that setting. If more than one hospital incurs these costs, either directly or through a third party, such hospitals shall count a proportional share of the time, as determined by written agreement between the hospitals, that a resident spends training in that setting.

(v) In determining the adjustment with respect to a hospital for discharges occurring on or after October 1, 1997, the total number of full-time equivalent interns and residents in the fields of allopathic and osteopathic medicine in either a hospital or nonhospital setting may not exceed the number (or, 130 percent of such number in the case of a hospital located in a rural area) of such full-time equivalent interns and residents in the hospital with respect to the hospital's most recent cost reporting period ending on or before December 31, 1996. Rules similar to the rules of subsection (h)(4)(F)(ii) shall apply for purposes of this clause. The provisions of subsections (h)(4)(H)(vi), (h)(7), and (h)(8) shall apply with respect to the first sentence of this clause in the same manner as they apply with respect to subsection (h)(4)(F)(i).

(vi) For purposes of clause (ii)—

(I) "r" may not exceed the ratio of the number of interns and residents, subject to the limit under clause (v), with respect to the hospital for its most recent cost reporting period to the hospital's available beds (as defined by the Secretary) during that cost reporting period, and

(II) for the hospital's cost reporting periods beginning on or after October 1, 1997, subject to the limits described in clauses (iv) and (v), the total number of full-time equivalent residents for payment purposes shall equal the average of the actual full-time equivalent resident count for the cost reporting period and the preceding two cost reporting periods. In the case of the first cost reporting period beginning on or after October 1, 1997, subclause (II) shall be applied by using the average for such period and the preceding cost reporting period.

(vii) If any cost reporting period beginning on or after October 1, 1997, is not equal to twelve months, the Secretary shall make appropriate modifications to ensure that the average full-time equivalent residency count pursuant to subclause (II) of clause (vi) is based on the equivalent of full twelve-month cost reporting periods.

(viii) Rules similar to the rules of subsection (h)(4)(H) shall apply for purposes of clauses (v) and (vi).

(ix) For discharges occurring on or after July 1, 2005, insofar as an additional payment amount under this subparagraph is attributable to resident positions redistributed to a hospital under subsection (h)(7)(B), in computing the indirect teaching adjustment factor under clause (ii) the adjustment shall be computed in a manner as if "c" were equal to 0.66 with respect to such resident positions.

(x) For discharges occurring on or after July 1, 2011, insofar as an additional payment amount under this subparagraph is attributable to resident positions distributed to a hospital under subsection (h)(8)(B), the indirect teaching adjustment factor shall be computed in the same manner as provided under clause (ii) with respect to such resident positions.

(x)(I) The provisions of subparagraph (K) of subsection (h)(4) shall apply under this subparagraph in the same manner as they apply under such subsection.

(II) In determining the hospital's number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in non-patient care activities, such as didactic conferences and seminars, as such time and activities are defined by the Secretary, that occurs in the hospital shall be counted toward the determination of full-time equivalency if the hospital—

(aa) is recognized as a subsection (d) hospital;

(bb) is recognized as a subsection (d) Puerto Rico hospital;

(cc) is reimbursed under a reimbursement system authorized under section 1814(b)(3); or

(dd) is a provider-based hospital outpatient department.

(III) In determining the hospital's number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in research activities that are not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall not be counted toward the determination of full-time equivalency.

(C)(i) The Secretary shall provide for such exceptions and adjustments to the payment amounts established under this subsection (other than under paragraph (9)) as the Secretary deems appropriate to take into account the special needs of regional and national referral centers (including those hospitals of 275 or more beds located in rural areas). A hospital which is classified as a rural

hospital may appeal to the Secretary to be classified as a rural referral center under this clause on the basis of criteria (established by the Secretary) which shall allow the hospital to demonstrate that it should be so reclassified by reason of certain of its operating characteristics being similar to those of a typical urban hospital located in the same census region and which shall not require a rural osteopathic hospital to have more than 3,000 discharges in a year in order to be classified as a rural referral center. Such characteristics may include wages, scope of services, service area, and the mix of medical specialties. The Secretary shall publish the criteria not later than August 17, 1984, for implementation by October 1, 1984. An appeal allowed under this clause must be submitted to the Secretary (in such form and manner as the Secretary may prescribe) during the quarter before the first quarter of the hospital's cost reporting period (or, in the case of a cost reporting period beginning during October 1984, during the first quarter of that period), and the Secretary must make a final determination with respect to such appeal within 60 days after the date the appeal was submitted. Any payment adjustments necessitated by a reclassification based upon the appeal shall be effective at the beginning of such cost reporting period.

(ii) The Secretary shall provide, under clause (i), for the classification of a rural hospital as a regional referral center if the hospital has a case mix index equal to or greater than the median case mix index for hospitals (other than hospitals with approved teaching programs) located in an urban area in the same region (as defined in paragraph (2)(D)), has at least 5,000 discharges a year or, if less, the median number of discharges in urban hospitals in the region in which the hospital is located (or, in the case of a rural osteopathic hospital, meets the criterion established by the Secretary under clause (i) with respect to the annual number of discharges for such hospitals), and meets any other criteria established by the Secretary under clause (i).

(D)(i) For any cost reporting period beginning on or after April 1, 1990, with respect to a subsection (d) hospital which is a sole community hospital, payment under paragraph (1)(A) shall be—

(I) an amount based on 100 percent of the hospital's target amount for the cost reporting period, as defined in subsection (b)(3)(C), or

(II) the amount determined under paragraph (1)(A)(iii),

whichever results in greater payment to the hospital.

(ii) In the case of a sole community hospital that experiences, in a cost reporting period compared to the previous cost reporting period, a decrease of more than 5 percent in its total number of inpatient cases due to circumstances beyond its control, the Secretary shall provide for such adjustment to the payment amounts under this subsection (other than under paragraph (9)) as may be necessary to fully compensate the hospital for the fixed costs it incurs in the period in providing inpatient hospital services, including the reasonable cost of maintaining necessary core staff and services.

(iii) For purposes of this title, the term "sole community hospital" means any hospital—

(I) that the Secretary determines is located more than 35 road miles from another hospital,

(II) that, by reason of factors such as the time required for an individual to travel to the nearest alternative source of appropriate inpatient care (in accordance with standards promulgated by the Secretary), location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to individuals in a geographic area who are entitled to benefits under part A, or

(III) that is located in a rural area and designated by the Secretary as an essential access community hospital under section 1820(i)(1) as in effect on September 30, 1997.

(iv) The Secretary shall promulgate a standard for determining whether a hospital meets the criteria for classification as a sole community hospital under clause (iii)(II) because of the time required for an individual to travel to the nearest alternative source of appropriate inpatient care.

(v) If the Secretary determines that, in the case of a hospital located in a rural area and designated by the Secretary as an essential access community hospital under section 1820(i)(1) as in effect on September 30, 1997, the hospital has incurred increases in reasonable costs during a cost reporting period as a result of becoming a member of a rural health network (as defined in section 1820(d)) in the State in which it is located, and in incurring such increases, the hospital will increase its costs for subsequent cost reporting periods, the Secretary shall increase the hospital's target amount under subsection (b)(3)(C) to account for such incurred increases.

(E)(i) The Secretary shall estimate the amount of reimbursement made for services described in section 1862(a)(14) with respect to which payment was made under part B in the base reporting periods referred to in paragraph (2)(A) and with respect to which payment is no longer being made.

(ii) The Secretary shall provide for an adjustment to the payment for subsection (d) hospitals in each fiscal year so as appropriately to reflect the net amount described in clause (i).

(F)(i) Subject to subsection (r), for discharges occurring on or after May 1, 1986, the Secretary shall provide, in accordance with this subparagraph, for an additional payment amount for each subsection (d) hospital which—

(I) serves a significantly disproportionate number of low-income patients (as defined in clause (v)), or

(II) is located in an urban area, has 100 or more beds, and can demonstrate that its net inpatient care revenues (excluding any of such revenues attributable to this title or State plans approved under title XIX), during the cost reporting period in which the discharges occur, for indigent care from State and local government sources exceed 30 percent of its total of such net inpatient care revenues during the period.

(ii) Subject to clause (ix), the amount of such payment for each discharge shall be determined by multiplying (I) the sum of the amount determined under paragraph (1)(A)(ii)(II) (or, if applicable, the amount determined under paragraph (1)(A)(iii)) and, for cases qualifying for additional payment under subparagraph (A)(i), the amount paid to the hospital under subparagraph (A) for that discharge, by (II) the disproportionate share adjustment percentage established under clause (iii) or (iv) for the cost reporting period in which the discharge occurs.

(iii) The disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (i)(II) is equal to 35 percent.

(iv) The disproportionate share adjustment percentage for a cost reporting period for a hospital that is not described in clause (i)(II) and that—

(I) is located in an urban area and has 100 or more beds or is described in the second sentence of clause (v), is equal to the percent determined in accordance with the applicable formula described in clause (vii);

(II) is located in an urban area and has less than 100 beds, is equal to 5 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xiii);

(III) is located in a rural area and is not described in subclause (IV) or (V) or in the second sentence of clause (v), is equal to 4 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xii);

(IV) is located in a rural area, is classified as a rural referral center under subparagraph (C), and is classified as a sole community hospital under subparagraph (D), is equal to 10 percent or, if greater, the percent determined in accordance with the applicable formula described in clause (viii) or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, the greater of the percentages determined under clause (x) or (xi);

(V) is located in a rural area, is classified as a rural referral center under subparagraph (C), and is not classified as a sole community hospital under subparagraph (D), is equal to the percent determined in accordance with the applicable formula described in clause (viii) or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xi); or

(VI) is located in a rural area, is classified as a sole community hospital under subparagraph (D), and is not classified as a rural referral center under subparagraph (C), is 10 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (x).

(v) In this subparagraph, a hospital "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals, or exceeds—

(I) 15 percent, if the hospital is located in an urban area and has 100 or more beds,

(II) 30 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and has more than 100 beds, or is located in a rural area and is classified as a sole community hospital under subparagraph (D),

(III) 40 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in an urban area and has less than 100 beds, or

(IV) 45 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and is not described in subclause (II).

A hospital located in a rural area and with 500 or more beds also "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a dispropor-

tionate patient percentage (as defined in clause (vi)) for that period which equals or exceeds a percentage specified by the Secretary.

(vi) In this subparagraph, the term "disproportionate patient percentage" means, with respect to a cost reporting period of a hospital, the sum of—

(I) the fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of this title and were entitled to supplementary security income benefits (excluding any State supplementation) under title XVI of this Act, and the denominator of which is the number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under part A of this title, and

(II) the fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under title XIX, but who were not entitled to benefits under part A of this title, and the denominator of which is the total number of the hospital's patient days for such period.

In determining under subclause (II) the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under title XIX, the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under title XI.

(vii) The formula used to determine the disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (iv)(I) is—

(I) in the case of such a hospital with a disproportionate patient percentage (as defined in clause (vi)) greater than 20.2—

(a) for discharges occurring on or after April 1, 1990, and on or before December 31, 1990, (P–20.2)(.65) + 5.62,

(b) for discharges occurring on or after January 1, 1991, and on or before September 30, 1993, (P–20.2)(.7) + 5.62,

(c) for discharges occurring on or after October 1, 1993, and on or before September 30, 1994, (P–20.2)(.8) + 5.88, and

(d) for discharges occurring on or after October 1, 1994, (P–20.2)(.825) + 5.88; or

(II) in the case of any other such hospital—

(a) for discharges occurring on or after April 1, 1990, and on or before December 31, 1990, (P–15)(.6) + 2.5,

(b) for discharges occurring on or after January 1, 1991, and on or before September 30, 1993, (P–15)(.6) + 2.5,

(c) for discharges occurring on or after October 1, 1993, (P–15)(.65) + 2.5,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(viii) Subject to clause (xiv), the formula used to determine the disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (iv)(IV) or (iv)(V) is the percentage determined in accordance with the following formula:(P–30)(.6) + 4.0, where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(ix) In the case of discharges occurring—

(I) during fiscal year 1998, the additional payment amount otherwise determined under clause (ii) shall be reduced by 1 percent;

(II) during fiscal year 1999, such additional payment amount shall be reduced by 2 percent;

(III) during fiscal years 2000 and 2001, such additional payment amount shall be reduced by 3 percent and 2 percent, respectively;

(IV) during fiscal year 2002, such additional payment amount shall be reduced by 3 percent; and

(V) during fiscal year 2003 and each subsequent fiscal year, such additional payment amount shall be reduced by 0 percent.

(x) Subject to clause (xiv), for purposes of clause (iv)(VI) (relating to sole community hospitals), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P–15)(.65) + 2.5;

(II) is equal to or exceeds 19.3, but is less than 30.0, such adjustment percentage is equal to 5.25 percent; or

(III) is equal to or exceeds 30, such adjustment percentage is equal to 10 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xi) Subject to clause (xiv), for purposes of clause (iv)(V) (relating to rural referral centers), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P–15)(.65) + 2.5;

(II) is equal to or exceeds 19.3, but is less than 30.0, such adjustment percentage is equal to 5.25 percent; or

(III) is equal to or exceeds 30, such adjustment percentage is determined in accordance with the following formula: (P–30)(.6) + 5.25,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xii) Subject to clause (xiv), for purposes of clause (iv)(III) (relating to small rural hospitals generally), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P–15)(.65) + 2.5; or

(II) is equal to or exceeds 19.3, such adjustment percentage is equal to 5.25 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xiii) Subject to clause (xiv), for purposes of clause (iv)(II) (relating to urban hospitals with less than 100 beds), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula: (P–15)(.65) + 2.5; or

(II) is equal to or exceeds 19.3, such adjustment percentage is equal to 5.25 percent,

where "P" is the hospital's disproportionate patient percentage (as defined in clause (vi)).

(xiv)(I) In the case of discharges occurring on or after April 1, 2004, subject to subclause (II), there shall be substituted for the disproportionate share adjustment percentage otherwise determined under clause (iv) (other than subclause (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the disproportionate share adjustment percentage determined under clause (vii) (relating to large, urban hospitals).

(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 12 percent for a hospital that is not classified as a rural referral center under subparagraph (C) or, in the case of discharges occurring on or after October 1, 2006, as a medicare-dependent, small rural hospital under subparagraph (G)(iv).

(G)(i) For any cost reporting period beginning on or after April 1, 1990, and before October 1, 1994, or discharges occurring on or after October 1, 1997, and before October 1, 2022, in the case of a subsection (d) hospital which is a medicare-dependent, small rural hospital, payment under paragraph (1)(A) shall be equal to the sum of the amount determined under clause (ii) and the amount determined under paragraph (1)(A)(iii).

(ii) The amount determined under this clause is—

(I) for discharges occurring during the 36-month period beginning with the first day of the cost reporting period that begins on or after April 1, 1990, the amount by which the hospital's target amount for the cost reporting period (as defined in subsection (b)(3)(D)) exceeds the amount determined under paragraph (1)(A)(iii); and

(II) for discharges occurring during any subsequent cost reporting period (or portion thereof) and before October 1, 1994, or discharges occurring on or after October 1, 1997, and before October 1, 2022, 50 percent (or 75 percent in the case of discharges occurring on or after October 1, 2006) of the amount by which the hospital's target amount for the cost reporting period or for discharges in the fiscal year (as defined in subsection (b)(3)(D)) exceeds the amount determined under paragraph (1)(A)(iii).

(iii) In the case of a medicare dependent, small rural hospital that experiences, in a cost reporting period compared to the previous cost reporting period, a decrease of more than 5 percent in its total number of inpatient cases due to circumstances beyond its control, the Secretary shall provide for such adjustment to the payment amounts under this subsection (other than under paragraph (9)) as may be necessary to fully compensate the hospital for the fixed costs it incurs in the

period in providing inpatient hospital services, including the reasonable cost of maintaining necessary core staff and services.

(iv) The term "medicare-dependent, small rural hospital" means, with respect to any cost reporting period to which clause (i) applies, any hospital—

(I) that is located in—

(aa) a rural area; or

(bb) a State with no rural area (as defined in paragraph (2)(D)) and satisfies any of the criteria in subclause (I), (II), or (III) of paragraph (8)(E)(ii),

(II) that has not more than 100 beds,

(III) that is not classified as a sole community hospital under subparagraph (D), and

(IV) for which not less than 60 percent of its inpatient days or discharges during the cost reporting period beginning in fiscal year 1987, or two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report, were attributable to inpatients entitled to benefits under part A.

Subclause (I)(bb) shall apply for purposes of payment under clause (ii) only for discharges of a hospital occurring on or after the effective date of a determination of medicare-dependent small rural hospital status made by the Secretary with respect to the hospital after the date of the enactment of this sentence. For purposes of applying subclause (II) of paragraph (8)(E)(ii) under subclause (I)(bb), such subclause (II) shall be applied by inserting "as of January 1, 2018," after "such State" each place it appears.

(H) The Secretary may provide for such adjustments to the payment amounts under this subsection as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii.

(I)(i) The Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate.

(ii) In making adjustments under clause (i) for transfer cases (as defined by the Secretary) in a fiscal year, not taking in account the effect of subparagraph (J), the Secretary may make adjustments to each of the average standardized amounts determined under paragraph (3) to assure that the aggregate payments made under this subsection for such fiscal year are not greater or lesser than those that would have otherwise been made in such fiscal year.

(J)(i) The Secretary shall treat the term "transfer case" (as defined in subparagraph (I)(ii)) as including the case of a qualified discharge (as defined in clause (ii)), which is classified within a diagnosis-related group described in clause (iii), and which occurs on or after October 1, 1998. In the case of a qualified discharge for which a substantial portion of the costs of care are incurred in the early days of the inpatient stay (as defined by the Secretary), in no case may the payment amount otherwise provided under this subsection exceed an amount equal to the sum of—

(I) 50 percent of the amount of payment under this subsection for transfer cases (as established under subparagraph (I)(i)), and

(II) 50 percent of the amount of payment which would have been made under this subsection with respect to the qualified discharge if no transfer were involved.

(ii) For purposes of clause (i), subject to clause (iii), the term "qualified discharge" means a discharge classified with a diagnosis-related group (described in clause (iii)) of an individual from a subsection (d) hospital, if upon such discharge the individual—

(I) is admitted as an inpatient to a hospital or hospital unit that is not a subsection (d) hospital for the provision of inpatient hospital services;

(II) is admitted to a skilled nursing facility;

(III) is provided home health services from a home health agency, if such services relate to the condition or diagnosis for which such individual received inpatient hospital services from the subsection (d) hospital, and if such services are provided within an appropriate period (as determined by the Secretary);

(IV) for discharges occurring on or after October 1, 2018, is provided hospice care by a hospice program; or

(V) for discharges occurring on or after October 1, 2000, the individual receives post discharge services described in clause (iv)(I).

(iii) Subject to clause (iv), a diagnosis-related group described in this clause is—

(I) 1 of 10 diagnosis-related groups selected by the Secretary based upon a high volume of discharges classified within such groups and a disproportionate use of post discharge services described in clause (ii); and

(II) a diagnosis-related group specified by the Secretary under clause (iv)(II).

(iv) The Secretary shall include in the proposed rule published under subsection (e)(5)(A) for fiscal year 2001, a description of the effect of this subparagraph. The Secretary shall include in the proposed rule published for fiscal year 2019, a description of the effect of clause (ii)(IV). The Secretary may include in the proposed rule (and in the final rule published under paragraph (6)) for fiscal year 2001 or a subsequent fiscal year, a description of—

(I) post-discharge services not described in subclauses (I), (II), (III), and, in the case of proposed and final rules for fiscal year 2019 and subsequent fiscal years, (IV) of clause (ii), the receipt of which results in a qualified discharge; and

(II) diagnosis-related groups described in clause (iii)(I) in addition to the 10 selected under such clause.

(K)(i) Effective for discharges beginning on or after October 1, 2001, the Secretary shall establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under this subsection. Such mechanism shall be established after notice and opportunity for public comment (in the publications required by subsection (e)(5) for a fiscal year or otherwise). Such mechanism shall be modified to meet the requirements of clause (viii).

(ii) The mechanism established pursuant to clause (i) shall—

(I) apply to a new medical service or technology if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate (applying a threshold specified by the Secretary that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved);

(II) provide for the collection of data with respect to the costs of a new medical service or technology described in subclause (I) for a period of not less than two years and not more than three years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology;

(III) provide for additional payment to be made under this subsection with respect to discharges involving a new medical service or technology described in subclause (I) that occur during the period described in subclause (II) in an amount that adequately reflects the estimated average cost of such service or technology; and

(IV) provide that discharges involving such a service or technology that occur after the close of the period described in subclause (II) will be classified within a new or existing diagnosis-related group with a weighting factor under paragraph (4)(B) that is derived from cost data collected with respect to discharges occurring during such period.

(iii) For purposes of clause (ii)(II), the term "inpatient hospital code" means any code that is used with respect to inpatient hospital services for which payment may be made under this subsection and includes an alphanumeric code issued under the International Classification of Diseases, 9th Revision, Clinical Modification ("ICD–9–CM") and its subsequent revisions.

(iv) For purposes of clause (ii)(III), the term "additional payment" means, with respect to a discharge for a new medical service or technology described in clause (ii)(I), an amount that exceeds the prospective payment rate otherwise applicable under this subsection to discharges involving such service or technology that would be made but for this subparagraph.

(v) The requirement under clause (ii)(III) for an additional payment may be satisfied by means of a new-technology group (described in subparagraph (L)), an add-on payment, a payment adjustment, or any other similar mechanism for increasing the amount otherwise payable with respect to a discharge under this subsection. The Secretary may not establish a separate fee schedule for such additional payment for such services and technologies, by utilizing a methodology established under subsection (a) or (h) of section 1834 to determine the amount of such additional payment, or by other similar mechanisms or methodologies.

(vi) For purposes of this subparagraph and subparagraph (L), a medical service or technology will be considered a "new medical service or technology" if the service or technology meets criteria established by the Secretary after notice and an opportunity for public comment.

(vii) Under the mechanism under this subparagraph, the Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) under this subsection until the fiscal year that begins after such date.

(viii) The mechanism established pursuant to clause (i) shall be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology rep-

resents an advance in medical technology that substantially improves the diagnosis or treatment of individuals entitled to benefits under part A as follows:

(I) The Secretary shall make public and periodically update a list of all the services and technologies for which an application for additional payment under this subparagraph is pending.

(II) The Secretary shall accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.

(III) The Secretary shall provide for a meeting at which organizations representing hospitals, physicians, such individuals, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of the Centers for Medicare & Medicaid Services before publication of a notice of proposed rulemaking regarding whether service or technology represents a substantial improvement.

(ix) Before establishing any add-on payment under this subparagraph with respect to a new technology, the Secretary shall seek to identify one or more diagnosis-related groups associated with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within such groups the Secretary shall assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. No add-on payment under this subparagraph shall be made with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).

(L)(i) In establishing the mechanism under subparagraph (K), the Secretary may establish new-technology groups into which a new medical service or technology will be classified if, based on the estimated average costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.

(ii) Such groups—

(I) shall not be based on the costs associated with a specific new medical service or technology; but

(II) shall, in combination with the applicable standardized amounts and the weighting factors assigned to such groups under paragraph (4)(B), reflect such cost cohorts as the Secretary determines are appropriate for all new medical services and technologies that are likely to be provided as inpatient hospital services in a fiscal year.

(iii) The methodology for classifying specific hospital discharges within a diagnosis-related group under paragraph (4)(A) or a new-technology group shall provide that a specific hospital discharge may not be classified within both a diagnosis-related group and a new-technology group.

(6) The Secretary shall provide for publication in the Federal Register, on or before the August 1 before each fiscal year (beginning with fiscal year 1984), of a description of the methodology and data used in computing the adjusted DRG prospective payment rates under this subsection, including any adjustments required under subsection (e)(1)(B).

(7) There shall be no administrative or judicial review under section 1878 or otherwise of—

(A) the determination of the requirement, or the proportional amount, of any adjustment effected pursuant to subsection (e)(1) or the determination of the applicable percentage increase under paragraph (12)(A)(ii),

(B) the establishment of diagnosis-related groups, of the methodology for the classification of discharges within such groups, and of the appropriate weighting factors thereof under paragraph (4), including the selection and revision of codes under paragraph (4)(D), and

(C) the determination of whether services provided prior to a patient's inpatient admission are related to the admission (as described in subsection (a)(4)).

(8)(A) In the case of any hospital which is located in an area which is, at any time after April 20, 1983, reclassified from an urban to a rural area, payments to such hospital for the first two cost reporting periods for which such reclassification is effective shall be made as follows:

(i) For the first such cost reporting period, payment shall be equal to the amount payable to such hospital for such reporting period on the basis of the rural classification, plus an amount equal to two-thirds of the amount (if any) by which—

(I) the amount which would have been payable to such hospital for such reporting period on the basis of an urban classification, exceeds

(II) the amount payable to such hospital for such reporting period on the basis of the rural classification.

(ii) For the second such cost reporting period, payment shall be equal to the amount payable to such hospital for such reporting period on the basis of the rural classification, plus an amount equal to one-third of the amount (if any) by which—

(I) the amount which would have been payable to such hospital for such reporting period on the basis of an urban classification, exceeds

(II) the amount payable to such hospital for such reporting period on the basis of the rural classification.

(B)(i) For purposes of this subsection, the Secretary shall treat a hospital located in a rural county adjacent to one or more urban areas as being located in the urban metropolitan statistical area to which the greatest number of workers in the county commute, if the rural county would otherwise be considered part of an urban area, under the standards for designating Metropolitan Statistical Areas (and for designating New England County Metropolitan Areas) described in clause (ii), if the commuting rates used in determining outlying counties (or, for New England, similar recognized areas) were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of all contiguous Metropolitan Statistical Areas (or New England County Metropolitan Areas).

(ii) The standards described in this clause for cost reporting periods beginning in a fiscal year—

(I) before fiscal year 2003, are the standards published in the Federal Register on January 3, 1980, or, at the election of the hospital with respect to fiscal years 2001 and 2002, standards so published on March 30, 1990; and

(II) after fiscal year 2002, are the standards published in the Federal Register by the Director of the Office of Management and Budget based on the most recent available decennial population data.

Subparagraphs (C) and (D) shall not apply with respect to the application of subclause (I).

(C)(i) If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), by treating hospitals located in a rural county or counties as being located in an urban area, or by treating hospitals located in one urban area as being located in another urban area—

(I) reduces the wage index for that urban area (as applied under this subsection) by 1 percentage point or less, the Secretary, in calculating such wage index under this subsection, shall exclude those hospitals so treated, or

(II) reduces the wage index for that urban area by more than 1 percentage point (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection separately to hospitals located in such urban area (excluding all the hospitals so treated) and to the hospitals so treated (as if such hospitals were located in such urban area).

(ii) If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), by treating hospitals located in a rural county or counties as not being located in the rural area in a State, reduces the wage index for that rural area (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection as if the hospitals so treated had not been excluded from calculation of the wage index for that rural area.

(iii) The application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10) may not result in the reduction of any county's wage index to a level below the wage index for rural areas in the State in which the county is located.

(iv) The application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or of the Secretary under paragraph (10) may not result in a reduction in an urban area's wage index if—

(I) the urban area has a wage index below the wage index for rural areas in the State in which it is located; or

(II) the urban area is located in a State that is composed of a single urban area.

(v) This subparagraph shall apply with respect to discharges occurring in a fiscal year only if the Secretary uses a method for making adjustments to the DRG prospective payment rate for area differences in hospital wage levels under paragraph (3)(E) for the fiscal year that is based on the use of Metropolitan Statistical Area classifications.

(D) The Secretary shall make a proportional adjustment in the standardized amounts determined under paragraph (3) to assure that the provisions of subparagraphs (B) and (C) or a decision

of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10) do not result in aggregate payments under this section that are greater or less than those that would otherwise be made.

(E)(i) For purposes of this subsection, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital described in clause (ii), the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located.

(ii) For purposes of clause (i), a subsection (d) hospital described in this clause is a subsection (d) hospital that is located in an urban area (as defined in paragraph (2)(D)) and satisfies any of the following criteria:

(I) The hospital is located in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)).

(II) The hospital is located in an area designated by any law or regulation of such State as a rural area (or is designated by such State as a rural hospital).

(III) The hospital would qualify as a rural, regional, or national referral center under paragraph (5)(C) or as a sole community hospital under paragraph (5)(D) if the hospital were located in a rural area.

(IV) The hospital meets such other criteria as the Secretary may specify.

(9)(A) Notwithstanding section 1814(b) but subject to the provisions of section 1813, the amount of the payment with respect to the operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges is equal to the sum of—

(i) the applicable Puerto Rico percentage (specified in subparagraph (E)) of the Puerto Rico adjusted DRG prospective payment rate (determined under subparagraph (B) or (C)) for such discharges,

(ii) the applicable Federal percentage (specified in subparagraph (E)) of—

(I) for discharges beginning in a fiscal year beginning on or after October 1, 1997, and before October 1, 2003, the discharge-weighted average of—

(aa) the national adjusted DRG prospective payment rate (determined under paragraph (3)(D)) for hospitals located in a large urban area,

(bb) such rate for hospitals located in other urban areas, and

(cc) such rate for hospitals located in a rural area,

for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels; and

(II) for discharges in a fiscal year beginning on or after October 1, 2003, the national DRG prospective payment rate determined under paragraph (3)(D)(iii) for hospitals located in any area for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels.

As used in this section, the term "subsection (d) Puerto Rico hospital" means a hospital that is located in Puerto Rico and that would be a subsection (d) hospital (as defined in paragraph (1)(B)) if it were located in one of the 50 States.

(B) The Secretary shall determine a Puerto Rico adjusted DRG prospective payment rate, for each inpatient hospital discharge in fiscal year 1988 involving inpatient hospital services of a subsection (d) Puerto Rico hospital for which payment may be made under part A of this title. Such rate shall be determined for such hospitals located in urban or rural areas within Puerto Rico, as follows:

(i) The Secretary shall determine the target amount (as defined in subsection (b)(3)(A)) for the hospital for the cost reporting period beginning in fiscal year 1987 and increase such amount by prorating the applicable percentage increase (as defined in subsection (b)(3)(B)) to update the amount to the midpoint in fiscal year 1988.

(ii) The Secretary shall standardize the amount determined under clause (i) for each hospital by—

(I) excluding an estimate of indirect medical education costs,

(II) adjusting for variations among hospitals by area in the average hospital wage level,

(III) adjusting for variations in case mix among hospitals, and

(IV) excluding an estimate of the additional payments to certain subsection (d) Puerto Rico hospitals to be made under subparagraph (D)(iii) (relating to disproportionate share payments).

(iii) The Secretary shall compute a discharge weighted average of the standardized amounts determined under clause (ii) for all hospitals located in an urban area and for all hospitals located in a rural area (as such terms are defined in paragraph (2)(D)).

(iv) The Secretary shall reduce the average standardized amount by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this paragraph which are additional payments described in subparagraph (D)(i) (relating to outlier payments).

(v) For each discharge classified within a diagnosis-related group for hospitals located in an urban or rural area, respectively, the Secretary shall establish a Puerto Rico DRG prospective payment rate equal to the product of—

(I) the average standardized amount (computed under clause (iii) and reduced under clause (iv)) for hospitals located in an urban or rural area, respectively, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(vi) The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the Puerto Rico DRG prospective payment rate computed under clause (v) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the Puerto Rican average hospital wage level.

(C) The Secretary shall determine a Puerto Rico adjusted DRG prospective payment rate, for each inpatient hospital discharge after fiscal year 1988 involving inpatient hospital services of a subsection (d) Puerto Rico hospital for which payment may be made under part A of this title. Such rate shall be determined for hospitals located in urban or rural areas within Puerto Rico as follows:

(i)(I) For discharges in a fiscal year after fiscal year 1988 and before fiscal year 2004, the Secretary shall compute an average standardized amount for hospitals located in an urban area and for hospitals located in a rural area equal to the respective average standardized amount computed for the previous fiscal year under subparagraph (B)(iii) or under this clause, increased for fiscal year 1989 by the applicable percentage increase under subsection (b)(3)(B), and adjusted for subsequent fiscal years in accordance with the final determination of the Secretary under subsection (e)(4), and adjusted to reflect the most recent case-mix data available.

(II) For discharges occurring in a fiscal year (beginning with fiscal year 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with fiscal year 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved.

(ii) The Secretary shall reduce each of the average standardized amounts (or for fiscal year 2004 and thereafter, the average standardized amount) by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this paragraph which are additional payments described in subparagraph (D)(i) (relating to outlier payments).

(iii) For each discharge classified within a diagnosis-related group for hospitals located in an urban or rural area, respectively, the Secretary shall establish a Puerto Rico DRG prospective payment rate equal to the product of—

(I) the average standardized amount (computed under clause (i) and reduced under clause (ii)), and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(iv)(I) The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the Puerto Rico DRG prospective payment rate computed under clause (iii) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the Puerto Rico average hospital wage level. The second and third sentences of paragraph (3)(E)(i) shall apply to subsection (d) Puerto Rico hospitals under this clause in the same manner as they apply to subsection (d) hospitals under such paragraph and, for purposes of this clause, any reference in such paragraph to a subsection (d) hospital is deemed a reference to a subsection (d) Puerto Rico hospital.

(II) For discharges occurring on or after October 1, 2004, the Secretary shall substitute "62 percent" for the proportion described in the first sentence of clause (i), unless the applica-

tion of this subclause would result in lower payments to a hospital than would otherwise be made.

(D) The following provisions of paragraph (5) shall apply to subsection (d) Puerto Rico hospitals receiving payment under this paragraph in the same manner and to the extent as they apply to subsection (d) hospitals receiving payment under this subsection:

(i) Subparagraph (A) (relating to outlier payments).

(ii) Subparagraph (B) (relating to payments for indirect medical education costs), except that for this purpose the sum of the amount determined under subparagraph (A) of this paragraph and the amount paid to the hospital under clause (i) of this subparagraph shall be substituted for the sum referred to in paragraph (5)(B)(i)(I).

(iii) Subparagraph (F) (relating to disproportionate share payments), except that for this purpose the sum described in clause (ii) of this subparagraph shall be substituted for the sum referred to in paragraph (5)(F)(ii)(I).

(iv) Subparagraph (H) (relating to exceptions and adjustments).

(E) For purposes of subparagraph (A), for discharges occurring—

(i) on or after October 1, 1987, and before October 1, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;

(ii) on or after October 1, 1997, and before April 1, 2004, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

(iii) on or after April 1, 2004, and before October 1, 2004, the applicable Puerto Rico percentage is 37.5 percent and the applicable Federal percentage is 62.5 percent;

(iv) on or after October 1, 2004, and before January 1, 2016, the applicable Puerto Rico percentage is 25 percent and the applicable Federal percentage is 75 percent; and

(v) on or after January 1, 2016, the applicable Puerto Rico percentage is 0 percent and the applicable Federal percentage is 100 percent.

(10)(A) There is hereby established the Medicare Geographic Classification Review Board (hereinafter in this paragraph referred to as the "Board").

(B)(i) The Board shall be composed of 5 members appointed by the Secretary without regard to the provisions of title 5, United States Code, governing appointments in the competitive service. Two of such members shall be representative of subsection (d) hospitals located in a rural area under paragraph (2)(D). At least 1 member shall be knowledgeable in the field of analyzing costs with respect to the provision of inpatient hospital services.

(ii) The Secretary shall make initial appointments to the Board as provided in this paragraph within 180 days after the date of the enactment of this paragraph.

(C)(i) The Board shall consider the application of any subsection (d) hospital requesting that the Secretary change the hospital's geographic classification for purposes of determining for a fiscal year—

(I) the hospital's average standardized amount under paragraph (2)(D), or

(II) the factor used to adjust the DRG prospective payment rate for area differences in hospital wage levels that applies to such hospital under paragraph (3)(E).

(ii) A hospital requesting a change in geographic classification under clause (i) for a fiscal year shall submit its application to the Board not later than the first day of the 13-month period ending on September 30 of the preceding fiscal year.

(iii)(I) The Board shall render a decision on an application submitted under clause (i) not later than 180 days after the deadline referred to in clause (ii).

(II) Appeal of decisions of the Board shall be subject to the provisions of section 557b of title 5, United States Code. The Secretary shall issue a decision on such an appeal not later than 90 days after the date on which the appeal is filed. The decision of the Secretary shall be final and shall not be subject to judicial review.

(D)(i) The Secretary shall publish guidelines to be utilized by the Board in rendering decisions on applications submitted under this paragraph, and shall include in such guidelines the following:

(I) Guidelines for comparing wages, taking into account (to the extent the Secretary determines appropriate) occupational mix, in the area in which the hospital is classified and the area in which the hospital is applying to be classified.

(II) Guidelines for determining whether the county in which the hospital is located should be treated as being a part of a particular Metropolitan Statistical Area.

(III) Guidelines for considering information provided by an applicant with respect to the effects of the hospital's geographic classification on access to inpatient hospital services by medicare beneficiaries.

(IV) Guidelines for considering the appropriateness of the criteria used to define New England County Metropolitan Areas.

(ii) Notwithstanding clause (i), if the Secretary uses a method for making adjustments to the DRG prospective payment rate for area differences in hospital wage levels under paragraph (3)(E) that is not based on the use of Metropolitan Statistical Area classifications, the Secretary may revise the guidelines published under clause (i) to the extent such guidelines are used to determine the appropriateness of the geographic area in which the hospital is determined to be located for purposes of making such adjustments.

(iii) Under the guidelines published by the Secretary under clause (i), in the case of a hospital which has ever been classified by the Secretary as a rural referral center under paragraph (5)(C), the Board may not reject the application of the hospital under this paragraph on the basis of any comparison between the average hourly wage of the hospital and the average hourly wage of hospitals in the area in which it is located.

(iv) The Secretary shall publish the guidelines described in clause (i) by July 1, 1990.

(v) Any decision of the Board to reclassify a subsection (d) hospital for purposes of the adjustment factor described in subparagraph (C)(i)(II) for fiscal year 2001 or any fiscal year thereafter shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to terminate such reclassification before the end of such period.

(vi) Such guidelines shall provide that, in making decisions on applications for reclassification for the purposes described in clause (v) for fiscal year 2003 and any succeeding fiscal year, the Board shall base any comparison of the average hourly wage for the hospital with the average hourly wage for hospitals in an area on—

(I) an average of the average hourly wage amount for the hospital from the most recently published hospital wage survey data of the Secretary (as of the date on which the hospital applies for reclassification) and such amount from each of the two immediately preceding surveys; and

(II) an average of the average hourly wage amount for hospitals in such area from the most recently published hospital wage survey data of the Secretary (as of the date on which the hospital applies for reclassification) and such amount from each of the two immediately preceding surveys.

(E)(i) The Board shall have full power and authority to make rules and establish procedures, not inconsistent with the provisions of this title or regulations of the Secretary, which are necessary or appropriate to carry out the provisions of this paragraph. In the course of any hearing the Board may administer oaths and affirmations. The provisions of subsections (d) and (e) of section 205 with respect to subpenas shall apply to the Board to the same extent as such provisions apply to the Secretary with respect to title II.

(ii) The Board is authorized to engage such technical assistance and to receive such information as may be required to carry out its functions, and the Secretary shall, in addition, make available to the Board such secretarial, clerical, and other assistance as the Board may require to carry out its functions.

(F)(i) Each member of the Board who is not an officer or employee of the Federal Government shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for grade GS–18 of the General Schedule under section 5332 of title 5, United States Code, for each day (including travel time) during which such member is engaged in the performance of the duties of the Board. Each member of the Board who is an officer or employee of the United States shall serve without compensation in addition to that received for service as an officer or employee of the United States.

(ii) Members of the Board shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Board.

(11) ADDITIONAL PAYMENTS FOR MANAGED CARE ENROLLEES.—

(A) IN GENERAL.—For portions of cost reporting periods occurring on or after January 1, 1998, the Secretary shall provide for an additional payment amount for each applicable discharge of any subsection (d) hospital that has an approved medical residency training program.

(B) APPLICABLE DISCHARGE.—For purposes of this paragraph, the term "applicable discharge" means the discharge of any individual who is enrolled under a risk-sharing con-

tract with an eligible organization under section 1876 and who is entitled to benefits under part A or any individual who is enrolled with a Medicare+Choice organization under part C.

(C) DETERMINATION OF AMOUNT.—The amount of the payment under this paragraph with respect to any applicable discharge shall be equal to the applicable percentage (as defined in subsection (h)(3)(D)(ii)) of the estimated average per discharge amount that would otherwise have been paid under paragraph (5)(B) if the individuals had not been enrolled as described in subparagraph (B).

(D) SPECIAL RULE FOR HOSPITALS UNDER REIMBURSEMENT SYSTEM.—The Secretary shall establish rules for the application of this paragraph to a hospital reimbursed under a reimbursement system authorized under section 1814(b)(3) in the same manner as it would apply to the hospital if it were not reimbursed under such section.

(12) PAYMENT ADJUSTMENT FOR LOW-VOLUME HOSPITALS.—

(A) IN GENERAL.—In addition to any payments calculated under this section for a subsection (d) hospital, for discharges occurring during a fiscal year (beginning with fiscal year 2005), the Secretary shall provide for an additional payment amount to each low-volume hospital (as defined in subparagraph (C)(i)) for discharges occurring during that fiscal year that is equal to the applicable percentage increase (determined under subparagraph (B) or (D) for the hospital involved) in the amount paid to such hospital under this section for such discharges (determined without regard to this paragraph).

(B) APPLICABLE PERCENTAGE INCREASE.—For discharges occurring in fiscal years 2005 through 2010 and for discharges occurring in fiscal year 2023 and subsequent fiscal years, the Secretary shall determine an applicable percentage increase for purposes of subparagraph (A) as follows:

(i) The Secretary shall determine the empirical relationship for subsection (d) hospitals between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges.

(ii) The applicable percentage increase shall be determined based upon such relationship in a manner that reflects, based upon the number of such discharges for a subsection (d) hospital, such additional incremental costs.

(iii) In no case shall the applicable percentage increase exceed 25 percent.

(C) DEFINITIONS.—

(i) LOW-VOLUME HOSPITAL.—For purposes of this paragraph, the term "low-volume hospital" means, for a fiscal year, a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is located more than 25 road miles (or, with respect to fiscal years 2011 through 2022, 15 road miles) from another subsection (d) hospital and has—

(I) with respect to each of fiscal years 2005 through 2010, less than 800 discharges during the fiscal year;

(II) with respect to each of fiscal years 2011 through 2018, less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under part A during the fiscal year or portion of fiscal year;

(III) with respect to each of fiscal years 2019 through 2022, less than 3,800 discharges during the fiscal year; and

(IV) with respect to fiscal year 2023 and each subsequent fiscal year, less than 800 discharges during the fiscal year.

(ii) DISCHARGE.—For purposes of subparagraphs (B) and (D) and clause (i), the term "discharge" means an inpatient acute care discharge of an individual regardless (except as provided in clause (i)(II) and subparagraph (D)(i)) of whether the individual is entitled to benefits under part A.

(iii) TREATMENT OF INDIAN HEALTH SERVICE AND NON-INDIAN HEALTH SERVICE FACILITIES.—For purposes of determining whether—

(I) a subsection (d) hospital of the Indian Health Service (whether operated by such Service or by an Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act)), or

(II) a subsection (d) hospital other than a hospital of the Indian Health Service meets the mileage criterion under clause (i) with respect to fiscal year 2011 or a succeeding fiscal year, the Secretary shall apply the policy described in the regulation at

part 412.101(e) of title 42, Code of Federal Regulations (as in effect on the date of enactment of this clause).

(D) TEMPORARY APPLICABLE PERCENTAGE INCREASE.—For discharges occurring in fiscal years 2011 through 2022, the Secretary shall determine an applicable percentage increase for purposes of subparagraph (A) using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals—

(i) with respect to each of fiscal years 2011 through 2018, with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under part A in the fiscal year or the portion of fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal yearor portion of fiscal year; and

(ii) with respect to each of fiscal years 2019 through 2022, with 500 or fewer discharges in the fiscal year to 0 percent for low-volume hospitals with greater than 3,800 discharges in the fiscal year.

(13)(A) In order to recognize commuting patterns among geographic areas, the Secretary shall establish a process through application or otherwise for an increase of the wage index applied under paragraph (3)(E) for subsection (d) hospitals located in a qualifying county described in subparagraph (B) in the amount computed under subparagraph (D) based on out-migration of hospital employees who reside in that county to any higher wage index area.

(B) The Secretary shall establish criteria for a qualifying county under this subparagraph based on the out-migration referred to in subparagraph (A) and differences in the area wage indices. Under such criteria the Secretary shall, utilizing such data as the Secretary determines to be appropriate, establish—

(i) a threshold percentage, established by the Secretary, of the weighted average of the area wage index or indices for the higher wage index areas involved;

(ii) a threshold (of not less than 10 percent) for minimum out-migration to a higher wage index area or areas; and

(iii) a requirement that the average hourly wage of the hospitals in the qualifying county equals or exceeds the average hourly wage of all the hospitals in the area in which the qualifying county is located.

(C) For purposes of this paragraph, the term "higher wage index area" means, with respect to a county, an area with a wage index that exceeds that of the county.

(D) The increase in the wage index under subparagraph (A) for a qualifying county shall be equal to the percentage of the hospital employees residing in the qualifying county who are employed in any higher wage index area multiplied by the sum of the products, for each higher wage index area of—

(i) the difference between—

(I) the wage index for such higher wage index area, and

(II) the wage index of the qualifying county; and

(ii) the number of hospital employees residing in the qualifying county who are employed in such higher wage index area divided by the total number of hospital employees residing in the qualifying county who are employed in any higher wage index area.

(E) The process under this paragraph may be based upon the process used by the Medicare Geographic Classification Review Board under paragraph (10). As the Secretary determines to be appropriate to carry out such process, the Secretary may require hospitals (including subsection (d) hospitals and other hospitals) and critical access hospitals, as required under section 1866(a)(1)(T), to submit data regarding the location of residence, or the Secretary may use data from other sources.

(F) A wage index increase under this paragraph shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to waive the application of such wage index increase.

(G) A hospital in a county that has a wage index increase under this paragraph for a period and that has not waived the application of such an increase under subparagraph (F) is not eligible for reclassification under paragraph (8) or (10) during that period.

(H) Any increase in a wage index under this paragraph for a county shall not be taken into account for purposes of—

(i) computing the wage index for portions of the wage index area (not including the county) in which the county is located; or

(ii) applying any budget neutrality adjustment with respect to such index under paragraph (8)(D).

(I) The thresholds described in subparagraph (B), data on hospital employees used under this paragraph, and any determination of the Secretary under the process described in subparagraph (E) shall be final and shall not be subject to judicial review.

(e)(1)(A) For cost reporting periods of hospitals beginning in fiscal year 1984 or fiscal year 1985, the Secretary shall provide for such proportional adjustment in the applicable percentage increase (otherwise applicable to the periods under subsection (b)(3)(B)) as may be necessary to assure that—

(i) the aggregate payment amounts otherwise provided under subsection (d)(1)(A)(i)(I) for that fiscal year for operating costs of inpatient hospital services of hospitals (excluding payments made under section 1866(a)(1)(F)),

are not greater or less than—

(ii) the target percentage (as defined in subsection (d)(1)(C)) of the payment amounts which would have been payable for such services for those same hospitals for that fiscal year under this section under the law as in effect before the date of the enactment of the Social Security Amendments of 1983 (excluding payments made under section 1866(a)(1)(F));

except that the adjustment made under this subparagraph shall apply only to subsection (d) hospitals and shall not apply for purposes of making computations under subsection (d)(2)(B)(ii) or subsection (d)(3)(A).

(B) For discharges occurring in fiscal year 1984 or fiscal year 1985, the Secretary shall provide under subsections (d)(2)(F) and (d)(3)(C) for such equal proportional adjustment in each of the average standardized amounts otherwise computed for that fiscal year as may be necessary to assure that—

(i) the aggregate payment amounts otherwise provided under subsection (d)(1)(A)(i)(II) and (d)(5) for that fiscal year for operating costs of inpatient hospital services of hospitals (excluding payments made under section 1866(a)(1)(F)),

are not greater or less than—

(ii) the DRG percentage (as defined in subsection (d)(1)(C)) of the payment amounts which would have been payable for such services for those same hospitals for that fiscal year under this section under the law as in effect before the date of the enactment of the Social Security Amendments of 1983 (excluding payments made under section 1866(a)(1)(F)).

(C) For discharges occurring in fiscal year 1988, the Secretary shall provide for such equal proportional adjustment in each of the average standardized amounts otherwise computed under subsection (d)(3) for that fiscal year as may be necessary to assure that—

(i) the aggregate payment amounts otherwise provided under subsections (d)(1)(A)(iii), (d)(5), and (d)(9) for that fiscal year for operating costs of inpatient hospital services of subsection (d) hospitals and subsection (d) Puerto Rico hospitals,

are not greater or less than—

(ii) the payment amounts that would have been payable for such services for those same hospitals for that fiscal year but for the enactment of the amendments made by section 9304 of the Omnibus Budget Reconciliation Act of 1986.

(4)(A) Taking into consideration the recommendations of the Commission, the Secretary shall recommend for each fiscal year (beginning with fiscal year 1988) an appropriate change factor for inpatient hospital services for discharges in that fiscal year which will take into account amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. The appropriate change factor may be different for all large urban subsection (d) hospitals, other urban subsection (d) hospitals, urban subsection (d) Puerto Rico hospitals, rural subsection (d) hospitals, and rural subsection (d) Puerto Rico hospitals, and all other hospitals and units not paid under subsection (d), and may vary among such other hospitals and units.

(B) In addition to the recommendation made under subparagraph (A), the Secretary shall, taking into consideration the recommendations of the Commission under paragraph (2)(B), recommend for each fiscal year (beginning with fiscal year 1992) other appropriate changes in each existing reimbursement policy under this title under which payments to an institution are based upon prospectively determined rates.

(5) The Secretary shall cause to have published in the Federal Register, not later than—

(A) the April 1 before each fiscal year (beginning with fiscal year 1986), the Secretary's proposed recommendations under paragraph (4) for that fiscal year for public comment, and

(B) the August 1 before such fiscal year after such consideration of public comment on the proposal as is feasible in the time available, the Secretary's final recommendations under such paragraph for that year.

The Secretary shall include in the publication referred to in subparagraph (A) for a fiscal year the report of the Commission's recommendations submitted under paragraph (3) for that fiscal year. To the extent that the Secretary's recommendations under paragraph (4) differ from the Commission's recommendations for that fiscal year, the Secretary shall include in the publication referred to in subparagraph (A) an explanation of the Secretary's grounds for not following the Commission's recommendations.

(f)(1)(A) The Secretary shall maintain a system for the reporting of costs of hospitals receiving payments computed under subsection (d).

(B)(i) Subject to clause (ii), the Secretary shall place into effect a standardized electronic cost reporting format for hospitals under this title.

(ii) The Secretary may delay or waive the implementation of such format in particular instances where such implementation would result in financial hardship (in particular with respect to hospitals with a small percentage of inpatients entitled to benefits under this title).

(2) If the Secretary determines, based upon information supplied by a quality improvement organization under part B of title XI, that a hospital, in order to circumvent the payment method established under subsection (b) or (d) of this section, has taken an action that results in the admission of individuals entitled to benefits under part A unnecessarily, unnecessary multiple admissions of the same such individuals, or other inappropriate medical or other practices with respect to such individuals, the Secretary may—

(A) deny payment (in whole or in part) under part A with respect to inpatient hospital services provided with respect to such an unnecessary admission (or subsequent admission of the same individual), or

(B) require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.

(3) The provisions of subsections (c) through (g) of section 1128 shall apply to determinations made under paragraph (2) in the same manner as they apply to exclusions effected under section 1128(b)(13).

(g)(1)(A) Notwithstanding section 1861(v), instead of any amounts that are otherwise payable under this title with respect to the reasonable costs of subsection (d) hospitals and subsection (d) Puerto Rico hospitals for capital-related costs of inpatient hospital services, the Secretary shall, for hospital cost reporting periods beginning on or after October 1, 1991, provide for payments for such costs in accordance with a prospective payment system established by the Secretary. Aggregate payments made under subsection (d) and this subsection during fiscal years 1992 through 1995 shall be reduced in a manner that results in a reduction (as estimated by the Secretary) in the amount of such payments equal to a 10 percent reduction in the amount of payments attributable to capital-related costs that would otherwise have been made during such fiscal year had the amount of such payments been based on reasonable costs (as defined in section 1861(v)). For discharges occurring after September 30, 1993, the Secretary shall reduce by 7.4 percent the unadjusted standard Federal capital payment rate (as described in 42 CFR 412.308(c), as in effect on the date of the enactment of the Omnibus Budget Reconciliation Act of 1993) and shall (for hospital cost reporting periods beginning on or after October 1, 1993) redetermine which payment methodology is applied to the hospital under such system to take into account such reduction. In addition to the reduction described in the preceding sentence, for discharges occurring on or after October 1, 1997, the Secretary shall apply the budget neutrality adjustment factor used to determine the Federal capital payment rate in effect on September 30, 1995 (as described in section 412.352 of title 42 of the Code of Federal Regulations), to (i) the unadjusted standard Federal capital payment rate (as described in section 412.308(c) of that title, as in effect on September 30, 1997), and (ii) the unadjusted hospital-specific rate (as described in section 412.328(e)(1) of that title, as in effect on September 30, 1997), and, for discharges occurring on or after October 1, 1997, and before October 1, 2002, reduce the rates described in clauses (i) and (ii) by 2.1 percent.

(B) Such system—

(i) shall provide for (I) a payment on a per discharge basis, and (II) an appropriate weighting of such payment amount as relates to the classification of the discharge;

(ii) may provide for an adjustment to take into account variations in the relative costs of capital and construction for the different types of facilities or areas in which they are located;

(iii) may provide for such exceptions (including appropriate exceptions to reflect capital obligations) as the Secretary determines to be appropriate, and

(iv) may provide for suitable adjustment to reflect hospital occupancy rate.

(C) In this paragraph, the term "capital-related costs" has the meaning given such term by the Secretary under subsection (a)(4) as of September 30, 1987, and does not include a return on equity capital.

(2)(A) The Secretary shall provide that the amount which is allowable, with respect to reasonable costs of inpatient hospital services for which payment may be made under this title, for a return on equity capital for hospitals shall, for cost reporting periods beginning on or after the date of the enactment of this subsection, be equal to amounts otherwise allowable under regulations in effect on March 1, 1983, except that the rate of return to be recognized shall be equal to the applicable percentage (described in subparagraph (B)) of the average of the rates of interest, for each of the months any part of which is included in the reporting period, on obligations issued for purchase by the Federal Hospital Insurance Trust Fund.

(B) In this paragraph, the "applicable percentage" is—

(i) 75 percent, for cost reporting periods beginning during fiscal year 1987,

(ii) 50 percent, for cost reporting periods beginning during fiscal year 1988,

(iii) 25 percent, for cost reporting periods beginning during fiscal year 1989, and

(iv) 0 percent, for cost reporting periods beginning on or after October 1, 1989.

(3)(A) Except as provided in subparagraph (B), in determining the amount of the payments that may be made under this title with respect to all the capital-related costs of inpatient hospital services of a subsection (d) hospital and a subsection (d) Puerto Rico hospital, the Secretary shall reduce the amounts of such payments otherwise established under this title by—

(i) 3.5 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1987,

(ii) 7 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1988 on or after October 1, 1987, and before January 1, 1988,

(iii) 12 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) in fiscal year 1988, occurring on or after January 1, 1988,

(iv) 15 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1989, and

(v) 15 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during the period beginning January 1, 1990, and ending September 30, 1991.

(B) Subparagraph (A) shall not apply to payments with respect to the capital-related costs of any hospital that is a sole community hospital (as defined in subsection (d)(5)(D)(iii)) or a critical access hospital (as defined in section 1861(mm)(1)).

(4) In determining the amount of the payments that are attributable to portions of cost reporting periods occurring during fiscal years 1998 through 2002 and that may be made under this title with respect to capital-related costs of inpatient hospital services of a hospital which is described in clause (i), (ii), or (iv) of subsection (d)(1)(B) or a unit described in the matter after clause (v) of such subsection, the Secretary shall reduce the amounts of such payments otherwise determined under this title by 15 percent.

(h) PAYMENTS FOR DIRECT GRADUATE MEDICAL EDUCATION COSTS.—

(1) SUBSTITUTION OF SPECIAL PAYMENT RULES.—Notwithstanding section 1861(v), instead of any amounts that are otherwise payable under this title with respect to the reasonable costs of hospitals for direct graduate medical education costs, the Secretary shall provide for payments for such costs in accordance with paragraph (3) of this subsection. In providing for such payments, the Secretary shall provide for an allocation of such payments between part A and part B (and the trust funds established under the respective parts) as reasonably reflects the proportion of direct graduate medical education costs of hospitals associated with the provision of services under each respective part.

(2) DETERMINATION OF HOSPITAL-SPECIFIC APPROVED FTE RESIDENT AMOUNTS.—The Secretary shall determine, for each hospital with an approved medical residency training program, an approved FTE resident amount for each cost reporting period beginning on or after July 1, 1985, as follows:

(A) DETERMINING ALLOWABLE AVERAGE COST PER FTE RESIDENT IN A HOSPITAL'S BASE PERIOD.—The Secretary shall determine, for the hospital's cost reporting period that began

during fiscal year 1984, the average amount recognized as reasonable under this title for direct graduate medical education costs of the hospital for each full-time-equivalent resident.

(B) UPDATING TO THE FIRST COST REPORTING PERIOD.—

(i) IN GENERAL.—The Secretary shall update each average amount determined under subparagraph (A) by the percentage increase in the consumer price index during the 12-month cost reporting period described in such subparagraph.

(ii) EXCEPTION.—The Secretary shall not perform an update under clause (i) in the case of a hospital if the hospital's reporting period, described in subparagraph (A), began on or after July 1, 1984, and before October 1, 1984.

(C) AMOUNT FOR FIRST COST REPORTING PERIOD.—For the first cost reporting period of the hospital beginning on or after July 1, 1985, the approved FTE resident amount for the hospital is equal to the amount determined under subparagraph (B) increased by 1 percent.

(D) AMOUNT FOR SUBSEQUENT COST REPORTING PERIODS.—

(i) IN GENERAL.—Except as provided in a subsequent clause, for each subsequent cost reporting period, the approved FTE resident amount for the hospital is equal to the approved FTE resident amount determined under this paragraph for the previous cost reporting period updated, through the midpoint of the period, by projecting the estimated percentage change in the consumer price index during the 12-month period ending at that midpoint, with appropriate adjustments to reflect previous under-or over-estimations under this subparagraph in the projected percentage change in the consumer price index.

(ii) FREEZE IN UPDATE FOR FISCAL YEARS 1994 AND 1995.—For cost reporting periods beginning during fiscal year 1994 or fiscal year 1995, the approved FTE resident amount for a hospital shall not be updated under clause (i) for a resident who is not a primary care resident (as defined in paragraph (5)(H)) or a resident enrolled in an approved medical residency training program in obstetrics and gynecology.

(iii) FLOOR FOR LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—The approved FTE resident amount for a hospital for the cost reporting period beginning during fiscal year 2001 shall not be less than 70 percent, and for the cost reporting period beginning during fiscal year 2002 shall not be less than 85 percent, of the locality adjusted national average per resident amount computed under subparagraph (E) for the hospital and period.

(iv) ADJUSTMENT IN RATE OF INCREASE FOR HOSPITALS WITH FTE APPROVED AMOUNT ABOVE 140 PERCENT OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—

(I) FREEZE FOR FISCAL YEARS 2001 AND 2002 AND 2004 THROUGH 2013.—For a cost reporting period beginning during fiscal year 2001 or fiscal year 2002 or during the period beginning with fiscal year 2004 and ending with fiscal year 2013, if the approved FTE resident amount for a hospital for the preceding cost reporting period exceeds 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital and period, subject to subclause (III), the approved FTE resident amount for the period involved shall be the same as the approved FTE resident amount for the hospital for such preceding cost reporting period.

(II) 2 PERCENT DECREASE IN UPDATE FOR FISCAL YEARS 2003, 2004, AND 2005.—For the cost reporting period beginning during fiscal year 2003, if the approved FTE resident amount for a hospital for the preceding cost reporting period exceeds 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital and preceding period, the approved FTE resident amount for the period involved shall be updated in the manner described in subparagraph (D)(i) except that, subject to subclause (III), the consumer price index applied for a 12-month period shall be reduced (but not below zero) by 2 percentage points.

(III) NO ADJUSTMENT BELOW 140 PERCENT.—In no case shall subclause (I) or (II) reduce an approved FTE resident amount for a hospital for a cost reporting period below 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for such hospital and period.

(E) DETERMINATION OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—The Secretary shall determine a locality adjusted national average per resident amount with respect to a cost reporting period of a hospital beginning during a fiscal year as follows:

(i) DETERMINING HOSPITAL SINGLE PER RESIDENT AMOUNT.—The Secretary shall compute for each hospital operating an approved graduate medical education program a single per resident amount equal to the average (weighted by number of full-time equivalent residents, as determined under paragraph (4)) of the primary care per resident amount and the non-primary care per resident amount computed under paragraph (2) for cost reporting periods ending during fiscal year 1997.

(ii) STANDARDIZING PER RESIDENT AMOUNTS.—The Secretary shall compute a standardized per resident amount for each such hospital by dividing the single per resident amount computed under clause (i) by an average of the 3 geographic index values (weighted by the national average weight for each of the work, practice expense, and malpractice components) as applied under section 1848(e) for 1999 for the fee schedule area in which the hospital is located.

(iii) COMPUTING OF WEIGHTED AVERAGE.—The Secretary shall compute the average of the standardized per resident amounts computed under clause (ii) for such hospitals, with the amount for each hospital weighted by the average number of full-time equivalent residents at such hospital (as determined under paragraph (4)).

(iv) COMPUTING NATIONAL AVERAGE PER RESIDENT AMOUNT.—The Secretary shall compute the national average per resident amount, for a hospital's cost reporting period that begins during fiscal year 2001, equal to the weighted average computed under clause (iii) increased by the estimated percentage increase in the consumer price index for all urban consumers during the period beginning with the month that represents the midpoint of the cost reporting periods described in clause (i) and ending with the midpoint of the hospital's cost reporting period that begins during fiscal year 2001.

(v) ADJUSTING FOR LOCALITY.—The Secretary shall compute the product of—

(I) the national average per resident amount computed under clause (iv) for the hospital, and

(II) the geographic index value average (described and applied under clause (ii)) for the fee schedule area in which the hospital is located.

(vi) COMPUTING LOCALITY ADJUSTED AMOUNT.—The locality adjusted national per resident amount for a hospital for—

(I) the cost reporting period beginning during fiscal year 2001 is the product computed under clause (v); or

(II) each subsequent cost reporting period is equal to the locality adjusted national per resident amount for the hospital for the previous cost reporting period (as determined under this clause) updated, through the midpoint of the period, by projecting the estimated percentage change in the consumer price index for all urban consumers during the 12-month period ending at that midpoint.

(F) TREATMENT OF CERTAIN HOSPITALS.—In the case of a hospital that did not have an approved medical residency training program or was not participating in the program under this title for a cost reporting period beginning during fiscal year 1984, the Secretary shall, for the first such period for which it has such a residency training program and is participating under this title, provide for such approved FTE resident amount as the Secretary determines to be appropriate, based on approved FTE resident amounts for comparable programs.

(3) HOSPITAL PAYMENT AMOUNT PER RESIDENT.—

(A) IN GENERAL.—The payment amount, for a hospital cost reporting period beginning on or after July 1, 1985, is equal to the product of—

(i) the aggregate approved amount (as defined in subparagraph (B)) for that period, and

(ii) the hospital's medicare patient load (as defined in subparagraph (C)) for that period.

(B) AGGREGATE APPROVED AMOUNT.—As used in subparagraph (A), the term "aggregate approved amount" means, for a hospital cost reporting period, the product of—

(i) the hospital's approved FTE resident amount (determined under paragraph (2)) for that period, and

(ii) the weighted average number of full-time-equivalent residents (as determined under paragraph (4)) in the hospital's approved medical residency training programs in that period.

The Secretary shall reduce the aggregate approved amount to the extent payment is made under subsection (k) for residents included in the hospital's count of full-time equivalent residents.

(C) MEDICARE PATIENT LOAD.—As used in subparagraph (A), the term "medicare patient load" means, with respect to a hospital's cost reporting period, the fraction of the total number of inpatient-bed-days (as established by the Secretary) during the period which are attributable to patients with respect to whom payment may be made under part A.

(D) PAYMENT FOR MANAGED CARE ENROLLEES.—

(i) IN GENERAL.—For portions of cost reporting periods occurring on or after January 1, 1998, the Secretary shall provide for an additional payment amount under this subsection for services furnished to individuals who are enrolled under a risk-sharing contract with an eligible organization under section 1876 and who are entitled to part A or with a Medicare+Choice organization under part C. The amount of such a payment shall equal, subject to clause (iii), the applicable percentage of the product of—

(I) the aggregate approved amount (as defined in subparagraph (B)) for that period; and

(II) the fraction of the total number of inpatient-bed days (as established by the Secretary) during the period which are attributable to such enrolled individuals.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the applicable percentage is—

(I) 20 percent in 1998,
(II) 40 percent in 1999,
(III) 60 percent in 2000,
(IV) 80 percent in 2001, and
(V) 100 percent in 2002 and subsequent years.

(iii) PROPORTIONAL REDUCTION FOR NURSING AND ALLIED HEALTH EDUCATION.—The Secretary shall estimate a proportional adjustment in payments to all hospitals determined under clauses (i) and (ii) for portions of cost reporting periods beginning in a year (beginning with 2000) such that the proportional adjustment reduces payments in an amount for such year equal to the total additional payment amounts for nursing and allied health education determined under subsection (l) for portions of cost reporting periods occurring in that year.

(iv) SPECIAL RULE FOR HOSPITALS UNDER REIMBURSEMENT SYSTEM.—The Secretary shall establish rules for the application of this subparagraph to a hospital reimbursed under a reimbursement system authorized under section 1814(b)(3) in the same manner as it would apply to the hospital if it were not reimbursed under such section.

(4) DETERMINATION OF FULL-TIME-EQUIVALENT RESIDENTS.—

(A) RULES.—The Secretary shall establish rules consistent with this paragraph for the computation of the number of full-time- equivalent residents in an approved medical residency training program.

(B) ADJUSTMENT FOR PART-YEAR OR PART-TIME RESIDENTS.—Such rules shall take into account individuals who serve as residents for only a portion of a period with a hospital or simultaneously with more than one hospital.

(C) WEIGHTING FACTORS FOR CERTAIN RESIDENTS.—Subject to subparagraph (D), such rules shall provide, in calculating the number of full-time-equivalent residents in an approved residency program—

(i) before July 1, 1986, for each resident the weighting factor is 1.00,

(ii) on or after July 1, 1986, for a resident who is in the resident's initial residency period (as defined in paragraph (5)(F)), the weighting factor is 1.00,

(iii) on or after July 1, 1986, and before July 1, 1987, for a resident who is not in the resident's initial residency period (as defined in paragraph (5)(F)), the weighting factor is .75, and

(iv) on or after July 1, 1987, for a resident who is not in the resident's initial residency period (as defined in paragraph (5)(F)), the weighting factor is .50.

(D) FOREIGN MEDICAL GRADUATES REQUIRED TO PASS FMGEMS EXAMINATION.—

(i) IN GENERAL.—Except as provided in clause (ii), such rules shall provide that, in the case of an individual who is a foreign medical graduate (as defined in paragraph (5)(D)), the individual shall not be counted as a resident on or after July 1, 1986, unless—

(I) the individual has passed the FMGEMS examination (as defined in paragraph (5)(E)), or

(II) the individual has previously received certification from, or has previously passed the examination of, the Educational Commission for Foreign Medical Graduates.

(ii) TRANSITION FOR CURRENT FMGS.—On or after July 1, 1986, but before July 1, 1987, in the case of a foreign medical graduate who—

(I) has served as a resident before July 1, 1986, and is serving as a resident after that date, but

(II) has not passed the FMGEMS examination or a previous examination of the Educational Commission for Foreign Medical Graduates before July 1, 1986,

the individual shall be counted as a resident at a rate equal to one-half of the rate at which the individual would otherwise be counted.

(E) COUNTING TIME SPENT IN OUTPATIENT SETTINGS.—Subject to subparagraphs (J) and (K), such rules shall provide that only time spent in activities relating to patient care shall be counted and that—

(i) effective for cost reporting periods beginning before July 1, 2010, all the time;

(ii) effective for cost reporting periods beginning on or after July 1, 2010, all the time so spent by a resident shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if a hospital incurs the costs of the stipends and fringe benefits of the resident during the time the resident spends in that setting. If more than one hospital incurs these costs, either directly or through a third party, such hospitals shall count a proportional share of the time, as determined by written agreement between the hospitals, that a resident spends training in that setting.

so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training program in that setting.

Any hospital claiming under this subparagraph for time spent in a nonprovider setting shall maintain and make available to the Secretary records regarding the amount of such time and such amount in comparison with amounts of such time in such base year as the Secretary shall specify.

(F) LIMITATION ON NUMBER OF RESIDENTS IN ALLOPATHIC AND OSTEOPATHIC MEDICINE.—

(i) IN GENERAL.—Such rules shall provide that for purposes of a cost reporting period beginning on or after October 1, 1997, subject to paragraphs (7) and (8), the total number of full-time equivalent residents before application of weighting factors (as determined under this paragraph) with respect to a hospital's approved medical residency training program in the fields of allopathic medicine and osteopathic medicine may not exceed the number (or, 130 percent of such number in the case of a hospital located in a rural area) of such full-time equivalent residents for the hospital's most recent cost reporting period ending on or before December 31, 1996.

(ii) COUNTING PRIMARY CARE RESIDENTS ON CERTAIN APPROVED LEAVES OF ABSENCE IN BASE YEAR FTE COUNT.—

(I) IN GENERAL.—In determining the number of such full-time equivalent residents for a hospital's most recent cost reporting period ending on or before December 31, 1996, for purposes of clause (i), the Secretary shall count an individual to the extent that the individual would have been counted as a primary care resident for such period but for the fact that the individual, as determined by the Secretary, was on maternity or disability leave or a similar approved leave of absence.

(II) LIMITATION TO 3 FTE RESIDENTS FOR ANY HOSPITAL.—The total number of individuals counted under subclause (I) for a hospital may not exceed 3 full-time equivalent residents.

(G) COUNTING INTERNS AND RESIDENTS FOR FY 1998 AND SUBSEQUENT YEARS.—

(i) IN GENERAL.—For cost reporting periods beginning during fiscal years beginning on or after October 1, 1997, subject to the limit described in subparagraph (F), the total number of full-time equivalent residents for determining a hospital's graduate medical education payment shall equal the average of the actual full-time equivalent resident counts for the cost reporting period and the preceding two cost reporting periods.

(ii) ADJUSTMENT FOR SHORT PERIODS.—If any cost reporting period beginning on or after October 1, 1997, is not equal to twelve months, the Secretary shall make appropriate modifications to ensure that the average full-time equivalent resident counts pursuant to clause (i) are based on the equivalent of full twelve-month cost reporting periods.

(iii) TRANSITION RULE FOR 1998.—In the case of a hospital's first cost reporting period beginning on or after October 1, 1997, clause (i) shall be applied by using the average for such period and the preceding cost reporting period.

(H) SPECIAL RULES FOR APPLICATION OF SUBPARAGRAPHS (F) AND (G).—

(i) NEW FACILITIES.—The Secretary shall, consistent with the principles of subparagraphs (F) and (G) and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs in the case of medical residency training programs established on or after January 1, 1995. In promulgating such rules for purposes of subparagraph (F), the Secretary shall give special consideration to facilities that meet the needs of underserved rural areas.

(ii) AGGREGATION.—The Secretary may prescribe rules which allow institutions which are members of the same affiliated group (as defined by the Secretary) to elect to apply the limitation of subparagraph (F) on an aggregate basis.

(iii) DATA COLLECTION.—The Secretary may require any entity that operates a medical residency training program and to which subparagraphs (F) and (G) apply to submit to the Secretary such additional information as the Secretary considers necessary to carry out such subparagraphs.

(iv) NONRURAL HOSPITALS OPERATING TRAINING PROGRAMS IN RURAL AREAS.—In the case of a hospital that is not located in a rural area but establishes separately accredited approved medical residency training programs (or rural tracks) in an rural area or has an accredited training program with an integrated rural track, the Secretary shall adjust the limitation under subparagraph (F) in an appropriate manner insofar as it applies to such programs in such rural areas in order to encourage the training of physicians in rural areas.

(v) SPECIAL PROVIDER AGREEMENT.—If an entity enters into a provider agreement pursuant to section 1866(a) to provide hospital services on the same physical site previously used by Medicare Provider No. 05–0578—

(I) the limitation on the number of total full time equivalent residents under subparagraph (F) and clauses (v) and (vi)(I) of subsection (d)(5)(B) applicable to such provider shall be equal to the limitation applicable under such provisions to Provider No. 05–0578 for its cost reporting period ending on June 30, 2006; and

(II) the provisions of subparagraph (G) and subsection (d)(5)(B)(vi)(II) shall not be applicable to such provider for the first three cost reporting years in which such provider trains residents under any approved medical residency training program.

(vi) REDISTRIBUTION OF RESIDENCY SLOTS AFTER A HOSPITAL CLOSES.—

(I) IN GENERAL.—Subject to the succeeding provisions of this clause, the Secretary shall, by regulation, establish a process under which, in the case where a hospital (other than a hospital described in clause (v)) with an approved medical residency program closes on or after a date that is 2 years before the date of enactment of this clause, the Secretary shall increase the otherwise applicable resident limit under this paragraph for other hospitals in accordance with this clause.

(II) PRIORITY FOR HOSPITALS IN CERTAIN AREAS.—Subject to the succeeding provisions of this clause, in determining for which hospitals the increase in the

otherwise applicable resident limit is provided under such process, the Secretary shall distribute the increase to hospitals in the following priority order (with preference given within each category to hospitals that are members of the same affiliated group (as defined by the Secretary under clause (ii)) as the closed hospital):

(aa) First, to hospitals located in the same core-based statistical area as, or a core-based statistical area contiguous to, the hospital that closed.

(bb) Second, to hospitals located in the same State as the hospital that closed.

(cc) Third, to hospitals located in the same region of the country as the hospital that closed.

(dd) Fourth, only if the Secretary is not able to distribute the increase to hospitals described in item (cc), to qualifying hospitals in accordance with the provisions of paragraph (8).

(III) REQUIREMENT HOSPITAL LIKELY TO FILL POSITION WITHIN CERTAIN TIME PERIOD.—The Secretary may only increase the otherwise applicable resident limit of a hospital under such process if the Secretary determines the hospital has demonstrated a likelihood of filling the positions made available under this clause within 3 years.

(IV) LIMITATION.—The aggregate number of increases in the otherwise applicable resident limits for hospitals under this clause shall be equal to the number of resident positions in the approved medical residency programs that closed on or after the date described in subclause (I).

(V) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the implementation of this clause.

(J) TREATMENT OF CERTAIN NONPROVIDER AND DIDACTIC ACTIVITIES.—Such rules shall provide that all time spent by an intern or resident in an approved medical residency training program in a nonprovider setting that is primarily engaged in furnishing patient care (as defined in paragraph (5)(K)) in non-patient care activities, such as didactic conferences and seminars, but not including research not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall be counted toward the determination of full-time equivalency.

(K) TREATMENT OF CERTAIN OTHER ACTIVITIES.—In determining the hospital's number of full-time equivalent residents for purposes of this subsection, all the time that is spent by an intern or resident in an approved medical residency training program on vacation, sick leave, or other approved leave, as such time is defined by the Secretary, and that does not prolong the total time the resident is participating in the approved program beyond the normal duration of the program shall be counted toward the determination of full-time equivalency.

(5) DEFINITIONS AND SPECIAL RULES.—As used in this subsection:

(A) APPROVED MEDICAL RESIDENCY TRAINING PROGRAM.—The term "approved medical residency training program" means a residency or other postgraduate medical training program participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary.

(B) CONSUMER PRICE INDEX.—The term "consumer price index" refers to the Consumer Price Index for All Urban Consumers (United States city average), as published by the Secretary of Commerce.

(C) DIRECT GRADUATE MEDICAL EDUCATION COSTS.—The term "direct graduate medical education costs" means direct costs of approved educational activities for approved medical residency training programs.

(D) FOREIGN MEDICAL GRADUATE.—The term "foreign medical graduate" means a resident who is not a graduate of—

(i) a school of medicine accredited by the Liaison Committee on Medical Education of the American Medical Association and the Association of American Medical Colleges (or approved by such Committee as meeting the standards necessary for such accreditation),

(ii) a school of osteopathy accredited by the American Osteopathic Association, or approved by such Association as meeting the standards necessary for such accreditation, or

(iii) a school of dentistry or podiatry which is accredited (or meets the standards for accreditation) by an organization recognized by the Secretary for such purpose.

(E) FMGEMS EXAMINATION.—The term "FMGEMS examination" means parts I and II of the Foreign Medical Graduate Examination in the Medical Sciences or any successor examination recognized by the Secretary for this purpose.

(F) INITIAL RESIDENCY PERIOD.—The term "initial residency period" means the period of board eligibility, except that—

(i) except as provided in clause (ii), in no case shall the initial period of residency exceed an aggregate period of formal training of more than five years for any individual, and

(ii) a period, of not more than two years, during which an individual is in a geriatric residency or fellowship program or a preventive medicine residency or fellowship program which meets such criteria as the Secretary may establish, shall be treated as part of the initial residency period, but shall not be counted against any limitation on the initial residency period.

Subject to subparagraph (G)(v), the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training program.

(G) PERIOD OF BOARD ELIGIBILITY.—

(i) GENERAL RULE.—Subject to clauses (ii), (iii), (iv), and (v), the term "period of board eligibility" means, for a resident, the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident is training.

(ii) APPLICATION OF 1985–1986 DIRECTORY.—Except as provided in clause (iii), the period of board eligibility shall be such period specified in the 1985–1986 Directory of Residency Training Programs published by the Accreditation Council on Graduate Medical Education.

(iii) CHANGES IN PERIOD OF BOARD ELIGIBILITY.—On or after July 1, 1989, if the Accreditation Council on Graduate Medical Education, in its Directory of Residency Training Programs—

(I) increases the minimum number of years of formal training necessary to satisfy the requirements for a specialty, above the period specified in its 1985–1986 Directory, the Secretary may increase the period of board eligibility for that specialty, but not to exceed the period of board eligibility specified in that later Directory, or

(II) decreases the minimum number of years of formal training necessary to satisfy the requirements for a specialty, below the period specified in its 1985–1986 Directory, the Secretary may decrease the period of board eligibility for that specialty, but not below the period of board eligibility specified in that later Directory.

(iv) SPECIAL RULE FOR CERTAIN PRIMARY CARE COMBINED RESIDENCY PROGRAMS.—(I) In the case of a resident enrolled in a combined medical residency training program in which all of the individual programs (that are combined) are for training a primary care resident (as defined in subparagraph (H)), the period of board eligibility shall be the minimum number of years of formal training required to satisfy the requirements for initial board eligibility in the longest of the individual programs plus one additional year.

(II) A resident enrolled in a combined medical residency training program that includes an obstetrics and gynecology program shall qualify for the period of board eligibility under subclause (I) if the other programs such resident combines with such obstetrics and gynecology program are for training a primary care resident.

(v) CHILD NEUROLOGY TRAINING PROGRAMS.—In the case of a resident enrolled in a child neurology residency training program, the period of board eligibility and the initial residency period shall be the period of board eligibility for pediatrics plus 2 years.

(H) PRIMARY CARE RESIDENT.—The term "primary care resident" means a resident enrolled in an approved medical residency training program in family medicine, general in-

ternal medicine, general pediatrics, preventive medicine, geriatric medicine, or osteopathic general practice.

(I) RESIDENT.—The term "resident" includes an intern or other participant in an approved medical residency training program.

(J) ADJUSTMENTS FOR CERTAIN FAMILY PRACTICE RESIDENCY PROGRAMS.—

(i) IN GENERAL.—In the case of an approved medical residency training program (meeting the requirements of clause (ii)) of a hospital which received funds from the United States, a State, or a political subdivision of a State or an instrumentality of such a State or political subdivision (other than payments under this title or a State plan under title XIX) for the program during the cost reporting period that began during fiscal year 1984, the Secretary shall—

(I) provide for an average amount under paragraph (2)(A) that takes into account the Secretary's estimate of the amount that would have been recognized as reasonable under this title if the hospital had not received such funds, and

(II) reduce the payment amount otherwise provided under this subsection in an amount equal to the proportion of such program funds received during the cost reporting period involved that is allocable to this title.

(ii) ADDITIONAL REQUIREMENTS.—A hospital's approved medical residency program meets the requirements of this clause if—

(I) the program is limited to training for family and community medicine;

(II) the program is the only approved medical residency program of the hospital; and

(III) the average amount determined under paragraph (2)(A) for the hospital (as determined without regard to the increase in such amount described in clause (i)(I)) does not exceed $10,000.

(K) NONPROVIDER SETTING THAT IS PRIMARILY ENGAGED IN FURNISHING PATIENT CARE.—The term "nonprovider setting that is primarily engaged in furnishing patient care" means a nonprovider setting in which the primary activity is the care and treatment of patients, as defined by the Secretary.

(6) INCENTIVE PAYMENT UNDER PLANS FOR VOLUNTARY REDUCTION IN NUMBER OF RESIDENTS.—

(A) IN GENERAL.—In the case of a voluntary residency reduction plan for which an application is approved under subparagraph (B), subject to subparagraph (F), each hospital which is part of the qualifying entity submitting the plan shall be paid an applicable hold harmless percentage (as specified in subparagraph (E)) of the sum of—

(i) the amount (if any) by which—

(I) the amount of payment which would have been made under this subsection if there had been a 5-percent reduction in the number of full-time equivalent residents in the approved medical education training programs of the hospital as of June 30, 1997, exceeds

(II) the amount of payment which is made under this subsection, taking into account the reduction in such number effected under the reduction plan; and

(ii) the amount of the reduction in payment under subsection (d)(5)(B) for the hospital that is attributable to the reduction in number of residents effected under the plan below 95 percent of the number of full-time equivalent residents in such programs of the hospital as of June 30, 1997.

The determination of the amounts under clauses (i) and (ii) for any year shall be made on the basis of the provisions of this title in effect on the application deadline date for the first calendar year to which the reduction plan applies.

(B) APPROVAL OF PLAN APPLICATIONS.—The Secretary may not approve the application of an qualifying entity unless—

(i) the application is submitted in a form and manner specified by the Secretary and by not later than November 1, 1999,

(ii) the application provides for the operation of a plan for the reduction in the number of full-time equivalent residents in the approved medical residency training programs of the entity consistent with the requirements of subparagraph (D);

(iii) the entity elects in the application the period of residency training years (not greater than 5) over which the reduction will occur;

(iv) the entity will not reduce the proportion of its residents in primary care (to the total number of residents) below such proportion as in effect as of the applicable time described in subparagraph (D)(v); and

(v) the Secretary determines that the application and the entity and such plan meet such other requirements as the Secretary specifies in regulations.

(C) QUALIFYING ENTITY.—For purposes of this paragraph, any of the following may be a qualifying entity:

(i) Individual hospitals operating one or more approved medical residency training programs.

(ii) Two or more hospitals that operate such programs and apply for treatment under this paragraph as a single qualifying entity.

(iii) A qualifying consortium (as described in section 4628 of the Balanced Budget Act of 1997).

(D) RESIDENCY REDUCTION REQUIREMENTS.—

(i) INDIVIDUAL HOSPITAL APPLICANTS.—In the case of a qualifying entity described in subparagraph (C)(i), the number of full-time equivalent residents in all the approved medical residency training programs operated by or through the entity shall be reduced as follows:

(I) If the base number of residents exceeds 750 residents, by a number equal to at least 20 percent of such base number.

(II) Subject to subclause (IV), if the base number of residents exceeds 600 but is less than 750 residents, by 150 residents.

(III) Subject to subclause (IV), if the base number of residents does not exceed 600 residents, by a number equal to at least 25 percent of such base number.

(IV) In the case of a qualifying entity which is described in clause (v) and which elects treatment under this subclause, by a number equal to at least 20 percent of the base number.

(ii) JOINT APPLICANTS.—In the case of a qualifying entity described in subparagraph (C)(ii), the number of full-time equivalent residents in the aggregate for all the approved medical residency training programs operated by or through the entity shall be reduced as follows:

(I) Subject to subclause (II), by a number equal to at least 25 percent of the base number.

(II) In the case of such a qualifying entity which is described in clause (v) and which elects treatment under this subclause, by a number equal to at least 20 percent of the base number.

(iii) CONSORTIA.—In the case of a qualifying entity described in subparagraph (C)(iii), the number of full-time equivalent residents in the aggregate for all the approved medical residency training programs operated by or through the entity shall be reduced by a number equal to at least 20 percent of the base number.

(iv) MANNER OF REDUCTION.—The reductions specified under the preceding provisions of this subparagraph for a qualifying entity shall be below the base number of residents for that entity and shall be fully effective not later than the 5th residency training year in which the application under subparagraph (B) is effective.

(v) ENTITIES PROVIDING ASSURANCE OF INCREASE IN PRIMARY CARE RESIDENTS.—An entity is described in this clause if—

(I) the base number of residents for the entity is less than 750 or the entity is described in subparagraph (C)(ii); and

(II) the entity represents in its application under subparagraph (B) that it will increase the number of full-time equivalent residents in primary care by at least 20 percent (from such number included in the base number of residents) by not later than the 5th residency training year in which the application under subparagraph (B) is effective.

If a qualifying entity fails to comply with the representation described in subclause (II) by the end of such 5th residency training year, the entity shall be subject to repayment of all amounts paid under this paragraph, in accordance with procedures established to carry out subparagraph (F).

(vi) BASE NUMBER OF RESIDENTS DEFINED.—For purposes of this paragraph, the term "base number of residents" means, with respect to a qualifying entity (or its par-

ticipating hospitals) operating approved medical residency training programs, the number of full-time equivalent residents in such programs (before application of weighting factors) of the entity as of the most recent residency training year ending before June 30, 1997, or, if less, for any subsequent residency training year that ends before the date the entity makes application under this paragraph.

(E) APPLICABLE HOLD HARMLESS PERCENTAGE.—For purposes of subparagraph (A), the "applicable hold harmless percentage" for the—

(i) first and second residency training years in which the reduction plan is in effect, 100 percent,

(ii) third such year, 75 percent,

(iii) fourth such year, 50 percent, and

(iv) fifth such year, 25 percent.

(F) PENALTY FOR NONCOMPLIANCE.—

(i) IN GENERAL.—No payment may be made under this paragraph to a hospital for a residency training year if the hospital has failed to reduce the number of full-time equivalent residents (in the manner required under subparagraph (D)) to the number agreed to by the Secretary and the qualifying entity in approving the application under this paragraph with respect to such year.

(ii) INCREASE IN NUMBER OF RESIDENTS IN SUBSEQUENT YEARS.—If payments are made under this paragraph to a hospital, and if the hospital increases the number of full-time equivalent residents above the number of such residents permitted under the reduction plan as of the completion of the plan, then, as specified by the Secretary, the entity is liable for repayment to the Secretary of the total amounts paid under this paragraph to the entity.

(G) TREATMENT OF ROTATING RESIDENTS.—In applying this paragraph, the Secretary shall establish rules regarding the counting of residents who are assigned to institutions the medical residency training programs in which are not covered under approved applications under this paragraph.

(7) REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.—

(A) REDUCTION IN LIMIT BASED ON UNUSED POSITIONS.—

(i) PROGRAMS SUBJECT TO REDUCTION.—

(I) IN GENERAL.—Except as provided in subclause (II), if a hospital's reference resident level (specified in clause (ii)) is less than the otherwise applicable resident limit (as defined in subparagraph (C)(ii)), effective for portions of cost reporting periods occurring on or after July 1, 2005, the otherwise applicable resident limit shall be reduced by 75 percent of the difference between such otherwise applicable resident limit and such reference resident level.

(II) EXCEPTION FOR SMALL RURAL HOSPITALS.—This subparagraph shall not apply to a hospital located in a rural area (as defined in subsection (d)(2)(D)(ii)) with fewer than 250 acute care inpatient beds.

(ii) REFERENCE RESIDENT LEVEL.—

(I) IN GENERAL.—Except as otherwise provided in subclauses (II) and (III), the reference resident level specified in this clause for a hospital is the resident level for the most recent cost reporting period of the hospital ending on or before September 30, 2002, for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

(II) USE OF MOST RECENT ACCOUNTING PERIOD TO RECOGNIZE EXPANSION OF EXISTING PROGRAMS.—If a hospital submits a timely request to increase its resident level due to an expansion of an existing residency training program that is not reflected on the most recent settled cost report, after audit and subject to the discretion of the Secretary, the reference resident level for such hospital is the resident level for the cost reporting period that includes July 1, 2003, as determined by the Secretary.

(III) EXPANSIONS UNDER NEWLY APPROVED PROGRAMS.—Upon the timely request of a hospital, the Secretary shall adjust the reference resident level specified under subclause (I) or (II) to include the number of medical residents that were approved in an application for a medical residency training program that was approved by an appropriate accrediting organization (as determined by the Secretary) before January 1, 2002, but which was not in operation during the cost

reporting period used under subclause (I) or (II), as the case may be, as determined by the Secretary.

(iii) AFFILIATION.—The provisions of clause (i) shall be applied to hospitals which are members of the same affiliated group (as defined by the Secretary under paragraph (4)(H)(ii)) as of July 1, 2003.

(B) REDISTRIBUTION.—

(i) IN GENERAL.—The Secretary is authorized to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2005. The aggregate number of increases in the otherwise applicable resident limits under this subparagraph may not exceed the Secretary's estimate of the aggregate reduction in such limits attributable to subparagraph (A).

(ii) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under clause (i), the Secretary shall take into account the demonstrated likelihood of the hospital filling the positions within the first 3 cost reporting periods beginning on or after July 1, 2005, made available under this subparagraph, as determined by the Secretary.

(iii) PRIORITY FOR RURAL AND SMALL URBAN AREAS.—In determining for which hospitals and residency training programs an increase in the otherwise applicable resident limit is provided under clause (i), the Secretary shall distribute the increase to programs of hospitals located in the following priority order:

(I) First, to hospitals located in rural areas (as defined in subsection (d)(2)(D)(ii)).

(II) Second, to hospitals located in urban areas that are not large urban areas (as defined for purposes of subsection (d)).

(III) Third, to other hospitals in a State if the residency training program involved is in a specialty for which there are not other residency training programs in the State.

Increases of residency limits within the same priority category under this clause shall be determined by the Secretary.

(iv) LIMITATION.—In no case shall more than 25 full-time equivalent additional residency positions be made available under this subparagraph with respect to any hospital.

(v) APPLICATION OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—With respect to additional residency positions in a hospital attributable to the increase provided under this subparagraph, notwithstanding any other provision of this subsection, the approved FTE resident amount is deemed to be equal to the locality adjusted national average per resident amount computed under paragraph (4)(E) for that hospital.

(vi) CONSTRUCTION.—Nothing in this subparagraph shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6), under a demonstration project approved as of October 31, 2003, under the authority of section 402 of Public Law 90–248, or as affecting the ability of a hospital to establish new medical residency training programs under paragraph (4)(H).

(C) RESIDENT LEVEL AND LIMIT DEFINED.—In this paragraph:

(i) RESIDENT LEVEL.—The term "resident level" means, with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under paragraph (4)), in the fields of allopathic and osteopathic medicine for the hospital.

(ii) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term "otherwise applicable resident limit" means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph.

(D) ADJUSTMENT BASED ON SETTLED COST REPORT.—In the case of a hospital with a dual accredited osteopathic and allopathic family practice program for which—

(i) the otherwise applicable resident limit was reduced under subparagraph (A)(i)(I); and

(ii) such reduction was based on a reference resident level that was determined using a cost report and where a revised or corrected notice of program reimbursement was issued for such cost report between September 1, 2006 and September 15, 2006, whether as a result of an appeal or otherwise, and the reference resident level under such settled cost report is higher than the level used for the reduction under subparagraph (A)(i)(I);

the Secretary shall apply subparagraph (A)(i)(I) using the higher resident reference level and make any necessary adjustments to such reduction. Any such necessary adjustments shall be effective for portions of cost reporting periods occurring on or after July 1, 2005.

(E) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, with respect to determinations made under this this paragraph, paragraph (8), or paragraph (4)(H)(vi).

(8) DISTRIBUTION OF ADDITIONAL RESIDENCY POSITIONS.—

(A) REDUCTIONS IN LIMIT BASED ON UNUSED POSITIONS.—

(i) IN GENERAL.—Except as provided in clause (ii), if a hospital's reference resident level (as defined in subparagraph (H)(i)) is less than the otherwise applicable resident limit (as defined in subparagraph (H)(iii)), effective for portions of cost reporting periods occurring on or after July 1, 2011, the otherwise applicable resident limit shall be reduced by 65 percent of the difference between such otherwise applicable resident limit and such reference resident level.

(ii) EXCEPTIONS.—This subparagraph shall not apply to—

(I) a hospital located in a rural area (as defined in subsection (d)(2)(D)(ii)) with fewer than 250 acute care inpatient beds;

(II) a hospital that was part of a qualifying entity which had a voluntary residency reduction plan approved under paragraph (6)(B) or under the authority of section 402 of Public Law 90–248, if the hospital demonstrates to the Secretary that it has a specified plan in place for filling the unused positions by not later than 2 years after the date of enactment of this paragraph; or

(III) a hospital described in paragraph (4)(H)(v).

(B) DISTRIBUTION.—

(i) IN GENERAL.—The Secretary shall increase the otherwise applicable resident limit for each qualifying hospital that submits an application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2011. The aggregate number of increases in the otherwise applicable resident limit under this subparagraph shall be equal to the aggregate reduction in such limits attributable to subparagraph (A) (as estimated by the Secretary).

(ii) REQUIREMENTS.—Subject to clause (iii), a hospital that receives an increase in the otherwise applicable resident limit under this subparagraph shall ensure, during the 5-year period beginning on the date of such increase, that—

(I) the number of full-time equivalent primary care residents, as defined in paragraph (5)(H) (as determined by the Secretary), excluding any additional positions under subclause (II), is not less than the average number of full-time equivalent primary care residents (as so determined) during the 3 most recent cost reporting periods ending prior to the date of enactment of this paragraph; and

(II) not less than 75 percent of the positions attributable to such increase are in a primary care or general surgery residency (as determined by the Secretary).

The Secretary may determine whether a hospital has met the requirements under this clause during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period.

(iii) REDISTRIBUTION OF POSITIONS IF HOSPITAL NO LONGER MEETS CERTAIN REQUIREMENTS.—In the case where the Secretary determines that a hospital described in clause (ii) does not meet either of the requirements under subclause (I) or (II) of such clause, the Secretary shall—

(I) reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this paragraph; and

(II) provide for the distribution of positions attributable to such reduction in accordance with the requirements of this paragraph.

(C) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subparagraph (B), the Secretary shall take into account—

(i) the demonstration likelihood of the hospital filling the positions made available under this paragraph within the first 3 cost reporting periods beginning on or after July 1, 2011, as determined by the Secretary; and

(ii) whether the hospital has an accredited rural training track (as described in paragraph (4)(H)(iv)).

(D) PRIORITY FOR CERTAIN AREAS.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subparagraph (B), subject to subparagraph (E), the Secretary shall distribute the increase to hospitals based on the following factors:

(i) Whether the hospital is located in a State with a resident-to-population ratio in the lowest quartile (as determined by the Secretary).

(ii) Whether the hospital is located in a State, a territory of the United States, or the District of Columbia that is among the top 10 States, territories, or Districts in terms of the ratio of—

(I) the total population of the State, territory, or District living in an area designated (under such section 332(a)(1)(A)) as a health professional shortage area (as of the date of enactment of this paragraph); to

(II) the total population of the State, territory, or District (as determined by the Secretary based on the most recent available population data published by the Bureau of the Census).

(iii) Whether the hospital is located in a rural area (as defined in subsection (d)(2)(D)(ii)).

(E) RESERVATION OF POSITIONS FOR CERTAIN HOSPITALS.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary shall reserve the positions available for distribution under this paragraph as follows:

(I) 70 percent of such positions for distribution to hospitals described in clause (i) of subparagraph (D).

(II) 30 percent of such positions for distribution to hospitals described in clause (ii) and (iii) of such subparagraph.

(ii) EXCEPTION IF POSITIONS NOT REDISTRIBUTED BY JULY 1, 2011.—In the case where the Secretary does not distribute positions to hospitals in accordance with clause (i) by July 1, 2011, the Secretary shall distribute such positions to other hospitals in accordance with the considerations described in subparagraph (C) and the priority described in subparagraph (D).

(F) LIMITATION.—A hospital may not receive more than 75 full-time equivalent additional residency positions under this paragraph.

(G) APPLICATION OF PER RESIDENT AMOUNTS FOR PRIMARY CARE AND NONPRIMARY CARE.—With respect to additional residency positions in a hospital attributable to the increase provided under this paragraph, the approved FTE per resident amounts are deemed to be equal to the hospital per resident amounts for primary care and nonprimary care computed under paragraph (2)(D) for that hospital.

(H) DEFINITIONS.—In this paragraph:

(i) REFERENCE RESIDENT LEVEL.—The term "reference resident level" means, with respect to a hospital, the highest resident level for any of the 3 most recent cost reporting periods (ending before the date of the enactment of this paragraph) of the hospital for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

(ii) RESIDENT LEVEL.—The term "resident level" has the meaning given such term in paragraph (7)(C)(i).

(iii) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term "otherwise applicable resident limit" means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraph (7)(A).

(I) AFFILIATION.—The provisions of this paragraph shall be applied to hospitals which are members of the same affiliated group (as defined by the Secretary under paragraph (4)(H)(ii)) and the reference resident level for each such hospital shall be the reference

resident level with respect to the cost reporting period that results in the smallest difference between the reference resident level and the otherwise applicable resident limit.

(i) AVOIDING DUPLICATIVE PAYMENTS TO HOSPITALS PARTICIPATING IN RURAL DEMONSTRATION PROGRAMS.—The Secretary shall reduce any payment amounts otherwise determined under this section to the extent necessary to avoid duplication of any payment made under section 4005(e) of the Omnibus Budget Reconciliation Act of 1987.

(j) PROSPECTIVE PAYMENT FOR INPATIENT REHABILITATION SERVICES.—

(1) PAYMENT DURING TRANSITION PERIOD.—

(A) IN GENERAL.—Notwithstanding section 1814(b), but subject to the provisions of section 1813, the amount of the payment with respect to the operating and capital costs of inpatient hospital services of a rehabilitation hospital or a rehabilitation unit (in this subsection referred to as a "rehabilitation facility"), other than a facility making an election under subparagraph (F) in a cost reporting period beginning on or after October 1, 2000, and before October 1, 2002, is equal to the sum of—

(i) the TEFRA percentage (as defined in subparagraph (C)) of the amount that would have been paid under part A with respect to such costs if this subsection did not apply, and

(ii) the prospective payment percentage (as defined in subparagraph (C)) of the product of (I) the per unit payment rate established under this subsection for the fiscal year in which the payment unit of service occurs, and (II) the number of such payment units occurring in the cost reporting period.

(B) FULLY IMPLEMENTED SYSTEM.—Notwithstanding section 1814(b), but subject to the provisions of section 1813, the amount of the payment with respect to the operating and capital costs of inpatient hospital services of a rehabilitation facility for a payment unit in a cost reporting period beginning on or after October 1, 2002, or, in the case of a facility making an election under subparagraph (F), for any cost reporting period described in such subparagraph, is equal to the per unit payment rate established under this subsection for the fiscal year in which the payment unit of service occurs.

(C) TEFRA AND PROSPECTIVE PAYMENT PERCENTAGES SPECIFIED.—For purposes of subparagraph (A), for a cost reporting period beginning—

(i) on or after October 1, 2000, and before October 1, 2001, the "TEFRA percentage" is 66⅔ percent and the "prospective payment percentage" is 33⅓ percent; and

(ii) on or after October 1, 2001, and before October 1, 2002, the "TEFRA percentage" is 33⅓ percent and the "prospective payment percentage" is 66⅔ percent.

(D) PAYMENT UNIT.—For purposes of this subsection, the term "payment unit" means a discharge.

(E) CONSTRUCTION RELATING TO TRANSFER AUTHORITY.—Nothing in this subsection shall be construed as preventing the Secretary from providing for an adjustment to payments to take into account the early transfer of a patient from a rehabilitation facility to another site of care.

(F) ELECTION TO APPLY FULL PROSPECTIVE PAYMENT SYSTEM.—A rehabilitation facility may elect, not later than 30 days before its first cost reporting period for which the payment methodology under this subsection applies to the facility, to have payment made to the facility under this subsection under the provisions of subparagraph (B) (rather than subparagraph (A)) for each cost reporting period to which such payment methodology applies.

(2) PATIENT CASE MIX GROUPS.—

(A) ESTABLISHMENT.—The Secretary shall establish—

(i) classes of patient discharges of rehabilitation facilities by functional-related groups (each in this subsection referred to as a "case mix group"), based on impairment, age, comorbidities, and functional capability of the patient and such other factors as the Secretary deems appropriate to improve the explanatory power of functional independence measure-function related groups; and

(ii) a method of classifying specific patients in rehabilitation facilities within these groups.

(B) WEIGHTING FACTORS.—For each case mix group the Secretary shall assign an appropriate weighting which reflects the relative facility resources used with respect to patients classified within that group compared to patients classified within other groups.

(C) ADJUSTMENTS FOR CASE MIX.—

(i) IN GENERAL.—The Secretary shall from time to time adjust the classifications and weighting factors established under this paragraph as appropriate to reflect changes in treatment patterns, technology, case mix, number of payment units for which payment is made under this title, and other factors which may affect the relative use of resources. Such adjustments shall be made in a manner so that changes in aggregate payments under the classification system are a result of real changes and are not a result of changes in coding that are unrelated to real changes in case mix.

(ii) ADJUSTMENT.—Insofar as the Secretary determines that such adjustments for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under the classification system during the fiscal year that are a result of changes in the coding or classification of patients that do not reflect real changes in case mix, the Secretary shall adjust the per payment unit payment rate for subsequent years so as to eliminate the effect of such coding or classification changes.

(D) DATA COLLECTION.—The Secretary is authorized to require rehabilitation facilities that provide inpatient hospital services to submit such data as the Secretary deems necessary to establish and administer the prospective payment system under this subsection.

(3) PAYMENT RATE.—

(A) IN GENERAL.—The Secretary shall determine a prospective payment rate for each payment unit for which such rehabilitation facility is entitled to receive payment under this title. Subject to subparagraph (B), such rate for payment units occurring during a fiscal year shall be based on the average payment per payment unit under this title for inpatient operating and capital costs of rehabilitation facilities using the most recent data available (as estimated by the Secretary as of the date of establishment of the system) adjusted—

(i) by updating such per-payment-unit amount to the fiscal year involved by the weighted average of the applicable percentage increases provided under subsection (b)(3)(B)(ii) (for cost reporting periods beginning during the fiscal year) covering the period from the midpoint of the period for such data through the midpoint of fiscal year 2000 and by an increase factor (described in subparagraph (C)) specified by the Secretary for subsequent fiscal years up to the fiscal year involved;

(ii) by reducing such rates by a factor equal to the proportion of payments under this subsection (as estimated by the Secretary) based on prospective payment amounts which are additional payments described in paragraph (4) (relating to outlier and related payments);

(iii) for variations among rehabilitation facilities by area under paragraph (6);

(iv) by the weighting factors established under paragraph (2)(B); and

(v) by such other factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities.

(B) BUDGET NEUTRAL RATES.—The Secretary shall establish the prospective payment amounts under this subsection for payment units during fiscal years 2001 and 2002 at levels such that, in the Secretary's estimation, the amount of total payments under this subsection for such fiscal years (including any payment adjustments pursuant to paragraphs (4) and (6) but not taking into account any payment adjustment resulting from an election permitted under paragraph (1)(F)) shall be equal to 98 percent for fiscal year 2001 and 100 percent for fiscal year 2002 of the amount of payments that would have been made under this title during the fiscal years for operating and capital costs of rehabilitation facilities had this subsection not been enacted. In establishing such payment amounts, the Secretary shall consider the effects of the prospective payment system established under this subsection on the total number of payment units from rehabilitation facilities and other factors described in subparagraph (A).

(C) INCREASE FACTOR.—

(i) IN GENERAL.—For purposes of this subsection for payment units in each fiscal year (beginning with fiscal year 2001), the Secretary shall establish an increase factor subject to clauses (ii) and (iii). Such factor shall be based on an appropriate percentage increase in a market basket of goods and services comprising services for which payment is made under this subsection, which may be the market basket percentage increase described in subsection (b)(3)(B)(iii). The increase factor to be applied under this subparagraph for each of fiscal years 2008 and 2009 shall be 0 percent.

(ii) PRODUCTIVITY AND OTHER ADJUSTMENT.—Subject to clause (iii), after establishing the increase factor described in clause (i) for a fiscal year, the Secretary shall reduce such increase factor—

(I) for fiscal year 2012 and each subsequent fiscal year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(II) for each of fiscal years 2010 through 2019, by the other adjustment described in subparagraph (D).

The application of this clause may result in the increase factor under this subparagraph being less than 0.0 for a fiscal year, and may result in payment rates under this subsection for a fiscal year being less than such payment rates for the preceding fiscal year.

(iii) SPECIAL RULE FOR FISCAL YEAR 2018.—The increase factor to be applied under this subparagraph for fiscal year 2018, after the application of clause (ii), shall be 1 percent.

(D) OTHER ADJUSTMENT.—For purposes of subparagraph (C)(ii)(II), the other adjustment described in this subparagraph is—

(i) for each of fiscal years 2010 and 2011, 0.25 percentage point;

(ii) for each of fiscal years 2012 and 2013, 0.1 percentage point;

(iii) for fiscal year 2014, 0.3 percentage point;

(iv) for each of fiscal years 2015 and 2016, 0.2 percentage point; and

(v) for each of fiscal years 2017, 2018, and 2019, 0.75 percentage point.

(4) OUTLIER AND SPECIAL PAYMENTS.—

(A) OUTLIERS.—

(i) IN GENERAL.—The Secretary may provide for an additional payment to a rehabilitation facility for patients in a case mix group, based upon the patient being classified as an outlier based on an unusual length of stay, costs, or other factors specified by the Secretary.

(ii) PAYMENT BASED ON MARGINAL COST OF CARE.—The amount of such additional payment under clause (i) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the cutoff point applicable under clause (i).

(iii) TOTAL PAYMENTS.—The total amount of the additional payments made under this subparagraph for payment units in a fiscal year may not exceed 5 percent of the total payments projected or estimated to be made based on prospective payment rates for payment units in that year.

(B) ADJUSTMENT.—The Secretary may provide for such adjustments to the payment amounts under this subsection as the Secretary deems appropriate to take into account the unique circumstances of rehabilitation facilities located in Alaska and Hawaii.

(5) PUBLICATION.—The Secretary shall provide for publication in the Federal Register, on or before August 1 before each fiscal year (beginning with fiscal year 2001), of the classification and weighting factors for case mix groups under paragraph (2) for such fiscal year and a description of the methodology and data used in computing the prospective payment rates under this subsection for that fiscal year.

(6) AREA WAGE ADJUSTMENT.—The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of rehabilitation facilities' costs which are attributable to wages and wage-related costs, of the prospective payment rates computed under paragraph (3) for area differences in wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for such facilities. Not later than October 1, 2001 (and at least every 36 months thereafter), the Secretary shall update the factor under the preceding sentence on the basis of information available to the Secretary (and updated as appropriate) of the wages and wage-related costs incurred in furnishing rehabilitation services. Any adjustments or updates made under this paragraph for a fiscal year shall be made in a manner that assures that the aggregated payments under this subsection in the fiscal year are not greater or less than those that would have been made in the year without such adjustment.

(7) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—For purposes of fiscal year 2014 and each subsequent fiscal year, in the case of a rehabilitation facility that does not submit data to the Secretary in accordance with subparagraphs (C) and (F) with respect to such a fiscal year, after

determining the increase factor described in paragraph (3)(C), and after application of subparagraphs (C)(iii) and (D) of paragraph (3), the Secretary shall reduce such increase factor for payments for discharges occurring during such fiscal year by 2 percentage points.

(ii) SPECIAL RULE.—The application of this subparagraph may result in the increase factor described in paragraph (3)(C) being less than 0.0 for a fiscal year, and may result in payment rates under this subsection for a fiscal year being less than such payment rates for the preceding fiscal year.

(B) NONCUMULATIVE APPLICATION.—Any reduction under subparagraph (A) shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the payment amount under this subsection for a subsequent fiscal year.

(C) SUBMISSION OF QUALITY DATA.—Subject to subparagraph (G), for fiscal year 2014 and each subsequent fiscal year, each rehabilitation facility shall submit to the Secretary data on quality measures specified under subparagraph (D). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) QUALITY MEASURES.—

(i) IN GENERAL.—Subject to clause (ii), any measure specified by the Secretary under this subparagraph must have been endorsed by the entity with a contract under section 1890(a).

(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(iii) TIME FRAME.—Not later than October 1, 2012, the Secretary shall publish the measures selected under this subparagraph that will be applicable with respect to fiscal year 2014.

(E) PUBLIC AVAILABILITY OF DATA SUBMITTED.—The Secretary shall establish procedures for making data submitted under subparagraph (C) and subparagraph (F)(i) available to the public. Such procedures shall ensure that a rehabilitation facility has the opportunity to review the data that is to be made public with respect to the facility prior to such data being made public. The Secretary shall report quality measures that relate to services furnished in inpatient settings in rehabilitation facilities on the Internet website of the Centers for Medicare & Medicaid Services.

(F) SUBMISSION OF ADDITIONAL DATA.—

(i) IN GENERAL.—For the fiscal year beginning on the specified application date (as defined in subsection (a)(2)(E) of section 1899B), as applicable with respect to inpatient rehabilitation facilities and quality measures under subsection (c)(1) of such section and measures under subsection (d)(1) of such section, and each subsequent fiscal year, in addition to such data on the quality measures described in subparagraph (C), each rehabilitation facility shall submit to the Secretary data on the quality measures under such subsection (c)(1) and any necessary data specified by the Secretary under such subsection (d)(1).

(ii) STANDARDIZED PATIENT ASSESSMENT DATA.—For fiscal year 2019 and each subsequent fiscal year, in addition to such data described in clause (i), each rehabilitation facility shall submit to the Secretary standardized patient assessment data required under subsection (b)(1) of section 1899B.

(iii) SUBMISSION.—Such data shall be submitted in the form and manner, and at the time, specified by the Secretary for purposes of this subparagraph.

(G) NON-DUPLICATION.—To the extent data submitted under subparagraph (F) duplicates other data required to be submitted under subparagraph (C), the submission of such data under subparagraph (F) shall be in lieu of the submission of such data under subparagraph (C). The previous sentence shall not apply insofar as the Secretary determines it is necessary to avoid a delay in the implementation of section 1899B, taking into account the different specified application dates under subsection (a)(2)(E) of such section.

(8) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise of the establishment of—

(A) case mix groups, of the methodology for the classification of patients within such groups, and of the appropriate weighting factors thereof under paragraph (2),

(B) the prospective payment rates under paragraph (3),

(C) outlier and special payments under paragraph (4), and

(D) area wage adjustments under paragraph (6).

(k) PAYMENT TO NONHOSPITAL PROVIDERS.—

(1) IN GENERAL.—For cost reporting periods beginning on or after October 1, 1997, the Secretary may establish rules for payment to qualified nonhospital providers for their direct costs of medical education, if those costs are incurred in the operation of an approved medical residency training program described in subsection (h). Such rules shall specify the amounts, form, and manner in which such payments will be made and the portion of such payments that will be made from each of the trust funds under this title.

(2) QUALIFIED NONHOSPITAL PROVIDERS.—For purposes of this subsection, the term "qualified nonhospital providers" means—

(A) a Federally qualified health center, as defined in section 1861(aa)(4);

(B) a rural health clinic, as defined in section 1861(aa)(2);

(C) Medicare+Choice organizations; and

(D) such other providers (other than hospitals) as the Secretary determines to be appropriate.

(l) PAYMENT FOR NURSING AND ALLIED HEALTH EDUCATION FOR MANAGED CARE ENROLLEES.—

(1) IN GENERAL.—For portions of cost reporting periods occurring in a year (beginning with 2000), the Secretary shall provide for an additional payment amount for any hospital that receives payments for the costs of approved educational activities for nurse and allied health professional training under section 1861(v)(1).

(2) PAYMENT AMOUNT.—The additional payment amount under this subsection for each hospital for portions of cost reporting periods occurring in a year shall be an amount specified by the Secretary in a manner consistent with the following:

(A) DETERMINATION OF MANAGED CARE ENROLLEE PAYMENT RATIO FOR GRADUATE MEDICAL EDUCATION PAYMENTS.—The Secretary shall estimate the ratio of payments for all hospitals for portions of cost reporting periods occurring in the year under subsection (h)(3)(D) to total direct graduate medical education payments estimated for such portions of periods under subsection (h)(3).

(B) APPLICATION TO FEE-FOR-SERVICE NURSING AND ALLIED HEALTH EDUCATION PAYMENTS.—Such ratio shall be applied to the Secretary's estimate of total payments for nursing and allied health education determined under section 1861(v) for portions of cost reporting periods occurring in the year to determine a total amount of additional payments for nursing and allied health education to be distributed to hospitals under this subsection for portions of cost reporting periods occurring in the year; except that in no case shall such total amount exceed $60,000,000 in any year.

(C) APPLICATION TO HOSPITAL.—The amount of payment under this subsection to a hospital for portions of cost reporting periods occurring in a year is equal to the total amount of payments determined under subparagraph (B) for the year multiplied by the ratio of—

(i) the product of (I) the Secretary's estimate of the ratio of the amount of payments made under section 1861(v) to the hospital for nursing and allied health education activities for the hospital's cost reporting period ending in the second preceding fiscal year, to the hospital's total inpatient days for such period, and (II) the total number of inpatient days (as established by the Secretary) for such period which are attributable to services furnished to individuals who are enrolled under a risk sharing contract with an eligible organization under section 1876 and who are entitled to benefits under part A or who are enrolled with a Medicare+Choice organization under part C; to

(ii) the sum of the products determined under clause (i) for such cost reporting periods.

(m) PROSPECTIVE PAYMENT FOR LONG-TERM CARE HOSPITALS.—

(1) REFERENCE TO ESTABLISHMENT AND IMPLEMENTATION OF SYSTEM.—For provisions related to the establishment and implementation of a prospective payment system for payments

under this title for inpatient hospital services furnished by a long-term care hospital described in subsection (d)(1)(B)(iv), see section 123 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.

(2) UPDATE FOR RATE YEAR 2008.—In implementing the system described in paragraph (1) for discharges occurring during the rate year ending in 2008 for a hospital, the base rate for such discharges for the hospital shall be the same as the base rate for discharges for the hospital occurring during the rate year ending in 2007.

(3) IMPLEMENTATION FOR RATE YEAR 2010 AND SUBSEQUENT YEARS.—

(A) IN GENERAL.—Subject to subparagraph (C), in implementing the system described in paragraph (1) for rate year 2010 and each subsequent rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, shall be reduced—

(i) for rate year 2012 and each subsequent rate year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(ii) for each of rate years 2010 through 2019, by the other adjustment described in paragraph (4).

(B) SPECIAL RULE.—The application of this paragraph may result in such annual update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(C) ADDITIONAL SPECIAL RULE.—For fiscal year 2018, the annual update under subparagraph (A) for the fiscal year, after application of clauses (i) and (ii) of subparagraph (A), shall be 1 percent.

(4) OTHER ADJUSTMENT.—For purposes of paragraph (3)(A)(ii), the other adjustment described in this paragraph is—

(A) for rate year 2010, 0.25 percentage point;

(B) for rate year 2011, 0.50 percentage point;

(C) for each of the rate years beginning in 2012 and 2013, 0.1 percentage point;

(D) for rate year 2014, 0.3 percentage point;

(E) for each of rate years 2015 and 2016, 0.2 percentage point; and

(F) for each of rate years 2017, 2018, and 2019, 0.75 percentage point.

(5) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—Under the system described in paragraph (1), for rate year 2014 and each subsequent rate year, in the case of a long-term care hospital that does not submit data to the Secretary in accordance with subparagraphs (C) and (F) with respect to such a rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of paragraph (3), shall be reduced by 2 percentage points.

(ii) SPECIAL RULE.—The application of this subparagraph may result in such annual update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(B) NONCUMULATIVE APPLICATION.—Any reduction under subparagraph (A) shall apply only with respect to the rate year involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in paragraph (1) for a subsequent rate year.

(C) SUBMISSION OF QUALITY DATA.—Subject to subparagraph (G), for rate year 2014 and each subsequent rate year, each long-term care hospital shall submit to the Secretary data on quality measures specified under subparagraph (D). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) QUALITY MEASURES.—

(i) IN GENERAL.—Subject to clause (ii), any measure specified by the Secretary under this subparagraph must have been endorsed by the entity with a contract under section 1890(a).

(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been en-

dorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(iii) TIME FRAME.—Not later than October 1, 2012, the Secretary shall publish the measures selected under this subparagraph that will be applicable with respect to rate year 2014.

(iv) ADDITIONAL QUALITY MEASURES.—Not later than October 1, 2015, the Secretary shall establish a functional status quality measure for change in mobility among inpatients requiring ventilator support.

(E) PUBLIC AVAILABILITY OF DATA SUBMITTED.—The Secretary shall establish procedures for making data submitted under subparagraph (C) and subparagraph (F)(i) available to the public. Such procedures shall ensure that a long-term care hospital has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures that relate to services furnished in inpatient settings in long-term care hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(F) SUBMISSION OF ADDITIONAL DATA.—

(i) IN GENERAL.—For the rate year beginning on the specified application date (as defined in subsection (a)(2)(E) of section 1899B), as applicable with respect to long-term care hospitals and quality measures under subsection (c)(1) of such section and measures under subsection (d)(1) of such section, and each subsequent rate year, in addition to the data on the quality measures described in subparagraph (C), each long-term care hospital (other than a hospital classified under subsection (d)(1)(B)(vi)) shall submit to the Secretary data on the quality measures under such subsection (c)(1) and any necessary data specified by the Secretary under such subsection (d)(1).

(ii) STANDARDIZED PATIENT ASSESSMENT DATA.—For rate year 2019 and each subsequent rate year, in addition to such data described in clause (i), each long-term care hospital (other than a hospital classified under subsection (d)(1)(B)(vi)) shall submit to the Secretary standardized patient assessment data required under subsection (b)(1) of section 1899B.

(iii) SUBMISSION.—Such data shall be submitted in the form and manner, and at the time, specified by the Secretary for purposes of this subparagraph.

(G) NON-DUPLICATION.—To the extent data submitted under subparagraph (F) duplicates other data required to be submitted under subparagraph (C), the submission of such data under subparagraph (F) shall be in lieu of the submission of such data under subparagraph (C). The previous sentence shall not apply insofar as the Secretary determines it is necessary to avoid a delay in the implementation of section 1899B, taking into account the different specified application dates under subsection (a)(2)(E) of such section.

(6) APPLICATION OF SITE NEUTRAL IPPS PAYMENT RATE IN CERTAIN CASES.—

(A) GENERAL APPLICATION OF SITE NEUTRAL IPPS PAYMENT AMOUNT FOR DISCHARGES FAILING TO MEET APPLICABLE CRITERIA.—

(i) IN GENERAL.—For a discharge in cost reporting periods beginning on or after October 1, 2015, except as provided in clause (ii) and subparagraphs (C), (E), (F), and (G), payment under this title to a long-term care hospital for inpatient hospital services shall be made at the applicable site neutral payment rate (as defined in subparagraph (B)).

(ii) EXCEPTION FOR CERTAIN DISCHARGES MEETING CRITERIA.—Clause (i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) for a discharge if—

(I) the discharge meets the ICU criterion under clause (iii) or the ventilator criterion under clause (iv); and

(II) the discharge does not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation.

(iii) INTENSIVE CARE UNIT (ICU) CRITERION.—

(I) IN GENERAL.—The criterion specified in this clause (in this paragraph referred to as the "ICU criterion"), for a discharge from a long-term care hospital, is that the stay in the long-term care hospital ending with such discharge was immediately preceded by a discharge from a stay in a subsection (d) hospital that

included at least 3 days in an intensive care unit (ICU), as determined by the Secretary.

(II) DETERMINING ICU DAYS.—In determining intensive care unit days under subclause (I), the Secretary shall use data from revenue center codes 020x or 021x (or such successor codes as the Secretary may establish).

(iv) VENTILATOR CRITERION.—The criterion specified in this clause (in this paragraph referred to as the "ventilator criterion"), for a discharge from a long-term care hospital, is that—

(I) the stay in the long-term care hospital ending with such discharge was immediately preceded by a discharge from a stay in a subsection (d) hospital; and

(II) the individual discharged was assigned to a Medicare-Severity-Long-Term-Care-Diagnosis-Related-Group (MS–LTC–DRG) based on the receipt of ventilator services of at least 96 hours.

(B) APPLICABLE SITE NEUTRAL PAYMENT RATE DEFINED.—

(i) IN GENERAL.—In this paragraph, the term "applicable site neutral payment rate" means—

(I) for discharges in cost reporting periods beginning during fiscal years 2016 through 2019, the blended payment rate specified in clause (iii); and

(II) for discharges in cost reporting periods beginning during fiscal year 2020 or a subsequent fiscal year, the site neutral payment rate (as defined in clause (ii)).

(ii) SITE NEUTRAL PAYMENT RATE DEFINED.—Subject to clause (iv), in this paragraph, the term "site neutral payment rate" means the lower of—

(I) the IPPS comparable per diem amount determined under paragraph (d)(4) of section 412.529 of title 42, Code of Federal Regulations, including any applicable outlier payments under section 412.525 of such title; or

(II) 100 percent of the estimated cost for the services involved.

(iii) BLENDED PAYMENT RATE.—The blended payment rate specified in this clause, for a long-term care hospital for inpatient hospital services for a discharge, is comprised of—

(I) half of the site neutral payment rate (as defined in clause (ii)) for the discharge; and

(II) half of the payment rate that would otherwise be applicable to such discharge without regard to this paragraph, as determined by the Secretary.

(iv) ADJUSTMENT.—For each of fiscal years 2018 through 2026, the amount that would otherwise apply under clause (ii)(I) for the year (determined without regard to this clause) shall be reduced by 4.6 percent.

(C) LIMITING PAYMENT FOR ALL HOSPITAL DISCHARGES TO SITE NEUTRAL PAYMENT RATE FOR HOSPITALS FAILING TO MEET APPLICABLE LTCH DISCHARGE THRESHOLDS.—

(i) NOTICE OF LTCH DISCHARGE PAYMENT PERCENTAGE.—For cost reporting periods beginning during or after fiscal year 2016, the Secretary shall inform each long-term care hospital of its LTCH discharge payment percentage (as defined in clause (iv)) for such period.

(ii) LIMITATION.—For cost reporting periods beginning during or after fiscal year 2020, if the Secretary determines for a long-term care hospital that its LTCH discharge payment percentage for the period is not at least 50 percent—

(I) the Secretary shall inform the hospital of such fact; and

(II) subject to clause (iii), for all discharges in the hospital in each succeeding cost reporting period, the payment amount under this subsection shall be the payment amount that would apply under subsection (d) for the discharge if the hospital were a subsection (d) hospital.

(iii) PROCESS FOR REINSTATEMENT.—The Secretary shall establish a process whereby a long-term care hospital may seek to and have the provisions of subclause (II) of clause (ii) discontinued with respect to that hospital.

(iv) LTCH DISCHARGE PAYMENT PERCENTAGE.—In this subparagraph, the term "LTCH discharge payment percentage" means, with respect to a long-term care hospital for a cost reporting period beginning during or after fiscal year 2020, the ratio (expressed as a percentage) of—

(I) the number of Medicare fee-for-service discharges for such hospital and period for which payment is not made at the site neutral payment rate, to

(II) the total number of Medicare fee-for-service discharges for such hospital and period.

(D) INCLUSION OF SUBSECTION (d) PUERTO RICO HOSPITALS.—In this paragraph, any reference in this paragraph to a subsection (d) hospital shall be deemed to include a reference to a subsection (d) Puerto Rico hospital.

(E) TEMPORARY EXCEPTION FOR CERTAIN SEVERE WOUND DISCHARGES FROM CERTAIN LONG-TERM CARE HOSPITALS.—

(i) IN GENERAL.—In the case of a discharge occurring prior to January 1, 2017, subparagraph (A)(i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) if such discharge—

(I) is from a long-term care hospital that is—

(aa) identified by the last sentence of subsection (d)(1)(B); and

(bb) located in a rural area (as defined in subsection (d)(2)(D)) or treated as being so located pursuant to subsection (d)(8)(E); and

(II) the individual discharged has a severe wound.

(ii) SEVERE WOUND DEFINED.—In this subparagraph, the term "severe wound" means a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, infected wound, fistula, osteomyelitis, or wound with morbid obesity, as identified in the claim from the long-term care hospital.

(F) TEMPORARY EXCEPTION FOR CERTAIN SPINAL CORD SPECIALTY HOSPITALS.—For discharges in cost reporting periods beginning during fiscal years 2018 and 2019, subparagraph (A)(i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) if such discharge is from a long-term care hospital that meets each of the following requirements:

(i) NOT-FOR-PROFIT.—The long-term care hospital was a not-for-profit long-term care hospital on June 1, 2014, as determined by cost report data.

(ii) PRIMARILY PROVIDING TREATMENT FOR CATASTROPHIC SPINAL CORD OR ACQUIRED BRAIN INJURIES OR OTHER PARALYZING NEUROMUSCULAR CONDITIONS.—Of the discharges in calendar year 2013 from the long-term care hospital for which payment was made under this section, at least 50 percent were classified under MS–LTCH–DRGs 28, 29, 52, 57, 551, 573, and 963.

(iii) SIGNIFICANT OUT-OF-STATE ADMISSIONS.—

(I) IN GENERAL.—The long-term care hospital discharged inpatients (including both individuals entitled to, or enrolled for, benefits under this title and individuals not so entitled or enrolled) during fiscal year 2014 who had been admitted from at least 20 of the 50 States, determined by the States of residency of such inpatients and based on such data submitted by the hospital to the Secretary as the Secretary may require.

(II) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement subclause (I) by program instruction or otherwise.

(III) NON-APPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to data collected under this clause.

(G) ADDITIONAL TEMPORARY EXCEPTION FOR CERTAIN SEVERE WOUND DISCHARGES FROM CERTAIN LONG-TERM CARE HOSPITALS.—

(i) IN GENERAL.—For a discharge occurring in a cost reporting period beginning during fiscal year 2018, subparagraph (A)(i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) if such discharge—

(I) is from a long-term care hospital identified by the last sentence of subsection (d)(1)(B);

(II) is classified under MS–LTCH–DRG 602, 603, 539, or 540; and

(III) is with respect to an individual treated by a long-term care hospital for a severe wound.

(ii) SEVERE WOUND DEFINED.—In this subparagraph, the term "severe wound" means a wound which is a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, or fistula as identified in the claim from the long-term care hospital.

(iii) WOUND DEFINED.—In this subparagraph, the term "wound" means an injury involving division of tissue or rupture of the integument or mucous membrane with exposure to the external environment.

(7) TREATMENT OF HIGH COST OUTLIER PAYMENTS.—

(A) ADJUSTMENT TO THE STANDARD FEDERAL PAYMENT RATE FOR ESTIMATED HIGH COST OUTLIER PAYMENTS.—Under the system described in paragraph (1), for fiscal years beginning on or after October 1, 2017, the Secretary shall reduce the standard Federal payment rate as if the estimated aggregate amount of high cost outlier payments for standard Federal payment rate discharges for each such fiscal year would be equal to 8 percent of estimated aggregate payments for standard Federal payment rate discharges for each such fiscal year.

(B) LIMITATION ON HIGH COST OUTLIER PAYMENT AMOUNTS.—Notwithstanding subparagraph (A), the Secretary shall set the fixed loss amount for high cost outlier payments such that the estimated aggregate amount of high cost outlier payments made for standard Federal payment rate discharges for fiscal years beginning on or after October 1, 2017, shall be equal to 99.6875 percent of 8 percent of estimated aggregate payments for standard Federal payment rate discharges for each such fiscal year.

(C) WAIVER OF BUDGET NEUTRALITY.—Any reduction in payments resulting from the application of subparagraph (B) shall not be taken into account in applying any budget neutrality provision under such system.

(D) NO EFFECT ON SITE NEUTRAL HIGH COST OUTLIER PAYMENT RATE.—This paragraph shall not apply with respect to the computation of the applicable site neutral payment rate under paragraph (6).

(n) INCENTIVES FOR ADOPTION AND MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—

(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, with respect to inpatient hospital services furnished by an eligible hospital during a payment year (as defined in paragraph (2)(G)), if the eligible hospital is a meaningful EHR user (as determined under paragraph (3)) for the EHR reporting period with respect to such year, in addition to the amount otherwise paid under this section, there also shall be paid to the eligible hospital, from the Federal Hospital Insurance Trust Fund established under section 1817, an amount equal to the applicable amount specified in paragraph (2)(A) for the hospital for such payment year.

(2) PAYMENT AMOUNT.—

(A) IN GENERAL.—Subject to the succeeding subparagraphs of this paragraph, the applicable amount specified in this subparagraph for an eligible hospital for a payment year is equal to the product of the following:

(i) INITIAL AMOUNT.—The sum of—

(I) the base amount specified in subparagraph (B); plus

(II) the discharge related amount specified in subparagraph (C) for a 12-month period selected by the Secretary with respect to such payment year.

(ii) MEDICARE SHARE.—The Medicare share as specified in subparagraph (D) for the eligible hospital for a period selected by the Secretary with respect to such payment year.

(iii) TRANSITION FACTOR.—The transition factor specified in subparagraph (E) for the eligible hospital for the payment year.

(B) BASE AMOUNT.—The base amount specified in this subparagraph is $2,000,000.

(C) DISCHARGE RELATED AMOUNT.—The discharge related amount specified in this subparagraph for a 12-month period selected by the Secretary shall be determined as the sum of the amount, estimated based upon total discharges for the eligible hospital (regardless of any source of payment) for the period, for each discharge up to the 23,000th discharge as follows:

(i) For the first through 1,149th discharge, $0.

(ii) For the 1,150th through the 23,000th discharge, $200.

(iii) For any discharge greater than the 23,000th, $0.

(D) MEDICARE SHARE.—The Medicare share specified under this subparagraph for an eligible hospital for a period selected by the Secretary for a payment year is equal to the fraction—

(i) the numerator of which is the sum (for such period and with respect to the eligible hospital) of—

(I) the estimated number of inpatient-bed-days (as established by the Secretary) which are attributable to individuals with respect to whom payment may be made under part A; and

(II) the estimated number of inpatient-bed-days (as so established) which are attributable to individuals who are enrolled with a Medicare Advantage organization under part C; and

(ii) the denominator of which is the product of—

(I) the estimated total number of inpatient-bed-days with respect to the eligible hospital during such period; and

(II) the estimated total amount of the eligible hospital's charges during such period, not including any charges that are attributable to charity care (as such term is used for purposes of hospital cost reporting under this title), divided by the estimated total amount of the hospital's charges during such period.

Insofar as the Secretary determines that data are not available on charity care necessary to calculate the portion of the formula specified in clause (ii)(II), the Secretary shall use data on uncompensated care and may adjust such data so as to be an appropriate proxy for charity care including a downward adjustment to eliminate bad debt data from uncompensated care data. In the absence of the data necessary, with respect to a hospital, for the Secretary to compute the amount described in clause (ii)(II), the amount under such clause shall be deemed to be 1. In the absence of data, with respect to a hospital, necessary to compute the amount described in clause (i)(II), the amount under such clause shall be deemed to be 0.

(E) TRANSITION FACTOR SPECIFIED.—

(i) IN GENERAL.—Subject to clause (ii), the transition factor specified in this subparagraph for an eligible hospital for a payment year is as follows:

(I) For the first payment year for such hospital, 1.

(II) For the second payment year for such hospital, ¾.

(III) For the third payment year for such hospital, ½.

(IV) For the fourth payment year for such hospital, ¼.

(V) For any succeeding payment year for such hospital, 0.

(ii) PHASE DOWN FOR ELIGIBLE HOSPITALS FIRST ADOPTING EHR AFTER 2013.—If the first payment year for an eligible hospital is after 2013, then the transition factor specified in this subparagraph for a payment year for such hospital is the same as the amount specified in clause (i) for such payment year for an eligible hospital for which the first payment year is 2013. If the first payment year for an eligible hospital is after 2015 then the transition factor specified in this subparagraph for such hospital and for such year and any subsequent year shall be 0.

(F) FORM OF PAYMENT.—The payment under this subsection for a payment year may be in the form of a single consolidated payment or in the form of such periodic installments as the Secretary may specify.

(G) PAYMENT YEAR DEFINED.—

(i) IN GENERAL.—For purposes of this subsection, the term "payment year" means a fiscal year beginning with fiscal year 2011.

(ii) FIRST, SECOND, ETC. PAYMENT YEAR.—The term "first payment year" means, with respect to inpatient hospital services furnished by an eligible hospital, the first fiscal year for which an incentive payment is made for such services under this subsection. The terms "second payment year", "third payment year", and "fourth payment year" mean, with respect to an eligible hospital, each successive year immediately following the first payment year for that hospital.

(3) MEANINGFUL EHR USER.—

(A) IN GENERAL.—For purposes of paragraph (1), an eligible hospital shall be treated as a meaningful EHR user for an EHR reporting period for a payment year (or, for purposes of subsection (b)(3)(B)(ix), for an EHR reporting period under such subsection for a fiscal year) if each of the following requirements are met:

(i) MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—The eligible hospital demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period the hospital is using certified EHR technology in a meaningful manner.

(ii) INFORMATION EXCHANGE.—The eligible hospital demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination, and the hospital demonstrates (through a process specified by the Secretary, such as the use of an attestation) that the hospital has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology.

(iii) REPORTING ON MEASURES USING EHR.—Subject to subparagraph (B)(ii) and using such certified EHR technology, the eligible hospital submits information for such period, in a form and manner specified by the Secretary, on such clinical quality measures and such other measures as selected by the Secretary under subparagraph (B)(i).

The Secretary shall seek to improve the use of electronic health records and health care quality over time.

(B) REPORTING ON MEASURES.—

(i) SELECTION.—The Secretary shall select measures for purposes of subparagraph (A)(iii) but only consistent with the following:

(I) The Secretary shall provide preference to clinical quality measures that have been selected for purposes of applying subsection (b)(3)(B)(viii) or that have been endorsed by the entity with a contract with the Secretary under section 1890(a).

(II) Prior to any measure (other than a clinical quality measure that has been selected for purposes of applying subsection (b)(3)(B)(viii)) being selected under this subparagraph, the Secretary shall publish in the Federal Register such measure and provide for a period of public comment on such measure.

(ii) LIMITATIONS.—The Secretary may not require the electronic reporting of information on clinical quality measures under subparagraph (A)(iii) unless the Secretary has the capacity to accept the information electronically, which may be on a pilot basis.

(iii) COORDINATION OF REPORTING OF INFORMATION.—In selecting such measures, and in establishing the form and manner for reporting measures under subparagraph (A)(iii), the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under subsection (b)(3)(B)(viii).

(C) DEMONSTRATION OF MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY AND INFORMATION EXCHANGE.—

(i) IN GENERAL.—An eligible hospital may satisfy the demonstration requirement of clauses (i) and (ii) of subparagraph (A) through means specified by the Secretary, which may include—

(I) an attestation;

(II) the submission of claims with appropriate coding (such as a code indicating that inpatient care was documented using certified EHR technology);

(III) a survey response;

(IV) reporting under subparagraph (A)(iii); and

(V) other means specified by the Secretary.

(ii) USE OF PART D DATA.—Notwithstanding sections 1860D–15(d)(2)(B) and 1860D–15(f)(2), the Secretary may use data regarding drug claims submitted for purposes of section 1860D–15 that are necessary for purposes of subparagraph (A).

(4) APPLICATION.—

(A) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

(i) the methodology and standards for determining payment amounts under this subsection and payment adjustments under subsection (b)(3)(B)(ix), including selection of periods under paragraph (2) for determining, and making estimates or using proxies of, discharges under paragraph (2)(C) and inpatient-bed-days, hospital charges, charity charges, and Medicare share under paragraph (2)(D);

(ii) the methodology and standards for determining a meaningful EHR user under paragraph (3), including selection of measures under paragraph (3)(B), specification of

the means of demonstrating meaningful EHR use under paragraph (3)(C), and the hardship exception under subsection (b)(3)(B)(ix)(II); and

(iii) the specification of EHR reporting periods under paragraph (6)(B) and the selection of the form of payment under paragraph (2)(F).

(B) POSTING ON WEBSITE.—The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names of the eligible hospitals that are meaningful EHR users under this subsection or subsection (b)(3)(B)(ix) (and a list of the names of critical access hospitals to which paragraph (3) or (4) of section 1814(l) applies), and other relevant data as determined appropriate by the Secretary. The Secretary shall ensure that an eligible hospital (or critical access hospital) has the opportunity to review the other relevant data that are to be made public with respect to the hospital (or critical access hospital) prior to such data being made public.

(5) CERTIFIED EHR TECHNOLOGY DEFINED.—The term "certified EHR technology" has the meaning given such term in section 1848(o)(4).

(6) DEFINITIONS.—For purposes of this subsection:

(A) EHR REPORTING PERIOD.—The term "EHR reporting period" means, with respect to a payment year, any period (or periods) as specified by the Secretary.

(B) ELIGIBLE HOSPITAL.—The term "eligible hospital" means a hospital that is a subsection (d) hospital or a subsection (d) Puerto Rico hospital.

(o) HOSPITAL VALUE-BASED PURCHASING PROGRAM.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, the Secretary shall establish a hospital value-based purchasing program (in this subsection referred to as the "Program") under which value-based incentive payments are made in a fiscal year to hospitals that meet the performance standards under paragraph (3) for the performance period for such fiscal year (as established under paragraph (4)).

(B) PROGRAM TO BEGIN IN FISCAL YEAR 2013.—The Program shall apply to payments for discharges occurring on or after October 1, 2012.

(C) APPLICABILITY OF PROGRAM TO HOSPITALS.—

(i) IN GENERAL.—For purposes of this subsection, subject to clause (ii), the term "hospital" means a subsection (d) hospital (as defined in subsection (d)(1)(B)).

(ii) EXCLUSIONS.—The term "hospital" shall not include, with respect to a fiscal year, a hospital—

(I) that is subject to the payment reduction under subsection (b)(3)(B)(viii)(I) for such fiscal year;

(II) for which, during the performance period for such fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients;

(III) for which there are not a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for such fiscal year; or

(IV) for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for such fiscal year.

(iii) INDEPENDENT ANALYSIS.—For purposes of determining the minimum numbers under subclauses (III) and (IV) of clause (ii), the Secretary shall have conducted an independent analysis of what numbers are appropriate.

(iv) EXEMPTION.—In the case of a hospital that is paid under section 1814(b)(3), the Secretary may exempt such hospital from the application of this subsection if the State which is paid under such section submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under this subsection.

(2) MEASURES.—

(A) IN GENERAL.—The Secretary shall select measures, other than measures of readmissions, for purposes of the Program. Such measures shall be selected from the measures specified under subsection (b)(3)(B)(viii).

(B) REQUIREMENTS.—

(i) FOR FISCAL YEAR 2013.—For value-based incentive payments made with respect to discharges occurring during fiscal year 2013, the Secretary shall ensure the following:

(I) CONDITIONS OR PROCEDURES.—Measures are selected under subparagraph (A) that cover at least the following 5 specific conditions or procedures:

(aa) Acute myocardial infarction (AMI).

(bb) Heart failure.

(cc) Pneumonia.

(dd) Surgeries, as measured by the Surgical Care Improvement Project (formerly referred to as "Surgical Infection Prevention" for discharges occurring before July 2006).

(ee) Healthcare-associated infections, as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent Healthcare-Associated Infections (or any successor plan) of the Department of Health and Human Services.

(II) HCAHPS.—Measures selected under subparagraph (A) shall be related to the Hospital Consumer Assessment of Healthcare Providers and Systems survey (HCAHPS).

(ii) INCLUSION OF EFFICIENCY MEASURES.—For value-based incentive payments made with respect to discharges occurring during fiscal year 2014 or a subsequent fiscal year, the Secretary shall ensure that measures selected under subparagraph (A) include efficiency measures, including measures of "Medicare spending per beneficiary". Such measures shall be adjusted for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate.

*(iii) HCAHPS PAIN QUESTIONS.—The Secretary may not include under subparagraph (A) a measure that is based on the questions appearing on the Hospital Consumer Assessment of Healthcare Providers and Systems survey in 2018 about communication by hospital staff with an individual about the individual's pain.*

(C) LIMITATIONS.—

(i) TIME REQUIREMENT FOR PRIOR REPORTING AND NOTICE.—The Secretary may not select a measure under subparagraph (A) for use under the Program with respect to a performance period for a fiscal year (as established under paragraph (4)) unless such measure has been specified under subsection (b)(3)(B)(viii) and included on the Hospital Compare Internet website for at least 1 year prior to the beginning of such performance period.

(ii) MEASURE NOT APPLICABLE UNLESS HOSPITAL FURNISHES SERVICES APPROPRIATE TO THE MEASURE.—A measure selected under subparagraph (A) shall not apply to a hospital if such hospital does not furnish services appropriate to such measure.

(D) REPLACING MEASURES.—Subclause (VI) of subsection (b)(3)(B)(viii) shall apply to measures selected under subparagraph (A) in the same manner as such subclause applies to measures selected under such subsection.

(3) PERFORMANCE STANDARDS.—

(A) ESTABLISHMENT.—The Secretary shall establish performance standards with respect to measures selected under paragraph (2) for a performance period for a fiscal year (as established under paragraph (4)).

(B) ACHIEVEMENT AND IMPROVEMENT.—The performance standards established under subparagraph (A) shall include levels of achievement and improvement.

(C) TIMING.—The Secretary shall establish and announce the performance standards under subparagraph (A) not later than 60 days prior to the beginning of the performance period for the fiscal year involved.

(D) CONSIDERATIONS IN ESTABLISHING STANDARDS.—In establishing performance standards with respect to measures under this paragraph, the Secretary shall take into account appropriate factors, such as—

(i) practical experience with the measures involved, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods;

(ii) historical performance standards;

(iii) improvement rates; and

(iv) the opportunity for continued improvement.

(4) PERFORMANCE PERIOD.—For purposes of the Program, the Secretary shall establish the performance period for a fiscal year. Such performance period shall begin and end prior to the beginning of such fiscal year.

(5) HOSPITAL PERFORMANCE SCORE.—

(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall develop a methodology for assessing the total performance of each hospital based on performance standards with respect to the measures selected under paragraph (2) for a performance period (as established under paragraph (4)). Using such methodology, the Secretary shall provide for an assessment (in this subsection referred to as the "hospital performance score") for each hospital for each performance period.

(B) APPLICATION.—

(i) APPROPRIATE DISTRIBUTION.—The Secretary shall ensure that the application of the methodology developed under subparagraph (A) results in an appropriate distribution of value-based incentive payments under paragraph (6) among hospitals achieving different levels of hospital performance scores, with hospitals achieving the highest hospital performance scores receiving the largest value-based incentive payments.

(ii) HIGHER OF ACHIEVEMENT OR IMPROVEMENT.—The methodology developed under subparagraph (A) shall provide that the hospital performance score is determined using the higher of its achievement or improvement score for each measure.

(iii) WEIGHTS.—The methodology developed under subparagraph (A) shall provide for the assignment of weights for categories of measures as the Secretary determines appropriate.

(iv) NO MINIMUM PERFORMANCE STANDARD.—The Secretary shall not set a minimum performance standard in determining the hospital performance score for any hospital.

(v) REFLECTION OF MEASURES APPLICABLE TO THE HOSPITAL.—The hospital performance score for a hospital shall reflect the measures that apply to the hospital.

(6) CALCULATION OF VALUE-BASED INCENTIVE PAYMENTS.—

(A) IN GENERAL.—In the case of a hospital that the Secretary determines meets (or exceeds) the performance standards under paragraph (3) for the performance period for a fiscal year (as established under paragraph (4)), the Secretary shall increase the base operating DRG payment amount (as defined in paragraph (7)(D)), as determined after application of paragraph (7)(B)(i), for a hospital for each discharge occurring in such fiscal year by the value-based incentive payment amount.

(B) VALUE-BASED INCENTIVE PAYMENT AMOUNT.—The value-based incentive payment amount for each discharge of a hospital in a fiscal year shall be equal to the product of—

(i) the base operating DRG payment amount (as defined in paragraph (7)(D)) for the discharge for the hospital for such fiscal year; and

(ii) the value-based incentive payment percentage specified under subparagraph (C) for the hospital for such fiscal year.

(C) VALUE-BASED INCENTIVE PAYMENT PERCENTAGE.—

(i) IN GENERAL.—The Secretary shall specify a value-based incentive payment percentage for a hospital for a fiscal year.

(ii) REQUIREMENTS.—In specifying the value-based incentive payment percentage for each hospital for a fiscal year under clause (i), the Secretary shall ensure that—

(I) such percentage is based on the hospital performance score of the hospital under paragraph (5); and

(II) the total amount of value-based incentive payments under this paragraph to all hospitals in such fiscal year is equal to the total amount available for value-based incentive payments for such fiscal year under paragraph (7)(A), as estimated by the Secretary.

(7) FUNDING FOR VALUE-BASED INCENTIVE PAYMENTS.—

(A) AMOUNT.—The total amount available for value-based incentive payments under paragraph (6) for all hospitals for a fiscal year shall be equal to the total amount of reduced payments for all hospitals under subparagraph (B) for such fiscal year, as estimated by the Secretary.

(B) ADJUSTMENT TO PAYMENTS.—

(i) IN GENERAL.—The Secretary shall reduce the base operating DRG payment amount (as defined in subparagraph (D)) for a hospital for each discharge in a fiscal

year (beginning with fiscal year 2013) by an amount equal to the applicable percent (as defined in subparagraph (C)) of the base operating DRG payment amount for the discharge for the hospital for such fiscal year. The Secretary shall make such reductions for all hospitals in the fiscal year involved, regardless of whether or not the hospital has been determined by the Secretary to have earned a value-based incentive payment under paragraph (6) for such fiscal year.

(ii) NO EFFECT ON OTHER PAYMENTS.—Payments described in items (aa) and (bb) of subparagraph (D)(i)(II) for a hospital shall be determined as if this subsection had not been enacted.

(C) APPLICABLE PERCENT DEFINED.—For purposes of subparagraph (B), the term "applicable percent" means—

(i) with respect to fiscal year 2013, 1.0 percent;

(ii) with respect to fiscal year 2014, 1.25 percent;

(iii) with respect to fiscal year 2015, 1.5 percent;

(iv) with respect to fiscal year 2016, 1.75 percent; and

(v) with respect to fiscal year 2017 and succeeding fiscal years, 2 percent.

(D) BASE OPERATING DRG PAYMENT AMOUNT DEFINED.—

(i) IN GENERAL.—Except as provided in clause (ii), in this subsection, the term "base operating DRG payment amount" means, with respect to a hospital for a fiscal year—

(I) the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (q)) for a discharge if this subsection did not apply; reduced by

(II) any portion of such payment amount that is attributable to—

(aa) payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d); and

(bb) such other payments under subsection (d) determined appropriate by the Secretary.

(ii) SPECIAL RULES FOR CERTAIN HOSPITALS.—

(I) SOLE COMMUNITY HOSPITALS AND MEDICARE-DEPENDENT, SMALL RURAL HOSPITALS.—In the case of a medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal year 2012 and 2013) or a sole community hospital, in applying subparagraph (A)(i), the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (I) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5).

(II) HOSPITALS PAID UNDER SECTION 1814.—In the case of a hospital that is paid under section 1814(b)(3), the term "base operating DRG payment amount" means the payment amount under such section.

(8) ANNOUNCEMENT OF NET RESULT OF ADJUSTMENTS.—Under the Program, the Secretary shall, not later than 60 days prior to the fiscal year involved, inform each hospital of the adjustments to payments to the hospital for discharges occurring in such fiscal year under paragraphs (6) and (7)(B)(i).

(9) NO EFFECT IN SUBSEQUENT FISCAL YEARS.—The value-based incentive payment under paragraph (6) and the payment reduction under paragraph (7)(B)(i) shall each apply only with respect to the fiscal year involved, and the Secretary shall not take into account such value-based incentive payment or payment reduction in making payments to a hospital under this section in a subsequent fiscal year.

(10) PUBLIC REPORTING.—

(A) HOSPITAL SPECIFIC INFORMATION.—

(i) IN GENERAL.—The Secretary shall make information available to the public regarding the performance of individual hospitals under the Program, including—

(I) the performance of the hospital with respect to each measure that applies to the hospital;

(II) the performance of the hospital with respect to each condition or procedure; and

(III) the hospital performance score assessing the total performance of the hospital.

(ii) OPPORTUNITY TO REVIEW AND SUBMIT CORRECTIONS.—The Secretary shall ensure that a hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the hospital under clause (i) prior to such information being made public.

(iii) WEBSITE.—Such information shall be posted on the Hospital Compare Internet website in an easily understandable format.

(B) AGGREGATE INFORMATION.—The Secretary shall periodically post on the Hospital Compare Internet website aggregate information on the Program, including—

(i) the number of hospitals receiving value-based incentive payments under paragraph (6) and the range and total amount of such value-based incentive payments; and

(ii) the number of hospitals receiving less than the maximum value-based incentive payment available to the hospital for the fiscal year involved and the range and amount of such payments.

(11) IMPLEMENTATION.—

(A) APPEALS.—The Secretary shall establish a process by which hospitals may appeal the calculation of a hospital's performance assessment with respect to the performance standards established under paragraph (3)(A) and the hospital performance score under paragraph (5). The Secretary shall ensure that such process provides for resolution of such appeals in a timely manner.

(B) LIMITATION ON REVIEW.—Except as provided in subparagraph (A), there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(i) The methodology used to determine the amount of the value-based incentive payment under paragraph (6) and the determination of such amount.

(ii) The determination of the amount of funding available for such value-based incentive payments under paragraph (7)(A) and the payment reduction under paragraph (7)(B)(i).

(iii) The establishment of the performance standards under paragraph (3) and the performance period under paragraph (4).

(iv) The measures specified under subsection (b)(3)(B)(viii) and the measures selected under paragraph (2).

(v) The methodology developed under paragraph (5) that is used to calculate hospital performance scores and the calculation of such scores.

(vi) The validation methodology specified in subsection (b)(3)(B)(viii)(XI).

(C) CONSULTATION WITH SMALL HOSPITALS.—The Secretary shall consult with small rural and urban hospitals on the application of the Program to such hospitals.

(12) PROMULGATION OF REGULATIONS.—The Secretary shall promulgate regulations to carry out the Program, including the selection of measures under paragraph (2), the methodology developed under paragraph (5) that is used to calculate hospital performance scores, and the methodology used to determine the amount of value-based incentive payments under paragraph (6).

(p) ADJUSTMENT TO HOSPITAL PAYMENTS FOR HOSPITAL ACQUIRED CONDITIONS.—

(1) IN GENERAL.—In order to provide an incentive for applicable hospitals to reduce hospital acquired conditions under this title, with respect to discharges from an applicable hospital occurring during fiscal year 2015 or a subsequent fiscal year, the amount of payment under this section or section 1814(b)(3), as applicable, for such discharges during the fiscal year shall be equal to 99 percent of the amount of payment that would otherwise apply to such discharges under this section or section 1814(b)(3) (determined after the application of subsections (o) and (q) and section 1814(l)(4) but without regard to this subsection).

(2) APPLICABLE HOSPITALS.—

(A) IN GENERAL.—For purposes of this subsection, the term "applicable hospital" means a subsection (d) hospital that meets the criteria described in subparagraph (B).

(B) CRITERIA DESCRIBED.—

(i) IN GENERAL.—The criteria described in this subparagraph, with respect to a subsection (d) hospital, is that the subsection (d) hospital is in the top quartile of all subsection (d) hospitals, relative to the national average, of hospital acquired conditions during the applicable period, as determined by the Secretary.

(ii) RISK ADJUSTMENT.—In carrying out clause (i), the Secretary shall establish and apply an appropriate risk adjustment methodology.

(C) EXEMPTION.—In the case of a hospital that is paid under section 1814(b)(3), the Secretary may exempt such hospital from the application of this subsection if the State which is paid under such section submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under this subsection.

(3) HOSPITAL ACQUIRED CONDITIONS.—For purposes of this subsection, the term "hospital acquired condition" means a condition identified for purposes of subsection (d)(4)(D)(iv) and any other condition determined appropriate by the Secretary that an individual acquires during a stay in an applicable hospital, as determined by the Secretary.

(4) APPLICABLE PERIOD.—In this subsection, the term "applicable period" means, with respect to a fiscal year, a period specified by the Secretary.

(5) REPORTING TO HOSPITALS.—Prior to fiscal year 2015 and each subsequent fiscal year, the Secretary shall provide confidential reports to applicable hospitals with respect to hospital acquired conditions of the applicable hospital during the applicable period.

(6) REPORTING HOSPITAL SPECIFIC INFORMATION.—

(A) IN GENERAL.—The Secretary shall make information available to the public regarding hospital acquired conditions of each applicable hospital.

(B) OPPORTUNITY TO REVIEW AND SUBMIT CORRECTIONS.—The Secretary shall ensure that an applicable hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the hospital under subparagraph (A) prior to such information being made public.

(C) WEBSITE.—Such information shall be posted on the Hospital Compare Internet website in an easily understandable format.

(7) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(A) The criteria described in paragraph (2)(A).

(B) The specification of hospital acquired conditions under paragraph (3).

(C) The specification of the applicable period under paragraph (4).

(D) The provision of reports to applicable hospitals under paragraph (5) and the information made available to the public under paragraph (6).

(q) HOSPITAL READMISSIONS REDUCTION PROGRAM.—

(1) IN GENERAL.—With respect to payment for discharges from an applicable hospital (as defined in paragraph (5)(C)) occurring during a fiscal year beginning on or after October 1, 2012, in order to account for excess readmissions in the hospital, the Secretary shall make payments (in addition to the payments described in paragraph (2)(A)(ii)) for such a discharge to such hospital under subsection (d) (or section 1814(b)(3), as the case may be) in an amount equal to the product of—

(A) the base operating DRG payment amount (as defined in paragraph (2)) for the discharge; and

(B) the adjustment factor (described in paragraph (3)(A)) for the hospital for the fiscal year.

(2) BASE OPERATING DRG PAYMENT AMOUNT DEFINED.—

(A) IN GENERAL.—Except as provided in subparagraph (B), in this subsection, the term "base operating DRG payment amount" means, with respect to a hospital for a fiscal year—

(i) the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (o)) for a discharge if this subsection did not apply; reduced by

(ii) any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d).

(B) SPECIAL RULES FOR CERTAIN HOSPITALS.—

(i) SOLE COMMUNITY HOSPITALS AND MEDICARE-DEPENDENT, SMALL RURAL HOSPITALS.—In the case of a medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal years 2012 and 2013) or a sole community hospital, in applying subparagraph (A)(i), the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (I) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5).

(ii) HOSPITALS PAID UNDER SECTION 1814.—In the case of a hospital that is paid under section 1814(b)(3), the Secretary may exempt such hospitals provided that States paid under such section submit an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established herein with respect to this section.

(3) ADJUSTMENT FACTOR.—

(A) IN GENERAL.—For purposes of paragraph (1), subject to subparagraph (D), the adjustment factor under this paragraph for an applicable hospital for a fiscal year is equal to the greater of—

(i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or

(ii) the floor adjustment factor specified in subparagraph (C).

(B) RATIO.—The ratio described in this subparagraph for a hospital for an applicable period is equal to 1 minus the ratio of—

(i) the aggregate payments for excess readmissions (as defined in paragraph (4)(A)) with respect to an applicable hospital for the applicable period; and

(ii) the aggregate payments for all discharges (as defined in paragraph (4)(B)) with respect to such applicable hospital for such applicable period.

(C) FLOOR ADJUSTMENT FACTOR.—For purposes of subparagraph (A), the floor adjustment factor specified in this subparagraph for—

(i) fiscal year 2013 is 0.99;

(ii) fiscal year 2014 is 0.98; or

(iii) fiscal year 2015 and subsequent fiscal years is 0.97.

(D) TRANSITIONAL ADJUSTMENT FOR DUAL ELIGIBLES.—

(i) IN GENERAL.—In determining a hospital's adjustment factor under this paragraph for purposes of making payments for discharges occurring during and after fiscal year 2019, and before the application of clause (i) of subparagraph (E), the Secretary shall assign hospitals to groups (as defined by the Secretary under clause (ii)) and apply the applicable provisions of this subsection using a methodology in a manner that allows for separate comparison of hospitals within each such group, as determined by the Secretary.

(ii) DEFINING GROUPS.—For purposes of this subparagraph, the Secretary shall define groups of hospitals, based on their overall proportion, of the inpatients who are entitled to, or enrolled for, benefits under part A, and who are full-benefit dual eligible individuals (as defined in section 1935(c)(6)). In defining groups, the Secretary shall consult the Medicare Payment Advisory Commission and may consider the analysis done by such Commission in preparing the portion of its report submitted to Congress in June 2013 relating to readmissions.

(iii) MINIMIZING REPORTING BURDEN ON HOSPITALS.—In carrying out this subparagraph, the Secretary shall not impose any additional reporting requirements on hospitals.

(iv) BUDGET NEUTRAL DESIGN METHODOLOGY.—The Secretary shall design the methodology to implement this subparagraph so that the estimated total amount of reductions in payments under this subsection equals the estimated total amount of reductions in payments that would otherwise occur under this subsection if this subparagraph did not apply.

(E) CHANGES IN RISK ADJUSTMENT.—

(i) CONSIDERATION OF RECOMMENDATIONS IN IMPACT REPORTS.—The Secretary may take into account the studies conducted and the recommendations made by the Secretary under section 2(d)(1) of the IMPACT Act of 2014 (Public Law 113–185; 42 U.S.C. 1395lll note) with respect to the application under this subsection of risk adjustment methodologies. Nothing in this clause shall be construed as precluding consideration of the use of groupings of hospitals.

(ii) CONSIDERATION OF EXCLUSION OF PATIENT CASES BASED ON V OR OTHER APPROPRIATE CODES.—In promulgating regulations to carry out this subsection with respect to discharges occurring after fiscal year 2018, the Secretary may consider the use of V or other ICD-related codes for removal of a readmission. The Secretary may consider

modifying measures under this subsection to incorporate V or other ICD-related codes at the same time as other changes are being made under this subparagraph.

(iii) REMOVAL OF CERTAIN READMISSIONS.—In promulgating regulations to carry out this subsection, with respect to discharges occurring after fiscal year 2018, the Secretary may consider removal as a readmission of an admission that is classified within one or more of the following: transplants, end-stage renal disease, burns, trauma, psychosis, or substance abuse. The Secretary may consider modifying measures under this subsection to remove readmissions at the same time as other changes are being made under this subparagraph.

(4) AGGREGATE PAYMENTS, EXCESS READMISSION RATIO DEFINED.—For purposes of this subsection:

(A) AGGREGATE PAYMENTS FOR EXCESS READMISSIONS.—The term "aggregate payments for excess readmissions" means, for a hospital for an applicable period, the sum, for applicable conditions (as defined in paragraph (5)(A)), of the product, for each applicable condition, of—

(i) the base operating DRG payment amount for such hospital for such applicable period for such condition;

(ii) the number of admissions for such condition for such hospital for such applicable period; and

(iii) the excess readmissions ratio (as defined in subparagraph (C)) for such hospital for such applicable period minus 1.

(B) AGGREGATE PAYMENTS FOR ALL DISCHARGES.—The term "aggregate payments for all discharges" means, for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period.

(C) EXCESS READMISSION RATIO.—

(i) IN GENERAL.—Subject to clause (ii), the term "excess readmissions ratio" means, with respect to an applicable condition for a hospital for an applicable period, the ratio (but not less than 1.0) of—

(I) the risk adjusted readmissions based on actual readmissions, as determined consistent with a readmission measure methodology that has been endorsed under paragraph (5)(A)(ii)(I), for an applicable hospital for such condition with respect to such applicable period; to

(II) the risk adjusted expected readmissions (as determined consistent with such a methodology) for such hospital for such condition with respect to such applicable period.

(ii) EXCLUSION OF CERTAIN READMISSIONS.—For purposes of clause (i), with respect to a hospital, excess readmissions shall not include readmissions for an applicable condition for which there are fewer than a minimum number (as determined by the Secretary) of discharges for such applicable condition for the applicable period and such hospital.

(5) DEFINITIONS.—For purposes of this subsection:

(A) APPLICABLE CONDITION.—The term "applicable condition" means, subject to subparagraph (B), a condition or procedure selected by the Secretary among conditions and procedures for which—

(i) readmissions (as defined in subparagraph (E)) that represent conditions or procedures that are high volume or high expenditures under this title (or other criteria specified by the Secretary); and

(ii) measures of such readmissions—

(I) have been endorsed by the entity with a contract under section 1890(a); and

(II) such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).

(B) EXPANSION OF APPLICABLE CONDITIONS.—Beginning with fiscal year 2015, the Secretary shall, to the extent practicable, expand the applicable conditions beyond the 3 conditions for which measures have been endorsed as described in subparagraph (A)(ii)(I) as of the date of the enactment of this subsection to the additional 4 conditions that have been identified by the Medicare Payment Advisory Commission in its report to Congress in June

2007 and to other conditions and procedures as determined appropriate by the Secretary. In expanding such applicable conditions, the Secretary shall seek the endorsement described in subparagraph (A)(ii)(I) but may apply such measures without such an endorsement in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(C) APPLICABLE HOSPITAL.—The term "applicable hospital" means a subsection (d) hospital or a hospital that is paid under section 1814(b)(3), as the case may be.

(D) APPLICABLE PERIOD.—The term "applicable period" means, with respect to a fiscal year, such period as the Secretary shall specify.

(E) READMISSION.—The term "readmission" means, in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge. Insofar as the discharge relates to an applicable condition for which there is an endorsed measure described in subparagraph (A)(ii)(I), such time period (such as 30 days) shall be consistent with the time period specified for such measure.

(6) REPORTING HOSPITAL SPECIFIC INFORMATION.—

(A) IN GENERAL.—The Secretary shall make information available to the public regarding readmission rates of each subsection (d) hospital under the program.

(B) OPPORTUNITY TO REVIEW AND SUBMIT CORRECTIONS.—The Secretary shall ensure that a subsection (d) hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the hospital under subparagraph (A) prior to such information being made public.

(C) WEBSITE.—Such information shall be posted on the Hospital Compare Internet website in an easily understandable format.

(7) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(A) The determination of base operating DRG payment amounts.

(B) The methodology for determining the adjustment factor under paragraph (3), including excess readmissions ratio under paragraph (4)(C), aggregate payments for excess readmissions under paragraph (4)(A), and aggregate payments for all discharges under paragraph (4)(B), and applicable periods and applicable conditions under paragraph (5).

(C) The measures of readmissions as described in paragraph (5)(A)(ii).

(8) READMISSION RATES FOR ALL PATIENTS.—

(A) CALCULATION OF READMISSION.—The Secretary shall calculate readmission rates for all patients (as defined in subparagraph (D)) for a specified hospital (as defined in subparagraph (D)(ii)) for an applicable condition (as defined in paragraph (5)(B)) and other conditions deemed appropriate by the Secretary for an applicable period (as defined in paragraph (5)(D)) in the same manner as used to calculate such readmission rates for hospitals with respect to this title and posted on the CMS Hospital Compare website.

(B) POSTING OF HOSPITAL SPECIFIC ALL PATIENT READMISSION RATES.—The Secretary shall make information on all patient readmission rates calculated under subparagraph (A) available on the CMS Hospital Compare website in a form and manner determined appropriate by the Secretary. The Secretary may also make other information determined appropriate by the Secretary available on such website.

(C) HOSPITAL SUBMISSION OF ALL PATIENT DATA.—

(i) Except as provided for in clause (ii), each specified hospital (as defined in subparagraph (D)(ii)) shall submit to the Secretary, in a form, manner and time specified by the Secretary, data and information determined necessary by the Secretary for the Secretary to calculate the all patient readmission rates described in subparagraph (A).

(ii) Instead of a specified hospital submitting to the Secretary the data and information described in clause (i), such data and information may be submitted to the Secretary, on behalf of such a specified hospital, by a state or an entity determined appropriate by the Secretary.

(D) DEFINITIONS.—For purposes of this paragraph:

(i) The term "all patients" means patients who are treated on an inpatient basis and discharged from a specified hospital (as defined in clause (ii)).

(ii) The term "specified hospital" means a subsection (d) hospital, hospitals described in clauses (i) through (v) of subsection (d)(1)(B) and, as determined feasible and appropriate by the Secretary, other hospitals not otherwise described in this subparagraph.

(r) ADJUSTMENTS TO MEDICARE DSH PAYMENTS.—

(1) EMPIRICALLY JUSTIFIED DSH PAYMENTS.—For fiscal year 2014 and each subsequent fiscal year, instead of the amount of disproportionate share hospital payment that would otherwise be made under subsection (d)(5)(F) to a subsection (d) hospital for the fiscal year, the Secretary shall pay to the subsection (d) hospital 25 percent of such amount (which represents the empirically justified amount for such payment, as determined by the Medicare Payment Advisory Commission in its March 2007 Report to the Congress).

(2) ADDITIONAL PAYMENT.—In addition to the payment made to a subsection (d) hospital under paragraph (1), for fiscal year 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospitals an additional amount equal to the product of the following factors:

(A) FACTOR ONE.—A factor equal to the difference between—

(i) the aggregate amount of payments that would be made to subsection (d) hospitals under subsection (d)(5)(F) if this subsection did not apply for such fiscal year (as estimated by the Secretary); and

(ii) the aggregate amount of payments that are made to subsection (d) hospitals under paragraph (1) for such fiscal year (as so estimated).

(B) FACTOR TWO.—

(i) FISCAL YEARS 2014, 2015, 2016, AND 2017.—For each of fiscal years 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, as determined by comparing the percent of such individuals—

(I) who are uninsured in 2013, the last year before coverage expansion under the Patient Protection and Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment); and

(II) who are uninsured in the most recent period for which data is available (as so calculated),

minus 0.1 percentage points for fiscal year 2014 and minus 0.2 percentage points for each of fiscal years 2015, 2016, and 2017.

(ii) 2018 AND SUBSEQUENT YEARS.—For fiscal year 2018 and each subsequent fiscal year, a factor equal to 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals—

(I) who are uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of the Centers for Medicare & Medicaid Services); and

(II) who are uninsured in the most recent period for which data is available (as so estimated and certified),

minus 0.2 percentage points for each of fiscal years 2018 and 2019.

(C) FACTOR THREE.—A factor equal to the percent, for each subsection (d) hospital, that represents the quotient of—

(i) the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines that alternative data is available which is a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and

(ii) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under this subsection for such period (as so estimated, based on such data).

(3) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(A) Any estimate of the Secretary for purposes of determining the factors described in paragraph (2).

(B) Any period selected by the Secretary for such purposes.

(s) PROSPECTIVE PAYMENT FOR PSYCHIATRIC HOSPITALS.—

(1) REFERENCE TO ESTABLISHMENT AND IMPLEMENTATION OF SYSTEM.—For provisions related to the establishment and implementation of a prospective payment system for payments under this title for inpatient hospital services furnished by psychiatric hospitals (as described in clause (i) of subsection (d)(1)(B)) and psychiatric units (as described in the matter following clause (v) of such subsection), see section 124 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999.

(2) IMPLEMENTATION FOR RATE YEAR BEGINNING IN 2010 AND SUBSEQUENT RATE YEARS.—

(A) IN GENERAL.—In implementing the system described in paragraph (1) for the rate year beginning in 2010 and any subsequent rate year, any update to a base rate for days during the rate year for a psychiatric hospital or unit, respectively, shall be reduced—

(i) for the rate year beginning in 2012 and each subsequent rate year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(ii) for each of the rate years beginning in 2010 through 2019, by the other adjustment described in paragraph (3).

(B) SPECIAL RULE.—The application of this paragraph may result in such update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(3) OTHER ADJUSTMENT.—For purposes of paragraph (2)(A)(ii), the other adjustment described in this paragraph is—

(A) for each of the rate years beginning in 2010 and 2011, 0.25 percentage point;

(B) for each of the rate years beginning in 2012 and 2013, 0.1 percentage point;

(C) for the rate year beginning in 2014, 0.3 percentage point;

(D) for each of the rate years beginning in 2015 and 2016, 0.2 percentage point; and

(E) for each of the rate years beginning in 2017, 2018, and 2019, 0.75 percentage point.

(4) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—Under the system described in paragraph (1), for rate year 2014 and each subsequent rate year, in the case of a psychiatric hospital or psychiatric unit that does not submit data to the Secretary in accordance with subparagraph (C) with respect to such a rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of paragraph (2), shall be reduced by 2 percentage points.

(ii) SPECIAL RULE.—The application of this subparagraph may result in such annual update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(B) NONCUMULATIVE APPLICATION.—Any reduction under subparagraph (A) shall apply only with respect to the rate year involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in paragraph (1) for a subsequent rate year.

(C) SUBMISSION OF QUALITY DATA.—For rate year 2014 and each subsequent rate year, each psychiatric hospital and psychiatric unit shall submit to the Secretary data on quality measures specified under subparagraph (D). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) QUALITY MEASURES.—

(i) IN GENERAL.—Subject to clause (ii), any measure specified by the Secretary under this subparagraph must have been endorsed by the entity with a contract under section 1890(a).

(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures

that have been endorsed or adopted by a consensus organization identified by the Secretary.

(iii) TIME FRAME.—Not later than October 1, 2012, the Secretary shall publish the measures selected under this subparagraph that will be applicable with respect to rate year 2014.

(E) PUBLIC AVAILABILITY OF DATA SUBMITTED.—The Secretary shall establish procedures for making data submitted under subparagraph (C) available to the public. Such procedures shall ensure that a psychiatric hospital and a psychiatric unit has the opportunity to review the data that is to be made public with respect to the hospital or unit prior to such data being made public. The Secretary shall report quality measures that relate to services furnished in inpatient settings in psychiatric hospitals and psychiatric units on the Internet website of the Centers for Medicare & Medicaid Services.

(t) RELATING SIMILAR INPATIENT AND OUTPATIENT HOSPITAL SERVICES.—

(1) DEVELOPMENT OF HCPCS VERSION OF MS–DRG CODES.—Not later than January 1, 2018, the Secretary shall develop HCPCS versions for MS–DRGs that are similar to the ICD–10–PCS for such MS–DRGs such that, to the extent possible, the MS–DRG assignment shall be similar for a claim coded with the HCPCS version as an identical claim coded with a ICD–10–PCS code.

(2) COVERAGE OF SURGICAL MS–DRGS.—In carrying out paragraph (1), the Secretary shall develop HCPCS versions of MS–DRG codes for not fewer than 10 surgical MS–DRGs.

(3) PUBLICATION AND DISSEMINATION OF THE HCPCS VERSIONS OF MS–DRGS.—

(A) IN GENERAL.—The Secretary shall develop a HCPCS MS–DRG definitions manual and software that is similar to the definitions manual and software for ICD–10–PCS codes for such MS–DRGs. The Secretary shall post the HCPCS MS–DRG definitions manual and software on the Internet website of the Centers for Medicare & Medicaid Services. The HCPCS MS–DRG definitions manual and software shall be in the public domain and available for use and redistribution without charge.

(B) USE OF PREVIOUS ANALYSIS DONE BY MEDPAC.—In developing the HCPCS MS–DRG definitions manual and software under subparagraph (A), the Secretary shall consult with the Medicare Payment Advisory Commission and shall consider the analysis done by such Commission in translating outpatient surgical claims into inpatient surgical MS–DRGs in preparing chapter 7 (relating to hospital short-stay policy issues) of its "Medicare and the Health Care Delivery System" report submitted to Congress in June 2015.

(4) DEFINITION AND REFERENCE.—In this subsection:

(A) HCPCS.—The term "HCPCS" means, with respect to hospital items and services, the code under the Healthcare Common Procedure Coding System (HCPCS) (or a successor code) for such items and services.

(B) ICD–10–PCS.—The term "ICD–10–PCS" means the International Classification of Diseases, 10th Revision, Procedure Coding System, and includes any subsequent revision of such International Classification of Diseases, Procedure Coding System.

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CONTRACT WITH A CONSENSUS-BASED ENTITY REGARDING PERFORMANCE MEASUREMENT

SEC. 1890. (a) CONTRACT.—

(1) IN GENERAL.—For purposes of activities conducted under this Act, the Secretary shall identify and have in effect a contract with a consensus-based entity, such as the National Quality Forum, that meets the requirements described in subsection (c). Such contract shall provide that the entity will perform the duties described in subsection (b).

(2) TIMING FOR FIRST CONTRACT.—As soon as practicable after the date of the enactment of this subsection, the Secretary shall enter into the first contract under paragraph (1).

(3) PERIOD OF CONTRACT.—A contract under paragraph (1) shall be for a period of 4 years (except as may be renewed after a subsequent bidding process).

(4) COMPETITIVE PROCEDURES.—Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))) shall be used to enter into a contract under paragraph (1).

(b) DUTIES.—The duties described in this subsection are the following:

(1) PRIORITY SETTING PROCESS.—The entity shall synthesize evidence and convene key stakeholders to make recommendations, with respect to activities conducted under this Act, on

an integrated national strategy and priorities for health care performance measurement in all applicable settings. In making such recommendations, the entity shall—

(A) ensure that priority is given to measures—

(i) that address the health care provided to patients with prevalent, high-cost chronic diseases;

(ii) with the greatest potential for improving the quality, efficiency, and patient-centeredness of health care; and

(iii) that may be implemented rapidly due to existing evidence, standards of care, or other reasons; and

(B) take into account measures that—

(i) may assist consumers and patients in making informed health care decisions;

(ii) address health disparities across groups and areas; and

(iii) address the continuum of care a patient receives, including services furnished by multiple health care providers or practitioners and across multiple settings.

(2) ENDORSEMENT OF MEASURES.—The entity shall provide for the endorsement of standardized health care performance measures. The endorsement process under the preceding sentence shall consider whether a measure—

(A) is evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level; and

(B) is consistent across types of health care providers, including hospitals and physicians.

*Such endorsement process shall, as determined practicable by the entity, provide for an expedited process with respect to the endorsement of such measures relating to opioids and opioid use disorders.*

(3) MAINTENANCE OF MEASURES.—The entity shall establish and implement a process to ensure that measures endorsed under paragraph (2) are updated (or retired if obsolete) as new evidence is developed.

(5) ANNUAL REPORT TO CONGRESS AND THE SECRETARY; SECRETARIAL PUBLICATION AND COMMENT.—

(A) ANNUAL REPORT.—By not later than March 1 of each year (beginning with 2009), the entity shall submit to Congress and the Secretary a report containing the following:

(i) A description of—

(I) the implementation of quality measurement initiatives under this Act and the coordination of such initiatives with quality initiatives implemented by other payers;

(II) the recommendations made under paragraph (1);

(III) the performance by the entity of the duties required under the contract entered into with the Secretary under subsection (a);

(IV) gaps in endorsed quality measures, which shall include measures that are within priority areas identified by the Secretary under the national strategy established under section 399HH of the Public Health Service Act, and where quality measures are unavailable or inadequate to identify or address such gaps;

(V) areas in which evidence is insufficient to support endorsement of quality measures in priority areas identified by the Secretary under the national strategy established under section 399HH of the Public Health Service Act and where targeted research may address such gaps; and

(VI) the matters described in clauses (i) and (ii) of paragraph (7)(A).

(ii) An itemization of financial information for the fiscal year ending September 30 of the preceding year, including—

(I) annual revenues of the entity (including any government funding, private sector contributions, grants, membership revenues, and investment revenue);

(II) annual expenses of the entity (including grants paid, benefits paid, salaries or other compensation, fundraising expenses, and overhead costs); and

(III) a breakdown of the amount awarded per contracted task order and the specific projects funded in each task order assigned to the entity.

(iii) Any updates or modifications of internal policies and procedures of the entity as they relate to the duties of the entity under this section, including—

(I) specifically identifying any modifications to the disclosure of interests and conflicts of interests for committees, work groups, task forces, and advisory panels of the entity; and

(II) information on external stakeholder participation in the duties of the entity under this section (including complete rosters for all committees, work groups, task forces, and advisory panels funded through government contracts, descriptions of relevant interests and any conflicts of interest for members of all committees, work groups, task forces, and advisory panels, and the total percentage by health care sector of all convened committees, work groups, task forces, and advisory panels.

(B) SECRETARIAL REVIEW AND PUBLICATION OF ANNUAL REPORT.—Not later than 6 months after receiving a report under subparagraph (A) for a year, the Secretary shall—

(i) review such report; and

(ii) publish such report in the Federal Register, together with any comments of the Secretary on such report.

(6) REVIEW AND ENDORSEMENT OF EPISODE GROUPER UNDER THE PHYSICIAN FEEDBACK PROGRAM.—The entity shall provide for the review and, as appropriate, the endorsement of the episode grouper developed by the Secretary under section 1848(n)(9)(A). Such review shall be conducted on an expedited basis.

(7) CONVENING MULTI-STAKEHOLDER GROUPS.—

(A) IN GENERAL.—The entity shall convene multi-stakeholder groups to provide input on—

(i) the selection of quality and efficiency measures described in subparagraph (B), from among—

(I) such measures that have been endorsed by the entity; and

(II) such measures that have not been considered for endorsement by such entity but are used or proposed to be used by the Secretary for the collection or reporting of quality and efficiency measures; and

(ii) national priorities (as identified under section 399HH of the Public Health Service Act) for improvement in population health and in the delivery of health care services for consideration under the national strategy established under section 399HH of the Public Health Service Act.

(B) QUALITY MEASURES.—

(i) IN GENERAL.—Subject to clause (ii), the quality and efficiency measures described in this subparagraph are quality and efficiency measures—

(I) for use pursuant to sections 1814(i)(5)(D), 1833(i)(7), 1833(t)(17), 1848(k)(2)(C), 1866(k)(3), 1881(h)(2)(A)(iii), 1886(b)(3)(B)(viii), 1886(j)(7)(D), 1886(m)(5)(D), 1886(o)(2), 1886(s)(4)(D), and 1895(b)(3)(B)(v);

(II) for use in reporting performance information to the public; and

(III) for use in health care programs other than for use under this Act.

(ii) EXCLUSION.—Data sets (such as the outcome and assessment information set for home health services and the minimum data set for skilled nursing facility services) that are used for purposes of classification systems used in establishing payment rates under this title shall not be quality and efficiency measures described in this subparagraph.

(C) REQUIREMENT FOR TRANSPARENCY IN PROCESS.—

(i) IN GENERAL.—In convening multi-stakeholder groups under subparagraph (A) with respect to the selection of quality and efficiency measures, the entity shall provide for an open and transparent process for the activities conducted pursuant to such convening.

(ii) SELECTION OF ORGANIZATIONS PARTICIPATING IN MULTI-STAKEHOLDER GROUPS.—The process described in clause (i) shall ensure that the selection of representatives comprising such groups provides for public nominations for, and the opportunity for public comment on, such selection.

(D) MULTI-STAKEHOLDER GROUP DEFINED.—In this paragraph, the term "multi-stakeholder group" means, with respect to a quality and efficiency measure, a voluntary collaborative of organizations representing a broad group of stakeholders interested in or affected by the use of such quality and efficiency measure.

(8) TRANSMISSION OF MULTI-STAKEHOLDER INPUT.—Not later than February 1 of each year (beginning with 2012), the entity shall transmit to the Secretary the input of multi-stakeholder groups provided under paragraph (7).

(c) REQUIREMENTS DESCRIBED.—The requirements described in this subsection are the following:

(1) PRIVATE NONPROFIT.—The entity is a private nonprofit entity governed by a board.

(2) BOARD MEMBERSHIP.—The members of the board of the entity include—

(A) representatives of health plans and health care providers and practitioners or representatives of groups representing such health plans and health care providers and practitioners;

(B) health care consumers or representatives of groups representing health care consumers; and

(C) representatives of purchasers and employers or representatives of groups representing purchasers or employers.

(3) ENTITY MEMBERSHIP.—The membership of the entity includes persons who have experience with—

(A) urban health care issues;

(B) safety net health care issues;

(C) rural and frontier health care issues; and

(D) health care quality and safety issues.

(4) OPEN AND TRANSPARENT.—With respect to matters related to the contract with the Secretary under subsection (a), the entity conducts its business in an open and transparent manner and provides the opportunity for public comment on its activities.

(5) VOLUNTARY CONSENSUS STANDARDS SETTING ORGANIZATION.—The entity operates as a voluntary consensus standards setting organization as defined for purposes of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Public Law 104–113) and Office of Management and Budget Revised Circular A–119 (published in the Federal Register on February 10, 1998).

(6) EXPERIENCE.—The entity has at least 4 years of experience in establishing national consensus standards.

(7) MEMBERSHIP FEES.—If the entity requires a membership fee for participation in the functions of the entity, such fees shall be reasonable and adjusted based on the capacity of the potential member to pay the fee. In no case shall membership fees pose a barrier to the participation of individuals or groups with low or nominal resources to participate in the functions of the entity.

(d) FUNDING.—(1) For purposes of carrying out this section, the Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841 (in such proportion as the Secretary determines appropriate), of $10,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2009 through 2013. Amounts transferred under the preceding sentence shall remain available until expended.

(2) For purposes of carrying out this section and section 1890A (other than subsections (e) and (f)), the Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841, in such proportion as the Secretary determines appropriate, to the Centers for Medicare & Medicaid Services Program Management Account of $5,000,000 for fiscal year 2014, $30,000,000 for each of fiscal years 2015 through 2017, and $7,500,000 for each of fiscal years 2018 and 2019. Amounts transferred under the preceding sentence shall remain available until expended. For purposes of carrying out this section and section 1890A (other than subsections (e) and (f)), the Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841, in such proportion as the Secretary determines appropriate, to the Centers for Medicare & Medicaid Services Program Management Account of $5,000,000 for fiscal year 2014 and $30,000,000 for each of fiscal years 2015 through 2017. Amounts transferred under the preceding sentence shall remain available until expended. Amounts transferred for each of fiscal years 2018 and 2019 shall be in addition to any unobligated funds transferred for a preceding fiscal year that are available under the preceding sentence.

(e) ANNUAL REPORT BY SECRETARY TO CONGRESS.—By not later than March 1 of each year (beginning with 2019), the Secretary shall submit to Congress a report containing the following:

(1) A comprehensive plan that identifies the quality measurement needs of programs and initiatives of the Secretary and provides a strategy for using the entity with a contract under subsection (a) and any other entity the Secretary has contracted with or may contract with to perform work associated with section 1890A to help meet those needs, specifically with respect to the programs under this title and title XIX. In years after the first plan under this paragraph is submitted, the requirements of this paragraph may be met by providing an update to the plan.

(2) The amount of funding provided under subsection (d) for purposes of carrying out this section and section 1890A that has been obligated by the Secretary, the amount of funding provided that has been expended, and the amount of funding provided that remains unobligated.

(3) With respect to the activities described under this section or section 1890A, a description of how the funds described in paragraph (2) have been obligated or expended, including how much of that funding has been obligated or expended for work performed by the Secretary, the entity with a contract under subsection (a), and any other entity the Secretary has contracted with to perform work.

(4) A description of the activities for which the funds described in paragraph (2) were used, including task orders and activities assigned to the entity with a contract under subsection (a), activities performed by the Secretary, and task orders and activities assigned to any other entity the Secretary has contracted with to perform work related to carrying out section 1890A.

(5) The amount of funding described in paragraph (2) that has been obligated or expended for each of the activities described in paragraph (4).

(6) Estimates for, and descriptions of, obligations and expenditures that the Secretary anticipates will be needed in the succeeding two year period to carry out each of the quality measurement activities required under this section and section 1890A, including any obligations that will require funds to be expended in a future year.

QUALITY MEASUREMENT

SEC. 1890A. (a) MULTI-STAKEHOLDER GROUP INPUT INTO SELECTION OF QUALITY MEASURES.—The Secretary shall establish a pre-rulemaking process under which the following steps occur with respect to the selection of quality and efficiency measures described in section 1890(b)(7)(B):

(1) INPUT.—Pursuant to section 1890(b)(7), the entity with a contract under section 1890 shall convene multi-stakeholder groups to provide input to the Secretary on the selection of quality and efficiency measures described in subparagraph (B) of such paragraph.

(2) PUBLIC AVAILABILITY OF MEASURES CONSIDERED FOR SELECTION.—Not later than December 1 of each year (beginning with 2011), the Secretary shall make available to the public a list of quality and efficiency measures described in section 1890(b)(7)(B) that the Secretary is considering under this title.

(3) TRANSMISSION OF MULTI-STAKEHOLDER INPUT.—Pursuant to section 1890(b)(8), not later than February 1 of each year (beginning with 2012), the entity shall transmit to the Secretary the input of multi-stakeholder groups described in paragraph (1).

(4) CONSIDERATION OF MULTI-STAKEHOLDER INPUT.—The Secretary shall take into consideration the input from multi-stakeholder groups described in paragraph (1) in selecting quality and efficiency measures described in section 1890(b)(7)(B) that have been endorsed by the entity with a contract under section 1890 and measures that have not been endorsed by such entity.

(5) RATIONALE FOR USE OF QUALITY MEASURES.—The Secretary shall publish in the Federal Register the rationale for the use of any quality and efficiency measure described in section 1890(b)(7)(B) that has not been endorsed by the entity with a contract under section 1890.

(6) ASSESSMENT OF IMPACT.—Not later than March 1, 2012, and at least once every three years thereafter, the Secretary shall—

(A) conduct an assessment of the quality and efficiency impact of the use of endorsed measures described in section 1890(b)(7)(B); and

(B) make such assessment available to the public.

(b) PROCESS FOR DISSEMINATION OF MEASURES USED BY THE SECRETARY.—

(1) IN GENERAL.—The Secretary shall establish a process for disseminating quality and efficiency measures used by the Secretary. Such process shall include the following:

(A) The incorporation of such measures, where applicable, in workforce programs, training curricula, and any other means of dissemination determined appropriate by the Secretary.

(B) The dissemination of such quality and efficiency measures through the national strategy developed under section 399HH of the Public Health Service Act.

(2) EXISTING METHODS.—To the extent practicable, the Secretary shall utilize and expand existing dissemination methods in disseminating quality and efficiency measures under the process established under paragraph (1).

(c) REVIEW OF QUALITY MEASURES USED BY THE SECRETARY.—

(1) IN GENERAL.—The Secretary shall—

(A) periodically (but in no case less often than once every 3 years) review quality and efficiency measures described in section 1890(b)(7)(B); and

(B) with respect to each such measure, determine whether to—

(i) maintain the use of such measure; or

(ii) phase out such measure.

(2) CONSIDERATIONS.—In conducting the review under paragraph (1), the Secretary shall take steps to—

(A) seek to avoid duplication of measures used; and

(B) take into consideration current innovative methodologies and strategies for quality and efficiency improvement practices in the delivery of health care services that represent best practices for such quality and efficiency improvement and measures endorsed by the entity with a contract under section 1890 since the previous review by the Secretary.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall preclude a State from using the quality and efficiency measures identified under sections 1139A and 1139B.

(e) DEVELOPMENT OF QUALITY MEASURES.—The Administrator of the Center for Medicare & Medicaid Services shall through contracts develop quality measures (as determined appropriate by the Administrator) for use under this Act. In developing such measures, the Administrator shall consult with the Director of the Agency for Healthcare Research and Quality.

(f) HOSPITAL ACQUIRED CONDITIONS.—The Secretary shall, to the extent practicable, publicly report on measures for hospital-acquired conditions that are currently utilized by the Centers for Medicare & Medicaid Services for the adjustment of the amount of payment to hospitals based on rates of hospital-acquired infections.

*(g) TECHNICAL EXPERT PANEL REVIEW OF OPIOID AND OPIOID USE DISORDER QUALITY MEASURES.—*

*(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this subsection, the Secretary shall establish a technical expert panel for purposes of reviewing quality measures relating to opioids and opioid use disorders, including care, prevention, diagnosis, health outcomes, and treatment furnished to individuals with opioid use disorders. The Secretary may use the entity with a contract under section 1890(a) and amend such contract as necessary to provide for the establishment of such technical expert panel.*

*(2) REVIEW AND ASSESSMENT.—Not later than 1 year after the date the technical expert panel described in paragraph (1) is established (and periodically thereafter as the Secretary determines appropriate), the technical expert panel shall—*

*(A) review quality measures that relate to opioids and opioid use disorders, including existing measures and those under development;*

*(B) identify gaps in areas of quality measurement that relate to opioids and opioid use disorders, and identify measure development priorities for such measure gaps; and*

*(C) make recommendations to the Secretary on quality measures with respect to opioids and opioid use disorders for purposes of improving care, prevention, diagnosis, health outcomes, and treatment, including recommendations for revisions of such measures, need for development of new measures, and recommendations for including such measures in the Merit-Based Incentive Payment System under section 1848(q), the alternative payment models under section 1833(z)(3)(C), the shared savings program under section 1899, the quality reporting requirements for inpatient hospitals under section 1886(b)(3)(B)(viii), and the hospital value-based purchasing program under section 1886(o).*

*(3) CONSIDERATION OF MEASURES BY SECRETARY.—The Secretary shall consider—*

*(A) using opioid and opioid use disorder measures (including measures used under the Merit-Based Incentive Payment System under section 1848(q), measures recommended under paragraph (2)(C), and other such measures identified by the Secretary) in alternative*

*payment models under section 1833(z)(3)(C) and in the shared savings program under section 1899; and*

*(B) using opioid measures described in subparagraph (A), as applicable, in the quality reporting requirements for inpatient hospitals under section 1886(b)(3)(B)(viii),and in the hospital value-based purchasing program under section 1886(o).*

*(4) PRIORITIZATION OF MEASURE DEVELOPMENT.—The Secretary shall prioritize for measure development the gaps in quality measures identified under paragraph (2)(B).*

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## TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

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### STATE PLANS FOR MEDICAL ASSISTANCE

SEC. 1902. (a) A State plan for medical assistance must—

(1) provide that it shall be in effect in all political subdivisions of the State, and, if administered by them, be mandatory upon them;

(2) provide for financial participation by the State equal to not less than 40 per centum of the non-Federal share of the expenditures under the plan with respect to which payments under section 1903 are authorized by this title; and, effective July 1, 1969, provide for financial participation by the State equal to all of such non-Federal share or provide for distribution of funds from Federal or State sources, for carrying out the State plan, on an equalization or other basis which will assure that the lack of adequate funds from local sources will not result in lowering the amount, duration, scope, or quality of care and services available under the plan;

(3) provide for granting an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance under the plan is denied or is not acted upon with reasonable promptness;

(4) provide (A) such methods of administration (including methods relating to the establishment and maintenance of personnel standards on a merit basis, except that the Secretary shall exercise no authority with respect to the selection, tenure of office, and compensation of any individual employed in accordance with such methods, and including provision for utilization of professional medical personnel in the administration and, where administered locally, supervision of administration of the plan) as are found by the Secretary to be necessary for the proper and efficient operation of the plan, (B) for the training and effective use of paid subprofessional staff, with particular emphasis on the full-time or part-time employment of recipients and other persons of low income, as community service aides, in the administration of the plan and for the use of nonpaid or partially paid volunteers in a social service volunteer program in providing services to applicants and recipients and in assisting any advisory committees established by the State agency, (C) that each State or local officer, employee, or independent contractor who is responsible for the expenditure of substantial amounts of funds under the State plan, each individual who formerly was such an officer, employee, or contractor, and each partner of such an officer, employee, or contractor shall be prohibited from committing any act, in relation to any activity under the plan, the commission of which, in connection with any activity concerning the United States Government, by an officer or employee of the United States Government, an individual who was such an officer or employee, or a partner of such an officer or employee is prohibited by section 207 or 208 of title 18, United States Code, and (D) that each State or local officer, employee, or independent contractor who is responsible for selecting, awarding, or otherwise obtaining items and services under the State plan shall be subject to safeguards against conflicts of interest that are at least as stringent as the safeguards that apply under section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423) to persons described in subsection (a)(2) of such section of that Act;

(5) either provide for the establishment or designation of a single State agency to administer or to supervise the administration of the plan; or provide for the establishment or designation of a single State agency to administer or to supervise the administration of the plan, except that the determination of eligibility for medical assistance under the plan shall be made by the State or local agency administering the State plan approved under title I or XVI (insofar as it relates to the aged) if the State is eligible to participate in the State plan program estab-

lished under title XVI, or by the agency or agencies administering the supplemental security income program established under title XVI or the State plan approved under part A of title IV if the State is not eligible to participate in the State plan program established under title XVI;

(6) provide that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time require, and comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports;

(7) provide—

(A) safeguards which restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with—

(i) the administration of the plan; and

(ii) the exchange of information necessary to certify or verify the certification of eligibility of children for free or reduced price breakfasts under the Child Nutrition Act of 1966 and free or reduced price lunches under the Richard B. Russell National School Lunch Act, in accordance with section 9(b) of that Act, using data standards and formats established by the State agency; and

(B) that, notwithstanding the Express Lane option under subsection (e)(13), the State may enter into an agreement with the State agency administering the school lunch program established under the Richard B. Russell National School Lunch Act under which the State shall establish procedures to ensure that—

(i) a child receiving medical assistance under the State plan under this title whose family income does not exceed 133 percent of the poverty line (as defined in section 673(2) of the Community Services Block Grant Act, including any revision required by such section), as determined without regard to any expense, block, or other income disregard, applicable to a family of the size involved, may be certified as eligible for free lunches under the Richard B. Russell National School Lunch Act and free breakfasts under the Child Nutrition Act of 1966 without further application; and

(ii) the State agencies responsible for administering the State plan under this title, and for carrying out the school lunch program established under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.) or the school breakfast program established by section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773), cooperate in carrying out paragraphs (3)(F) and (15) of section 9(b) of that Act;

(8) provide that all individuals wishing to make application for medical assistance under the plan shall have opportunity to do so, and that such assistance shall be furnished with reasonable promptness to all eligible individuals;

(9) provide—

(A) that the State health agency, or other appropriate State medical agency (whichever is utilized by the Secretary for the purpose specified in the first sentence of section 1864(a)), shall be responsible for establishing and maintaining health standards for private or public institutions in which recipients of medical assistance under the plan may receive care or services,

(B) for the establishment or designation of a State authority or authorities which shall be responsible for establishing and maintaining standards, other than those relating to health, for such institutions,

(C) that any laboratory services paid for under such plan must be provided by a laboratory which meets the applicable requirements of section 1861(e)(9) or paragraphs (16) and (17) of section 1861(s), or, in the case of a laboratory which is in a rural health clinic, of section 1861(aa)(2)(G), and

(D) that the State maintain a consumer-oriented website providing useful information to consumers regarding all skilled nursing facilities and all nursing facilities in the State, including for each facility, Form 2567 State inspection reports (or a successor form), complaint investigation reports, the facility's plan of correction, and such other information that the State or the Secretary considers useful in assisting the public to assess the quality of long term care options and the quality of care provided by individual facilities;

(10) provide—

(A) for making medical assistance available, including at least the care and services listed in paragraphs (1) through (5), (17), (21), [and (28)] *(28), and (29)* of section 1905(a), to—

(i) all individuals—

(I) who are receiving aid or assistance under any plan of the State approved under title I, X, XIV, or XVI, or part A or part E of title IV (including individuals eligible under this title by reason of section 402(a)(37), 406(h), or 473(b), or considered by the State to be receiving such aid as authorized under section 482(e)(6)),

(II)(aa) with respect to whom supplemental security income benefits are being paid under title XVI (or were being paid as of the date of the enactment of section 211(a) of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (P.L. 104–193) and would continue to be paid but for the enactment of that section), (bb) who are qualified severely impaired individuals (as defined in section 1905(q)), or (cc) who are under 21 years of age and with respect to whom supplemental security income benefits would be paid under title XVI if subparagraphs (A) and (B) of section 1611(c)(7) were applied without regard to the phrase "the first day of the month following",

(III) who are qualified pregnant women or children as defined in section 1905(n),

(IV) who are described in subparagraph (A) or (B) of subsection (l)(1) and whose family income does not exceed the minimum income level the State is required to establish under subsection (l)(2)(A) for such a family;

(V) who are qualified family members as defined in section 1905(m)(1),

(VI) who are described in subparagraph (C) of subsection (l)(1) and whose family income does not exceed the income level the State is required to establish under subsection (l)(2)(B) for such a family,

(VII) who are described in subparagraph (D) of subsection (l)(1) and whose family income does not exceed the income level the State is required to establish under subsection (l)(2)(C) for such a family;

(VIII) beginning January 1, 2014, who are under 65 years of age, not pregnant, not entitled to, or enrolled for, benefits under part A of title XVIII, or enrolled for benefits under part B of title XVIII, and are not described in a previous subclause of this clause, and whose income (as determined under subsection (e)(14)) does not exceed 133 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved, subject to subsection (k); or

(IX) who—

(aa) are under 26 years of age;

(bb) **[**are not described in or enrolled under**]** *are not described in and are not enrolled under* any of subclauses (I) through (VII) of this clause or are described in any of such subclauses but have income that exceeds the level of income applicable under the State plan for eligibility to enroll for medical assistance under such subclause;

(cc) were in foster care under the **[**responsibility of the State**]** *responsibility of a State* on the date of attaining 18 years of age or such higher age as the State has elected under section 475(8)(B)(iii); and

(dd) were enrolled in **[**the State plan under this title or under a waiver of the**]** *a State plan under this title or under a waiver of such a* plan while in such foster care;

(ii) at the option of the State, to any group or groups of individuals described in section 1905(a) (or, in the case of individuals described in section 1905(a)(i), to any reasonable categories of such individuals) who are not individuals described in clause (i) of this subparagraph but—

(I) who meet the income and resources requirements of the appropriate State plan described in clause (i) or the supplemental security income program (as the case may be),

(II) who would meet the income and resources requirements of the appropriate State plan described in clause (i) if their work-related child care costs were paid from their earnings rather than by a State agency as a service expenditure,

(III) who would be eligible to receive aid under the appropriate State plan described in clause (i) if coverage under such plan was as broad as allowed under Federal law,

(IV) with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them, aid or assistance under the appropriate State plan described in clause (i), supplemental security income benefits under title XVI, or a State supplementary payment;

(V) who are in a medical institution for a period of not less than 30 consecutive days (with eligibility by reason of this subclause beginning on the first day of such period), who meet the resource requirements of the appropriate State plan described in clause (i) or the supplemental security income program, and whose income does not exceed a separate income standard established by the State which is consistent with the limit established under section 1903(f)(4)(C),

(VI) who would be eligible under the State plan under this title if they were in a medical institution, with respect to whom there has been a determination that but for the provision of home or community-based services described in subsection (c), (d), or (e) of section 1915 they would require the level of care provided in a hospital, nursing facility or intermediate care facility for the mentally retarded the cost of which could be reimbursed under the State plan, and who will receive home or community-based services pursuant to a waiver granted by the Secretary under subsection (c), (d), or (e) of section 1915,

(VII) who would be eligible under the State plan under this title if they were in a medical institution, who are terminally ill, and who will receive hospice care pursuant to a voluntary election described in section 1905(o);

(VIII) who is a child described in section 1905(a)(i)—

(aa) for whom there is in effect an adoption assistance agreement (other than an agreement under part E of title IV) between the State and an adoptive parent or parents,

(bb) who the State agency responsible for adoption assistance has determined cannot be placed with adoptive parents without medical assistance because such child has special needs for medical or rehabilitative care, and

(cc) who was eligible for medical assistance under the State plan prior to the adoption assistance agreement being entered into, or who would have been eligible for medical assistance at such time if the eligibility standards and methodologies of the State's foster care program under part E of title IV were applied rather than the eligibility standards and methodologies of the State's aid to families with dependent children program under part A of title IV;

(IX) who are described in subsection (l)(1) and are not described in clause (i)(IV), clause (i)(VI), or clause (i)(VII);

(X) who are described in subsection (m)(1);

(XI) who receive only an optional State supplementary payment based on need and paid on a regular basis, equal to the difference between the individual's countable income and the income standard used to determine eligibility for such supplementary payment (with countable income being the income remaining after deductions as established by the State pursuant to standards that may be more restrictive than the standards for supplementary security income benefits under title XVI), which are available to all individuals in the State (but which may be based on different income standards by political subdivision according to cost of living differences), and which are paid by a State that does not have an agreement with the Commissioner of Social Security under section 1616 or 1634;

(XII) who are described in subsection (z)(1) (relating to certain TB-infected individuals);

(XIII) who are in families whose income is less than 250 percent of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved, and who but for earnings in excess of the limit established under section 1905(q)(2)(B), would be considered to be receiving supplemental security income (subject, notwithstanding section 1916, to payment of premiums or other cost-sharing charges (set on a sliding scale based on income) that the State may determine);

(XIV) who are optional targeted low-income children described in section 1905(u)(2)(B);

(XV) who, but for earnings in excess of the limit established under section 1905(q)(2)(B), would be considered to be receiving supplemental security income, who is at least 16, but less than 65, years of age, and whose assets, resources, and earned or unearned income (or both) do not exceed such limitations (if any) as the State may establish;

(XVI) who are employed individuals with a medically improved disability described in section 1905(v)(1) and whose assets, resources, and earned or unearned income (or both) do not exceed such limitations (if any) as the State may establish, but only if the State provides medical assistance to individuals described in subclause (XV);

(XVII) who are independent foster care adolescents (as defined in section 1905(w)(1)), or who are within any reasonable categories of such adolescents specified by the State;

(XVIII) who are described in subsection (aa) (relating to certain breast or cervical cancer patients);

(XIX) who are disabled children described in subsection (cc)(1);

(XX) beginning January 1, 2014, who are under 65 years of age and are not described in or enrolled under a previous subclause of this clause, and whose income (as determined under subsection (e)(14)) exceeds 133 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved but does not exceed the highest income eligibility level established under the State plan or under a waiver of the plan, subject to subsection (hh);

(XXI) who are described in subsection (ii) (relating to individuals who meet certain income standards); or

(XXII) who are eligible for home and community-based services under needs-based criteria established under paragraph (1)(A) of section 1915(i), or who are eligible for home and community-based services under paragraph (6) of such section, and who will receive home and community-based services pursuant to a State plan amendment under such subsection;

(B) that the medical assistance made available to any individual described in subparagraph (A)—

(i) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual, and

(ii) shall not be less in amount, duration, or scope than the medical assistance made available to individuals not described in subparagraph (A);

(C) that if medical assistance is included for any group of individuals described in section 1905(a) who are not described in subparagraph (A) or (E), then—

(i) the plan must include a description of (I) the criteria for determining eligibility of individuals in the group for such medical assistance, (II) the amount, duration, and scope of medical assistance made available to individuals in the group, and (III) the single standard to be employed in determining income and resource eligibility for all such groups, and the methodology to be employed in determining such eligibility, which shall be no more restrictive than the methodology which would be employed under the supplemental security income program in the case of groups consisting of aged, blind, or disabled individuals in a State in which such program is in effect, and which shall be no more restrictive than the methodology which would be employed under the appropriate State plan (described in subparagraph (A)(i)) to which such group is most closely categorically related in the case of other groups;

(ii) the plan must make available medical assistance—

(I) to individuals under the age of 18 who (but for income and resources) would be eligible for medical assistance as an individual described in subparagraph (A)(i), and

(II) to pregnant women, during the course of their pregnancy, who (but for income and resources) would be eligible for medical assistance as an individual described in subparagraph (A);

(iii) such medical assistance must include (I) with respect to children under 18 and individuals entitled to institutional services, ambulatory services, and (II) with respect to pregnant women, prenatal care and delivery services; and

(iv) if such medical assistance includes services in institutions for mental diseases or in an intermediate care facility for the mentally retarded (or both) for any such group, it also must include for all groups covered at least the care and services listed in paragraphs (1) through (5) and (17) of section 1905(a) or the care and services listed in any 7 of the paragraphs numbered (1) through (24) of such section;

(D) for the inclusion of home health services for any individual who, under the State plan, is entitled to nursing facility services;

(E)(i) for making medical assistance available for medicare cost-sharing (as defined in section 1905(p)(3)) for qualified medicare beneficiaries described in section 1905(p)(1);

(ii) for making medical assistance available for payment of medicare cost-sharing described in section 1905(p)(3)(A)(i) for qualified disabled and working individuals described in section 1905(s);

(iii) for making medical assistance available for medicare cost sharing described in section 1905(p)(3)(A)(ii) subject to section 1905(p)(4), for individuals who would be qualified medicare beneficiaries described in section 1905(p)(1) but for the fact that their income exceeds the income level established by the State under section 1905(p)(2) but is less than 110 percent in 1993 and 1994, and 120 percent in 1995 and years thereafter of the official poverty line (referred to in such section) for a family of the size involved; and

(iv) subject to sections 1933 and 1905(p)(4), for making medical assistance available for medicare cost-sharing described in section 1905(p)(3)(A)(ii) for individuals who would be qualified medicare beneficiaries described in section 1905(p)(1) but for the fact that their income exceeds the income level established by the State under section 1905(p)(2) and is at least 120 percent, but less than 135 percent, of the official poverty line (referred to in such section) for a family of the size involved and who are not otherwise eligible for medical assistance under the State plan;

(F) at the option of a State, for making medical assistance available for COBRA premiums (as defined in subsection (u)(2)) for qualified COBRA continuation beneficiaries described in section 1902(u)(1); and

(G) that, in applying eligibility criteria of the supplemental security income program under title XVI for purposes of determining eligibility for medical assistance under the State plan of an individual who is not receiving supplemental security income, the State will disregard the provisions of subsections (c) and (e) of section 1613;

except that (I) the making available of the services described in paragraph (4), (14), or (16) of section 1905(a) to individuals meeting the age requirements prescribed therein shall not, by reason of this paragraph (10), require the making available of any such services, or the making available of such services of the same amount, duration, and scope, to individuals of any other ages, (II) the making available of supplementary medical insurance benefits under part B of title XVIII to individuals eligible therefor (either pursuant to an agreement entered into under section 1843 or by reason of the payment of premiums under such title by the State agency on behalf of such individuals), or provision for meeting part or all of the cost of deductibles, cost sharing, or similar charges under part B of title XVIII for individuals eligible for benefits under such part, shall not, by reason of this paragraph (10), require the making available of any such benefits, or the making available of services of the same amount, duration, and scope, to any other individuals, (III) the making available of medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in clause (A) to any classification of individuals approved by the Secretary with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them, a State supplementary payment shall not, by reason of this paragraph (10), require the making available of any such assistance, or the making available of such assistance of the same amount, duration, and scope, to any other individuals not described in clause (A), (IV) the imposition of a deductible, cost sharing, or similar charge for any item or service furnished to an individual not eligible for the exemption under section 1916(a)(2) or (b)(2) shall not require the imposition of a deductible, cost sharing, or similar charge for the same item or service furnished to an individual who is eligible for such exemption, (V) the making available to pregnant women covered under the plan of services relating to pregnancy (including prenatal, delivery, and postpartum services) or to any other condition

which may complicate pregnancy shall not, by reason of this paragraph (10), require the making available of such services, or the making available of such services of the same amount, duration, and scope, to any other individuals, provided such services are made available (in the same amount, duration, and scope) to all pregnant women covered under the State plan, (VI) with respect to the making available of medical assistance for hospice care to terminally ill individuals who have made a voluntary election described in section 1905(o) to receive hospice care instead of medical assistance for certain other services, such assistance may not be made available in an amount, duration, or scope less than that provided under title XVIII, and the making available of such assistance shall not, by reason of this paragraph (10), require the making available of medical assistance for hospice care to other individuals or the making available of medical assistance for services waived by such terminally ill individuals, (VII) the medical assistance made available to an individual described in subsection (l)(1)(A) who is eligible for medical assistance only because of subparagraph (A)(i)(IV) or (A)(ii)(IX) shall be limited to medical assistance for services related to pregnancy (including prenatal, delivery, postpartum, and family planning services) and to other conditions which may complicate pregnancy, (VIII) the medical assistance made available to a qualified medicare beneficiary described in section 1905(p)(1) who is only entitled to medical assistance because the individual is such a beneficiary shall be limited to medical assistance for medicare cost-sharing (described in section 1905(p)(3)), subject to the provisions of subsection (n) and section 1916(b), (IX) the making available of respiratory care services in accordance with subsection (e)(9) shall not, by reason of this paragraph (10), require the making available of such services, or the making available of such services of the same amount, duration, and scope, to any individuals not included under subsection (e)(9)(A), provided such services are made available (in the same amount, duration, and scope) to all individuals described in such subsection, (X) if the plan provides for any fixed durational limit on medical assistance for inpatient hospital services (whether or not such a limit varies by medical condition or diagnosis), the plan must establish exceptions to such a limit for medically necessary inpatient hospital services furnished with respect to individuals under one year of age in a hospital defined under the State plan, pursuant to section 1923(a)(1)(A), as a disproportionate share hospital and subparagraph (B) (relating to comparability) shall not be construed as requiring such an exception for other individuals, services, or hospitals, (XI) the making available of medical assistance to cover the costs of premiums, deductibles, coinsurance, and other cost-sharing obligations for certain individuals for private health coverage as described in section 1906 shall not, by reason of paragraph (10), require the making available of any such benefits or the making available of services of the same amount, duration, and scope of such private coverage to any other individuals, (XII) the medical assistance made available to an individual described in subsection (u)(1) who is eligible for medical assistance only because of subparagraph (F) shall be limited to medical assistance for COBRA continuation premiums (as defined in subsection (u)(2)), (XIII) the medical assistance made available to an individual described in subsection (z)(1) who is eligible for medical assistance only because of subparagraph (A)(ii)(XII) shall be limited to medical assistance for TB-related services (described in subsection (z)(2)), (XIV) the medical assistance made available to an individual described in subsection (aa) who is eligible for medical assistance only because of subparagraph (A)(10)(ii)(XVIII) shall be limited to medical assistance provided during the period in which such an individual requires treatment for breast or cervical cancer (XV) the medical assistance made available to an individual described in subparagraph (A)(i)(VIII) shall be limited to medical assistance described in subsection (k)(1), (XVI) the medical assistance made available to an individual described in subsection (ii) shall be limited to family planning services and supplies described in section 1905(a)(4)(C) including medical diagnosis and treatment services that are provided pursuant to a family planning service in a family planning setting and (XVII) if an individual is described in subclause (IX) of subparagraph (A)(i) and is also described in subclause (VIII) of that subparagraph, the medical assistance shall be made available to the individual through subclause (IX) instead of through subclause (VIII);

(11)(A) provide for entering into cooperative arrangements with the State agencies responsible for administering or supervising the administration of health services and vocational rehabilitation services in the State looking toward maximum utilization of such services in the provision of medical assistance under the plan, (B) provide, to the extent prescribed by the Secretary, for entering into agreements, with any agency, institution, or organization receiving payments under (or through an allotment under) title V, (i) providing for utilizing such agency,

institution, or organization in furnishing care and services which are available under such title or allotment and which are included in the State plan approved under this section (ii) making such provision as may be appropriate for reimbursing such agency, institution, or organization for the cost of any such care and services furnished any individual for which payment would otherwise be made to the State with respect to the individual under section 1903, and (iii) providing for coordination of information and education on pediatric vaccinations and delivery of immunization services, and (C) provide for coordination of the operations under this title, including the provision of information and education on pediatric vaccinations and the delivery of immunization services, with the State's operations under the special supplemental nutrition program for women, infants, and children under section 17 of the Child Nutrition Act of 1966;

(12) provide that, in determining whether an individual is blind, there shall be an examination by a physician skilled in the diseases of the eye or by an optometrist, whichever the individual may select;

(13) provide—

(A) for a public process for determination of rates of payment under the plan for hospital services, nursing facility services, and services of intermediate care facilities for the mentally retarded under which—

(i) proposed rates, the methodologies underlying the establishment of such rates, and justifications for the proposed rates are published,

(ii) providers, beneficiaries and their representatives, and other concerned State residents are given a reasonable opportunity for review and comment on the proposed rates, methodologies, and justifications,

(iii) final rates, the methodologies underlying the establishment of such rates, and justifications for such final rates are published, and

(iv) in the case of hospitals, such rates take into account (in a manner consistent with section 1923) the situation of hospitals which serve a disproportionate number of low-income patients with special needs;

(B) for payment for hospice care in amounts no lower than the amounts, using the same methodology, used under part A of title XVIII and for payment of amounts under section 1905(o)(3); except that in the case of hospice care which is furnished to an individual who is a resident of a nursing facility or intermediate care facility for the mentally retarded, and who would be eligible under the plan for nursing facility services or services in an intermediate care facility for the mentally retarded if he had not elected to receive hospice care, there shall be paid an additional amount, to take into account the room and board furnished by the facility, equal to at least 95 percent of the rate that would have been paid by the State under the plan for facility services in that facility for that individual; and

(C) payment for primary care services (as defined in subsection (jj)) furnished in 2013 and 2014 by a physician with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine at a rate not less than 100 percent of the payment rate that applies to such services and physician under part B of title XVIII (or, if greater, the payment rate that would be applicable under such part if the conversion factor under section 1848(d) for the year involved were the conversion factor under such section for 2009);

(14) provide that enrollment fees, premiums, or similar charges, and deductions, cost sharing, or similar charges, may be imposed only as provided in section 1916;

(15) provide for payment for services described in clause (B) or (C) of section 1905(a)(2) under the plan in accordance with subsection (bb);

(16) provide for inclusion, to the extent required by regulations prescribed by the Secretary, of provisions (conforming to such regulations) with respect to the furnishing of medical assistance under the plan to individuals who are residents of the State but are absent therefrom;

(17) except as provided in subsections (e)(14), (e)(15), (l)(3), (m)(3), and (m)(4), include reasonable standards (which shall be comparable for all groups and may, in accordance with standards prescribed by the Secretary, differ with respect to income levels, but only in the case of applicants or recipients of assistance under the plan who are not receiving aid or assistance under any plan of the State approved under title I, X, XIV, or XVI, or part A of title IV, and with respect to whom supplemental security income benefits are not being paid under title XVI, based on the variations between shelter costs in urban areas and in rural areas) for deter-

mining eligibility for and the extent of medical assistance under the plan which (A) are consistent with the objectives of this title, (B) provide for taking into account only such income and resources as are, as determined in accordance with standards prescribed by the Secretary, available to the applicant or recipient and (in the case of any applicant or recipient who would, except for income and resources, be eligible for aid or assistance in the form of money payments under any plan of the State approved under title I, X, XIV, or XVI, or part A of title IV, or to have paid with respect to him supplemental security income benefits under title XVI) as would not be disregarded (or set aside for future needs) in determining his eligibility for such aid, assistance, or benefits, (C) provide for reasonable evaluation of any such income or resources, and (D) do not take into account the financial responsibility of any individual for any applicant or recipient of assistance under the plan unless such applicant or recipient is such individual's spouse or such individual's child who is under age 21 or (with respect to States eligible to participate in the State program established under title XVI), is blind or permanently and totally disabled, or is blind or disabled as defined in section 1614 (with respect to States which are not eligible to participate in such program); and provide for flexibility in the application of such standards with respect to income by taking into account, except to the extent prescribed by the Secretary, the costs (whether in the form of insurance premiums, payments made to the State under section 1903(f)(2)(B), or otherwise and regardless of whether such costs are reimbursed under another public program of the State or political subdivision thereof) incurred for medical care or for any other type of remedial care recognized under State law;

(18) comply with the provisions of section 1917 with respect to liens, adjustments and recoveries of medical assistance correctly paid, transfers of assets, and treatment of certain trusts;

(19) provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients;

(20) if the State plan includes medical assistance in behalf of individuals 65 years of age or older who are patients in institutions for mental diseases—

(A) provide for having in effect such agreements or other arrangements with State authorities concerned with mental diseases, and, where appropriate, with such institutions, as may be necessary for carrying out the State plan, including arrangements for joint planning and for development of alternate methods of care, arrangements providing assurance of immediate readmittance to institutions where needed for individuals under alternate plans of care, and arrangements providing for access to patients and facilities, for furnishing information, and for making reports;

(B) provide for an individual plan for each such patient to assure that the institutional care provided to him is in his best interests, including, to that end, assurances that there will be initial and periodic review of his medical and other needs, that he will be given appropriate medical treatment within the institution, and that there will be a periodic determination of his need for continued treatment in the institution; and

(C) provide for the development of alternate plans of care, making maximum utilization of available resources, for recipients 65 years of age or older who would otherwise need care in such institutions, including appropriate medical treatment and other aid or assistance; for services referred to in section 3(a)(4)(A)(i) and (ii) or section 1603(a)(4)(A)(i) and (ii) which are appropriate for such recipients and for such patients; and for methods of administration necessary to assure that the responsibilities of the State agency under the State plan with respect to such recipients and such patients will be effectively carried out;

(21) if the State plan includes medical assistance in behalf of individuals 65 years of age or older who are patients in public institutions for mental diseases, show that the State is making satisfactory progress toward developing and implementing a comprehensive mental health program, including provision for utilization of community mental health centers, nursing facilities, and other alternatives to care in public institutions for mental diseases;

(22) include descriptions of (A) the kinds and numbers of professional medical personnel and supporting staff that will be used in the administration of the plan and of the responsibilities they will have, (B) the standards, for private or public institutions in which recipients of medical assistance under the plan may receive care or services, that will be utilized by the State authority or authorities responsible for establishing and maintaining such standards, (C)

the cooperative arrangements with State health agencies and State vocational rehabilitation agencies entered into with a view to maximum utilization of and coordination of the provision of medical assistance with the services administered or supervised by such agencies, and (D) other standards and methods that the State will use to assure that medical or remedial care and services provided to recipients of medical assistance are of high quality;

(23) provide that (A) any individual eligible for medical assistance (including drugs) may obtain such assistance from any institution, agency, community pharmacy, or person, qualified to perform the service or services required (including an organization which provides such services, or arranges for their availability, on a prepayment basis), who undertakes to provide him such services, and (B) an enrollment of an individual eligible for medical assistance in a primary care case-management system (described in section 1915(b)(1)), a medicaid managed care organization, or a similar entity shall not restrict the choice of the qualified person from whom the individual may receive services under section 1905(a)(4)(C), except as provided in subsection (g) and in section 1915, except that this paragraph shall not apply in the case of Puerto Rico, the Virgin Islands, and Guam, and except that nothing in this paragraph shall be construed as requiring a State to provide medical assistance for such services furnished by a person or entity convicted of a felony under Federal or State law for an offense which the State agency determines is inconsistent with the best interests of beneficiaries under the State plan or by a provider or supplier to which a moratorium under subsection (kk)(4) is applied during the period of such moratorium';

(24) effective July 1, 1969, provide for consultative services by health agencies and other appropriate agencies of the State to hospitals, nursing facilities, home health agencies, clinics, laboratories, and such other institutions as the Secretary may specify in order to assist them (A) to qualify for payments under this Act, (B) to establish and maintain such fiscal records as may be necessary for the proper and efficient administration of this Act, and (C) to provide information needed to determine payments due under this Act on account of care and services furnished to individuals;

(25) provide—

(A) that the State or local agency administering such plan will take all reasonable measures to ascertain the legal liability of third parties (including health insurers, self-insured plans, group health plans (as defined in section 607(1) of the Employee Retirement Income Security Act of 1974), service benefit plans, managed care organizations, pharmacy benefit managers, or other parties that are, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service) to pay for care and services available under the plan, including—

(i) the collection of sufficient information (as specified by the Secretary in regulations) to enable the State to pursue claims against such third parties, with such information being collected at the time of any determination or redetermination of eligibility for medical assistance, and

(ii) the submission to the Secretary of a plan (subject to approval by the Secretary) for pursuing claims against such third parties, which plan shall be integrated with, and be monitored as a part of the Secretary's review of, the State's mechanized claims processing and information retrieval systems required under section 1903(r);

(B) that in any case where such a legal liability is found to exist after medical assistance has been made available on behalf of the individual and where the amount of reimbursement the State can reasonably expect to recover exceeds the costs of such recovery, the State or local agency will seek reimbursement for such assistance to the extent of such legal liability;

(C) that in the case of an individual who is entitled to medical assistance under the State plan with respect to a service for which a third party is liable for payment, the person furnishing the service may not seek to collect from the individual (or any financially responsible relative or representative of that individual) payment of an amount for that service (i) if the total of the amount of the liabilities of third parties for that service is at least equal to the amount payable for that service under the plan (disregarding section 1916), or (ii) in an amount which exceeds the lesser of (I) the amount which may be collected under section 1916, or (II) the amount by which the amount payable for that service under the plan (disregarding section 1916) exceeds the total of the amount of the liabilities of third parties for that service;

(D) that a person who furnishes services and is participating under the plan may not refuse to furnish services to an individual (who is entitled to have payment made under the plan for the services the person furnishes) because of a third party's potential liability for payment for the service;

(E) that in the case of preventive pediatric care (including early and periodic screening and diagnosis services under section 1905(a)(4)(B)) covered under the State plan, the State shall—

(i) make payment for such service in accordance with the usual payment schedule under such plan for such services without regard to the liability of a third party for payment for such services; and

(ii) seek reimbursement from such third party in accordance with subparagraph (B);

(F) that in the case of any services covered under such plan which are provided to an individual on whose behalf child support enforcement is being carried out by the State agency under part D of title IV of this Act, the State shall—

(i) make payment for such service in accordance with the usual payment schedule under such plan for such services without regard to any third-party liability for payment for such services, if such third-party liability is derived (through insurance or otherwise) from the parent whose obligation to pay support is being enforced by such agency, if payment has not been made by such third party within 30 days after such services are furnished;

(ii) seek reimbursement from such third party in accordance with subparagraph (B);

(G) that the State prohibits any health insurer (including a group health plan, as defined in section 607(1) of the Employee Retirement Income Security Act of 1974, a self-insured plan, a service benefit plan, a managed care organization, a pharmacy benefit manager, or other party that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service), in enrolling an individual or in making any payments for benefits to the individual or on the individual's behalf, from taking into account that the individual is eligible for or is provided medical assistance under a plan under this title for such State, or any other State;

(H) that to the extent that payment has been made under the State plan for medical assistance in any case where a third party has a legal liability to make payment for such assistance, the State has in effect laws under which, to the extent that payment has been made under the State plan for medical assistance for health care items or services furnished to an individual, the State is considered to have acquired the rights of such individual to payment by any other party for such health care items or services; and

(I) that the State shall provide assurances satisfactory to the Secretary that the State has in effect laws requiring health insurers, including self-insured plans, group health plans (as defined in section 607(1) of the Employee Retirement Income Security Act of 1974), service benefit plans, managed care organizations, pharmacy benefit managers, or other parties that are, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service, as a condition of doing business in the State, to—

(i) provide, with respect to individuals who are eligible (and, at State option, individuals who apply or whose eligibility for medical assistance is being evaluated in accordance with section 1902(e)(13)(D)) for, or are provided, medical assistance under a State plan (or under a waiver of the plan) under this title and child health assistance under title XXI, upon the request of the State, information to determine during what period the individual or their spouses or their dependents may be (or may have been) covered by a health insurer and the nature of the coverage that is or was provided by the health insurer (including the name, address, and identifying number of the plan) in a manner prescribed by the Secretary;

(ii) accept the State's right of recovery and the assignment to the State of any right of an individual or other entity to payment from the party for an item or service for which payment has been made under the State plan;

(iii) respond to any inquiry by the State regarding a claim for payment for any health care item or service that is submitted not later than 3 years after the date of the provision of such health care item or service; and

(iv) agree not to deny a claim submitted by the State solely on the basis of the date of submission of the claim, the type or format of the claim form, or a failure to present proper documentation at the point-of-sale that is the basis of the claim, if—

(I) the claim is submitted by the State within the 3-year period beginning on the date on which the item or service was furnished; and

(II) any action by the State to enforce its rights with respect to such claim is commenced within 6 years of the State's submission of such claim;

(26) if the State plan includes medical assistance for inpatient mental hospital services, provide, with respect to each patient receiving such services, for a regular program of medical review (including medical evaluation) of his need for such services, and for a written plan of care;

(27) provide for agreements with every person or institution providing services under the State plan under which such person or institution agrees (A) to keep such records as are necessary fully to disclose the extent of the services provided to individuals receiving assistance under the State plan, and (B) to furnish the State agency or the Secretary with such information, regarding any payments claimed by such person or institution for providing services under the State plan, as the State agency or the Secretary may from time to time request;

(28) provide—

(A) that any nursing facility receiving payments under such plan must satisfy all the requirements of subsections (b) through (d) of section 1919 as they apply to such facilities;

(B) for including in "nursing facility services" at least the items and services specified (or deemed to be specified) by the Secretary under section 1919(f)(7) and making available upon request a description of the items and services so included;

(C) for procedures to make available to the public the data and methodology used in establishing payment rates for nursing facilities under this title; and

(D) for compliance (by the date specified in the respective sections) with the requirements of—

(i) section 1919(e);

(ii) section 1919(g) (relating to responsibility for survey and certification of nursing facilities); and

(iii) sections 1919(h)(2)(B) and 1919(h)(2)(D) (relating to establishment and application of remedies);

(29) include a State program which meets the requirements set forth in section 1908, for the licensing of administrators of nursing homes;

(30)(A) provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4)) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area; and

(B) provide, under the program described in subparagraph (A), that—

(i) each admission to a hospital, intermediate care facility for the mentally retarded, or hospital for mental diseases is reviewed or screened in accordance with criteria established by medical and other professional personnel who are not themselves directly responsible for the care of the patient involved, and who do not have a significant financial interest in any such institution and are not, except in the case of a hospital, employed by the institution providing the care involved, and

(ii) the information developed from such review or screening, along with the data obtained from prior reviews of the necessity for admission and continued stay of patients by such professional personnel, shall be used as the basis for establishing the size and composition of the sample of admissions to be subject to review and evaluation by such personnel, and any such sample may be of any size up to 100 percent of all admissions and must be of sufficient size to serve the purpose of (I) identifying the patterns of care being provided and the changes occurring over time in such patterns so that the need for modification may be ascertained, and (II) subjecting admissions to early or more extensive review where information indicates that such consideration is warranted to a hospital, intermediate care facility for the mentally retarded, or hospital for mental diseases;

(31) with respect to services in an intermediate care facility for the mentally retarded (where the State plan includes medical assistance for such services) provide, with respect to each patient receiving such services, for a written plan of care, prior to admission to or authorization of benefits in such facility, in accordance with regulations of the Secretary, and for a regular program of independent professional review (including medical evaluation) which shall periodically review his need for such services;

(32) provide that no payment under the plan for any care or service provided to an individual shall be made to anyone other than such individual or the person or institution providing such care or service, under an assignment or power of attorney or otherwise; except that—

(A) in the case of any care or service provided by a physician, dentist, or other individual practitioner, such payment may be made (i) to the employer of such physician, dentist, or other practitioner if such physician, dentist, or practitioner is required as a condition of his employment to turn over his fee for such care or service to his employer, or (ii) (where the care or service was provided in a hospital, clinic, or other facility) to the facility in which the care or service was provided if there is a contractual arrangement between such physician, dentist, or practitioner and such facility under which such facility submits the bill for such care or service;

(B) nothing in this paragraph shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the person or institution providing the care or service involved if such assignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of such person or institution from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such person or institution under the plan is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment;

(C) in the case of services furnished (during a period that does not exceed 14 continuous days in the case of an informal reciprocal arrangement or 90 continuous days (or such longer period as the Secretary may provide) in the case of an arrangement involving per diem or other fee-for-time compensation) by, or incident to the services of, one physician to the patients of another physician who submits the claim for such services, payment shall be made to the physician submitting the claim (as if the services were furnished by, or incident to, the physician's services), but only if the claim identifies (in a manner specified by the Secretary) the physician who furnished the services; and

(D) in the case of payment for a childhood vaccine administered before October 1, 1994, to individuals entitled to medical assistance under the State plan, the State plan may make payment directly to the manufacturer of the vaccine under a voluntary replacement program agreed to by the State pursuant to which the manufacturer (i) supplies doses of the vaccine to providers administering the vaccine, (ii) periodically replaces the supply of the vaccine, and (iii) charges the State the manufacturer's price to the Centers for Disease Control and Prevention for the vaccine so administered (which price includes a reasonable amount to cover shipping and the handling of returns);

(33) provide—

(A) that the State health agency, or other appropriate State medical agency, shall be responsible for establishing a plan, consistent with regulations prescribed by the Secretary, for the review by appropriate professional health personnel of the appropriateness and quality of care and services furnished to recipients of medical assistance under the plan in order to provide guidance with respect thereto in the administration of the plan to the State agency established or designated pursuant to paragraph (5) and, where applicable, to the State agency described in the second sentence of this subsection; and

(B) that, except as provided in section 1919(g), the State or local agency utilized by the Secretary for the purpose specified in the first sentence of section 1864(a), or, if such agency is not the State agency which is responsible for licensing health institutions, the State agency responsible for such licensing, will perform for the State agency administering or supervising the administration of the plan approved under this title the function of determining whether institutions and agencies meet the requirements for participation in the program under such plan, except that, if the Secretary has cause to question

the adequacy of such determinations, the Secretary is authorized to validate State determinations and, on that basis, make independent and binding determinations concerning the extent to which individual institutions and agencies meet the requirements for participation;

(34) provide that in the case of any individual who has been determined to be eligible for medical assistance under the plan, such assistance will be made available to him for care and services included under the plan and furnished in or after the third month before the month in which he made application (or application was made on his behalf in the case of a deceased individual) for such assistance if such individual was (or upon application would have been) eligible for such assistance at the time such care and services were furnished;

(35) provide that any disclosing entity (as defined in section 1124(a)(2)) receiving payments under such plan complies with the requirements of section 1124;

(36) provide that within 90 days following the completion of each survey of any health care facility, laboratory, agency, clinic, or organization, by the appropriate State agency described in paragraph (9), such agency shall (in accordance with regulations of the Secretary) make public in readily available form and place the pertinent findings of each such survey relating to the compliance of each such health care facility, laboratory, clinic, agency, or organization with (A) the statutory conditions of participation imposed under this title, and (B) the major additional conditions which the Secretary finds necessary in the interest of health and safety of individuals who are furnished care or services by any such facility, laboratory, clinic, agency, or organization;

(37) provide for claims payment procedures which (A) ensure that 90 per centum of claims for payment (for which no further written information or substantiation is required in order to make payment) made for services covered under the plan and furnished by health care practitioners through individual or group practices or through shared health facilities are paid within 30 days of the date of receipt of such claims and that 99 per centum of such claims are paid within 90 days of the date of receipt of such claims, and (B) provide for procedures of prepayment and postpayment claims review, including review of appropriate data with respect to the recipient and provider of a service and the nature of the service for which payment is claimed, to ensure the proper and efficient payment of claims and management of the program;

(38) require that an entity (other than an individual practitioner or a group of practitioners) that furnishes, or arranges for the furnishing of, items or services under the plan, shall supply (within such period as may be specified in regulations by the Secretary or by the single State agency which administers or supervises the administration of the plan) upon request specifically addressed to such entity by the Secretary or such State agency, the information described in section 1128(b)(9);

(39) provide that the State agency shall exclude any specified individual or entity from participation in the program under the State plan for the period specified by the Secretary, when required by him to do so pursuant to section 1128 or section 1128A, terminate the participation of any individual or entity in such program if (subject to such exceptions as are permitted with respect to exclusion under sections 1128(c)(3)(B) and 1128(d)(3)(B)) participation of such individual or entity is terminated under title XVIII, any other State plan under this title (or waiver of the plan), or any State child health plan under title XXI (or waiver of the plan) and such termination is included by the Secretary in any database or similar system developed pursuant to section 6401(b)(2) of the Patient Protection and Affordable Care Act, and provide that no payment may be made under the plan with respect to any item or service furnished by such individual or entity during such period;

(40) require each health services facility or organization which receives payments under the plan and of a type for which a uniform reporting system has been established under section 1121(a) to make reports to the Secretary of information described in such section in accordance with the uniform reporting system (established under such section) for that type of facility or organization;

(41) provide, in accordance with subsection (kk)(8) (as applicable), that whenever a provider of services or any other person is terminated, suspended, or otherwise sanctioned or prohibited from participating under the State plan, the State agency shall promptly notify the Secretary and, in the case of a physician and notwithstanding paragraph (7), the State medical licensing board of such action;

(42) provide that—

(A) the records of any entity participating in the plan and providing services reimbursable on a cost-related basis will be audited as the Secretary determines to be necessary to insure that proper payments are made under the plan; and

(B) not later than December 31, 2010, the State shall—

(i) establish a program under which the State contracts (consistent with State law and in the same manner as the Secretary enters into contracts with recovery audit contractors under section 1893(h), subject to such exceptions or requirements as the Secretary may require for purposes of this title or a particular State) with 1 or more recovery audit contractors for the purpose of identifying underpayments and overpayments and recouping overpayments under the State plan and under any waiver of the State plan with respect to all services for which payment is made to any entity under such plan or waiver; and

(ii) provide assurances satisfactory to the Secretary that—

(I) under such contracts, payment shall be made to such a contractor only from amounts recovered;

(II) from such amounts recovered, payment—

(aa) shall be made on a contingent basis for collecting overpayments; and

(bb) may be made in such amounts as the State may specify for identifying underpayments;

(III) the State has an adequate process for entities to appeal any adverse determination made by such contractors; and

(IV) such program is carried out in accordance with such requirements as the Secretary shall specify, including—

(aa) for purposes of section 1903(a)(7), that amounts expended by the State to carry out the program shall be considered amounts expended as necessary for the proper and efficient administration of the State plan or a waiver of the plan;

(bb) that section 1903(d) shall apply to amounts recovered under the program; and

(cc) that the State and any such contractors under contract with the State shall coordinate such recovery audit efforts with other contractors or entities performing audits of entities receiving payments under the State plan or waiver in the State, including efforts with Federal and State law enforcement with respect to the Department of Justice, including the Federal Bureau of Investigations, the Inspector General of the Department of Health and Human Services, and the State medicaid fraud control unit; and

(43) provide for—

(A) informing all persons in the State who are under the age of 21 and who have been determined to be eligible for medical assistance including services described in section 1905(a)(4)(B), of the availability of early and periodic screening, diagnostic, and treatment services as described in section 1905(r) and the need for age-appropriate immunizations against vaccine-preventable diseases,

(B) providing or arranging for the provision of such screening services in all cases where they are requested,

(C) arranging for (directly or through referral to appropriate agencies, organizations, or individuals) corrective treatment the need for which is disclosed by such child health screening services, and

(D) reporting to the Secretary (in a uniform form and manner established by the Secretary, by age group and by basis of eligibility for medical assistance, and by not later than April 1 after the end of each fiscal year, beginning with fiscal year 1990) the following information relating to early and periodic screening, diagnostic, and treatment services provided under the plan during each fiscal year:

(i) the number of children provided child health screening services,

(ii) the number of children referred for corrective treatment (the need for which is disclosed by such child health screening services),

(iii) the number of children receiving dental services, and other information relating to the provision of dental services to such children described in section 2108(e) and

(iv) the State's results in attaining the participation goals set for the State under section 1905(r);

(44) in each case for which payment for inpatient hospital services, services in an intermediate care facility for the mentally retarded, or inpatient mental hospital services is made under the State plan—

(A) a physician (or, in the case of skilled nursing facility services or intermediate care facility services, a physician, or a nurse practitioner or clinical nurse specialist who is not an employee of the facility but is working in collaboration with a physician) certifies at the time of admission, or, if later, the time the individual applies for medical assistance under the State plan (and a physician, a physician assistant under the supervision of a physician, or, in the case of skilled nursing facility services or intermediate care facility services, a physician, or a nurse practitioner or clinical nurse specialist who is not an employee of the facility but is working in collaboration with a physician, recertifies, where such services are furnished over a period of time, in such cases, at least as often as required under section 1903(g)(6) (or, in the case of services that are services provided in an intermediate care facility for the mentally retarded, every year), and accompanied by such supporting material, appropriate to the case involved, as may be provided in regulations of the Secretary), that such services are or were required to be given on an inpatient basis because the individual needs or needed such services, and

(B) such services were furnished under a plan established and periodically reviewed and evaluated by a physician, or, in the case of skilled nursing facility services or intermediate care facility services, a physician, or a nurse practitioner or clinical nurse specialist who is not an employee of the facility but is working in collaboration with a physician;

(45) provide for mandatory assignment of rights of payment for medical support and other medical care owed to recipients, in accordance with section 1912;

(46)(A) provide that information is requested and exchanged for purposes of income and eligibility verification in accordance with a State system which meets the requirements of section 1137 of this Act; and

(B) provide, with respect to an individual declaring to be a citizen or national of the United States for purposes of establishing eligibility under this title, that the State shall satisfy the requirements of—

(i) section 1903(x); or

(ii) subsection (ee);

(47) provide—

(A) at the option of the State, for making ambulatory prenatal care available to pregnant women during a presumptive eligibility period in accordance with section 1920 and provide for making medical assistance for items and services described in subsection (a) of section 1920A available to children during a presumptive eligibility period in accordance with such section and provide for making medical assistance available to individuals described in subsection (a) of section 1920B during a presumptive eligibility period in accordance with such section and provide for making medical assistance available to individuals described in subsection (a) of section 1920C during a presumptive eligibility period in accordance with such section; and

(B) that any hospital that is a participating provider under the State plan may elect to be a qualified entity for purposes of determining, on the basis of preliminary information, whether any individual is eligible for medical assistance under the State plan or under a waiver of the plan for purposes of providing the individual with medical assistance during a presumptive eligibility period, in the same manner, and subject to the same requirements, as apply to the State options with respect to populations described in section 1920, 1920A, 1920B, or 1920C (but without regard to whether the State has elected to provide for a presumptive eligibility period under any such sections), subject to such guidance as the Secretary shall establish;

(48) provide a method of making cards evidencing eligibility for medical assistance available to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address;

(49) provide that the State will provide information and access to certain information respecting sanctions taken against health care practitioners and providers by State licensing authorities in accordance with section 1921;

(50) provide, in accordance with subsection (q), for a monthly personal needs allowance for certain institutionalized individuals and couples;

(51) meet the requirements of section 1924 (relating to protection of community spouses);

(52) meet the requirements of section 1925 (relating to extension of eligibility for medical assistance);

(53) provide—

(A) for notifying in a timely manner all individuals in the State who are determined to be eligible for medical assistance and who are pregnant women, breastfeeding or postpartum women (as defined in section 17 of the Child Nutrition Act of 1966), or children below the age of 5, of the availability of benefits furnished by the special supplemental nutrition program under such section, and

(B) for referring any such individual to the State agency responsible for administering such program;

(54) in the case of a State plan that provides medical assistance for covered outpatient drugs (as defined in section 1927(k)), comply with the applicable requirements of section 1927;

(55) provide for receipt and initial processing of applications of individuals for medical assistance under subsection (a)(10)(A)(i)(IV), (a)(10)(A)(i)(VI), (a)(10)(A)(i)(VII), or (a)(10)(A)(ii)(IX)—

(A) at locations which are other than those used for the receipt and processing of applications for aid under part A of title IV and which include facilities defined as disproportionate share hospitals under section 1923(a)(1)(A) and Federally-qualified health centers described in section 1905(1)(2)(B), and

(B) using applications which are other than those used for applications for aid under such part;

(56) provide, in accordance with subsection (s), for adjusted payments for certain inpatient hospital services;

(57) provide that each hospital, nursing facility, provider of home health care or personal care services, hospice program, or medicaid managed care organization (as defined in section 1903(m)(1)(A)) receiving funds under the plan shall comply with the requirements of subsection (w);

(58) provide that the State, acting through a State agency, association, or other private nonprofit entity, develop a written description of the law of the State (whether statutory or as recognized by the courts of the State) concerning advance directives that would be distributed by providers or organizations under the requirements of subsection (w);

(59) maintain a list (updated not less often than monthly, and containing each physician's unique identifier provided under the system established under subsection (x)) of all physicians who are certified to participate under the State plan;

(60) provide that the State agency shall provide assurances satisfactory to the Secretary that the State has in effect the laws relating to medical child support required under section 1908A;

(61) provide that the State must demonstrate that it operates a medicaid fraud and abuse control unit described in section 1903(q) that effectively carries out the functions and requirements described in such section, as determined in accordance with standards established by the Secretary, unless the State demonstrates to the satisfaction of the Secretary that the effective operation of such a unit in the State would not be cost-effective because minimal fraud exists in connection with the provision of covered services to eligible individuals under the State plan, and that beneficiaries under the plan will be protected from abuse and neglect in connection with the provision of medical assistance under the plan without the existence of such a unit;

(62) provide for a program for the distribution of pediatric vaccines to program-registered providers for the immunization of vaccine-eligible children in accordance with section 1928;

(63) provide for administration and determinations of eligibility with respect to individuals who are (or seek to be) eligible for medical assistance based on the application of section 1931;

(64) provide, not later than 1 year after the date of the enactment of this paragraph, a mechanism to receive reports from beneficiaries and others and compile data concerning alleged instances of waste, fraud, and abuse relating to the operation of this title;

(65) provide that the State shall issue provider numbers for all suppliers of medical assistance consisting of durable medical equipment, as defined in section 1861(n), and the State shall not issue or renew such a supplier number for any such supplier unless—

(A)(i) full and complete information as to the identity of each person with an ownership or control interest (as defined in section 1124(a)(3)) in the supplier or in any subcon-

tractor (as defined by the Secretary in regulations) in which the supplier directly or indirectly has a 5 percent or more ownership interest; and

(ii) to the extent determined to be feasible under regulations of the Secretary, the name of any disclosing entity (as defined in section 1124(a)(2)) with respect to which a person with such an ownership or control interest in the supplier is a person with such an ownership or control interest in the disclosing entity; and

(B) a surety bond in a form specified by the Secretary under section 1834(a)(16)(B) and in an amount that is not less than $50,000 or such comparable surety bond as the Secretary may permit under the second sentence of such section;

(66) provide for making eligibility determinations under section 1935(a);

(67) provide, with respect to services covered under the State plan (but not under title XVIII) that are furnished to a PACE program eligible individual enrolled with a PACE provider by a provider participating under the State plan that does not have a contract or other agreement with the PACE provider that establishes payment amounts for such services, that such participating provider may not require the PACE provider to pay the participating provider an amount greater than the amount that would otherwise be payable for the service to the participating provider under the State plan for the State where the PACE provider is located (in accordance with regulations issued by the Secretary);

(68) provide that any entity that receives or makes annual payments under the State plan of at least $5,000,000, as a condition of receiving such payments, shall—

(A) establish written policies for all employees of the entity (including management), and of any contractor or agent of the entity, that provide detailed information about the False Claims Act established under sections 3729 through 3733 of title 31, United States Code, administrative remedies for false claims and statements established under chapter 38 of title 31, United States Code, any State laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under such laws, with respect to the role of such laws in preventing and detecting fraud, waste, and abuse in Federal health care programs (as defined in section 1128B(f));

(B) include as part of such written policies, detailed provisions regarding the entity's policies and procedures for detecting and preventing fraud, waste, and abuse; and

(C) include in any employee handbook for the entity, a specific discussion of the laws described in subparagraph (A), the rights of employees to be protected as whistleblowers, and the entity's policies and procedures for detecting and preventing fraud, waste, and abuse;

(69) provide that the State must comply with any requirements determined by the Secretary to be necessary for carrying out the Medicaid Integrity Program established under section 1936;

(70) at the option of the State and notwithstanding paragraphs (1), (10)(B), and (23), provide for the establishment of a non-emergency medical transportation brokerage program in order to more cost-effectively provide transportation for individuals eligible for medical assistance under the State plan who need access to medical care or services and have no other means of transportation which—

(A) may include a wheelchair van, taxi, stretcher car, bus passes and tickets, secured transportation, and such other transportation as the Secretary determines appropriate; and

(B) may be conducted under contract with a broker who—

(i) is selected through a competitive bidding process based on the State's evaluation of the broker's experience, performance, references, resources, qualifications, and costs;

(ii) has oversight procedures to monitor beneficiary access and complaints and ensure that transport personnel are licensed, qualified, competent, and courteous;

(iii) is subject to regular auditing and oversight by the State in order to ensure the quality of the transportation services provided and the adequacy of beneficiary access to medical care and services; and

(iv) complies with such requirements related to prohibitions on referrals and conflict of interest as the Secretary shall establish (based on the prohibitions on physician referrals under section 1877 and such other prohibitions and requirements as the Secretary determines to be appropriate);

(71) provide that the State will implement an asset verification program as required under section 1940;

(72) provide that the State will not prevent a Federally-qualified health center from entering into contractual relationships with private practice dental providers in the provision of Federally-qualified health center services;

(73) in the case of any State in which 1 or more Indian Health Programs or Urban Indian Organizations furnishes health care services, provide for a process under which the State seeks advice on a regular, ongoing basis from designees of such Indian Health Programs and Urban Indian Organizations on matters relating to the application of this title that are likely to have a direct effect on such Indian Health Programs and Urban Indian Organizations and that—

(A) shall include solicitation of advice prior to submission of any plan amendments, waiver requests, and proposals for demonstration projects likely to have a direct effect on Indians, Indian Health Programs, or Urban Indian Organizations; and

(B) may include appointment of an advisory committee and of a designee of such Indian Health Programs and Urban Indian Organizations to the medical care advisory committee advising the State on its State plan under this title;

(74) provide for maintenance of effort under the State plan or under any waiver of the plan in accordance with subsection (gg); and

(75) provide that, beginning January 2015, and annually thereafter, the State shall submit a report to the Secretary that contains—

(A) the total number of enrolled and newly enrolled individuals in the State plan or under a waiver of the plan for the fiscal year ending on September 30 of the preceding calendar year, disaggregated by population, including children, parents, nonpregnant childless adults, disabled individuals, elderly individuals, and such other categories or subcategories of individuals eligible for medical assistance under the State plan or under a waiver of the plan as the Secretary may require;

(B) a description, which may be specified by population, of the outreach and enrollment processes used by the State during such fiscal year; and

(C) any other data reporting determined necessary by the Secretary to monitor enrollment and retention of individuals eligible for medical assistance under the State plan or under a waiver of the plan;

(76) provide that any data collected under the State plan meets the requirements of section 3101 of the Public Health Service Act;

(77) provide that the State shall comply with provider and supplier screening, oversight, and reporting requirements in accordance with subsection (kk);

(78) provide that, not later than January 1, 2017, in the case of a State that pursuant to its State plan or waiver of the plan for medical assistance pays for medical assistance on a fee-for-service basis, the State shall require each provider furnishing items and services to, or ordering, prescribing, referring, or certifying eligibility for, services for individuals eligible to receive medical assistance under such plan to enroll with the State agency and provide to the State agency the provider's identifying information, including the name, specialty, date of birth, Social Security number, national provider identifier (if applicable), Federal taxpayer identification number, and the State license or certification number of the provider (if applicable);

(79) provide that any agent, clearinghouse, or other alternate payee (as defined by the Secretary) that submits claims on behalf of a health care provider must register with the State and the Secretary in a form and manner specified by the Secretary;

(80) provide that the State shall not provide any payments for items or services provided under the State plan or under a waiver to any financial institution or entity located outside of the United States;

(81) provide for implementation of the payment models specified by the Secretary under section 1115A(c) for implementation on a nationwide basis unless the State demonstrates to the satisfaction of the Secretary that implementation would not be administratively feasible or appropriate to the health care delivery system of the State;

(82) provide that the State agency responsible for administering the State plan under this title provides assurances to the Secretary that the State agency is in compliance with subparagraphs (A), (B), and (C) of section 1128K(b)(2); **[**and**]**

(83) provide that, not later than January 1, 2017, in the case of a State plan (or waiver of the plan) that provides medical assistance on a fee-for-service basis or through a primary

care case-management system described in section 1915(b)(1) (other than a primary care case management entity (as defined by the Secretary)), the State shall publish (and update on at least an annual basis) on the public website of the State agency administering the State plan, a directory of the physicians described in subsection (mm) and, at State option, other providers described in such subsection that—

(A) includes—

(i) with respect to each such physician or provider—

(I) the name of the physician or provider;

(II) the specialty of the physician or provider;

(III) the address at which the physician or provider provides services; and

(IV) the telephone number of the physician or provider; and

(ii) with respect to any such physician or provider participating in such a primary care case-management system, information regarding—

(I) whether the physician or provider is accepting as new patients individuals who receive medical assistance under this title; and

(II) the physician's or provider's cultural and linguistic capabilities, including the languages spoken by the physician or provider or by the skilled medical interpreter providing interpretation services at the physician's or provider's office; and

(B) may include, at State option, with respect to each such physician or provider—

(i) the Internet website of such physician or provider; or

(ii) whether the physician or provider is accepting as new patients individuals who receive medical assistance under this title**[**.**]***;*

*(84) provide that—*

*(A) the State shall not terminate eligibility for medical assistance under the State plan for an individual who is an eligible juvenile (as defined in subsection (nn)(2)) because the juvenile is an inmate of a public institution (as defined in subsection (nn)(3)), but may suspend coverage during the period the juvenile is such an inmate;*

*(B) in the case of an individual who is an eligible juvenile described in paragraph (2)(A) of subsection (nn), the State shall, prior to the individual's release from such a public institution, conduct a redetermination of eligibility for such individual with respect to such medical assistance (without requiring a new application from the individual) and, if the State determines pursuant to such redetermination that the individual continues to meet the eligibility requirements for such medical assistance, the State shall restore coverage for such medical assistance to such an individual upon the individual's release from such public institution; and*

*(C) in the case of an individual who is an eligible juvenile described in paragraph (2)(B) of subsection (nn), the State shall process any application for medical assistance submitted by, or on behalf of, such individual such that the State makes a determination of eligibility for such individual with respect to such medical assistance upon release of such individual from such public institution; and*

*(85) provide that the State is in compliance with the drug review and utilization requirements under subsection (oo)(1).*

Notwithstanding paragraph (5), if on January 1, 1965, and on the date on which a State submits its plan for approval under this title, the State agency which administered or supervised the administration of the plan of such State approved under title X (or title XVI, insofar as it relates to the blind) was different from the State agency which administered or supervised the administration of the State plan approved under title I (or title XVI, insofar as it relates to the aged), the State agency which administered or supervised the administration of such plan approved under title X (or title XVI, insofar as it relates to the blind) may be designated to administer or supervise the administration of the portion of the State plan for medical assistance which relates to blind individuals and a different State agency may be established or designated to administer or supervise the administration of the rest of the State plan for medical assistance; and in such case the part of the plan which each such agency administers, or the administration of which each such agency supervises, shall be regarded as a separate plan for purposes of this title (except for purposes of paragraph (10)). The provisions of paragraphs (9)(A), (31), and (33) and of section 1903(i)(4) shall not apply to a religious nonmedical health care institution (as defined in section 1861(ss)(1)).

For purposes of paragraph (10) any individual who, for the month of August 1972, was eligible for or receiving aid or assistance under a State plan approved under title I, X, XIV, or XVI, or part

A of title IV and who for such month was entitled to monthly insurance benefits under title II shall for purposes of this title only be deemed to be eligible for financial aid or assistance for any month thereafter if such individual would have been eligible for financial aid or assistance for such month had the increase in monthly insurance benefits under title II resulting from enactment of Public Law 92-336 not been applicable to such individual.

The requirement of clause (A) of paragraph (37) with respect to a State plan may be waived by the Secretary if he finds that the State has exercised good faith in trying to meet such requirement. For purposes of this title, any child who meets the requirements of paragraph (1) or (2) of section 473(b) shall be deemed to be a dependent child as defined in section 406 and shall be deemed to be a recipient of aid to families with dependent children under part A of title IV in the State where such child resides. Notwithstanding paragraph (10)(B) or any other provision of this subsection, a State plan shall provide medical assistance with respect to an alien who is not lawfully admitted for permanent residence or otherwise permanently residing in the United States under color of law only in accordance with section 1903(v).

(b) The Secretary shall approve any plan which fulfills the conditions specified in subsection (a) of this section, except that he shall not approve any plan which imposes, as a condition of eligibility for medical assistance under the plan—

(1) an age requirement of more than 65 years; or

(2) any residence requirement which excludes any individual who resides in the State, regardless of whether or not the residence is maintained permanently or at a fixed address; or

(3) any citizenship requirement which excludes any citizen of the United States.

(c) Notwithstanding subsection (b), the Secretary shall not approve any State plan for medical assistance if the State requires individuals described in subsection (l)(1) to apply for assistance under the State program funded under part A of title IV as a condition of applying for or receiving medical assistance under this title.

(d) If a State contracts with an entity which meets the requirements of section 1152, as determined by the Secretary, or a utilization and quality control peer review organization having a contract with the Secretary under part B of title XI for the performance of medical or utilization review functions (including quality review functions described in subsection (a)(30)(C)) required under this title of a State plan with respect to specific services or providers (or services or providers in a geographic area of the State), such requirements shall be deemed to be met for those services or providers (or services or providers in that area) by delegation to such an entity or organization under the contract of the State's authority to conduct such review activities if the contract provides for the performance of activities not inconsistent with part B of title XI and provides for such assurances of satisfactory performance by such an entity or organization as the Secretary may prescribe.

(e)(1) Beginning April 1, 1990, for provisions relating to the extension of eligibility for medical assistance for certain families who have received aid pursuant to a State plan approved under part A of title IV and have earned income, see section 1925.

(2)(A) In the case of an individual who is enrolled with a medicaid managed care organization (as defined in section 1903(m)(1)(A)), with a primary care case manager (as defined in section 1905(t)), or with an eligible organization with a contract under section 1876 and who would (but for this paragraph) lose eligibility for benefits under this title before the end of the minimum enrollment period (defined in subparagraph (B)), the State plan may provide, notwithstanding any other provision of this title, that the individual shall be deemed to continue to be eligible for such benefits until the end of such minimum period, but, except for benefits furnished under section 1905(a)(4)(C), only with respect to such benefits provided to the individual as an enrollee of such organization or entity or by or through the case manager.

(B) For purposes of subparagraph (A), the term "minimum enrollment period" means, with respect to an individual's enrollment with an organization or entity under a State plan, a period, established by the State, of not more than six months beginning on the date the individual's enrollment with the organization or entity becomes effective.

(3) At the option of the State, any individual who—

(A) is 18 years of age or younger and qualifies as a disabled individual under section 1614(a);

(B) with respect to whom there has been a determination by the State that—

(i) the individual requires a level of care provided in a hospital, nursing facility, or intermediate care facility for the mentally retarded,

(ii) it is appropriate to provide such care for the individual outside such an institution, and

(iii) the estimated amount which would be expended for medical assistance for the individual for such care outside an institution is not greater than the estimated amount which would otherwise be expended for medical assistance for the individual within an appropriate institution; and

(C) if the individual were in a medical institution, would be eligible for medical assistance under the State plan under this title,

shall be deemed, for purposes of this title only, to be an individual with respect to whom a supplemental security income payment, or State supplemental payment, respectively, is being paid under title XVI.

(4) A child born to a woman eligible for and receiving medical assistance under a State plan on the date of the child's birth shall be deemed to have applied for medical assistance and to have been found eligible for such assistance under such plan on the date of such birth and to remain eligible for such assistance for a period of one year. During the period in which a child is deemed under the preceding sentence to be eligible for medical assistance, the medical assistance eligibility identification number of the mother shall also serve as the identification number of the child, and all claims shall be submitted and paid under such number (unless the State issues a separate identification number for the child before such period expires). Notwithstanding the preceding sentence, in the case of a child who is born in the United States to an alien mother for whom medical assistance for the delivery of the child is made available pursuant to section 1903(v), the State immediately shall issue a separate identification number for the child upon notification by the facility at which such delivery occurred of the child's birth.

(5) A woman who, while pregnant, is eligible for, has applied for, and has received medical assistance under the State plan, shall continue to be eligible under the plan, as though she were pregnant, for all pregnancy-related and postpartum medical assistance under the plan, through the end of the month in which the 60-day period (beginning on the last day of her pregnancy) ends.

(6) In the case of a pregnant woman described in subsection (a)(10) who, because of a change in income of the family of which she is a member, would not otherwise continue to be described in such subsection, the woman shall be deemed to continue to be an individual described in subsection (a)(10)(A)(i)(IV) and subsection (l)(1)(A) without regard to such change of income through the end of the month in which the 60-day period (beginning on the last day of her pregnancy) ends. The preceding sentence shall not apply in the case of a woman who has been provided ambulatory prenatal care pursuant to section 1920 during a presumptive eligibility period and is then, in accordance with such section, determined to be ineligible for medical assistance under the State plan.

(7) In the case of an infant or child described in subparagraph (B), (C), or (D) of subsection (l)(1) or paragraph (2) of section 1905(n)—

(A) who is receiving inpatient services for which medical assistance is provided on the date the infant or child attains the maximum age with respect to which coverage is provided under the State plan for such individuals, and

(B) who, but for attaining such age, would remain eligible for medical assistance under such subsection,

the infant or child shall continue to be treated as an individual described in such respective provision until the end of the stay for which the inpatient services are furnished.

(8) If an individual is determined to be a qualified medicare beneficiary (as defined in section 1905(p)(1)), such determination shall apply to services furnished after the end of the month in which the determination first occurs. For purposes of payment to a State under section 1903(a), such determination shall be considered to be valid for an individual for a period of 12 months, except that a State may provide for such determinations more frequently, but not more frequently than once every 6 months for an individual.

(9)(A) At the option of the State, the plan may include as medical assistance respiratory care services for any individual who—

(i) is medically dependent on a ventilator for life support at least six hours per day;

(ii) has been so dependent for at least 30 consecutive days (or the maximum number of days authorized under the State plan, whichever is less) as an inpatient;

(iii) but for the availability of respiratory care services, would require respiratory care as an inpatient in a hospital, nursing facility, or intermediate care facility for the mentally retarded and would be eligible to have payment made for such inpatient care under the State plan;

(iv) has adequate social support services to be cared for at home; and
(v) wishes to be cared for at home.

(B) The requirements of subparagraph (A)(ii) may be satisfied by a continuous stay in one or more hospitals, nursing facilities, or intermediate care facilities for the mentally retarded.

(C) For purposes of this paragraph, respiratory care services means services provided on a part-time basis in the home of the individual by a respiratory therapist or other health care professional trained in respiratory therapy (as determined by the State), payment for which is not otherwise included within other items and services furnished to such individual as medical assistance under the plan.

(10)(A) The fact that an individual, child, or pregnant woman may be denied aid under part A of title IV pursuant to section 402(a)(43) shall not be construed as denying (or permitting a State to deny) medical assistance under this title to such individual, child, or woman who is eligible for assistance under this title on a basis other than the receipt of aid under such part.

(B) If an individual, child, or pregnant woman is receiving aid under part A of title IV and such aid is terminated pursuant to section 402(a)(43), the State may not discontinue medical assistance under this title for the individual, child, or woman until the State has determined that the individual, child, or woman is not eligible for assistance under this title on a basis other than the receipt of aid under such part.

(11)(A) In the case of an individual who is enrolled with a group health plan under section 1906 and who would (but for this paragraph) lose eligibility for benefits under this title before the end of the minimum enrollment period (defined in subparagraph (B)), the State plan may provide, notwithstanding any other provision of this title, that the individual shall be deemed to continue to be eligible for such benefits until the end of such minimum period, but only with respect to such benefits provided to the individual as an enrollee of such plan.

(B) For purposes of subparagraph (A), the term "minimum enrollment period" means, with respect to an individual's enrollment with a group health plan, a period established by the State, of not more than 6 months beginning on the date the individual's enrollment under the plan becomes effective.

(12) At the option of the State, the plan may provide that an individual who is under an age specified by the State (not to exceed 19 years of age) and who is determined to be eligible for benefits under a State plan approved under this title under subsection (a)(10)(A) shall remain eligible for those benefits until the earlier of—

(A) the end of a period (not to exceed 12 months) following the determination; or
(B) the time that the individual exceeds that age.

(13) EXPRESS LANE OPTION.—

(A) IN GENERAL.—

(i) OPTION TO USE A FINDING FROM AN EXPRESS LANE AGENCY.—At the option of the State, the State plan may provide that in determining eligibility under this title for a child (as defined in subparagraph (G)), the State may rely on a finding made within a reasonable period (as determined by the State) from an Express Lane agency (as defined in subparagraph (F)) when it determines whether a child satisfies one or more components of eligibility for medical assistance under this title. The State may rely on a finding from an Express Lane agency notwithstanding sections 1902(a)(46)(B) and 1137(d) or any differences in budget unit, disregard, deeming or other methodology, if the following requirements are met:

(I) PROHIBITION ON DETERMINING CHILDREN INELIGIBLE FOR COVERAGE.—If a finding from an Express Lane agency would result in a determination that a child does not satisfy an eligibility requirement for medical assistance under this title and for child health assistance under title XXI, the State shall determine eligibility for assistance using its regular procedures.

(II) NOTICE REQUIREMENT.—For any child who is found eligible for medical assistance under the State plan under this title or child health assistance under title XXI and who is subject to premiums based on an Express Lane agency's finding of such child's income level, the State shall provide notice that the child may qualify for lower premium payments if evaluated by the State using its regular policies and of the procedures for requesting such an evaluation.

(III) COMPLIANCE WITH SCREEN AND ENROLL REQUIREMENT.—The State shall satisfy the requirements under subparagraphs (A) and (B) of section 2102(b)(3) (relating to screen and enroll) before enrolling a child in child health assistance under title XXI.

At its option, the State may fulfill such requirements in accordance with either option provided under subparagraph (C) of this paragraph.

(IV) VERIFICATION OF CITIZENSHIP OR NATIONALITY STATUS.—The State shall satisfy the requirements of section 1902(a)(46)(B) or 2105(c)(9), as applicable for verifications of citizenship or nationality status.

(V) CODING.—The State meets the requirements of subparagraph (E).

(ii) OPTION TO APPLY TO RENEWALS AND REDETERMINATIONS.—The State may apply the provisions of this paragraph when conducting initial determinations of eligibility, redeterminations of eligibility, or both, as described in the State plan.

(B) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

(i) to limit or prohibit a State from taking any actions otherwise permitted under this title or title XXI in determining eligibility for or enrolling children into medical assistance under this title or child health assistance under title XXI; or

(ii) to modify the limitations in section 1902(a)(5) concerning the agencies that may make a determination of eligibility for medical assistance under this title.

(C) OPTIONS FOR SATISFYING THE SCREEN AND ENROLL REQUIREMENT.—

(i) IN GENERAL.—With respect to a child whose eligibility for medical assistance under this title or for child health assistance under title XXI has been evaluated by a State agency using an income finding from an Express Lane agency, a State may carry out its duties under subparagraphs (A) and (B) of section 2102(b)(3) (relating to screen and enroll) in accordance with either clause (ii) or clause (iii).

(ii) ESTABLISHING A SCREENING THRESHOLD.—

(I) IN GENERAL.—Under this clause, the State establishes a screening threshold set as a percentage of the Federal poverty level that exceeds the highest income threshold applicable under this title to the child by a minimum of 30 percentage points or, at State option, a higher number of percentage points that reflects the value (as determined by the State and described in the State plan) of any differences between income methodologies used by the program administered by the Express Lane agency and the methodologies used by the State in determining eligibility for medical assistance under this title.

(II) CHILDREN WITH INCOME NOT ABOVE THRESHOLD.—If the income of a child does not exceed the screening threshold, the child is deemed to satisfy the income eligibility criteria for medical assistance under this title regardless of whether such child would otherwise satisfy such criteria.

(III) CHILDREN WITH INCOME ABOVE THRESHOLD.—If the income of a child exceeds the screening threshold, the child shall be considered to have an income above the Medicaid applicable income level described in section 2110(b)(4) and to satisfy the requirement under section 2110(b)(1)(C) (relating to the requirement that CHIP matching funds be used only for children not eligible for Medicaid). If such a child is enrolled in child health assistance under title XXI, the State shall provide the parent, guardian, or custodial relative with the following:

(aa) Notice that the child may be eligible to receive medical assistance under the State plan under this title if evaluated for such assistance under the State's regular procedures and notice of the process through which a parent, guardian, or custodial relative can request that the State evaluate the child's eligibility for medical assistance under this title using such regular procedures.

(bb) A description of differences between the medical assistance provided under this title and child health assistance under title XXI, including differences in cost-sharing requirements and covered benefits.

(iii) TEMPORARY ENROLLMENT IN CHIP PENDING SCREEN AND ENROLL.—

(I) IN GENERAL.—Under this clause, a State enrolls a child in child health assistance under title XXI for a temporary period if the child appears eligible for such assistance based on an income finding by an Express Lane agency.

(II) DETERMINATION OF ELIGIBILITY.—During such temporary enrollment period, the State shall determine the child's eligibility for child health assistance under title XXI or for medical assistance under this title in accordance with this clause.

(III) PROMPT FOLLOW UP.—In making such a determination, the State shall take prompt action to determine whether the child should be enrolled in medical assistance

under this title or child health assistance under title XXI pursuant to subparagraphs (A) and (B) of section 2102(b)(3) (relating to screen and enroll).

(IV) REQUIREMENT FOR SIMPLIFIED DETERMINATION.—In making such a determination, the State shall use procedures that, to the maximum feasible extent, reduce the burden imposed on the individual of such determination. Such procedures may not require the child's parent, guardian, or custodial relative to provide or verify information that already has been provided to the State agency by an Express Lane agency or another source of information unless the State agency has reason to believe the information is erroneous.

(V) AVAILABILITY OF CHIP MATCHING FUNDS DURING TEMPORARY ENROLLMENT PERIOD.—Medical assistance for items and services that are provided to a child enrolled in title XXI during a temporary enrollment period under this clause shall be treated as child health assistance under such title.

(D) OPTION FOR AUTOMATIC ENROLLMENT.—

(i) IN GENERAL.—The State may initiate and determine eligibility for medical assistance under the State Medicaid plan or for child health assistance under the State CHIP plan without a program application from, or on behalf of, the child based on data obtained from sources other than the child (or the child's family), but a child can only be automatically enrolled in the State Medicaid plan or the State CHIP plan if the child or the family affirmatively consents to being enrolled through affirmation in writing, by telephone, orally, through electronic signature, or through any other means specified by the Secretary or by signature on an Express Lane agency application, if the requirement of clause (ii) is met.

(ii) INFORMATION REQUIREMENT.—The requirement of this clause is that the State informs the parent, guardian, or custodial relative of the child of the services that will be covered, appropriate methods for using such services, premium or other cost sharing charges (if any) that apply, medical support obligations (under section 1912(a)) created by enrollment (if applicable), and the actions the parent, guardian, or relative must take to maintain enrollment and renew coverage.

(E) CODING; APPLICATION TO ENROLLMENT ERROR RATES.—

(i) IN GENERAL.—For purposes of subparagraph (A)(iv), the requirement of this subparagraph for a State is that the State agrees to—

(I) assign such codes as the Secretary shall require to the children who are enrolled in the State Medicaid plan or the State CHIP plan through reliance on a finding made by an Express Lane agency for the duration of the State's election under this paragraph;

(II) annually provide the Secretary with a statistically valid sample (that is approved by Secretary) of the children enrolled in such plans through reliance on such a finding by conducting a full Medicaid eligibility review of the children identified for such sample for purposes of determining an eligibility error rate (as described in clause (iv)) with respect to the enrollment of such children (and shall not include such children in any data or samples used for purposes of complying with a Medicaid Eligibility Quality Control (MEQC) review or a payment error rate measurement (PERM) requirement);

(III) submit the error rate determined under subclause (II) to the Secretary;

(IV) if such error rate exceeds 3 percent for either of the first 2 fiscal years in which the State elects to apply this paragraph, demonstrate to the satisfaction of the Secretary the specific corrective actions implemented by the State to improve upon such error rate; and

(V) if such error rate exceeds 3 percent for any fiscal year in which the State elects to apply this paragraph, a reduction in the amount otherwise payable to the State under section 1903(a) for quarters for that fiscal year, equal to the total amount of erroneous excess payments determined for the fiscal year only with respect to the children included in the sample for the fiscal year that are in excess of a 3 percent error rate with respect to such children.

(ii) NO PUNITIVE ACTION BASED ON ERROR RATE.—The Secretary shall not apply the error rate derived from the sample under clause (i) to the entire population of children enrolled in the State Medicaid plan or the State CHIP plan through reliance on a finding made by an Express Lane agency, or to the population of children enrolled in such plans

on the basis of the State's regular procedures for determining eligibility, or penalize the State on the basis of such error rate in any manner other than the reduction of payments provided for under clause (i)(V).

(iii) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as relieving a State that elects to apply this paragraph from being subject to a penalty under section 1903(u), for payments made under the State Medicaid plan with respect to ineligible individuals and families that are determined to exceed the error rate permitted under that section (as determined without regard to the error rate determined under clause (i)(II)).

(iv) ERROR RATE DEFINED.—In this subparagraph, the term "error rate" means the rate of erroneous excess payments for medical assistance (as defined in section 1903(u)(1)(D)) for the period involved, except that such payments shall be limited to individuals for which eligibility determinations are made under this paragraph and except that in applying this paragraph under title XXI, there shall be substituted for references to provisions of this title corresponding provisions within title XXI.

(F) EXPRESS LANE AGENCY.—

(i) IN GENERAL.—In this paragraph, the term "Express Lane agency" means a public agency that—

(I) is determined by the State Medicaid agency or the State CHIP agency (as applicable) to be capable of making the determinations of one or more eligibility requirements described in subparagraph (A)(i);

(II) is identified in the State Medicaid plan or the State CHIP plan; and

(III) notifies the child's family—

(aa) of the information which shall be disclosed in accordance with this paragraph;

(bb) that the information disclosed will be used solely for purposes of determining eligibility for medical assistance under the State Medicaid plan or for child health assistance under the State CHIP plan; and

(cc) that the family may elect to not have the information disclosed for such purposes; and

(IV) enters into, or is subject to, an interagency agreement to limit the disclosure and use of the information disclosed.

(ii) INCLUSION OF SPECIFIC PUBLIC AGENCIES AND INDIAN TRIBES AND TRIBAL ORGANIZATIONS.—Such term includes the following:

(I) A public agency that determines eligibility for assistance under any of the following:

(aa) The temporary assistance for needy families program funded under part A of title IV.

(bb) A State program funded under part D of title IV.

(cc) The State Medicaid plan.

(dd) The State CHIP plan.

(ee) The Food and Nutrition Act of 2008 (7 U.S.C. 2011 et seq.).

(ff) The Head Start Act (42 U.S.C. 9801 et seq.).

(gg) The Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.).

(hh) The Child Nutrition Act of 1966 (42 U.S.C. 1771 et seq.).

(ii) The Child Care and Development Block Grant Act of 1990 (42 U.S.C. 9858 et seq.).

(jj) The Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11301 et seq.).

(kk) The United States Housing Act of 1937 (42 U.S.C. 1437 et seq.).

(ll) The Native American Housing Assistance and Self-Determination Act of 1996 (25 U.S.C. 4101 et seq.).

(II) A State-specified governmental agency that has fiscal liability or legal responsibility for the accuracy of the eligibility determination findings relied on by the State.

(III) A public agency that is subject to an interagency agreement limiting the disclosure and use of the information disclosed for purposes of determining eligibility under the State Medicaid plan or the State CHIP plan.

(IV) The Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization (as defined in section 1139(c)).

(iii) EXCLUSIONS.—Such term does not include an agency that determines eligibility for a program established under the Social Services Block Grant established under title XX or a private, for-profit organization.

(iv) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed as—

(I) exempting a State Medicaid agency from complying with the requirements of section 1902(a)(4) relating to merit-based personnel standards for employees of the State Medicaid agency and safeguards against conflicts of interest); or

(II) authorizing a State Medicaid agency that elects to use Express Lane agencies under this subparagraph to use the Express Lane option to avoid complying with such requirements for purposes of making eligibility determinations under the State Medicaid plan.

(v) ADDITIONAL DEFINITIONS.—In this paragraph:

(I) STATE.—The term "State" means 1 of the 50 States or the District of Columbia.

(II) STATE CHIP AGENCY.—The term "State CHIP agency" means the State agency responsible for administering the State CHIP plan.

(III) STATE CHIP PLAN.—The term "State CHIP plan" means the State child health plan established under title XXI and includes any waiver of such plan.

(IV) STATE MEDICAID AGENCY.—The term "State Medicaid agency" means the State agency responsible for administering the State Medicaid plan.

(V) STATE MEDICAID PLAN.—The term "State Medicaid plan" means the State plan established under title XIX and includes any waiver of such plan.

(G) CHILD DEFINED.—For purposes of this paragraph, the term "child" means an individual under 19 years of age, or, at the option of a State, such higher age, not to exceed 21 years of age, as the State may elect.

(H) STATE OPTION TO RELY ON STATE INCOME TAX DATA OR RETURN.—At the option of the State, a finding from an Express Lane agency may include gross income or adjusted gross income shown by State income tax records or returns.

(I) APPLICATION.—This paragraph shall not apply with respect to eligibility determinations made after September 30, 2027.

(14) INCOME DETERMINED USING MODIFIED ADJUSTED GROSS INCOME.—

(A) IN GENERAL.—Notwithstanding subsection (r) or any other provision of this title, except as provided in subparagraph (D), for purposes of determining income eligibility for medical assistance under the State plan or under any waiver of such plan and for any other purpose applicable under the plan or waiver for which a determination of income is required, including with respect to the imposition of premiums and cost-sharing, a State shall use the modified adjusted gross income of an individual and, in the case of an individual in a family greater than 1, the household income of such family. A State shall establish income eligibility thresholds for populations to be eligible for medical assistance under the State plan or a waiver of the plan using modified adjusted gross income and household income that are not less than the effective income eligibility levels that applied under the State plan or waiver on the date of enactment of the Patient Protection and Affordable Care Act. For purposes of complying with the maintenance of effort requirements under subsection (gg) during the transition to modified adjusted gross income and household income, a State shall, working with the Secretary, establish an equivalent income test that ensures individuals eligible for medical assistance under the State plan or under a waiver of the plan on the date of enactment of the Patient Protection and Affordable Care Act, do not lose coverage under the State plan or under a waiver of the plan. The Secretary may waive such provisions of this title and title XXI as are necessary to ensure that States establish income and eligibility determination systems that protect beneficiaries.

(B) NO INCOME OR EXPENSE DISREGARDS.—Subject to subparagraph (I), no type of expense, block, or other income disregard shall be applied by a State to determine income eligibility for medical assistance under the State plan or under any waiver of such plan or for any other purpose applicable under the plan or waiver for which a determination of income is required.

(C) NO ASSETS TEST.—A State shall not apply any assets or resources test for purposes of determining eligibility for medical assistance under the State plan or under a waiver of the plan.

(D) EXCEPTIONS.—

(i) INDIVIDUALS ELIGIBLE BECAUSE OF OTHER AID OR ASSISTANCE, ELDERLY INDIVIDUALS, MEDICALLY NEEDY INDIVIDUALS, AND INDIVIDUALS ELIGIBLE FOR MEDICARE COST-SHARING.—Subparagraphs (A), (B), and (C) shall not apply to the determination of eligibility under the State plan or under a waiver for medical assistance for the following:

(I) Individuals who are eligible for medical assistance under the State plan or under a waiver of the plan on a basis that does not require a determination of income by the State agency administering the State plan or waiver, including as a result of eligibility for, or receipt of, other Federal or State aid or assistance, individuals who are eligible on the basis of receiving (or being treated as if receiving) supplemental security income benefits under title XVI, and individuals who are eligible as a result of being or being deemed to be a child in foster care under the responsibility of the State.

(II) Individuals who have attained age 65.

(III) Individuals who qualify for medical assistance under the State plan or under any waiver of such plan on the basis of being blind or disabled (or being treated as being blind or disabled) without regard to whether the individual is eligible for supplemental security income benefits under title XVI on the basis of being blind or disabled and including an individual who is eligible for medical assistance on the basis of section 1902(e)(3).

(IV) Individuals described in subsection (a)(10)(C).

(V) Individuals described in any clause of subsection (a)(10)(E).

(ii) EXPRESS LANE AGENCY FINDINGS.—In the case of a State that elects the Express Lane option under paragraph (13), notwithstanding subparagraphs (A), (B), and (C), the State may rely on a finding made by an Express Lane agency in accordance with that paragraph relating to the income of an individual for purposes of determining the individual's eligibility for medical assistance under the State plan or under a waiver of the plan.

(iii) MEDICARE PRESCRIPTION DRUG SUBSIDIES DETERMINATIONS.—Subparagraphs (A), (B), and (C) shall not apply to any determinations of eligibility for premium and cost-sharing subsidies under and in accordance with section 1860D–14 made by the State pursuant to section 1935(a)(2).

(iv) LONG-TERM CARE.—Subparagraphs (A), (B), and (C) shall not apply to any determinations of eligibility of individuals for purposes of medical assistance for nursing facility services, a level of care in any institution equivalent to that of nursing facility services, home or community-based services furnished under a waiver or State plan amendment under section 1915 or a waiver under section 1115, and services described in section 1917(c)(1)(C)(ii).

(v) GRANDFATHER OF CURRENT ENROLLEES UNTIL DATE OF NEXT REGULAR REDETERMINATION.—An individual who, on January 1, 2014, is enrolled in the State plan or under a waiver of the plan and who would be determined ineligible for medical assistance solely because of the application of the modified adjusted gross income or household income standard described in subparagraph (A), shall remain eligible for medical assistance under the State plan or waiver (and subject to the same premiums and cost-sharing as applied to the individual on that date) through March 31, 2014, or the date on which the individual's next regularly scheduled redetermination of eligibility is to occur, whichever is later.

(E) TRANSITION PLANNING AND OVERSIGHT.—Each State shall submit to the Secretary for the Secretary's approval the income eligibility thresholds proposed to be established using modified adjusted gross income and household income, the methodologies and procedures to be used to determine income eligibility using modified adjusted gross income and household income and, if applicable, a State plan amendment establishing an optional eligibility category under subsection (a)(10)(A)(ii)(XX). To the extent practicable, the State shall use the same methodologies and procedures for purposes of making such determinations as the State used on the date of enactment of the Patient Protection and Affordable Care Act. The Secretary shall ensure that the income eligibility thresholds proposed to be established using modified adjusted gross income and household income, including under the eligibility category established under subsection (a)(10)(A)(ii)(XX), and the methodologies and procedures proposed to be used to determine income eligibility, will not result in

children who would have been eligible for medical assistance under the State plan or under a waiver of the plan on the date of enactment of the Patient Protection and Affordable Care Act no longer being eligible for such assistance.

(F) LIMITATION ON SECRETARIAL AUTHORITY.—The Secretary shall not waive compliance with the requirements of this paragraph except to the extent necessary to permit a State to coordinate eligibility requirements for dual eligible individuals (as defined in section 1915(h)(2)(B)) under the State plan or under a waiver of the plan and under title XVIII and individuals who require the level of care provided in a hospital, a nursing facility, or an intermediate care facility for the mentally retarded.

(G) DEFINITIONS OF MODIFIED ADJUSTED GROSS INCOME AND HOUSEHOLD INCOME.—In this paragraph, the terms "modified adjusted gross income" and "household income" have the meanings given such terms in section 36B(d)(2) of the Internal Revenue Code of 1986.

(H) CONTINUED APPLICATION OF MEDICAID RULES REGARDING POINT-IN-TIME INCOME AND SOURCES OF INCOME.—The requirement under this paragraph for States to use modified adjusted gross income and household income to determine income eligibility for medical assistance under the State plan or under any waiver of such plan and for any other purpose applicable under the plan or waiver for which a determination of income is required shall not be construed as affecting or limiting the application of—

(i) the requirement under this title and under the State plan or a waiver of the plan to determine an individual's income as of the point in time at which an application for medical assistance under the State plan or a waiver of the plan is processed; or

(ii) any rules established under this title or under the State plan or a waiver of the plan regarding sources of countable income.

(I) TREATMENT OF PORTION OF MODIFIED ADJUSTED GROSS INCOME.—For purposes of determining the income eligibility of an individual for medical assistance whose eligibility is determined based on the application of modified adjusted gross income under subparagraph (A), the State shall—

(i) determine the dollar equivalent of the difference between the upper income limit on eligibility for such an individual (expressed as a percentage of the poverty line) and such upper income limit increased by 5 percentage points; and

(ii) notwithstanding the requirement in subparagraph (A) with respect to use of modified adjusted gross income, utilize as the applicable income of such individual, in determining such income eligibility, an amount equal to the modified adjusted gross income applicable to such individual reduced by such dollar equivalent amount.

(J) EXCLUSION OF PARENT MENTOR COMPENSATION FROM INCOME DETERMINATION.—Any nominal amount received by an individual as compensation, including a stipend, for participation as a parent mentor (as defined in paragraph (5) of section 2113(f)) in an activity or program funded through a grant under such section shall be disregarded for purposes of determining the income eligibility of such individual for medical assistance under the State plan or any waiver of such plan.

(K) TREATMENT OF CERTAIN LOTTERY WINNINGS AND INCOME RECEIVED AS A LUMP SUM.—

(i) IN GENERAL.—In the case of an individual who is the recipient of qualified lottery winnings (pursuant to lotteries occurring on or after January 1, 2018) or qualified lump sum income (received on or after such date) and whose eligibility for medical assistance is determined based on the application of modified adjusted gross income under subparagraph (A), a State shall, in determining such eligibility, include such winnings or income (as applicable) as income received—

(I) in the month in which such winnings or income (as applicable) is received if the amount of such winnings or income is less than $80,000;

(II) over a period of 2 months if the amount of such winnings or income (as applicable) is greater than or equal to $80,000 but less than $90,000;

(III) over a period of 3 months if the amount of such winnings or income (as applicable) is greater than or equal to $90,000 but less than $100,000; and

(IV) over a period of 3 months plus 1 additional month for each increment of $10,000 of such winnings or income (as applicable) received, not to exceed a period of 120 months (for winnings or income of $1,260,000 or more), if the amount of such winnings or income is greater than or equal to $100,000.

(ii) COUNTING IN EQUAL INSTALLMENTS.—For purposes of subclauses (II), (III), and (IV) of clause (i), winnings or income to which such subclause applies shall be counted in equal monthly installments over the period of months specified under such subclause.

(iii) HARDSHIP EXEMPTION.—An individual whose income, by application of clause (i), exceeds the applicable eligibility threshold established by the State, shall continue to be eligible for medical assistance to the extent that the State determines, under procedures established by the State (in accordance with standards specified by the Secretary), that the denial of eligibility of the individual would cause an undue medical or financial hardship as determined on the basis of criteria established by the Secretary.

(iv) NOTIFICATIONS AND ASSISTANCE REQUIRED IN CASE OF LOSS OF ELIGIBILITY.—A State shall, with respect to an individual who loses eligibility for medical assistance under the State plan (or a waiver of such plan) by reason of clause (i)—

(I) before the date on which the individual loses such eligibility, inform the individual—

(aa) of the individual's opportunity to enroll in a qualified health plan offered through an Exchange established under title I of the Patient Protection and Affordable Care Act during the special enrollment period specified in section 9801(f)(3) of the Internal Revenue Code of 1986 (relating to loss of Medicaid or CHIP coverage); and

(bb) of the date on which the individual would no longer be considered ineligible by reason of clause (i) to receive medical assistance under the State plan or under any waiver of such plan and be eligible to reapply to receive such medical assistance; and

(II) provide technical assistance to the individual seeking to enroll in such a qualified health plan.

(v) QUALIFIED LOTTERY WINNINGS DEFINED.—In this subparagraph, the term "qualified lottery winnings" means winnings from a sweepstakes, lottery, or pool described in paragraph (3) of section 4402 of the Internal Revenue Code of 1986 or a lottery operated by a multistate or multijurisdictional lottery association, including amounts awarded as a lump sum payment.

(vi) QUALIFIED LUMP SUM INCOME DEFINED.—In this subparagraph, the term "qualified lump sum income" means income that is received as a lump sum from monetary winnings from gambling (as defined by the Secretary and including gambling activities described in section 1955(b)(4) of title 18, United States Code).

(15) EXCLUSION OF COMPENSATION FOR PARTICIPATION IN A CLINICAL TRIAL FOR TESTING OF TREATMENTS FOR A RARE DISEASE OR CONDITION.—The first $2,000 received by an individual (who has attained 19 years of age) as compensation for participation in a clinical trial meeting the requirements of section 1612(b)(26) shall be disregarded for purposes of determining the income eligibility of such individual for medical assistance under the State plan or any waiver of such plan.

(f) Notwithstanding any other provision of this title, except as provided in subsection (e) and section 1619(b)(3) and section 1924, except with respect to qualified disabled and working individuals (described in section 1905(s)), and except with respect to qualified medicare beneficiaries, qualified severely impaired individuals, and individuals described in subsection (m)(1), no State not eligible to participate in the State plan program established under title XVI shall be required to provide medical assistance to any aged, blind, or disabled individual (within the meaning of title XVI) for any month unless such State would be (or would have been) required to provide medical assistance to such individual for such month had its plan for medical assistance approved under this title and in effect on January 1, 1972, been in effect in such month, except that for this purpose any such individual shall be deemed eligible for medical assistance under such State plan if (in addition to meeting such other requirements as are or may be imposed under the State plan) the income of any such individual as determined in accordance with section 1903(f) (after deducting any supplemental security income payment and State supplementary payment made with respect to such individual, and incurred expenses for medical care as recognized under State law regardless of whether such expenses are reimbursed under another public program of the State or political subdivision thereof) is not in excess of the standard for medical assistance established under the State plan as in effect on January 1, 1972. In States which provide medical assistance to indi-

viduals pursuant to paragraph (10)(C) of subsection (a) of this section, an individual who is eligible for medical assistance by reason of the requirements of this section concerning the deduction of incurred medical expenses from income shall be considered an individual eligible for medical assistance under paragraph (10)(A) of that subsection if that individual is, or is eligible to be (1) an individual with respect to whom there is payable a State supplementary payment on the basis of which similarly situated individuals are eligible to receive medical assistance equal in amount, duration, and scope to that provided to individuals eligible under paragraph (10)(A), or (2) an eligible individual or eligible spouse, as defined in title XVI, with respect to whom supplemental security income benefits are payable; otherwise that individual shall be considered to be an individual eligible for medical assistance under paragraph (10)(C) of that subsection. In States which do not provide medical assistance to individuals pursuant to paragraph (10)(C) of that subsection, an individual who is eligible for medical assistance by reason of the requirements of this section concerning the deduction of incurred medical expenses from income shall be considered an individual eligible for medical assistance under paragraph (10)(A) of that subsection.

(g) In addition to any other sanction available to a State, a State may provide for a reduction of any payment amount otherwise due with respect to a person who furnishes services under the plan in an amount equal to up to three times the amount of any payment sought to be collected by that person in violation of subsection (a)(25)(C).

(h) Nothing in this title (including subsections (a)(13) and (a)(30) of this section) shall be construed as authorizing the Secretary to limit the amount of payment that may be made under a plan under this title for home and community care.

(i)(1) In addition to any other authority under State law, where a State determines that a intermediate care facility for the mentally retarded which is certified for participation under its plan no longer substantially meets the requirements for such a facility under this title and further determines that the facility's deficiencies—

(A) immediately jeopardize the health and safety of its patients, the State shall provide for the termination of the facility's certification for participation under the plan and may provide, or

(B) do not immediately jeopardize the health and safety of its patients, the State may, in lieu of providing for terminating the facility's certification for participation under the plan, establish alternative remedies if the State demonstrates to the Secretary's satisfaction that the alternative remedies are effective in deterring noncompliance and correcting deficiencies, and may provide

that no payment will be made under the State plan with respect to any individual admitted to such facility after a date specified by the State.

(2) The State shall not make such a decision with respect to a facility until the facility has had a reasonable opportunity, following the initial determination that it no longer substantially meets the requirements for such a facility under this title, to correct its deficiencies, and, following this period, has been given reasonable notice and opportunity for a hearing.

(3) The State's decision to deny payment may be made effective only after such notice to the public and to the facility as may be provided for by the State, and its effectiveness shall terminate (A) when the State finds that the facility is in substantial compliance (or is making good faith efforts to achieve substantial compliance) with the requirements for such a facility under this title, or (B) in the case described in paragraph (1)(B), with the end of the eleventh month following the month such decision is made effective, whichever occurs first. If a facility to which clause (B) of the previous sentence applies still fails to substantially meet the provisions of the respective section on the date specified in such clause, the State shall terminate such facility's certification for participation under the plan effective with the first day of the first month following the month specified in such clause.

(j) Notwithstanding any other requirement of this title, the Secretary may waive or modify any requirement of this title with respect to the medical assistance program in American Samoa and the Northern Mariana Islands, other than a waiver of the Federal medical assistance percentage, the limitation in section 1108(f), or the requirement that payment may be made for medical assistance only with respect to amounts expended by American Samoa or the Northern Mariana Islands for care and services described in a numbered paragraph of section 1905(a).

(k)(1) The medical assistance provided to an individual described in subclause (VIII) of subsection (a)(10)(A)(i) shall consist of benchmark coverage described in section 1937(b)(1) or benchmark equivalent coverage described in section 1937(b)(2). Such medical assistance shall be provided subject to the requirements of section 1937, without regard to whether a State otherwise has elect-

ed the option to provide medical assistance through coverage under that section, unless an individual described in subclause (VIII) of subsection (a)(10)(A)(i) is also an individual for whom, under subparagraph (B) of section 1937(a)(2), the State may not require enrollment in benchmark coverage described in subsection (b)(1) of section 1937 or benchmark equivalent coverage described in subsection (b)(2) of that section.

(2) Beginning with the first day of any fiscal year quarter that begins on or after April 1, 2010, and before January 1, 2014, a State may elect through a State plan amendment to provide medical assistance to individuals who would be described in subclause (VIII) of subsection (a)(10)(A)(i) if that subclause were effective before January 1, 2014. A State may elect to phase-in the extension of eligibility for medical assistance to such individuals based on income, so long as the State does not extend such eligibility to individuals described in such subclause with higher income before making individuals described in such subclause with lower income eligible for medical assistance.

(3) If an individual described in subclause (VIII) of subsection (a)(10)(A)(i) is the parent of a child who is under 19 years of age (or such higher age as the State may have elected) who is eligible for medical assistance under the State plan or under a waiver of such plan (under that subclause or under a State plan amendment under paragraph (2), the individual may not be enrolled under the State plan unless the individual's child is enrolled under the State plan or under a waiver of the plan or is enrolled in other health insurance coverage. For purposes of the preceding sentence, the term "parent" includes an individual treated as a caretaker relative for purposes of carrying out section 1931.

(l)(1) Individuals described in this paragraph are—

(A) women during pregnancy (and during the 60-day period beginning on the last day of the pregnancy),

(B) infants under one year of age,

(C) children who have attained one year of age but have not attained 6 years of age, and

(D) children born after September 30, 1983 (or, at the option of a State, after any earlier date), who have attained 6 years of age but have not attained 19 years of age,

who are not described in any of subclauses (I) through (III) of subsection (a)(10)(A)(i) and whose family income does not exceed the income level established by the State under paragraph (2) for a family size equal to the size of the family, including the woman, infant, or child.

(2)(A)(i) For purposes of paragraph (1) with respect to individuals described in subparagraph (A) or (B) of that paragraph, the State shall establish an income level which is a percentage (not less than the percentage provided under clause (ii) and not more than 185 percent) of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

(ii) The percentage provided under this clause, with respect to eligibility for medical assistance on or after—

(I) July 1, 1989, is 75 percent, or, if greater, the percentage provided under clause (iii), and

(II) April 1, 1990, 133 percent, or, if greater, the percentage provided under clause (iv).

(iii) In the case of a State which, as of the date of the enactment of this clause, has elected to provide, and provides, medical assistance to individuals described in this subsection or has enacted legislation authorizing, or appropriating funds, to provide such assistance to such individuals before July 1, 1989, the percentage provided under clause (ii)(I) shall not be less than—

(I) the percentage specified by the State in an amendment to its State plan (whether approved or not) as of the date of the enactment of this clause, or

(II) if no such percentage is specified as of the date of the enactment of this clause, the percentage established under the State's authorizing legislation or provided for under the State's appropriations;

but in no case shall this clause require the percentage provided under clause (ii)(I) to exceed 100 percent.

(iv) In the case of a State which, as of the date of the enactment of this clause, has established under clause (i), or has enacted legislation authorizing, or appropriating funds, to provide for, a percentage (of the income official poverty line) that is greater than 133 percent, the percentage provided under clause (ii) for medical assistance on or after April 1, 1990, shall not be less than—

(I) the percentage specified by the State in an amendment to its State plan (whether approved or not) as of the date of the enactment of this clause, or

(II) if no such percentage is specified as of the date of the enactment of this clause, the percentage established under the State's authorizing legislation or provided for under the State's appropriations.

(B) For purposes of paragraph (1) with respect to individuals described in subparagraph (C) of such paragraph, the State shall establish an income level which is equal to 133 percent of the income official poverty line described in subparagraph (A) applicable to a family of the size involved.

(C) For purposes of paragraph (1) with respect to individuals described in subparagraph (D) of that paragraph, the State shall establish an income level which is equal to 100 percent (or, beginning January 1, 2014, 133 percent) of the income official poverty line described in subparagraph (A) applicable to a family of the size involved.

(3) Notwithstanding subsection (a)(17), for individuals who are eligible for medical assistance because of subsection (a)(10)(A)(i)(IV), (a)(10)(A)(i)(VI), (a)(10)(A)(i)(VII), or (a)(10)(A)(ii)(IX)—

(A) application of a resource standard shall be at the option of the State;

(B) any resource standard or methodology that is applied with respect to an individual described in subparagraph (A) of paragraph (1) may not be more restrictive than the resource standard or methodology that is applied under title XVI;

(C) any resource standard or methodology that is applied with respect to an individual described in subparagraph (B), (C), or (D) of paragraph (1) may not be more restrictive than the corresponding methodology that is applied under the State plan under part A of title IV;

(D) the income standard to be applied is the appropriate income standard established under paragraph (2); and

(E) family income shall be determined in accordance with the methodology employed under the State plan under part A or E of title IV (except to the extent such methodology is inconsistent with clause (D) of subsection (a)(17)), and costs incurred for medical care or for any other type of remedial care shall not be taken into account.

Any different treatment provided under this paragraph for such individuals shall not, because of subsection (a)(17), require or permit such treatment for other individuals.

(4)(A) In the case of any State which is providing medical assistance to its residents under a waiver granted under section 1115, the Secretary shall require the State to provide medical assistance for pregnant women and infants under age 1 described in subsection (a)(10)(A)(i)(IV) and for children described in subsection (a)(10)(A)(i)(VI) or subsection (a)(10)(A)(i)(VII) in the same manner as the State would be required to provide such assistance for such individuals if the State had in effect a plan approved under this title.

(B) In the case of a State which is not one of the 50 States or the District of Columbia, the State need not meet the requirement of subsection (a)(10)(A)(i)(IV), (a)(10)(A)(i)(VI), or (a)(10)(A)(i)(VII) and, for purposes of paragraph (2)(A), the State may substitute for the percentage provided under clause (ii) of such paragraph any percentage.

(m)(1) Individuals described in this paragraph are individuals—

(A) who are 65 years of age or older or are disabled individuals (as determined under section 1614(a)(3)),

(B) whose income (as determined under section 1612 for purposes of the supplemental security income program, except as provided in paragraph (2)(C)) does not exceed an income level established by the State consistent with paragraph (2)(A), and

(C) whose resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed (except as provided in paragraph (2)(B)) the maximum amount of resources that an individual may have and obtain benefits under that program.

(2)(A) The income level established under paragraph (1)(B) may not exceed a percentage (not more than 100 percent) of the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

(B) In the case of a State that provides medical assistance to individuals not described in subsection (a)(10)(A) and at the State's option, the State may use under paragraph (1)(C) such resource level (which is higher than the level described in that paragraph) as may be applicable with respect to individuals described in paragraph (1)(A) who are not described in subsection (a)(10)(A).

(C) The provisions of section 1905(p)(2)(D) shall apply to determinations of income under this subsection in the same manner as they apply to determinations of income under section 1905(p).

(3) Notwithstanding subsection (a)(17), for individuals described in paragraph (1) who are covered under the State plan by virtue of subsection (a)(10)(A)(ii)(X)—

(A) the income standard to be applied is the income standard described in paragraph (1)(B), and

(B) except as provided in section 1612(b)(4)(B)(ii), costs incurred for medical care or for any other type of remedial care shall not be taken into account in determining income.

Any different treatment provided under this paragraph for such individuals shall not, because of subsection (a)(17), require or permit such treatment for other individuals.

(4) Notwithstanding subsection (a)(17), for qualified medicare beneficiaries described in section 1905(p)(1)—

(A) the income standard to be applied is the income standard described in section 1905(p)(1)(B), and

(B) except as provided in section 1612(b)(4)(B)(ii), costs incurred for medical care or for any other type of remedial care shall not be taken into account in determining income.

Any different treatment provided under this paragraph for such individuals shall not, because of subsection (a)(17), require or permit such treatment for other individuals.

(n)(1) In the case of medical assistance furnished under this title for medicare cost-sharing respecting the furnishing of a service or item to a qualified medicare beneficiary, the State plan may provide payment in an amount with respect to the service or item that results in the sum of such payment amount and any amount of payment made under title XVIII with respect to the service or item exceeding the amount that is otherwise payable under the State plan for the item or service for eligible individuals who are not qualified medicare beneficiaries.

(2) In carrying out paragraph (1), a State is not required to provide any payment for any expenses incurred relating to payment for deductibles, coinsurance, or copayments for medicare cost-sharing to the extent that payment under title XVIII for the service would exceed the payment amount that otherwise would be made under the State plan under this title for such service if provided to an eligible recipient other than a medicare beneficiary.

(3) In the case in which a State's payment for medicare cost-sharing for a qualified medicare beneficiary with respect to an item or service is reduced or eliminated through the application of paragraph (2)—

(A) for purposes of applying any limitation under title XVIII on the amount that the beneficiary may be billed or charged for the service, the amount of payment made under title XVIII plus the amount of payment (if any) under the State plan shall be considered to be payment in full for the service;

(B) the beneficiary shall not have any legal liability to make payment to a provider or to an organization described in section 1903(m)(1)(A) for the service; and

(C) any lawful sanction that may be imposed upon a provider or such an organization for excess charges under this title or title XVIII shall apply to the imposition of any charge imposed upon the individual in such case.

This paragraph shall not be construed as preventing payment of any medicare cost-sharing by a medicare supplemental policy or an employer retiree health plan on behalf of an individual.

(o) Notwithstanding any provision of subsection (a) to the contrary, a State plan under this title shall provide that any supplemental security income benefits paid by reason of subparagraph (E) or (G) of section 1611(e)(1) to an individual who—

(1) is eligible for medical assistance under the plan, and

(2) is in a hospital, skilled nursing facility, or intermediate care facility at the time such benefits are paid,

will be disregarded for purposes of determining the amount of any post-eligibility contribution by the individual to the cost of the care and services provided by the hospital, skilled nursing facility, or intermediate care facility.

(p)(1) In addition to any other authority, a State may exclude any individual or entity for purposes of participating under the State plan under this title for any reason for which the Secretary could exclude the individual or entity from participation in a program under title XVIII under section 1128, 1128A, or 1866(b)(2).

(2) In order for a State to receive payments for medical assistance under section 1903(a), with respect to payments the State makes to a medicaid managed care organization (as defined in section 1903(m)) or to an entity furnishing services under a waiver approved under section 1915(b)(1), the State must provide that it will exclude from participation, as such an organization or entity, any organization or entity that—

(A) could be excluded under section 1128(b)(8) (relating to owners and managing employees who have been convicted of certain crimes or received other sanctions),

(B) has, directly or indirectly, a substantial contractual relationship (as defined by the Secretary) with an individual or entity that is described in section 1128(b)(8)(B), or

(C) employs or contracts with any individual or entity that is excluded from participation under this title under section 1128 or 1128A for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services.

(3) As used in this subsection, the term "exclude" includes the refusal to enter into or renew a participation agreement or the termination of such an agreement.

(q)(1)(A) In order to meet the requirement of subsection (a)(50), the State plan must provide that, in the case of an institutionalized individual or couple described in subparagraph (B), in determining the amount of the individual's or couple's income to be applied monthly to payment for the cost of care in an institution, there shall be deducted from the monthly income (in addition to other allowances otherwise provided under the State plan) a monthly personal needs allowance—

(i) which is reasonable in amount for clothing and other personal needs of the individual (or couple) while in an institution, and

(ii) which is not less (and may be greater) than the minimum monthly personal needs allowance described in paragraph (2).

(B) In this subsection, the term "institutionalized individual or couple" means an individual or married couple—

(i) who is an inpatient (or who are inpatients) in a medical institution or nursing facility for which payments are made under this title throughout a month, and

(ii) who is or are determined to be eligible for medical assistance under the State plan.

(2) The minimum monthly personal needs allowance described in this paragraph is $30 for an institutionalized individual and $60 for an institutionalized couple (if both are aged, blind, or disabled, and their incomes are considered available to each other in determining eligibility).

(r)(1)(A) For purposes of sections 1902(a)(17) and 1924(d)(1)(D) and for purposes of a waiver under section 1915, with respect to the post-eligibility treatment of income of individuals who are institutionalized or receiving home or community-based services under such a waiver, the treatment described in subparagraph (B) shall apply, there shall be disregarded reparation payments made by the Federal Republic of Germany, and there shall be taken into account amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) medicare and other health insurance premiums, deductibles, or coinsurance, and

(ii) necessary medical or remedial care recognized under State law but not covered under the State plan under this title, subject to reasonable limits the State may establish on the amount of these expenses.

(B)(i) In the case of a veteran who does not have a spouse or a child, if the veteran—

(I) receives, after the veteran has been determined to be eligible for medical assistance under the State plan under this title, a veteran's pension in excess of $90 per month, and

(II) resides in a State veterans home with respect to which the Secretary of Veterans Affairs makes per diem payments for nursing home care pursuant to section 1741(a) of title 38, United States Code,

any such pension payment, including any payment made due to the need for aid and attendance, or for unreimbursed medical expenses, that is in excess of $90 per month shall be counted as income only for the purpose of applying such excess payment to the State veterans home's cost of providing nursing home care to the veteran.

(ii) The provisions of clause (i) shall apply with respect to a surviving spouse of a veteran who does not have a child in the same manner as they apply to a veteran described in such clause.

(2)(A) The methodology to be employed in determining income and resource eligibility for individuals under subsection (a)(10)(A)(i)(III), (a)(10)(A)(i)(IV), (a)(10)(A)(i)(VI), (a)(10)(A)(i)(VII), (a)(10)(A)(ii), (a)(10)(C)(i)(III), or (f) or under section 1905(p) may be less restrictive, and shall be no more restrictive, than the methodology—

(i) in the case of groups consisting of aged, blind, or disabled individuals, under the supplemental security income program under title XVI, or

(ii) in the case of other groups, under the State plan most closely categorically related.

(B) For purposes of this subsection and subsection (a)(10), methodology is considered to be "no more restrictive" if, using the methodology, additional individuals may be eligible for medical assistance and no individuals who are otherwise eligible are made ineligible for such assistance.

(s) In order to meet the requirements of subsection (a)(55), the State plan must provide that payments to hospitals under the plan for inpatient hospital services furnished to infants who have not attained the age of 1 year, and to children who have not attained the age of 6 years and who receive such services in a disproportionate share hospital described in section 1923(b)(1), shall—

(1) if made on a prospective basis (whether per diem, per case, or otherwise) provide for an outlier adjustment in payment amounts for medically necessary inpatient hospital services involving exceptionally high costs or exceptionally long lengths of stay,

(2) not be limited by the imposition of day limits with respect to the delivery of such services to such individuals, and

(3) not be limited by the imposition of dollar limits (other than such limits resulting from prospective payments as adjusted pursuant to paragraph (1)) with respect to the delivery of such services to any such individual who has not attained their first birthday (or in the case of such an individual who is an inpatient on his first birthday until such individual is discharged).

(t) Nothing in this title (including sections 1903(a) and 1905(a)) shall be construed as authorizing the Secretary to deny or limit payments to a State for expenditures, for medical assistance for items or services, attributable to taxes of general applicability imposed with respect to the provision of such items or services.

(u)(1) Individuals described in this paragraph are individuals—

(A) who are entitled to elect COBRA continuation coverage (as defined in paragraph (3)),

(B) whose income (as determined under section 1612 for purposes of the supplemental security income program) does not exceed 100 percent of the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved,

(C) whose resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed twice the maximum amount of resources that an individual may have and obtain benefits under that program, and

(D) with respect to whose enrollment for COBRA continuation coverage the State has determined that the savings in expenditures under this title resulting from such enrollment is likely to exceed the amount of payments for COBRA premiums made.

(2) For purposes of subsection (a)(10)(F) and this subsection, the term "COBRA premiums" means the applicable premium imposed with respect to COBRA continuation coverage.

(3) In this subsection, the term "COBRA continuation coverage" means coverage under a group health plan provided by an employer with 75 or more employees provided pursuant to title XXII of the Public Health Service Act, section 4980B of the Internal Revenue Code of 1986, or title VI of the Employee Retirement Income Security Act of 1974.

(4) Notwithstanding subsection (a)(17), for individuals described in paragraph (1) who are covered under the State plan by virtue of subsection (a)(10)(A)(ii)(XI)—

(A) the income standard to be applied is the income standard described in paragraph (1)(B), and

(B) except as provided in section 1612(b)(4)(B)(ii), costs incurred for medical care or for any other type of remedial care shall not be taken into account in determining income.

Any different treatment provided under this paragraph for such individuals shall not, because of subsection (a)(10)(B) or (a)(17), require or permit such treatment for other individuals.

(v) A State plan may provide for the making of determinations of disability or blindness for the purpose of determining eligibility for medical assistance under the State plan by the single State agency or its designee, and make medical assistance available to individuals whom it finds to be blind or disabled and who are determined otherwise eligible for such assistance during the period of time prior to which a final determination of disability or blindness is made by the Social Security Administration with respect to such an individual. In making such determinations, the State must apply the definitions of disability and blindness found in section 1614(a) of the Social Security Act.

(w)(1) For purposes of subsection (a)(57) and sections 1903(m)(1)(A) and 1919(c)(2)(E), the requirement of this subsection is that a provider or organization (as the case may be) maintain written policies and procedures with respect to all adult individuals receiving medical care by or through the provider or organization—

(A) to provide written information to each such individual concerning—

(i) an individual's rights under State law (whether statutory or as recognized by the courts of the State) to make decisions concerning such medical care, including the right

to accept or refuse medical or surgical treatment and the right to formulate advance directives (as defined in paragraph (3)), and

(ii) the provider's or organization's written policies respecting the implementation of such rights;

(B) to document in the individual's medical record whether or not the individual has executed an advance directive;

(C) not to condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(D) to ensure compliance with requirements of State law (whether statutory or as recognized by the courts of the State) respecting advance directives; and

(E) to provide (individually or with others) for education for staff and the community on issues concerning advance directives.

Subparagraph (C) shall not be construed as requiring the provision of care which conflicts with an advance directive.

(2) The written information described in paragraph (1)(A) shall be provided to an adult individual—

(A) in the case of a hospital, at the time of the individual's admission as an inpatient,

(B) in the case of a nursing facility, at the time of the individual's admission as a resident,

(C) in the case of a provider of home health care or personal care services, in advance of the individual coming under the care of the provider,

(D) in the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program, and

(E) in the case of a medicaid managed care organization, at the time of enrollment of the individual with the organization.

(3) Nothing in this section shall be construed to prohibit the application of a State law which allows for an objection on the basis of conscience for any health care provider or any agent of such provider which as a matter of conscience cannot implement an advance directive.

(4) In this subsection, the term "advance directive" means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State) and relating to the provision of such care when the individual is incapacitated.

(5) For construction relating to this subsection, see section 7 of the Assisted Suicide Funding Restriction Act of 1997 (relating to clarification respecting assisted suicide, euthanasia, and mercy killing).

(x) The Secretary shall establish a system, for implementation by not later than July 1, 1991, which provides for a unique identifier for each physician who furnishes services for which payment may be made under a State plan approved under this title.

(y)(1) In addition to any other authority under State law, where a State determines that a psychiatric hospital which is certified for participation under its plan no longer meets the requirements for a psychiatric hospital (referred to in section 1905(h)) and further finds that the hospital's deficiencies—

(A) immediately jeopardize the health and safety of its patients, the State shall terminate the hospital's participation under the State plan; or

(B) do not immediately jeopardize the health and safety of its patients, the State may terminate the hospital's participation under the State plan, or provide that no payment will be made under the State plan with respect to any individual admitted to such hospital after the effective date of the finding, or both.

(2) Except as provided in paragraph (3), if a psychiatric hospital described in paragraph (1)(B) has not complied with the requirements for a psychiatric hospital under this title—

(A) within 3 months after the date the hospital is found to be out of compliance with such requirements, the State shall provide that no payment will be made under the State plan with respect to any individual admitted to such hospital after the end of such 3-month period, or

(B) within 6 months after the date the hospital is found to be out of compliance with such requirements, no Federal financial participation shall be provided under section 1903(a) with respect to further services provided in the hospital until the State finds that the hospital is in compliance with the requirements of this title.

(3) The Secretary may continue payments, over a period of not longer than 6 months from the date the hospital is found to be out of compliance with such requirements, if—

(A) the State finds that it is more appropriate to take alternative action to assure compliance of the hospital with the requirements than to terminate the certification of the hospital,

(B) the State has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action, and

(C) the State agrees to repay to the Federal Government payments received under this paragraph if the corrective action is not taken in accordance with the approved plan and timetable.

(z)(1) Individuals described in this paragraph are individuals not described in subsection (a)(10)(A)(i)—

(A) who are infected with tuberculosis;

(B) whose income (as determined under the State plan under this title with respect to disabled individuals) does not exceed the maximum amount of income a disabled individual described in subsection (a)(10)(A)(i) may have and obtain medical assistance under the plan; and

(C) whose resources (as determined under the State plan under this title with respect to disabled individuals) do not exceed the maximum amount of resources a disabled individual described in subsection (a)(10)(A)(i) may have and obtain medical assistance under the plan.

(2) For purposes of subsection (a)(10), the term "TB-related services" means each of the following services relating to treatment of infection with tuberculosis:

(A) Prescribed drugs.

(B) Physicians' services and services described in section 1905(a)(2).

(C) Laboratory and X-ray services (including services to confirm the presence of infection).

(D) Clinic services and Federally-qualified health center services.

(E) Case management services (as defined in section 1915(g)(2)).

(F) Services (other than room and board) designed to encourage completion of regimens of prescribed drugs by outpatients, including services to observe directly the intake of prescribed drugs.

(aa) Individuals described in this subsection are individuals who—

(1) are not described in subsection (a)(10)(A)(i);

(2) have not attained age 65;

(3) have been screened for breast and cervical cancer under the Centers for Disease Control and Prevention breast and cervical cancer early detection program established under title XV of the Public Health Service Act (42 U.S.C. 300k et seq.) in accordance with the requirements of section 1504 of that Act (42 U.S.C. 300n) and need treatment for breast or cervical cancer; and

(4) are not otherwise covered under creditable coverage, as defined in section 2701(c) of the Public Health Service Act (42 U.S.C. 300gg(c)), but applied without regard to paragraph (1)(F) of such section.

(bb) PAYMENT FOR SERVICES PROVIDED BY FEDERALLY-QUALIFIED HEALTH CENTERS AND RURAL HEALTH CLINICS.—

(1) IN GENERAL.—Beginning with fiscal year 2001 with respect to services furnished on or after January 1, 2001, and each succeeding fiscal year, the State plan shall provide for payment for services described in section 1905(a)(2)(C) furnished by a Federally-qualified health center and services described in section 1905(a)(2)(B) furnished by a rural health clinic in accordance with the provisions of this subsection.

(2) FISCAL YEAR 2001.—Subject to paragraph (4), for services furnished on and after January 1, 2001, during fiscal year 2001, the State plan shall provide for payment for such services in an amount (calculated on a per visit basis) that is equal to 100 percent of the average of the costs of the center or clinic of furnishing such services during fiscal years 1999 and 2000 which are reasonable and related to the cost of furnishing such services, or based on such other tests of reasonableness as the Secretary prescribes in regulations under section 1833(a)(3), or, in the case of services to which such regulations do not apply, the same methodology used under section 1833(a)(3), adjusted to take into account any increase or decrease in the scope of such services furnished by the center or clinic during fiscal year 2001.

(3) FISCAL YEAR 2002 AND SUCCEEDING FISCAL YEARS.—Subject to paragraph (4), for services furnished during fiscal year 2002 or a succeeding fiscal year, the State plan shall provide for payment for such services in an amount (calculated on a per visit basis) that is equal to the amount calculated for such services under this subsection for the preceding fiscal year—

(A) increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) applicable to primary care services (as defined in section 1842(i)(4)) for that fiscal year; and

(B) adjusted to take into account any increase or decrease in the scope of such services furnished by the center or clinic during that fiscal year.

(4) ESTABLISHMENT OF INITIAL YEAR PAYMENT AMOUNT FOR NEW CENTERS OR CLINICS.—In any case in which an entity first qualifies as a Federally-qualified health center or rural health clinic after fiscal year 2000, the State plan shall provide for payment for services described in section 1905(a)(2)(C) furnished by the center or services described in section 1905(a)(2)(B) furnished by the clinic in the first fiscal year in which the center or clinic so qualifies in an amount (calculated on a per visit basis) that is equal to 100 percent of the costs of furnishing such services during such fiscal year based on the rates established under this subsection for the fiscal year for other such centers or clinics located in the same or adjacent area with a similar case load or, in the absence of such a center or clinic, in accordance with the regulations and methodology referred to in paragraph (2) or based on such other tests of reasonableness as the Secretary may specify. For each fiscal year following the fiscal year in which the entity first qualifies as a Federally-qualified health center or rural health clinic, the State plan shall provide for the payment amount to be calculated in accordance with paragraph (3).

(5) ADMINISTRATION IN THE CASE OF MANAGED CARE.—

(A) IN GENERAL.—In the case of services furnished by a Federally-qualified health center or rural health clinic pursuant to a contract between the center or clinic and a managed care entity (as defined in section 1932(a)(1)(B)), the State plan shall provide for payment to the center or clinic by the State of a supplemental payment equal to the amount (if any) by which the amount determined under paragraphs (2), (3), and (4) of this subsection exceeds the amount of the payments provided under the contract.

(B) PAYMENT SCHEDULE.—The supplemental payment required under subparagraph (A) shall be made pursuant to a payment schedule agreed to by the State and the Federally-qualified health center or rural health clinic, but in no case less frequently than every 4 months.

(6) ALTERNATIVE PAYMENT METHODOLOGIES.—Notwithstanding any other provision of this section, the State plan may provide for payment in any fiscal year to a Federally-qualified health center for services described in section 1905(a)(2)(C) or to a rural health clinic for services described in section 1905(a)(2)(B) in an amount which is determined under an alternative payment methodology that—

(A) is agreed to by the State and the center or clinic; and

(B) results in payment to the center or clinic of an amount which is at least equal to the amount otherwise required to be paid to the center or clinic under this section.

(cc)(1) Individuals described in this paragraph are individuals—

(A) who are children who have not attained 19 years of age and are born—

(i) on or after January 1, 2001 (or, at the option of a State, on or after an earlier date), in the case of the second, third, and fourth quarters of fiscal year 2007;

(ii) on or after October 1, 1995 (or, at the option of a State, on or after an earlier date), in the case of each quarter of fiscal year 2008; and

(iii) after October 1, 1989, in the case of each quarter of fiscal year 2009 and each quarter of any fiscal year thereafter;

(B) who would be considered disabled under section 1614(a)(3)(C) (as determined under title XVI for children but without regard to any income or asset eligibility requirements that apply under such title with respect to children); and

(C) whose family income does not exceed such income level as the State establishes and does not exceed—

(i) 300 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved; or

(ii) such higher percent of such poverty line as a State may establish, except that—

(I) any medical assistance provided to an individual whose family income exceeds 300 percent of such poverty line may only be provided with State funds; and

(II) no Federal financial participation shall be provided under section 1903(a) for any medical assistance provided to such an individual.

(2)(A) If an employer of a parent of an individual described in paragraph (1) offers family coverage under a group health plan (as defined in section 2791(a) of the Public Health Service Act), the State shall—

(i) notwithstanding section 1906, require such parent to apply for, enroll in, and pay premiums for such coverage as a condition of such parent's child being or remaining eligible for medical assistance under subsection (a)(10)(A)(ii)(XIX) if the parent is determined eligible for such coverage and the employer contributes at least 50 percent of the total cost of annual premiums for such coverage; and

(ii) if such coverage is obtained—

(I) subject to paragraph (2) of section 1916(h), reduce the premium imposed by the State under that section in an amount that reasonably reflects the premium contribution made by the parent for private coverage on behalf of a child with a disability; and

(II) treat such coverage as a third party liability under subsection (a)(25).

(B) In the case of a parent to which subparagraph (A) applies, a State, notwithstanding section 1906 but subject to paragraph (1)(C)(ii), may provide for payment of any portion of the annual premium for such family coverage that the parent is required to pay. Any payments made by the State under this subparagraph shall be considered, for purposes of section 1903(a), to be payments for medical assistance.

(dd) ELECTRONIC TRANSMISSION OF INFORMATION.—If the State agency determining eligibility for medical assistance under this title or child health assistance under title XXI verifies an element of eligibility based on information from an Express Lane Agency (as defined in subsection (e)(13)(F)), or from another public agency, then the applicant's signature under penalty of perjury shall not be required as to such element. Any signature requirement for an application for medical assistance may be satisfied through an electronic signature, as defined in section 1710(1) of the Government Paperwork Elimination Act (44 U.S.C. 3504 note). The requirements of subparagraphs (A) and (B) of section 1137(d)(2) may be met through evidence in digital or electronic form.

(ee)(1) For purposes of subsection (a)(46)(B)(ii), the requirements of this subsection with respect to an individual declaring to be a citizen or national of the United States for purposes of establishing eligibility under this title, are, in lieu of requiring the individual to present satisfactory documentary evidence of citizenship or nationality under section 1903(x) (if the individual is not described in paragraph (2) of that section), as follows:

(A) The State submits the name and social security number of the individual to the Commissioner of Social Security as part of the program established under paragraph (2).

(B) If the State receives notice from the Commissioner of Social Security that the name or social security number, or the declaration of citizenship or nationality, of the individual is inconsistent with information in the records maintained by the Commissioner—

(i) the State makes a reasonable effort to identify and address the causes of such inconsistency, including through typographical or other clerical errors, by contacting the individual to confirm the accuracy of the name or social security number submitted or declaration of citizenship or nationality and by taking such additional actions as the Secretary, through regulation or other guidance, or the State may identify, and continues to provide the individual with medical assistance while making such effort; and

(ii) in the case such inconsistency is not resolved under clause (i), the State—

(I) notifies the individual of such fact;

(II) provides the individual with a period of 90 days from the date on which the notice required under subclause (I) is received by the individual to either present satisfactory documentary evidence of citizenship or nationality (as defined in section 1903(x)(3)) or resolve the inconsistency with the Commissioner of Social Security (and continues to provide the individual with medical assistance during such 90-day period); and

(III) disenrolls the individual from the State plan under this title within 30 days after the end of such 90-day period if no such documentary evidence is presented or if such inconsistency is not resolved.

(2)(A) Each State electing to satisfy the requirements of this subsection for purposes of section 1902(a)(46)(B) shall establish a program under which the State submits at least monthly to the Commissioner of Social Security for comparison of the name and social security number, of each individual newly enrolled in the State plan under this title that month who is not described in section 1903(x)(2) and who declares to be a United States citizen or national, with information in records maintained by the Commissioner.

(B) In establishing the State program under this paragraph, the State may enter into an agreement with the Commissioner of Social Security—

(i) to provide, through an on-line system or otherwise, for the electronic submission of, and response to, the information submitted under subparagraph (A) for an individual enrolled in the State plan under this title who declares to be citizen or national on at least a monthly basis; or

(ii) to provide for a determination of the consistency of the information submitted with the information maintained in the records of the Commissioner through such other method as agreed to by the State and the Commissioner and approved by the Secretary, provided that such method is no more burdensome for individuals to comply with than any burdens that may apply under a method described in clause (i).

(C) The program established under this paragraph shall provide that, in the case of any individual who is required to submit a social security number to the State under subparagraph (A) and who is unable to provide the State with such number, shall be provided with at least the reasonable opportunity to present satisfactory documentary evidence of citizenship or nationality (as defined in section 1903(x)(3)) as is provided under clauses (i) and (ii) of section 1137(d)(4)(A) to an individual for the submittal to the State of evidence indicating a satisfactory immigration status.

(3)(A) The State agency implementing the plan approved under this title shall, at such times and in such form as the Secretary may specify, provide information on the percentage each month that the inconsistent submissions bears to the total submissions made for comparison for such month. For purposes of this subparagraph, a name, social security number, or declaration of citizenship or nationality of an individual shall be treated as inconsistent and included in the determination of such percentage only if—

(i) the information submitted by the individual is not consistent with information in records maintained by the Commissioner of Social Security;

(ii) the inconsistency is not resolved by the State;

(iii) the individual was provided with a reasonable period of time to resolve the inconsistency with the Commissioner of Social Security or provide satisfactory documentation of citizenship status and did not successfully resolve such inconsistency; and

(iv) payment has been made for an item or service furnished to the individual under this title.

(B) If, for any fiscal year, the average monthly percentage determined under subparagraph (A) is greater than 3 percent—

(i) the State shall develop and adopt a corrective plan to review its procedures for verifying the identities of individuals seeking to enroll in the State plan under this title and to identify and implement changes in such procedures to improve their accuracy; and

(ii) pay to the Secretary an amount equal to the amount which bears the same ratio to the total payments under the State plan for the fiscal year for providing medical assistance to individuals who provided inconsistent information as the number of individuals with inconsistent information in excess of 3 percent of such total submitted bears to the total number of individuals with inconsistent information.

(C) The Secretary may waive, in certain limited cases, all or part of the payment under subparagraph (B)(ii) if the State is unable to reach the allowable error rate despite a good faith effort by such State.

(D) Subparagraphs (A) and (B) shall not apply to a State for a fiscal year if there is an agreement described in paragraph (2)(B) in effect as of the close of the fiscal year that provides for the submission on a real-time basis of the information described in such paragraph.

(4) Nothing in this subsection shall affect the rights of any individual under this title to appeal any disenrollment from a State plan.

(ff) Notwithstanding any other requirement of this title or any other provision of Federal or State law, a State shall disregard the following property from resources for purposes of determining the eligibility of an individual who is an Indian for medical assistance under this title:

(1) Property, including real property and improvements, that is held in trust, subject to Federal restrictions, or otherwise under the supervision of the Secretary of the Interior, located on a reservation, including any federally recognized Indian Tribe's reservation, pueblo, or colony, including former reservations in Oklahoma, Alaska Native regions established by the Alaska Native Claims Settlement Act, and Indian allotments on or near a reservation as designated and approved by the Bureau of Indian Affairs of the Department of the Interior.

(2) For any federally recognized Tribe not described in paragraph (1), property located within the most recent boundaries of a prior Federal reservation.

(3) Ownership interests in rents, leases, royalties, or usage rights related to natural resources (including extraction of natural resources or harvesting of timber, other plants and plant products, animals, fish, and shellfish) resulting from the exercise of federally protected rights.

(4) Ownership interests in or usage rights to items not covered by paragraphs (1) through (3) that have unique religious, spiritual, traditional, or cultural significance or rights that support subsistence or a traditional lifestyle according to applicable tribal law or custom.

(gg) MAINTENANCE OF EFFORT.—

(1) GENERAL REQUIREMENT TO MAINTAIN ELIGIBILITY STANDARDS UNTIL STATE EXCHANGE IS FULLY OPERATIONAL.—Subject to the succeeding paragraphs of this subsection, during the period that begins on the date of enactment of the Patient Protection and Affordable Care Act and ends on the date on which the Secretary determines that an Exchange established by the State under section 1311 of the Patient Protection and Affordable Care Act is fully operational, as a condition for receiving any Federal payments under section 1903(a) for calendar quarters occurring during such period, a State shall not have in effect eligibility standards, methodologies, or procedures under the State plan under this title or under any waiver of such plan that is in effect during that period, that are more restrictive than the eligibility standards, methodologies, or procedures, respectively, under the plan or waiver that are in effect on the date of enactment of the Patient Protection and Affordable Care Act.

(2) CONTINUATION OF ELIGIBILITY STANDARDS FOR CHILDREN THROUGH SEPTEMBER 30, 2027.—The requirement under paragraph (1) shall continue to apply to a State through September 30, 2027 (but during the period that begins on October 1, 2019, and ends on September 30, 2027 only with respect to children in families whose income does not exceed 300 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved) with respect to the eligibility standards, methodologies, and procedures under the State plan under this title or under any waiver of such plan that are applicable to determining the eligibility for medical assistance of any child who is under 19 years of age (or such higher age as the State may have elected).

(3) NONAPPLICATION.—During the period that begins on January 1, 2011, and ends on December 31, 2013, the requirement under paragraph (1) shall not apply to a State with respect to nonpregnant, nondisabled adults who are eligible for medical assistance under the State plan or under a waiver of the plan at the option of the State and whose income exceeds 133 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved if, on or after December 31, 2010, the State certifies to the Secretary that, with respect to the State fiscal year during which the certification is made, the State has a budget deficit, or with respect to the succeeding State fiscal year, the State is projected to have a budget deficit. Upon submission of such a certification to the Secretary, the requirement under paragraph (1) shall not apply to the State with respect to any remaining portion of the period described in the preceding sentence.

(4) DETERMINATION OF COMPLIANCE.—

(A) STATES SHALL APPLY MODIFIED ADJUSTED GROSS INCOME.—A State's determination of income in accordance with subsection (e)(14) shall not be considered to be eligibility standards, methodologies, or procedures that are more restrictive than the standards, methodologies, or procedures in effect under the State plan or under a waiver of the plan on the date of enactment of the Patient Protection and Affordable Care Act for purposes of determining compliance with the requirements of paragraph (1), (2), or (3).

(B) STATES MAY EXPAND ELIGIBILITY OR MOVE WAIVERED POPULATIONS INTO COVERAGE UNDER THE STATE PLAN.—With respect to any period applicable under paragraph (1), (2), or (3), a State that applies eligibility standards, methodologies, or procedures under the State plan under this title or under any waiver of the plan that are less restrictive than the eligibility standards, methodologies, or procedures, applied under the State plan or under a waiver of the plan on the date of enactment of the Patient Protection and Affordable Care Act, or that makes individuals who, on such date of enactment, are eligible for medical assistance under a waiver of the State plan, after such date of enactment eligible for medical assistance through a State plan amendment with an income eligibility level that is not less than the income eligibility level that applied under the waiver, or as a result of the application of subclause (VIII) of section 1902(a)(10)(A)(i), shall not be consid-

ered to have in effect eligibility standards, methodologies, or procedures that are more restrictive than the standards, methodologies, or procedures in effect under the State plan or under a waiver of the plan on the date of enactment of the Patient Protection and Affordable Care Act for purposes of determining compliance with the requirements of paragraph (1), (2), or (3).

(hh)(1) A State may elect to phase-in the extension of eligibility for medical assistance to individuals described in subclause (XX) of subsection (a)(10)(A)(ii) based on the categorical group (including nonpregnant childless adults) or income, so long as the State does not extend such eligibility to individuals described in such subclause with higher income before making individuals described in such subclause with lower income eligible for medical assistance.

(2) If an individual described in subclause (XX) of subsection (a)(10)(A)(ii) is the parent of a child who is under 19 years of age (or such higher age as the State may have elected) who is eligible for medical assistance under the State plan or under a waiver of such plan, the individual may not be enrolled under the State plan unless the individual's child is enrolled under the State plan or under a waiver of the plan or is enrolled in other health insurance coverage. For purposes of the preceding sentence, the term "parent" includes an individual treated as a caretaker relative for purposes of carrying out section 1931.

(ii)(1) Individuals described in this subsection are individuals—

(A) whose income does not exceed an income eligibility level established by the State that does not exceed the highest income eligibility level established under the State plan under this title (or under its State child health plan under title XXI) for pregnant women; and

(B) who are not pregnant.

(2) At the option of a State, individuals described in this subsection may include individuals who, had individuals applied on or before January 1, 2007, would have been made eligible pursuant to the standards and processes imposed by that State for benefits described in clause (XVI) of the matter following subparagraph (G) of section subsection (a)(10) pursuant to a waiver granted under section 1115.

(3) At the option of a State, for purposes of subsection (a)(17)(B), in determining eligibility for services under this subsection, the State may consider only the income of the applicant or recipient.

(jj) PRIMARY CARE SERVICES DEFINED.—For purposes of subsection (a)(13)(C), the term "primary care services" means—

(1) evaluation and management services that are procedure codes (for services covered under title XVIII) for services in the category designated Evaluation and Management in the Healthcare Common Procedure Coding System (established by the Secretary under section 1848(c)(5) as of December 31, 2009, and as subsequently modified); and

(2) services related to immunization administration for vaccines and toxoids for which CPT codes 90465, 90466, 90467, 90468, 90471, 90472, 90473, or 90474 (as subsequently modified) apply under such System.

(kk) PROVIDER AND SUPPLIER SCREENING, OVERSIGHT, AND REPORTING REQUIREMENTS.—For purposes of subsection (a)(77), the requirements of this subsection are the following:

(1) SCREENING.—The State complies with the process for screening providers and suppliers under this title, as established by the Secretary under section 1866(j)(2).

(2) PROVISIONAL PERIOD OF ENHANCED OVERSIGHT FOR NEW PROVIDERS AND SUPPLIERS.—The State complies with procedures to provide for a provisional period of enhanced oversight for new providers and suppliers under this title, as established by the Secretary under section 1866(j)(3).

(3) DISCLOSURE REQUIREMENTS.—The State requires providers and suppliers under the State plan or under a waiver of the plan to comply with the disclosure requirements established by the Secretary under section 1866(j)(5).

(4) TEMPORARY MORATORIUM ON ENROLLMENT OF NEW PROVIDERS OR SUPPLIERS.—

(A) TEMPORARY MORATORIUM IMPOSED BY THE SECRETARY.—

(i) IN GENERAL.—Subject to clause (ii), the State complies with any temporary moratorium on the enrollment of new providers or suppliers imposed by the Secretary under section 1866(j)(7).

(ii) EXCEPTIONS.—

(I) COMPLIANCE WITH MORATORIUM.—A State shall not be required to comply with a temporary moratorium described in clause (i) if the State determines that

the imposition of such temporary moratorium would adversely impact beneficiaries' access to medical assistance.

(II) FFP AVAILABLE.—Notwithstanding section 1903(i)(2)(E), payment may be made to a State under this title with respect to amounts expended for items and services described in such section if the Secretary, in consultation with the State agency administering the State plan under this title (or a waiver of the plan), determines that denying payment to the State pursuant to such section would adversely impact beneficiaries' access to medical assistance.

(iii) LIMITATION ON CHARGES TO BENEFICIARIES.—With respect to any amount expended for items or services furnished during calendar quarters beginning on or after October 1, 2017, the State prohibits, during the period of a temporary moratorium described in clause (i), a provider meeting the requirements specified in subparagraph (C)(iii) of section 1866(j)(7) from charging an individual or other person eligible to receive medical assistance under the State plan under this title (or a waiver of the plan) for an item or service described in section 1903(i)(2)(E) furnished to such an individual.

(B) MORATORIUM ON ENROLLMENT OF PROVIDERS AND SUPPLIERS.—At the option of the State, the State imposes, for purposes of entering into participation agreements with providers or suppliers under the State plan or under a waiver of the plan, periods of enrollment moratoria, or numerical caps or other limits, for providers or suppliers identified by the Secretary as being at high-risk for fraud, waste, or abuse as necessary to combat fraud, waste, or abuse, but only if the State determines that the imposition of any such period, cap, or other limits would not adversely impact beneficiaries' access to medical assistance.

(5) COMPLIANCE PROGRAMS.—The State requires providers and suppliers under the State plan or under a waiver of the plan to establish, in accordance with the requirements of section 1866(j)(7), a compliance program that contains the core elements established under subparagraph (B) of that section 1866(j)(7) for providers or suppliers within a particular industry or category.

(6) REPORTING OF ADVERSE PROVIDER ACTIONS.—The State complies with the national system for reporting criminal and civil convictions, sanctions, negative licensure actions, and other adverse provider actions to the Secretary, through the Administrator of the Centers for Medicare & Medicaid Services, in accordance with regulations of the Secretary.

(7) ENROLLMENT AND NPI OF ORDERING OR REFERRING PROVIDERS.—The State requires—

(A) all ordering or referring physicians or other professionals to be enrolled under the State plan or under a waiver of the plan as a participating provider; and

(B) the national provider identifier of any ordering or referring physician or other professional to be specified on any claim for payment that is based on an order or referral of the physician or other professional.

(8) PROVIDER TERMINATIONS.—

(A) IN GENERAL.—Beginning on July 1, 2018, in the case of a notification under subsection (a)(41) with respect to a termination for a reason specified in section 455.101 of title 42, Code of Federal Regulations (as in effect on November 1, 2015) or for any other reason specified by the Secretary, of the participation of a provider of services or any other person under the State plan (or under a waiver of the plan), the State, not later than 30 days after the effective date of such termination, submits to the Secretary with respect to any such provider or person, as appropriate—

(i) the name of such provider or person;

(ii) the provider type of such provider or person;

(iii) the specialty of such provider's or person's practice;

(iv) the date of birth, Social Security number, national provider identifier (if applicable), Federal taxpayer identification number, and the State license or certification number of such provider or person (if applicable);

(v) the reason for the termination;

(vi) a copy of the notice of termination sent to the provider or person;

(vii) the date on which such termination is effective, as specified in the notice; and

(viii) any other information required by the Secretary.

(B) EFFECTIVE DATE DEFINED.—For purposes of this paragraph, the term "effective date" means, with respect to a termination described in subparagraph (A), the later of—

(i) the date on which such termination is effective, as specified in the notice of such termination; or

(ii) the date on which all appeal rights applicable to such termination have been exhausted or the timeline for any such appeal has expired.

(9) OTHER STATE OVERSIGHT.—Nothing in this subsection shall be interpreted to preclude or limit the ability of a State to engage in provider and supplier screening or enhanced provider and supplier oversight activities beyond those required by the Secretary.

(ll) TERMINATION NOTIFICATION DATABASE.—In the case of a provider of services or any other person whose participation under this title or title XXI is terminated (as described in subsection (kk)(8)), the Secretary shall, not later than 30 days after the date on which the Secretary is notified of such termination under subsection (a)(41) (as applicable), review such termination and, if the Secretary determines appropriate, include such termination in any database or similar system developed pursuant to section 6401(b)(2) of the Patient Protection and Affordable Care Act (42 U.S.C. 1395cc note; Public Law 111–148).

(mm) DIRECTORY PHYSICIAN OR PROVIDER DESCRIBED.—A physician or provider described in this subsection is—

(1) in the case of a physician or provider of a provider type for which the State agency, as a condition on receiving payment for items and services furnished by the physician or provider to individuals eligible to receive medical assistance under the State plan, requires the enrollment of the physician or provider with the State agency, a physician or a provider that—

(A) is enrolled with the agency as of the date on which the directory is published or updated (as applicable) under subsection (a)(83); and

(B) received payment under the State plan in the 12-month period preceding such date; and

(2) in the case of a physician or provider of a provider type for which the State agency does not require such enrollment, a physician or provider that received payment under the State plan (or a waiver of the plan) in the 12-month period preceding the date on which the directory is published or updated (as applicable) under subsection (a)(83).

*(nn) JUVENILE; ELIGIBLE JUVENILE; PUBLIC INSTITUTION.—For purposes of subsection (a)(84) and this subsection:*

*(1) JUVENILE.—The term "juvenile" means an individual who is—*

*(A) under 21 years of age; or*

*(B) described in subsection (a)(10)(A)(i)(IX).*

*(2) ELIGIBLE JUVENILE.—The term "eligible juvenile" means a juvenile who is an inmate of a public institution and who—*

*(A) was determined eligible for medical assistance under the State plan immediately before becoming an inmate of such a public institution; or*

*(B) is determined eligible for such medical assistance while an inmate of a public institution.*

*(3) INMATE OF A PUBLIC INSTITUTION.—The term "inmate of a public institution" has the meaning given such term for purposes of applying the subdivision (A) following paragraph (29) of section 1905(a), taking into account the exception in such subdivision for a patient of a medical institution.*

*(oo) DRUG REVIEW AND UTILIZATION REQUIREMENTS.—*

*(1) IN GENERAL.—For purposes of subsection (a)(85), the drug review and utilization requirements under this subsection are, subject to paragraph (3) and beginning October 1, 2019, the following:*

*(A) CLAIMS REVIEW LIMITATIONS.—*

*(i) IN GENERAL.—The State has in place—*

*(I) safety edits (as specified by the State) for subsequent fills for opioids and a claims review automated process (as designed and implemented by the State) that indicates when an individual enrolled under the State plan (or under a waiver of the State plan) is prescribed a subsequent fill of opioids in excess of any limitation that may be identified by the State;*

*(II) safety edits (as specified by the State) on the maximum daily morphine equivalent that can be prescribed to an individual enrolled under the State plan (or under a waiver of the State plan) for treatment of chronic pain and a claims review automated process (as designed and implemented by the State) that indicates when an individual enrolled under the plan (or waiver) is prescribed the mor-*

*phine equivalent for such treatment in excess of any limitation that may be identified by the State; and*

*(III) a claims review automated process (as designed and implemented by the State) that monitors when an individual enrolled under the State plan (or under a waiver of the State plan) is concurrently prescribed opioids and—*

*(aa) benzodiazepines; or*

*(bb) antipsychotics.*

*(ii) MANAGED CARE ENTITIES.—The State requires each managed care entity (as defined in section 1932(a)(1)(B)) with respect to which the State has a contract under section 1903(m) or under section 1905(t)(3) to have in place, subject to paragraph (3), with respect to individuals who are eligible for medical assistance under the State plan (or under a waiver of the State plan) and who are enrolled with the entity, the limitations described in subclauses (I) and (II) of clause (i) and a claims review automated process described in subclause (III) of such clause.*

*(iii) RULES OF CONSTRUCTION.—Nothing in this subparagraph may be construed as prohibiting a State or managed care entity from designing and implementing a claims review automated process under this subparagraph that provides for prospective or retrospective reviews of claims. Nothing in this subparagraph shall be understood as prohibiting the exercise of clinical judgment from a provider enrolled as a participating provider in a State plan (or waiver of the State plan) or contracting with a managed care entity regarding the best items and services for an individual enrolled under such State plan (or waiver).*

*(B) PROGRAM TO MONITOR ANTIPSYCHOTIC MEDICATIONS BY CHILDREN.—The State has in place a program (as designed and implemented by the State) to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the State plan (or under a waiver of the State plan) and submits annually to the Secretary such information as the Secretary may require on activities carried out under such program for individuals not more than the age of 18 years generally and children in foster care specifically.*

*(C) FRAUD AND ABUSE IDENTIFICATION.—The State has in place a process (as designed and implemented by the State) that identifies potential fraud or abuse of controlled substances by individuals enrolled under the State plan (or under a waiver of the State plan), health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.*

*(D) REPORTS.—The State shall include in the annual report submitted to the Secretary under section 1927(g)(3)(D) information on the limitations, requirement, program, and processes applied by the State under subparagraphs (A) through (C) in accordance with such manner and time as specified by the Secretary.*

*(E) CLARIFICATION.—Nothing shall prevent a State from satisfying the requirement—*

*(i) described in subparagraph (A) by having safety edits or a claims review automated process described in such subparagraph that was in place before October 1, 2019;*

*(ii) described in subparagraph (B) by having a program described in such subparagraph that was in place before such date; or*

*(iii) described in subparagraph (C) by having a process described in such subparagraph that was in place before such date.*

*(2) ANNUAL REPORT BY SECRETARY.—For each fiscal year beginning with fiscal year 2020, the Secretary shall submit to Congress a report on the most recent information submitted by States under paragraph (1)(D).*

*(3) EXCEPTIONS.—*

*(A) CERTAIN INDIVIDUALS EXEMPTED.—The drug review and utilization requirements under this subsection shall not apply with respect to an individual who—*

*(i) is receiving—*

*(I) hospice or palliative care; or*

*(II) treatment for cancer;*

*(ii) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or*

*(iii) the State elects to treat as exempted from such requirements.*

*(B) EXCEPTION RELATING TO ENSURING ACCESS.—In order to ensure reasonable access to health care, the Secretary shall waive the drug review and utilization requirements under this subsection, with respect to a State, in the case of natural disasters and similar situations, and in the case of the provision of emergency services (as defined for purposes of section 1860D–4(c)(5)(D)(ii)(II)).*

PAYMENT TO STATES

SEC. 1903. (a) From the sums appropriated therefor, the Secretary (except as otherwise provided in this section) shall pay to each State which has a plan approved under this title, for each quarter, beginning with the quarter commencing January 1, 1966—

(1) an amount equal to the Federal medical assistance percentage (as defined in section 1905(b), subject to subsections (g) and (j) of this section and subsection 1923(f)) of the total amount expended during such quarter as medical assistance under the State plan; plus

(2)(A) an amount equal to 75 per centum of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to compensation or training of skilled professional medical personnel, and staff directly supporting such personnel, of the State agency or any other public agency; plus

(B) notwithstanding paragraph (1) or subparagraph (A), with respect to amounts expended for nursing aide training and competency evaluation programs, and competency evaluation programs, described in section 1919(e)(1) (including the costs for nurse aides to complete such competency evaluation programs), regardless of whether the programs are provided in or outside nursing facilities or of the skill of the personnel involved in such programs, an amount equal to 50 percent (or, for calendar quarters beginning on or after July 1, 1988, and before October 1, 1990, the lesser of 90 percent or the Federal medical assistance percentage plus 25 percentage points) of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to such programs; plus

(C) an amount equal to 75 percent of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to preadmission screening and resident review activities conducted by the State under section 1919(e)(7); plus

(D) for each calendar quarter during—

(i) fiscal year 1991, an amount equal to 90 percent,

(ii) fiscal year 1992, an amount equal to 85 percent,

(iii) fiscal year 1993, an amount equal to 80 percent, and

(iv) fiscal year 1994 and thereafter, an amount equal to 75 percent,

of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to State activities under section 1919(g); plus

(E) an amount equal to 75 percent of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to translation or interpretation services in connection with the enrollment of, retention of, and use of services under this title by, children of families for whom English is not the primary language; plus

(3) an amount equal to—

(A)(i) 90 per centum of so much of the sums expended during such quarter as are attributable to the design, development, or installation of such mechanized claims processing and information retrieval systems as the Secretary determines are likely to provide more efficient, economical, and effective administration of the plan and to be compatible with the claims processing and information retrieval systems utilized in the administration of title XVIII, including the State's share of the cost of installing such a system to be used jointly in the administration of such State's plan and the plan of any other State approved under this title,

(ii) 90 per centum of so much of the sums expended during any such quarter in the fiscal year ending June 30, 1972, or the fiscal year ending June 30, 1973, as are attributable to the design, development, or installation of cost determination systems for State-

owned general hospitals (except that the total amount paid to all States under this clause for either such fiscal year shall not exceed $150,000), and

(iii) an amount equal to the Federal medical assistance percentage (as defined in section 1905(b)) of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to such developments or modifications of systems of the type described in clause (i) as are necessary for the efficient collection and reporting on child health measures; and

(B) 75 per centum of so much of the sums expended during such quarter as are attributable to the operation of systems (whether such systems are operated directly by the State or by another person under a contract with the State) of the type described in subparagraph (A)(i) (whether or not designed, developed, or installed with assistance under such subparagraph) which are approved by the Secretary and which include provision for prompt written notice to each individual who is furnished services covered by the plan, or to each individual in a sample group of individuals who are furnished such services, of the specific services (other than confidential services) so covered, the name of the person or persons furnishing the services, the date or dates on which the services were furnished, and the amount of the payment or payments made under the plan on account of the services; and

(C)(i) 75 per centum of the sums expended with respect to costs incurred during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to the performance of medical and utilization review by a utilization and quality control peer review organization or by an entity which meets the requirements of section 1152, as determined by the Secretary, under a contract entered into under section 1902(d); and

(ii) 75 percent of the sums expended with respect to costs incurred during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to the performance of independent external reviews conducted under section 1932(c)(2); and

(D) 75 percent of so much of the sums expended by the State plan during a quarter in 1991, 1992, or 1993, as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of section 1927(g);

(E) 50 percent of the sums expended with respect to costs incurred during such quarter as are attributable to providing—

(i) services to identify and educate individuals who are likely to be eligible for medical assistance under this title and who have Sickle Cell Disease or who are carriers of the sickle cell gene, including education regarding how to identify such individuals; or

(ii) education regarding the risks of stroke and other complications, as well as the prevention of stroke and other complications, in individuals who are likely to be eligible for medical assistance under this title and who have Sickle Cell Disease; and

(F)(i) 100 percent of so much of the sums expended during such quarter as are attributable to payments to Medicaid providers described in subsection (t)(1) to encourage the adoption and use of certified EHR technology; and

(ii) 90 percent of so much of the sums expended during such quarter as are attributable to payments for reasonable administrative expenses related to the administration of payments described in clause (i) if the State meets the condition described in subsection (t)(9); plus

(H)(i) 90 percent of the sums expended during the quarter as are attributable to the design, development, or installation of such mechanized verification and information retrieval systems as the Secretary determines are necessary to implement section 1902(ee) (including a system described in paragraph (2)(B) thereof), and

(ii) 75 percent of the sums expended during the quarter as are attributable to the operation of systems to which clause (i) applies, plus

(4) an amount equal to 100 percent of the sums expended during the quarter which are attributable to the costs of the implementation and operation of the immigration status verification system described in section 1137(d); plus

(5) an amount equal to 90 per centum of the sums expended during such quarter which are attributable to the offering, arranging, and furnishing (directly or on a contract basis) of family planning services and supplies;

(6) subject to subsection (b)(3), an amount equal to—

(A) 90 per centum of the sums expended during such a quarter within the twelve-quarter period beginning with the first quarter in which a payment is made to the State pursuant to this paragraph, and

(B) 75 per centum of the sums expended during each succeeding calendar quarter,

with respect to costs incurred during such quarter (as found necessary by the Secretary for the elimination of fraud in the provision and administration of medical assistance provided under the State plan) which are attributable to the establishment and operation of (including the training of personnel employed by) a State medicaid fraud control unit (described in subsection (q)); plus

(7) subject to section 1919(g)(3)(B), an amount equal to 50 per centum of the remainder of the amounts expended during such quarter as found necessary by the Secretary for the proper and efficient administration of the State plan.

(b)(1) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State for any quarter beginning after December 31, 1969, shall not take into account any amounts expended as medical assistance with respect to individuals aged 65 or over and disabled individuals entitled to hospital insurance benefits under title XVIII which would not have been so expended if the individuals involved had been enrolled in the insurance program established by part B of title XVIII, other than amounts expended under provisions of the plan of such State required by section 1902(a)(34).

(2) For limitation on Federal participation for capital expenditures which are out of conformity with a comprehensive plan of a State or areawide planning agency, see section 1122.

(3) The amount of funds which the Secretary is otherwise obligated to pay a State during a quarter under subsection (a)(6) may not exceed the higher of—

(A) $125,000, or

(B) one-quarter of 1 per centum of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State's plan under this title.

(4) Amounts expended by a State for the use of an enrollment broker in marketing medicaid managed care organizations and other managed care entities to eligible individuals under this title shall be considered, for purposes of subsection (a)(7), to be necessary for the proper and efficient administration of the State plan but only if the following conditions are met with respect to the broker:

(A) The broker is independent of any such entity and of any health care providers (whether or not any such provider participates in the State plan under this title) that provide coverage of services in the same State in which the broker is conducting enrollment activities.

(B) No person who is an owner, employee, consultant, or has a contract with the broker either has any direct or indirect financial interest with such an entity or health care provider or has been excluded from participation in the program under this title or title XVIII or debarred by any Federal agency, or subject to a civil money penalty under this Act.

(5) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State shall be decreased in a quarter by the amount of any health care related taxes (described in section 1902(w)(3)(A)) that are imposed on a hospital described in subsection (w)(3)(F) in that quarter.

(c) Nothing in this title shall be construed as prohibiting or restricting, or authorizing the Secretary to prohibit or restrict, payment under subsection (a) for medical assistance for covered services furnished to a child with a disability because such services are included in the child's individualized education program established pursuant to part B of the Individuals with Disabilities Education Act or furnished to an infant or toddler with a disability because such services are included in the child's individualized family service plan adopted pursuant to part C of such Act.

(d)(1) Prior to the beginning of each quarter, the Secretary shall estimate the amount to which a State will be entitled under subsections (a) and (b) for such quarter, such estimates to be based on (A) a report filed by the State containing its estimate of the total sum to be expended in such quarter in accordance with the provisions of such subsections, and stating the amount appropriated or made available by the State and its political subdivisions for such expenditures in such quarter, and if such amount is less than the State's proportionate share of the total sum of such estimated expenditures, the source or sources from which the difference is expected to be derived, and (B) such other investigation as the Secretary may find necessary.

(2)(A) The Secretary shall then pay to the State, in such installments as he may determine, the amount so estimated, reduced or increased to the extent of any overpayment or underpayment

which the Secretary determines was made under this section to such State for any prior quarter and with respect to which adjustment has not already been made under this subsection.

(B) Expenditures for which payments were made to the State under subsection (a) shall be treated as an overpayment to the extent that the State or local agency administering such plan has been reimbursed for such expenditures by a third party pursuant to the provisions of its plan in compliance with section 1902(a)(25).

(C) For purposes of this subsection, when an overpayment is discovered, which was made by a State to a person or other entity, the State shall have a period of 1 year in which to recover or attempt to recover such overpayment before adjustment is made in the Federal payment to such State on account of such overpayment. Except as otherwise provided in subparagraph (D), the adjustment in the Federal payment shall be made at the end of the 1-year period, whether or not recovery was made.

(D)(i) In any case where the State is unable to recover a debt which represents an overpayment (or any portion thereof) made to a person or other entity on account of such debt having been discharged in bankruptcy or otherwise being uncollectable, no adjustment shall be made in the Federal payment to such State on account of such overpayment (or portion thereof).

(ii) In any case where the State is unable to recover a debt which represents an overpayment (or any portion thereof) made to a person or other entity due to fraud within 1 year of discovery because there is not a final determination of the amount of the overpayment under an administrative or judicial process (as applicable), including as a result of a judgment being under appeal, no adjustment shall be made in the Federal payment to such State on account of such overpayment (or portion thereof) before the date that is 30 days after the date on which a final judgment (including, if applicable, a final determination on an appeal) is made.

(3)(A) The pro rata share to which the United States is equitably entitled, as determined by the Secretary, of the net amount recovered during any quarter by the State or any political subdivision thereof with respect to medical assistance furnished under the State plan shall be considered an overpayment to be adjusted under this subsection.

(B)(i) Subparagraph (A) and paragraph (2)(B) shall not apply to any amount recovered or paid to a State as part of the comprehensive settlement of November 1998 between manufacturers of tobacco products, as defined in section 5702(d) of the Internal Revenue Code of 1986, and State Attorneys General, or as part of any individual State settlement or judgment reached in litigation initiated or pursued by a State against one or more such manufacturers.

(ii) Except as provided in subsection (i)(19), a State may use amounts recovered or paid to the State as part of a comprehensive or individual settlement, or a judgment, described in clause (i) for any expenditures determined appropriate by the State.

(4) Upon the making of any estimate by the Secretary under this subsection, any appropriations available for payments under this section shall be deemed obligated.

(5) In any case in which the Secretary estimates that there has been an overpayment under this section to a State on the basis of a claim by such State that has been disallowed by the Secretary under section 1116(d), and such State disputes such disallowance, the amount of the Federal payment in controversy shall, at the option of the State, be retained by such State or recovered by the Secretary pending a final determination with respect to such payment amount. If such final determination is to the effect that any amount was properly disallowed, and the State chose to retain payment of the amount in controversy, the Secretary shall offset, from any subsequent payments made to such State under this title, an amount equal to the proper amount of the disallowance plus interest on such amount disallowed for the period beginning on the date such amount was disallowed and ending on the date of such final determination at a rate (determined by the Secretary) based on the average of the bond equivalent of the weekly 90-day treasury bill auction rates during such period.

(6)(A) Each State (as defined in subsection (w)(7)(D)) shall include, in the first report submitted under paragraph (1) after the end of each fiscal year, information related to—

(i) provider-related donations made to the State or units of local government during such fiscal year, and

(ii) health care related taxes collected by the State or such units during such fiscal year.

(B) Each State shall include, in the first report submitted under paragraph (1) after the end of each fiscal year, information related to the total amount of payment adjustments made, and the amount of payment adjustments made to individual providers (by provider), under section 1923(c) during such fiscal year.

(e) A State plan approved under this title may include, as a cost with respect to hospital services under the plan under this title, periodic expenditures made to reflect transitional allowances established with respect to a hospital closure or conversion under section 1884.

(f)(1)(A) Except as provided in paragraph (4), payment under the preceding provisions of this section shall not be made with respect to any amount expended as medical assistance in a calendar quarter, in any State, for any member of a family the annual income of which exceeds the applicable income limitation determined under this paragraph.

(B)(i) Except as provided in clause (ii) of this subparagraph, the applicable income limitation with respect to any family is the amount determined, in accordance with standards prescribed by the Secretary, to be equivalent to 133⅓ percent of the highest amount which would ordinarily be paid to a family of the same size without any income or resources, in the form of money payments, under the plan of the State approved under part A of title IV of this Act.

(ii) If the Secretary finds that the operation of a uniform maximum limits payments to families of more than one size, he may adjust the amount otherwise determined under clause (i) to take account of families of different sizes.

(C) The total amount of any applicable income limitation determined under subparagraph (B) shall, if it is not a multiple of $100 or such other amount as the Secretary may prescribe, be rounded to the next higher multiple of $100 or such other amount, as the case may be.

(2)(A) In computing a family's income for purposes of paragraph (1), there shall be excluded any costs (whether in the form of insurance premiums or otherwise and regardless of whether such costs are reimbursed under another public program of the State or political subdivision thereof) incurred by such family for medical care or for any other type of remedial care recognized under State law or, (B) notwithstanding section 1916 at State option, an amount paid by such family, at the family's option, to the State, provided that the amount, when combined with costs incurred in prior months, is sufficient when excluded from the family's income to reduce such family's income below the applicable income limitation described in paragraph (1). The amount of State expenditures for which medical assistance is available under subsection (a)(1) will be reduced by amounts paid to the State pursuant to this subparagraph.

(3) For purposes of paragraph (1)(B), in the case of a family consisting of only one individual, the "highest amount which would ordinarily be paid" to such family under the State's plan approved under part A of title IV of this Act shall be the amount determined by the State agency (on the basis of reasonable relationship to the amounts payable under such plan to families consisting of two or more persons) to be the amount of the aid which would ordinarily be payable under such plan to a family (without any income or resources) consisting of one person if such plan provided for aid to such a family.

(4) The limitations on payment imposed by the preceding provisions of this subsection shall not apply with respect to any amount expended by a State as medical assistance for any individual described in section 1902(a)(10)(A)(i)(III), 1902(a)(10)(A)(i)(IV), 1902(a)(10)(A)(i)(V), 1902(a)(10)(A)(i)(VI), 1902(a)(10)(A)(i)(VII), 1902(a)(10)(A)(i)(VIII),1902(a)(10)(A)(i)(IX), 1902(a)(10)(A)(ii)(IX), 1902(a)(10)(A)(ii)(X), 1902(a)(10)(A)(ii)(XIII), 1902(a)(10)(A)(ii)(XIV), or 1902(a)(10)(A)(ii)(XV), 1902(a)(10)(A)(ii)(XVI), 1902(a)(10)(A)(ii)(XVII), 1902(a)(10)(A)(ii)(XVIII), 1902(a)(10)(A)(ii)(XIX), 1902(a)(10)(A)(ii)(XX), 1902(a)(10)(A)(ii)(XXI), 1902(a)(10)(A)(ii)(XXII), 1905(p)(1) or for any individual—

(A) who is receiving aid or assistance under any plan of the State approved under title I, X, XIV or XVI, or part A of title IV, or with respect to whom supplemental security income benefits are being paid under title XVI, or

(B) who is not receiving such aid or assistance, and with respect to whom such benefits are not being paid, but (i) is eligible to receive such aid or assistance, or to have such benefits paid with respect to him, or (ii) would be eligible to receive such aid or assistance, or to have such benefits paid with respect to him if he were not in a medical institution, or

(C) with respect to whom there is being paid, or who is eligible, or would be eligible if he were not in a medical institution, to have paid with respect to him, a State supplementary payment and is eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1902(a)(10)(A), or who is a PACE program eligible individual enrolled in a PACE program under section 1934, but only if the income of such individual (as determined under section 1612, but without regard to subsection (b) thereof) does not exceed 300 percent of the supplemental security income benefit rate established by section 1611(b)(1),

at the time of the provision of the medical assistance giving rise to such expenditure.

(g)(1) Subject to paragraph (3), with respect to amounts paid for the following services furnished under the State plan after June 30, 1973 (other than services furnished pursuant to a contract with a health maintenance organization as defined in section 1876 or which is a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act)), the Federal medical assistance percentage shall be decreased as follows: After an individual has received inpatient hospital services or services in an intermediate care facility for the mentally retarded for 60 days or inpatient mental hospital services for 90 days (whether or not such days are consecutive), during any fiscal year, the Federal medical assistance percentage with respect to amounts paid for any such care furnished thereafter to such individual shall be decreased by a per centum thereof (determined under paragraph (5)) unless the State agency responsible for the administration of the plan makes a showing satisfactory to the Secretary that, with respect to each calendar quarter for which the State submits a request for payment at the full Federal medical assistance percentage for amounts paid for inpatient hospital services or services in an intermediate care facility for the mentally retarded furnished beyond 60 days (or inpatient mental hospital services furnished beyond 90 days), such State has an effective program of medical review of the care of patients in mental hospitals and intermediate care facilities for the mentally retarded pursuant to paragraphs (26) and (31) of section 1902(a) whereby the professional management of each case is reviewed and evaluated at least annually by independent professional review teams. In determining the number of days on which an individual has received services described in this subsection, there shall not be counted any days with respect to which such individual is entitled to have payments made (in whole or in part) on his behalf under section 1812.

(2) The Secretary shall, as part of his validation procedures under this subsection, conduct timely sample onsite surveys of private and public institutions in which recipients of medical assistance may receive care and services under a State plan approved under this title, and his findings with respect to such surveys (as well as the showings of the State agency required under this subsection) shall be made available for public inspection.

(3)(A) No reduction in the Federal medical assistance percentage of a State otherwise required to be imposed under this subsection shall take effect—

(i) if such reduction is due to the State's unsatisfactory or invalid showing made with respect to a calendar quarter beginning before January 1, 1977;

(ii) before January 1, 1978;

(iii) unless a notice of such reduction has been provided to the State at least 30 days before the date such reduction takes effect; or

(iv) due to the State's unsatisfactory or invalid showing made with respect to a calendar quarter beginning after September 30, 1977, unless notice of such reduction has been provided to the State no later than the first day of the fourth calendar quarter following the calendar quarter with respect to which such showing was made.

(B) The Secretary shall waive application of any reduction in the Federal medical assistance percentage of a State otherwise required to be imposed under paragraph (1) because a showing by the State, made under such paragraph with respect to a calendar quarter ending after January 1, 1977, and before January 1, 1978, is determined to be either unsatisfactory under such paragraph or invalid under paragraph (2), if the Secretary determines that the State's showing made under paragraph (1) with respect to any calendar quarter ending on or before December 31, 1978, is satisfactory under such paragraph and is valid under paragraph (2).

(4)(A) The Secretary may not find the showing of a State, with respect to a calendar quarter under paragraph (1), to be satisfactory if the showing is submitted to the Secretary later than the 30th day after the last day of the calendar quarter, unless the State demonstrates to the satisfaction of the Secretary good cause for not meeting such deadline.

(B) The Secretary shall find a showing of a State, with respect to a calendar quarter under paragraph (1), to be satisfactory under such paragraph with respect to the requirement that the State conduct annual onsite inspections in mental hospitals and intermediate care facilities for the mentally retarded under paragraphs (26) and (31) of section 1902(a), if the showing demonstrates that the State has conducted such an onsite inspection during the 12-month period ending on the last date of the calendar quarter—

(i) in each of not less than 98 per centum of the number of such hospitals and facilities requiring such inspection, and

(ii) in every such hospital or facility which has 200 or more beds,

and that, with respect to such hospitals and facilities not inspected within such period, the State has exercised good faith and due diligence in attempting to conduct such inspection, or if the State

demonstrates to the satisfaction of the Secretary that it would have made such a showing but for failings of a technical nature only.

(5) In the case of a State's unsatisfactory or invalid showing made with respect to a type of facility or institutional services in a calendar quarter, the per centum amount of the reduction of the State's Federal medical assistance percentage for that type of services under paragraph (1) is equal to 33⅓ per centum multiplied by a fraction, the denominator of which is equal to the total number of patients receiving that type of services in that quarter under the State plan in facilities or institutions for which a showing was required to be made under this subsection, and the numerator of which is equal to the number of such patients receiving such type of services in that quarter in those facilities or institutions for which a satisfactory and valid showing was not made for that calendar quarter.

(6)(A) Recertifications required under section 1902(a)(44) shall be conducted at least every 60 days in the case of inpatient hospital services.

(B) Such recertifications in the case of services in an intermediate care facility for the mentally retarded shall be conducted at least—

(i) 60 days after the date of the initial certification,
(ii) 180 days after the date of the initial certification,
(iii) 12 months after the date of the initial certification,
(iv) 18 months after the date of the initial certification,
(v) 24 months after the date of the initial certification, and
(vi) every 12 months thereafter.

(C) For purposes of determining compliance with the schedule established by this paragraph, a recertification shall be considered to have been done on a timely basis if it was performed not later than 10 days after the date the recertification was otherwise required and the State establishes good cause why the physician or other person making such recertification did not meet such schedule.

(i) Payment under the preceding provisions of this section shall not be made—

(1) for organ transplant procedures unless the State plan provides for written standards respecting the coverage of such procedures and unless such standards provide that—

(A) similarly situated individuals are treated alike; and

(B) any restriction, on the facilities or practitioners which may provide such procedures, is consistent with the accessibility of high quality care to individuals eligible for the procedures under the State plan; or

(2) with respect to any amount expended for an item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished—

(A) under the plan by any individual or entity during any period when the individual or entity is excluded from participation under title V, XVIII, or XX or under this title pursuant to section 1128, 1128A, 1156, or 1842(j)(2);

(B) at the medical direction or on the prescription of a physician, during the period when such physician is excluded from participation under title V, XVIII, or XX or under this title pursuant to section 1128, 1128A, 1156, or 1842(j)(2) and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after reasonable notice has been furnished to the person);

(C) by any individual or entity to whom the State has failed to suspend payments under the plan during any period when there is pending an investigation of a credible allegation of fraud against the individual or entity, as determined by the State in accordance with regulations promulgated by the Secretary for purposes of section 1862(o) and this subparagraph, unless the State determines in accordance with such regulations there is good cause not to suspend such payments;

(D) beginning on July 1, 2018, under the plan by any provider of services or person whose participation in the State plan is terminated (as described in section 1902(kk)(8)) after the date that is 60 days after the date on which such termination is included in the database or other system under section 1902(ll); or

(E) with respect to any amount expended for such an item or service furnished during calendar quarters beginning on or after October 1, 2017, subject to section 1902(kk)(4)(A)(ii)(II), within a geographic area that is subject to a moratorium imposed under section 1866(j)(7) by a provider or supplier that meets the requirements specified in subparagraph (C)(iii) of such section, during the period of such moratorium; or

(3) with respect to any amount expended for inpatient hospital services furnished under the plan (other than amounts attributable to the special situation of a hospital which serves a disproportionate number of low income patients with special needs) to the extent that such amount exceeds the hospital's customary charges with respect to such services or (if such services are furnished under the plan by a public institution free of charge or at nominal charges to the public) exceeds an amount determined on the basis of those items (specified in regulations prescribed by the Secretary) included in the determination of such payment which the Secretary finds will provide fair compensation to such institution for such services; or

(4) with respect to any amount expended for care or services furnished under the plan by a hospital unless such hospital has in effect a utilization review plan which meets the requirements imposed by section 1861(k) for purposes of title XVIII; and if such hospital has in effect such a utilization review plan for purposes of title XVIII, such plan shall serve as the plan required by this subsection (with the same standards and procedures and the same review committee or group) as a condition of payment under this title; the Secretary is authorized to waive the requirements of this paragraph if the State agency demonstrates to his satisfaction that it has in operation utilization review procedures which are superior in their effectiveness to the procedures required under section 1861(k); or

(5) with respect to any amount expended for any drug product for which payment may not be made under part B of title XVIII because of section 1862(c); or

(6) with respect to any amount expended for inpatient hospital tests (other than in emergency situations) not specifically ordered by the attending physician or other responsible practitioner; or

(7) with respect to any amount expended for clinical diagnostic laboratory tests performed by a physician, independent laboratory, or hospital, to the extent such amount exceeds the amount that would be recognized under section 1833(h) for such tests performed for an individual enrolled under part B of title XVIII; or

(8) with respect to any amount expended for medical assistance (A) for nursing facility services to reimburse (or otherwise compensate) a nursing facility for payment of a civil money penalty imposed under section 1919(h) or (B) for home and community care to reimburse (or otherwise compensate) a provider of such care for payment of a civil money penalty imposed under this title or title XI or for legal expenses in defense of an exclusion or civil money penalty under this title or title XI if there is no reasonable legal ground for the provider's case; or

(10)(A) with respect to covered outpatient drugs unless there is a rebate agreement in effect under section 1927 with respect to such drugs or unless section 1927(a)(3) applies,

(B) with respect to any amount expended for an innovator multiple source drug (as defined in section 1927(k)) dispensed on or after July 1, 1991, if, under applicable State law, a less expensive multiple source drug could have been dispensed, but only to the extent that such amount exceeds the upper payment limit for such multiple source drug;

(C) with respect to covered outpatient drugs described in section 1927(a)(7), unless information respecting utilization data and coding on such drugs that is required to be submitted under such section is submitted in accordance with such section, and

(D) with respect to any amount expended for reimbursement to a pharmacy under this title for the ingredient cost of a covered outpatient drug for which the pharmacy has already received payment under this title (other than with respect to a reasonable restocking fee for such drug); or

(11) with respect to any amount expended for physicians' services furnished on or after the first day of the first quarter beginning more than 60 days after the date of establishment of the physician identifier system under section 1902(x), unless the claim for the services includes the unique physician identifier provided under such system; or

(13) with respect to any amount expended to reimburse (or otherwise compensate) a nursing facility for payment of legal expenses associated with any action initiated by the facility that is dismissed on the basis that no reasonable legal ground existed for the institution of such action; or

(14) with respect to any amount expended on administrative costs to carry out the program under section 1928; or

(15) with respect to any amount expended for a single-antigen vaccine and its administration in any case in which the administration of a combined-antigen vaccine was medically appropriate (as determined by the Secretary); or

(16) with respect to any amount expended for which funds may not be used under the Assisted Suicide Funding Restriction Act of 1997; or

(17) with respect to any amount expended for roads, bridges, stadiums, or any other item or service not covered under a State plan under this title; or

(18) with respect to any amount expended for home health care services provided by an agency or organization unless the agency or organization provides the State agency on a continuing basis a surety bond in a form specified by the Secretary under paragraph (7) of section 1861(o) and in an amount that is not less than $50,000 or such comparable surety bond as the Secretary may permit under the last sentence of such section; or

(19) with respect to any amount expended on administrative costs to initiate or pursue litigation described in subsection (d)(3)(B);

(20) with respect to amounts expended for medical assistance provided to an individual described in subclause (XV) or (XVI) of section 1902(a)(10)(A)(ii) for a fiscal year unless the State demonstrates to the satisfaction of the Secretary that the level of State funds expended for such fiscal year for programs to enable working individuals with disabilities to work (other than for such medical assistance) is not less than the level expended for such programs during the most recent State fiscal year ending before the date of the enactment of this paragraph;

(21) with respect to amounts expended for covered outpatient drugs described in section 1927(d)(2)(C) (relating to drugs when used for cosmetic purposes or hair growth), except where medically necessary, and section 1927(d)(2)(K) (relating to drugs when used for treatment of sexual or erectile dysfunction);

(22) with respect to amounts expended for medical assistance for an individual who declares under section 1137(d)(1)(A) to be a citizen or national of the United States for purposes of establishing eligibility for benefits under this title, unless the requirement of section 1902(a)(46)(B) is met;

(23) with respect to amounts expended for medical assistance for covered outpatient drugs (as defined in section 1927(k)(2)) for which the prescription was executed in written (and non-electronic) form unless the prescription was executed on a tamper-resistant pad;

(24) if a State is required to implement an asset verification program under section 1940 and fails to implement such program in accordance with such section, with respect to amounts expended by such State for medical assistance for individuals subject to asset verification under such section, unless—

(A) the State demonstrates to the Secretary's satisfaction that the State made a good faith effort to comply;

(B) not later than 60 days after the date of a finding that the State is in noncompliance, the State submits to the Secretary (and the Secretary approves) a corrective action plan to remedy such noncompliance; and

(C) not later than 12 months after the date of such submission (and approval), the State fulfills the terms of such corrective action plan;

(25) with respect to any amounts expended for medical assistance for individuals for whom the State does not report enrollee encounter data (as defined by the Secretary) to the Medicaid Statistical Information System (MSIS) in a timely manner (as determined by the Secretary);

(26) with respect to any amounts expended for medical assistance for individuals described in subclause (VIII) of subsection (a)(10)(A)(i) other than medical assistance provided through benchmark coverage described in section 1937(b)(1) or benchmark equivalent coverage described in section 1937(b)(2); or

(27) with respect to any amounts expended by the State on the basis of a fee schedule for items described in section 1861(n) and furnished on or after January 1, 2018, as determined in the aggregate with respect to each class of such items as defined by the Secretary, in excess of the aggregate amount, if any, that would be paid for such items within such class on a fee-for-service basis under the program under part B of title XVIII, including, as applicable, under a competitive acquisition program under section 1847 in an area of the State.

Nothing in paragraph (1) shall be construed as permitting a State to provide services under its plan under this title that are not reasonable in amount, duration, and scope to achieve their purpose. Paragraphs (1), (2), (16), (17), and (18) shall apply with respect to items or services furnished and amounts expended by or through a managed care entity (as defined in section 1932(a)(1)(B)) in the same manner as such paragraphs apply to items or services furnished and amounts expended directly by the State.

(j) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State for any quarter shall be adjusted in accordance with section 1914.

(k) The Secretary is authorized to provide at the request of any State (and without cost to such State) such technical and actuarial assistance as may be necessary to assist such State to contract with any medicaid managed care organization which meets the requirements of subsection (m) of this section for the purpose of providing medical care and services to individuals who are entitled to medical assistance under this title.

(l)(1) Subject to paragraphs (3) and (4), with respect to any amount expended for personal care services or home health care services requiring an in-home visit by a provider that are provided under a State plan under this title (or under a waiver of the plan) and furnished in a calendar quarter beginning on or after January 1, 2019 (or, in the case of home health care services, on or after January 1, 2023), unless a State requires the use of an electronic visit verification system for such services furnished in such quarter under the plan or such waiver, the Federal medical assistance percentage shall be reduced—

(A) in the case of personal care services—

(i) for calendar quarters in 2019 and 2020, by .25 percentage points;

(ii) for calendar quarters in 2021, by .5 percentage points;

(iii) for calendar quarters in 2022, by .75 percentage points; and

(iv) for calendar quarters in 2023 and each year thereafter, by 1 percentage point; and

(B) in the case of home health care services—

(i) for calendar quarters in 2023 and 2024, by .25 percentage points;

(ii) for calendar quarters in 2025, by .5 percentage points;

(iii) for calendar quarters in 2026, by .75 percentage points; and

(iv) for calendar quarters in 2027 and each year thereafter, by 1 percentage point.

(2) Subject to paragraphs (3) and (4), in implementing the requirement for the use of an electronic visit verification system under paragraph (1), a State shall—

(A) consult with agencies and entities that provide personal care services, home health care services, or both under the State plan (or under a waiver of the plan) to ensure that such system—

(i) is minimally burdensome;

(ii) takes into account existing best practices and electronic visit verification systems in use in the State; and

(iii) is conducted in accordance with the requirements of HIPAA privacy and security law (as defined in section 3009 of the Public Health Service Act);

(B) take into account a stakeholder process that includes input from beneficiaries, family caregivers, individuals who furnish personal care services or home health care services, and other stakeholders, as determined by the State in accordance with guidance from the Secretary; and

(C) ensure that individuals who furnish personal care services, home health care services, or both under the State plan (or under a waiver of the plan) are provided the opportunity for training on the use of such system.

(3) Paragraphs (1) and (2) shall not apply in the case of a State that, as of the date of the enactment of this subsection, requires the use of any system for the electronic verification of visits conducted as part of both personal care services and home health care services, so long as the State continues to require the use of such system with respect to the electronic verification of such visits.

(4)(A) In the case of a State described in subparagraph (B), the reduction under paragraph (1) shall not apply—

(i) in the case of personal care services, for calendar quarters in 2019; and

(ii) in the case of home health care services, for calendar quarters in 2023.

(B) For purposes of subparagraph (A), a State described in this subparagraph is a State that demonstrates to the Secretary that the State—

(i) has made a good faith effort to comply with the requirements of paragraphs (1) and (2) (including by taking steps to adopt the technology used for an electronic visit verification system); and

(ii) in implementing such a system, has encountered unavoidable system delays.

(5) In this subsection:

(A) The term "electronic visit verification system" means, with respect to personal care services or home health care services, a system under which visits conducted as part of such services are electronically verified with respect to—

(i) the type of service performed;
(ii) the individual receiving the service;
(iii) the date of the service;
(iv) the location of service delivery;
(v) the individual providing the service; and
(vi) the time the service begins and ends.

(B) The term "home health care services" means services described in section 1905(a)(7) provided under a State plan under this title (or under a waiver of the plan).

(C) The term "personal care services" means personal care services provided under a State plan under this title (or under a waiver of the plan), including services provided under section 1905(a)(24), 1915(c), 1915(i), 1915(j), or 1915(k) or under a wavier under section 1115.

(6)(A) In the case in which a State requires personal care service and home health care service providers to utilize an electronic visit verification system operated by the State or a contractor on behalf of the State, the Secretary shall pay to the State, for each quarter, an amount equal to 90 per centum of so much of the sums expended during such quarter as are attributable to the design, development, or installation of such system, and 75 per centum of so much of the sums for the operation and maintenance of such system.

(B) Subparagraph (A) shall not apply in the case in which a State requires personal care service and home health care service providers to utilize an electronic visit verification system that is not operated by the State or a contractor on behalf of the State.

(m)(1)(A) The term "medicaid managed care organization" means a health maintenance organization, an eligible organization with a contract under section 1876 or a Medicare+Choice organization with a contract under part C of title XVIII, a provider sponsored organization, or any other public or private organization, which meets the requirement of section 1902(w) and—

(i) makes services it provides to individuals eligible for benefits under this title accessible to such individuals, within the area served by the organization, to the same extent as such services are made accessible to individuals (eligible for medical assistance under the State plan) not enrolled with the organization, and

(ii) has made adequate provision against the risk of insolvency, which provision is satisfactory to the State, meets the requirements of subparagraph (C)(i) (if applicable), and which assures that individuals eligible for benefits under this title are in no case held liable for debts of the organization in case of the organization's insolvency.

An organization that is a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act) is deemed to meet the requirements of clauses (i) and (ii).

(B) The duties and functions of the Secretary, insofar as they involve making determinations as to whether an organization is a medicaid managed care organization within the meaning of subparagraph (A), shall be integrated with the administration of section 1312 (a) and (b) of the Public Health Service Act.

(C)(i) Subject to clause (ii), a provision meets the requirements of this subparagraph for an organization if the organization meets solvency standards established by the State for private health maintenance organizations or is licensed or certified by the State as a risk-bearing entity.

(ii) Clause (i) shall not apply to an organization if—

(I) the organization is not responsible for the provision (directly or through arrangements with providers of services) of inpatient hospital services and physicians' services;

(II) the organization is a public entity;

(III) the solvency of the organization is guaranteed by the State; or

(IV) the organization is (or is controlled by) one or more Federally-qualified health centers and meets solvency standards established by the State for such an organization.

For purposes of subclause (IV), the term "control" means the possession, whether direct or indirect, of the power to direct or cause the direction of the management and policies of the organization through membership, board representation, or an ownership interest equal to or greater than 50.1 percent.

(2)(A) Except as provided in subparagraphs (B), (C), and (G), no payment shall be made under this title to a State with respect to expenditures incurred by it for payment (determined under a prepaid capitation basis or under any other risk basis) for services provided by any entity (including a health insuring organization) which is responsible for the provision (directly or through arrangements with providers of services) of inpatient hospital services and any other service described in paragraph (2), (3), (4), (5), or (7) of section 1905(a) or for the provision of any three or more of the services described in such paragraphs unless—

(i) the Secretary has determined that the entity is a medicaid managed care organization organization as defined in paragraph (1);

(iii) such services are provided for the benefit of individuals eligible for benefits under this title in accordance with a contract between the State and the entity under which prepaid payments to the entity are made on an actuarially sound basis and under which the Secretary must provide prior approval for contracts providing for expenditures in excess of $1,000,000 for 1998 and, for a subsequent year, the amount established under this clause for the previous year increased by the percentage increase in the consumer price index for all urban consumers over the previous year;

(iv) such contract provides that the Secretary and the State (or any person or organization designated by either) shall have the right to audit and inspect any books and records of the entity (and of any subcontractor) that pertain (I) to the ability of the entity to bear the risk of potential financial losses, or (II) to services performed or determinations of amounts payable under the contract;

(v) such contract provides that in the entity's enrollment, reenrollment, or disenrollment of individuals who are eligible for benefits under this title and eligible to enroll, reenroll, or disenroll with the entity pursuant to the contract, the entity will not discriminate among such individuals on the basis of their health status or requirements for health care services;

(vi) such contract (I) permits individuals who have elected under the plan to enroll with the entity for provision of such benefits to terminate such enrollment in accordance with section 1932(a)(4), and (II) provides for notification in accordance with such section of each such individual, at the time of the individual's enrollment, of such right to terminate such enrollment;

(vii) such contract provides that, in the case of medically necessary services which were provided (I) to an individual enrolled with the entity under the contract and entitled to benefits with respect to such services under the State's plan and (II) other than through the organization because the services were immediately required due to an unforeseen illness, injury, or condition, either the entity or the State provides for reimbursement with respect to those services,

(viii) such contract provides for disclosure of information in accordance with section 1124 and paragraph (4) of this subsection;

(ix) such contract provides, in the case of an entity that has entered into a contract for the provision of services with a Federally-qualified health center or a rural health clinic, that the entity shall provide payment that is not less than the level and amount of payment which the entity would make for the services if the services were furnished by a provider which is not a Federally-qualified health center or a rural health clinic;

(x) any physician incentive plan that it operates meets the requirements described in section 1876(i)(8);

(xi) such contract provides for maintenance of sufficient patient encounter data to identify the physician who delivers services to patients and for the provision of such data to the State at a frequency and level of detail to be specified by the Secretary;

(xii) such contract, and the entity complies with the applicable requirements of section 1932; and

(xiii) such contract provides that (I) covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the entity shall be subject to the same rebate required by the agreement entered into under section 1927 as the State is subject to and that the State shall collect such rebates from manufacturers, (II) capitation rates paid to the entity shall be based on actual cost experience related to rebates and subject to the Federal regulations requiring actuarially sound rates, and (III) the entity shall report to the State, on such timely and periodic basis as specified by the Secretary in order to include in the information submitted by the State to a manufacturer and the Secretary under section 1927(b)(2)(A), information on the total number of units of each dosage form and strength and package size by National Drug Code of each covered outpatient drug dispensed to individuals eligible for medical assistance who are enrolled with the entity and for which the entity is responsible for coverage of such drug under this subsection (other than covered outpatient drugs that under subsection (j)(1) of section 1927 are not subject to the requirements of that section) and such other data as the Secretary determines necessary to carry out this subsection.

(B) Subparagraph (A) except with respect to clause (ix) of subparagraph (A), does not apply with respect to payments under this title to a State with respect to expenditures incurred by it for payment for services provided by an entity which—

(i)(I) received a grant of at least $100,000 in the fiscal year ending June 30, 1976, under section 329(d)(1)(A) or 330(d)(1) of the Public Health Service Act, and for the period beginning July 1, 1976, and ending on the expiration of the period for which payments are to be made under this title has been the recipient of a grant under either such section; and

(II) provides to its enrollees, on a prepaid capitation risk basis or on any other risk basis, all of the services and benefits described in paragraphs (1), (2), (3), (4)(C), and (5) of section 1905(a) and, to the extent required by section 1902(a)(10)(D) to be provided under a State plan for medical assistance, the services and benefits described in paragraph (7) of section 1905(a); or

(ii) is a nonprofit primary health care entity located in a rural area (as defined by the Appalachian Regional Commission)—

(I) which received in the fiscal year ending June 30, 1976, at least $100,000 (by grant, subgrant, or subcontract) under the Appalachian Regional Development Act of 1965, and

(II) for the period beginning July 1, 1976, and ending on the expiration of the period for which payments are to be made under this title either has been the recipient of a grant, subgrant, or subcontract under such Act or has provided services under a contract (initially entered into during a year in which the entity was the recipient of such a grant, subgrant, or subcontract) with a State agency under this title on a prepaid capitation risk basis or on any other risk basis; or

(iii) which has contracted with the single State agency for the provision of services (but not including inpatient hospital services) to persons eligible under this title on a prepaid risk basis prior to 1970.

(G) In the case of an entity which is receiving (and has received during the previous two years) a grant of at least $100,000 under section 329(d)(1)(A) or 330(d)(1) of the Public Health Service Act or is receiving (and has received during the previous two years) at least $100,000 (by grant, subgrant, or subcontract) under the Appalachian Regional Development Act of 1965, clause (i) of subparagraph (A) shall not apply.

(H) In the case of an individual who—

(i) in a month is eligible for benefits under this title and enrolled with a medicaid managed care organization with a contract under this paragraph or with a primary care case manager with a contract described in section 1905(t)(3),

(ii) in the next month (or in the next 2 months) is not eligible for such benefits, but

(iii) in the succeeding month is again eligible for such benefits,

the State plan, subject to subparagraph (A)(vi), may enroll the individual for that succeeding month with the organization described in clause (i) if the organization continues to have a contract under this paragraph with the State or with the manager described in such clause if the manager continues to have a contract described in section 1905(t)(3) with the State.

(3) No payment shall be made under this title to a State with respect to expenditures incurred by the State for payment for services provided by a managed care entity (as defined under section 1932(a)(1)) under the State plan under this title (or under a waiver of the plan) unless the State—

(A) beginning on July 1, 2018, has a contract with such entity that complies with the requirement specified in section 1932(d)(5); and

(B) beginning on January 1, 2018, complies with the requirement specified in section 1932(d)(6)(A).

(4)(A) Each medicaid managed care organization which is not a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act) must report to the State and, upon request, to the Secretary, the Inspector General of the Department of Health and Human Services, and the Comptroller General a description of transactions between the organization and a party in interest (as defined in section 1318(b) of such Act), including the following transactions:

(i) Any sale or exchange, or leasing of any property between the organization and such a party.

(ii) Any furnishing for consideration of goods, services (including management services), or facilities between the organization and such a party, but not including salaries paid to employees for services provided in the normal course of their employment.

(iii) Any lending of money or other extension of credit between the organization and such a party.

The State or Secretary may require that information reported respecting an organization which controls, or is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(B) Each organization shall make the information reported pursuant to subparagraph (A) available to its enrollees upon reasonable request.

(5)(A) If the Secretary determines that an entity with a contract under this subsection—

(i) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(ii) imposes premiums on individuals enrolled under this subsection in excess of the premiums permitted under this title;

(iii) acts to discriminate among individuals in violation of the provision of paragraph (2)(A)(v), including expulsion or refusal to re-enroll an individual or engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this subsection) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(iv) misrepresents or falsifies information that is furnished—

(I) to the Secretary or the State under this subsection, or

(II) to an individual or to any other entity under this subsection, or

(v) fails to comply with the requirements of section 1876(i)(8),

the Secretary may provide, in addition to any other remedies available under law, for any of the remedies described in subparagraph (B).

(B) The remedies described in this subparagraph are—

(i) civil money penalties of not more than $25,000 for each determination under subparagraph (A), or, with respect to a determination under clause (iii) or (iv)(I) of such subparagraph, of not more than $100,000 for each such determination, plus, with respect to a determination under subparagraph (A)(ii), double the excess amount charged in violation of such subparagraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under subparagraph (A)(iii), $15,000 for each individual not enrolled as a result of a practice described in such subparagraph, or

(ii) denial of payment to the State for medical assistance furnished under the contract under this subsection for individuals enrolled after the date the Secretary notifies the organization of a determination under subparagraph (A) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (i) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(6)(A) For purposes of this subsection and section 1902(e)(2)(A), in the case of the State of New Jersey, the term "contract" shall be deemed to include an undertaking by the State agency, in the State plan under this title, to operate a program meeting all requirements of this subsection.

(B) The undertaking described in subparagraph (A) must provide—

(i) for the establishment of a separate entity responsible for the operation of a program meeting the requirements of this subsection, which entity may be a subdivision of the State agency administering the State plan under this title;

(ii) for separate accounting for the funds used to operate such program; and

(iii) for setting the capitation rates and any other payment rates for services provided in accordance with this subsection using a methodology satisfactory to the Secretary designed to ensure that total Federal matching payments under this title for such services will be lower than the matching payments that would be made for the same services, if provided under the State plan on a fee for service basis to an actuarially equivalent population.

(C) The undertaking described in subparagraph (A) shall be subject to approval (and annual re-approval) by the Secretary in the same manner as a contract under this subsection.

(D) The undertaking described in subparagraph (A) shall not be eligible for a waiver under section 1915(b).

*(7)(A) With respect to expenditures described in subparagraph (B) that are incurred by a State for any fiscal year after fiscal year 2020 (and before fiscal year 2025), in determining the pro rata share to which the United States is equitably entitled under subsection (d)(3), the Secretary shall substitute the Federal medical assistance percentage that applies for such fiscal year to the State under section 1905(b) (without regard to any adjustments to such percentage applicable under such section or any other provision of law) for the percentage that applies to such expenditures under section 1905(y).*

*(B) Expenditures described in this subparagraph, with respect to a fiscal year to which subparagraph (A) applies, are expenditures incurred by a State for payment for medical assistance provided to individuals described in subclause (VIII) of section 1902(a)(10)(A)(i) by a managed care entity, or other specified entity (as defined in subparagraph (D)(iii)), that are treated as remittances because the State—*

*(i) has satisfied the requirement of section 438.8 of title 42, Code of Federal Regulations (or any successor regulation), by electing—*

*(I) in the case of a State described in subparagraph (C), to apply a minimum medical loss ratio (as defined in subparagraph (D)(ii)) that is equal to or greater than 85 percent; or*

*(II) in the case of a State not described in subparagraph (C), to apply a minimum medical loss ratio that is equal to 85 percent; and*

*(ii) recovered all or a portion of the expenditures as a result of the entity's failure to meet such ratio.*

*(C) For purposes of subparagraph (B), a State described in this subparagraph is a State that as of May 31, 2018, applied a minimum medical loss ratio (as calculated under subsection (d) of section 438.8 of title 42, Code of Federal Regulations (as in effect on June 1, 2018)) for payment for services provided by entities described in such subparagraph under the State plan under this title (or a waiver of the plan) that is equal to or greater than 85 percent.*

*(D) For purposes of this paragraph:*

*(i) The term "managed care entity" means a medicaid managed care organization described in section 1932(a)(1)(B)(i).*

*(ii) The term "minimum medical loss ratio" means, with respect to a State, a minimum medical loss ratio (as calculated under subsection (d) of section 438.8 of title 42, Code of Federal Regulations (as in effect on June 1, 2018)) for payment for services provided by entities described in subparagraph (B) under the State plan under this title (or a waiver of the plan).*

*(iii) The term "other specified entity" means—*

*(I) a prepaid inpatient health plan, as defined in section 438.2 of title 42, Code of Federal Regulations (or any successor regulation); and*

*(II) a prepaid ambulatory health plan, as defined in such section (or any successor regulation).*

(o) Notwithstanding the preceding provisions of this section, no payment shall be made to a State under the preceding provisions of this section for expenditures for medical assistance provided for an individual under its State plan approved under this title to the extent that a private insurer (as defined by the Secretary by regulation and including a group health plan (as defined in section 607(1) of the Employee Retirement Income Security Act of 1974), a service benefit plan, and a health maintenance organization) would have been obligated to provide such assistance but for a provision of its insurance contract which has the effect of limiting or excluding such obligation because the individual is eligible for or is provided medical assistance under the plan.

(p)(1) When a political subdivision of a State makes, for the State of which it is a political subdivision, or one State makes, for another State, the enforcement and collection of rights of support or payment assigned under section 1912, pursuant to a cooperative arrangement under such section (either within or outside of such State), there shall be paid to such political subdivision or such other State from amounts which would otherwise represent the Federal share of payments for medical assistance provided to the eligible individuals on whose behalf such enforcement and collection was made, an amount equal to 15 percent of any amount collected which is attributable to such rights of support or payment.

(2) Where more than one jurisdiction is involved in such enforcement or collection, the amount of the incentive payment determined under paragraph (1) shall be allocated among the jurisdictions in a manner to be prescribed by the Secretary.

(q) For the purposes of this section, the term "State medicaid fraud control unit" means a single identifiable entity of the State government which the Secretary certifies (and annually recertifies) as meeting the following requirements:

(1) The entity (A) is a unit of the office of the State Attorney General or of another department of State government which possesses statewide authority to prosecute individuals for criminal violations, (B) is in a State the constitution of which does not provide for the criminal prosecution of individuals by a statewide authority and has formal procedures, approved by the Secretary, that (i) assure its referral of suspected criminal violations relating to the program under this title to the appropriate authority or authorities in the State for prosecution and (ii) assure its assistance of, and coordination with, such authority or authorities in such prosecutions, or (C) has a formal working relationship with the office of the State Attorney General and has formal procedures (including procedures for its referral of suspected criminal violations to such office) which are approved by the Secretary and which provide effective coordination of activities between the entity and such office with respect to the detection, investigation, and prosecution of suspected criminal violations relating to the program under this title.

(2) The entity is separate and distinct from the single State agency that administers or supervises the administration of the State plan under this title.

(3) The entity's function is conducting a statewide program for the investigation and prosecution of violations of all applicable State laws regarding any and all aspects of fraud in connection with (A) any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan under this title; and (B) upon the approval of the Inspector General of the relevant Federal agency, any aspect of the provision of health care services and activities of providers of such services under any Federal health care program (as defined in section 1128B(f)(1)), if the suspected fraud or violation of law in such case or investigation is primarily related to the State plan under this title.

(4)(A) The entity has—

(i) procedures for reviewing complaints of abuse or neglect of patients in health care facilities which receive payments under the State plan under this title;

(ii) at the option of the entity, procedures for reviewing complaints of abuse or neglect of patients residing in board and care facilities; and

(iii) procedures for acting upon such complaints under the criminal laws of the State or for referring such complaints to other State agencies for action.

(B) For purposes of this paragraph, the term "board and care facility" means a residential setting which receives payment (regardless of whether such payment is made under the State plan under this title) from or on behalf of two or more unrelated adults who reside in such facility, and for whom one or both of the following is provided:

(i) Nursing care services provided by, or under the supervision of, a registered nurse, licensed practical nurse, or licensed nursing assistant.

(ii) A substantial amount of personal care services that assist residents with the activities of daily living, including personal hygiene, dressing, bathing, eating, toileting, ambulation, transfer, positioning, self-medication, body care, travel to medical services, essential shopping, meal preparation, laundry, and housework.

(5) The entity provides for the collection, or referral for collection to a single State agency, of overpayments that are made under the State plan or under any Federal health care program (as so defined) to health care facilities and that are discovered by the entity in carrying out its activities. All funds collected in accordance with this paragraph shall be credited exclusively to, and available for expenditure under, the Federal health care program (including the State plan under this title) that was subject to the activity that was the basis for the collection.

(6) The entity employs such auditors, attorneys, investigators, and other necessary personnel and is organized in such a manner as is necessary to promote the effective and efficient conduct of the entity's activities.

(7) The entity submits to the Secretary an application and annual reports containing such information as the Secretary determines, by regulation, to be necessary to determine whether the entity meets the other requirements of this subsection.

(r)(1) In order to receive payments under subsection (a) for use of automated data systems in administration of the State plan under this title, a State must, in addition to meeting the requirements of paragraph (3), have in operation mechanized claims processing and information retrieval systems that meet the requirements of this subsection and that the Secretary has found—

(A) are adequate to provide efficient, economical, and effective administration of such State plan;

(B) are compatible with the claims processing and information retrieval systems used in the administration of title XVIII, and for this purpose—

(i) have a uniform identification coding system for providers, other payees, and beneficiaries under this title or title XVIII;

(ii) provide liaison between States and carriers and intermediaries with agreements under title XVIII to facilitate timely exchange of appropriate data;

(iii) provide for exchange of data between the States and the Secretary with respect to persons sanctioned under this title or title XVIII; and

(iv) effective for claims filed on or after October 1, 2010, incorporate compatible methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment) and such other methodologies of that Initiative (or such other national correct coding methodologies) as the Secretary identifies in accordance with paragraph (4);

(C) are capable of providing accurate and timely data;

(D) are complying with the applicable provisions of part C of title XI;

(E) are designed to receive provider claims in standard formats to the extent specified by the Secretary; and

(F) effective for claims filed on or after January 1, 1999, provide for electronic transmission of claims data in the format specified by the Secretary and consistent with the Medicaid Statistical Information System (MSIS) (including detailed individual enrollee encounter data and other information that the Secretary may find necessary and including, for data submitted to the Secretary on or after January 1, 2010, data elements from the automated data system that the Secretary determines to be necessary for program integrity, program oversight, and administration, at such frequency as the Secretary shall determine).

(2) In order to meet the requirements of this paragraph, mechanized claims processing and information retrieval systems must meet the following requirements:

(A) The systems must be capable of developing provider, physician, and patient profiles which are sufficient to provide specific information as to the use of covered types of services and items, including prescribed drugs.

(B) The State must provide that information on probable fraud or abuse which is obtained from, or developed by, the systems, is made available to the State's medicaid fraud control unit (if any) certified under subsection (q) of this section.

(C) The systems must meet all performance standards and other requirements for initial approval developed by the Secretary.

(3) In order to meet the requirements of this paragraph, a State must have in operation an eligibility determination system which provides for data matching through the Public Assistance Reporting Information System (PARIS) facilitated by the Secretary (or any successor system), including matching with medical assistance programs operated by other States.

(4) For purposes of paragraph (1)(B)(iv), the Secretary shall do the following:

(A) Not later than September 1, 2010:

(i) Identify those methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment) which are compatible to claims filed under this title.

(ii) Identify those methodologies of such Initiative (or such other national correct coding methodologies) that should be incorporated into claims filed under this title with respect to items or services for which States provide medical assistance under this title and no national correct coding methodologies have been established under such Initiative with respect to title XVIII.

(iii) Notify States of—

(I) the methodologies identified under subparagraphs (A) and (B) (and of any other national correct coding methodologies identified under subparagraph (B)); and

(II) how States are to incorporate such methodologies into claims filed under this title.

(B) Not later than March 1, 2011, submit a report to Congress that includes the notice to States under clause (iii) of subparagraph (A) and an analysis supporting the identification of the methodologies made under clauses (i) and (ii) of subparagraph (A).

(s) Notwithstanding the preceding provisions of this section, no payment shall be made to a State under this section for expenditures for medical assistance under the State plan consisting of a designated health service (as defined in subsection (h)(6) of section 1877) furnished to an individual on the basis of a referral that would result in the denial of payment for the service under title XVIII if such title provided for coverage of such service to the same extent and under the same terms and conditions as under the State plan, and subsections (f) and (g)(5) of such section shall apply to a provider of such a designated health service for which payment may be made under this title in the same manner as such subsections apply to a provider of such a service for which payment may be made under such title.

(t)(1) For purposes of subsection (a)(3)(F), the payments described in this paragraph to encourage the adoption and use of certified EHR technology are payments made by the State in accordance with this subsection —

(A) to Medicaid providers described in paragraph (2)(A) not in excess of 85 percent of net average allowable costs (as defined in paragraph (3)(E)) for certified EHR technology (and support services including maintenance and training that is for, or is necessary for the adoption and operation of, such technology) with respect to such providers; and

(B) to Medicaid providers described in paragraph (2)(B) not in excess of the maximum amount permitted under paragraph (5) for the provider involved.

(2) In this subsection and subsection (a)(3)(F), the term "Medicaid provider" means—

(A) an eligible professional (as defined in paragraph (3)(B))—

(i) who is not hospital-based and has at least 30 percent of the professional's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title;

(ii) who is not described in clause (i), who is a pediatrician, who is not hospital-based, and who has at least 20 percent of the professional's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title; and

(iii) who practices predominantly in a Federally qualified health center or rural health clinic and has at least 30 percent of the professional's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to needy individuals (as defined in paragraph (3)(F)); and

(B)(i) a children's hospital, or

(ii) an acute-care hospital that is not described in clause (i) and that has at least 10 percent of the hospital's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title.

An eligible professional shall not qualify as a Medicaid provider under this subsection unless any right to payment under sections 1848(o) and 1853(l) with respect to the eligible professional has been waived in a manner specified by the Secretary. For purposes of calculating patient volume under subparagraph (A)(iii), insofar as it is related to uncompensated care, the Secretary may require the adjustment of such uncompensated care data so that it would be an appropriate proxy for charity care, including a downward adjustment to eliminate bad debt data from uncompensated care. In applying subparagraphs (A) and (B)(ii), the methodology established by the Secretary for patient volume shall include individuals enrolled in a Medicaid managed care plan (under section 1903(m) or section 1932).

(3) In this subsection and subsection (a)(3)(F):

(A) The term "certified EHR technology" means a qualified electronic health record (as defined in 3000(13) of the Public Health Service Act) that is certified pursuant to section 3001(c)(5) of such Act as meeting standards adopted under section 3004 of such Act that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

(B) The term "eligible professional" means a—

(i) physician;

(ii) dentist;

(iii) certified nurse mid-wife;

(iv) nurse practitioner; and

(v) physician assistant insofar as the assistant is practicing in a rural health clinic that is led by a physician assistant or is practicing in a Federally qualified health center that is so led.

(C) The term "average allowable costs" means, with respect to certified EHR technology of Medicaid providers described in paragraph (2)(A) for—

(i) the first year of payment with respect to such a provider, the average costs for the purchase and initial implementation or upgrade of such technology (and support services including training that is for, or is necessary for the adoption and initial operation of, such technology) for such providers, as determined by the Secretary based upon studies conducted under paragraph (4)(C); and

(ii) a subsequent year of payment with respect to such a provider, the average costs not described in clause (i) relating to the operation, maintenance, and use of such technology for such providers, as determined by the Secretary based upon studies conducted under paragraph (4)(C).

(D) The term "hospital-based" means, with respect to an eligible professional, a professional (such as a pathologist, anesthesiologist, or emergency physician) who furnishes substantially all of the individual's professional services in a hospital inpatient or emergency room setting and through the use of the facilities and equipment, including qualified electronic health records, of the hospital. The determination of whether an eligible professional is a hospital-based eligible professional shall be made on the basis of the site of service (as defined by the Secretary) and without regard to any employment or billing arrangement between the eligible professional and any other provider.

(E) The term "net average allowable costs" means, with respect to a Medicaid provider described in paragraph (2)(A), average allowable costs reduced by the average payment the Secretary estimates will be made to such Medicaid providers (determined on a percentage or other basis for such classes or types of providers as the Secretary may specify) from other sources (other than under this subsection, or by the Federal government or a State or local government) that is directly attributable to payment for certified EHR technology or support services described in subparagraph (C).

(F) The term "needy individual" means, with respect to a Medicaid provider, an individual—

(i) who is receiving assistance under this title;

(ii) who is receiving assistance under title XXI;

(iii) who is furnished uncompensated care by the provider; or

(iv) for whom charges are reduced by the provider on a sliding scale basis based on an individual's ability to pay.

(4)(A) With respect to a Medicaid provider described in paragraph (2)(A), subject to subparagraph (B), in no case shall—

(i) the net average allowable costs under this subsection for the first year of payment (which may not be later than 2016), which is intended to cover the costs described in paragraph (3)(C)(i), exceed $25,000 (or such lesser amount as the Secretary determines based on studies conducted under subparagraph (C));

(ii) the net average allowable costs under this subsection for a subsequent year of payment, which is intended to cover costs described in paragraph (3)(C)(ii), exceed $10,000; and

(iii) payments be made for costs described in clause (ii) after 2021 or over a period of longer than 5 years.

(B) In the case of Medicaid provider described in paragraph (2)(A)(ii), the dollar amounts specified in subparagraph (A) shall be ⅔ of the dollar amounts otherwise specified.

(C) For the purposes of determining average allowable costs under this subsection, the Secretary shall study the average costs to Medicaid providers described in paragraph (2)(A) of purchase and initial implementation and upgrade of certified EHR technology described in paragraph (3)(C)(i) and the average costs to such providers of operations, maintenance, and use of such technology described in paragraph (3)(C)(ii). In determining such costs for such providers, the Secretary may utilize studies of such amounts submitted by States.

(5)(A) In no case shall the payments described in paragraph (1)(B) with respect to a Medicaid provider described in paragraph (2)(B) exceed—

(i) in the aggregate the product of—

(I) the overall hospital EHR amount for the provider computed under subparagraph (B); and

(II) the Medicaid share for such provider computed under subparagraph (C);

(ii) in any year 50 percent of the product described in clause (i); and

(iii) in any 2-year period 90 percent of such product.

(B) For purposes of this paragraph, the overall hospital EHR amount, with respect to a Medicaid provider, is the sum of the applicable amounts specified in section 1886(n)(2)(A) for such provider for the first 4 payment years (as estimated by the Secretary) determined as if the Medicare share specified in clause (ii) of such section were 1. The Secretary shall establish, in consultation with the State, the overall hospital EHR amount for each such Medicaid provider eligible for payments under paragraph (1)(B). For purposes of this subparagraph in computing the amounts under section 1886(n)(2)(C) for payment years after the first payment year, the Secretary shall assume that in subsequent payment years discharges increase at the average annual rate of growth of the most recent 3 years for which discharge data are available per year.

(C) The Medicaid share computed under this subparagraph, for a Medicaid provider for a period specified by the Secretary, shall be calculated in the same manner as the Medicare share under section 1886(n)(2)(D) for such a hospital and period, except that there shall be substituted for the numerator under clause (i) of such section the amount that is equal to the number of inpatient-bed-days (as established by the Secretary) which are attributable to individuals who are receiving medical assistance under this title and who are not described in section 1886(n)(2)(D)(i). In computing inpatient-bed-days under the previous sentence, the Secretary shall take into account inpatient-bed-days attributable to inpatient-bed-days that are paid for individuals enrolled in a Medicaid managed care plan (under section 1903(m) or section 1932).

(D) In no case may the payments described in paragraph (1)(B) with respect to a Medicaid provider described in paragraph (2)(B) be paid—

(i) for any year beginning after 2016 unless the provider has been provided payment under paragraph (1)(B) for the previous year; and

(ii) over a period of more than 6 years of payment.

(6) Payments described in paragraph (1) are not in accordance with this subsection unless the following requirements are met:

(A)(i) The State provides assurances satisfactory to the Secretary that amounts received under subsection (a)(3)(F) with respect to payments to a Medicaid provider are paid, subject to clause (ii), directly to such provider (or to an employer or facility to which such provider has assigned payments) without any deduction or rebate.

(ii) Amounts described in clause (i) may also be paid to an entity promoting the adoption of certified EHR technology, as designated by the State, if participation in such a payment arrangement is voluntary for the eligible professional involved and if such entity does not retain more than 5 percent of such payments for costs not related to certified EHR technology (and support services including maintenance and training) that is for, or is necessary for the operation of, such technology.

(B) A Medicaid provider described in paragraph (2)(A) is responsible for payment of the remaining 15 percent of the net average allowable cost and shall be determined to have met such responsibility to the extent that the payment to the Medicaid provider is not in excess of 85 percent of the net average allowable cost.

(C)(i) Subject to clause (ii), with respect to payments to a Medicaid provider—

(I) for the first year of payment to the Medicaid provider under this subsection, the Medicaid provider demonstrates that it is engaged in efforts to adopt, implement, or upgrade certified EHR technology; and

(II) for a year of payment, other than the first year of payment to the Medicaid provider under this subsection, the Medicaid provider demonstrates meaningful use of certified EHR technology through a means that is approved by the State and acceptable to the Secretary, and that may be based upon the methodologies applied under section 1848(o) or 1886(n).

(ii) In the case of a Medicaid provider who has completed adopting, implementing, or upgrading such technology prior to the first year of payment to the Medicaid provider under this subsection, clause (i)(I) shall not apply and clause (i)(II) shall apply to each year of payment to the Medicaid provider under this subsection, including the first year of payment.

(D) To the extent specified by the Secretary, the certified EHR technology is compatible with State or Federal administrative management systems.

For purposes of subparagraph (B), a Medicaid provider described in paragraph (2)(A) may accept payments for the costs described in such subparagraph from a State or local government. For purposes of subparagraph (C), in establishing the means described in such subparagraph, which may include clinical quality reporting to the State, the State shall ensure that populations with unique needs, such as children, are appropriately addressed.

(7) With respect to Medicaid providers described in paragraph (2)(A), the Secretary shall ensure coordination of payment with respect to such providers under sections 1848(o) and 1853(l) and under this subsection to assure no duplication of funding. Such coordination shall include, to the extent practicable, a data matching process between State Medicaid agencies and the Centers for Medicare & Medicaid Services using national provider identifiers. For such purposes, the Secretary may require the submission of such data relating to payments to such Medicaid providers as the Secretary may specify.

(8) In carrying out paragraph (6)(C), the State and Secretary shall seek, to the maximum extent practicable, to avoid duplicative requirements from Federal and State governments to demonstrate meaningful use of certified EHR technology under this title and title XVIII. In doing so, the Secretary may deem satisfaction of requirements for such meaningful use for a payment year under title XVIII to be sufficient to qualify as meaningful use under this subsection. The Secretary may also specify the reporting periods under this subsection in order to carry out this paragraph.

(9) In order to be provided Federal financial participation under subsection (a)(3)(F)(ii), a State must demonstrate to the satisfaction of the Secretary, that the State—

(A) is using the funds provided for the purposes of administering payments under this subsection, including tracking of meaningful use by Medicaid providers;

(B) is conducting adequate oversight of the program under this subsection, including routine tracking of meaningful use attestations and reporting mechanisms; and

(C) is pursuing initiatives to encourage the adoption of certified EHR technology to promote health care quality and the exchange of health care information under this title, subject to applicable laws and regulations governing such exchange.

(10) The Secretary shall periodically submit reports to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate on status, progress, and oversight of payments described in paragraph (1), including steps taken to carry out paragraph (7). Such reports shall also describe the extent of adoption of certified EHR technology among Medicaid providers resulting from the provisions of this subsection and any improvements in health outcomes, clinical quality, or efficiency resulting from such adoption.

(u)(1)(A) Notwithstanding subsection (a)(1), if the ratio of a State's erroneous excess payments for medical assistance (as defined in subparagraph (D)) to its total expenditures for medical assistance under the State plan approved under this title exceeds 0.03, for the period consisting of the third and fourth quarters of fiscal year 1983, or for any full fiscal year thereafter, then the Secretary shall make no payment for such period or fiscal year with respect to so much of such erroneous excess payments as exceeds such allowable error rate of 0.03.

(B) The Secretary may waive, in certain limited cases, all or part of the reduction required under subparagraph (A) with respect to any State if such State is unable to reach the allowable error rate for a period or fiscal year despite a good faith effort by such State.

(C) In estimating the amount to be paid to a State under subsection (d), the Secretary shall take into consideration the limitation on Federal financial participation imposed by subparagraph (A) and shall reduce the estimate he makes under subsection (d)(1), for purposes of payment to the State under subsection (d)(3), in light of any expected erroneous excess payments for medical assistance (estimated in accordance with such criteria, including sampling procedures, as he may prescribe and subject to subsequent adjustment, if necessary, under subsection (d)(2)).

(D)(i) For purposes of this subsection, the term "erroneous excess payments for medical assistance" means the total of—

(I) payments under the State plan with respect to ineligible individuals and families, and

(II) overpayments on behalf of eligible individuals and families by reason of error in determining the amount of expenditures for medical care required of an individual or family as a condition of eligibility.

(ii) In determining the amount of erroneous excess payments for medical assistance to an ineligible individual or family under clause (i)(I), if such ineligibility is the result of an error in determining the amount of the resources of such individual or family, the amount of the erroneous excess payment shall be the smaller of (I) the amount of the payment with respect to such individual

or family, or (II) the difference between the actual amount of such resources and the allowable resource level established under the State plan.

(iii) In determining the amount of erroneous excess payments for medical assistance to an individual or family under clause (i)(II), the amount of the erroneous excess payment shall be the smaller of (I) the amount of the payment on behalf of the individual or family, or (II) the difference between the actual amount incurred for medical care by the individual or family and the amount which should have been incurred in order to establish eligibility for medical assistance.

(iv) In determining the amount of erroneous excess payments, there shall not be included any error resulting from a failure of an individual to cooperate or give correct information with respect to third-party liability as required under section 1912(a)(1)(C) or 402(a)(26)(C) or with respect to payments made in violation of section 1906.

(v) In determining the amount of erroneous excess payments, there shall not be included any erroneous payments made for ambulatory prenatal care provided during a presumptive eligibility period (as defined in section 1920(b)(1)), for items and services described in subsection (a) of section 1920A provided to a child during a presumptive eligibility period under such section, for medical assistance provided to an individual described in subsection (a) of section 1920B during a presumptive eligibility period under such section, or for medical assistance provided to an individual during a presumptive eligibility period resulting from a determination of presumptive eligibility made by a hospital that elects under section 1902(a)(47)(B) to be a qualified entity for such purpose.

(E) For purposes of subparagraph (D), there shall be excluded, in determining both erroneous excess payments for medical assistance and total expenditures for medical assistance—

(i) payments with respect to any individual whose eligibility therefor was determined exclusively by the Secretary under an agreement pursuant to section 1634 and such other classes of individuals as the Secretary may by regulation prescribe whose eligibility was determined in part under such an agreement; and

(ii) payments made as the result of a technical error.

(2) The State agency administering the plan approved under this title shall, at such times and in such form as the Secretary may specify, provide information on the rates of erroneous excess payments made (or expected, with respect to future periods specified by the Secretary) in connection with its administration of such plan, together with any other data he requests that are reasonably necessary for him to carry out the provisions of this subsection.

(3)(A) If a State fails to cooperate with the Secretary in providing information necessary to carry out this subsection, the Secretary, directly or through contractual or such other arrangements as he may find appropriate, shall establish the error rates for that State on the basis of the best data reasonably available to him and in accordance with such techniques for sampling and estimating as he finds appropriate.

(B) In any case in which it is necessary for the Secretary to exercise his authority under subparagraph (A) to determine a State's error rates for a fiscal year, the amount that would otherwise be payable to such State under this title for quarters in such year shall be reduced by the costs incurred by the Secretary in making (directly or otherwise) such determination.

(4) This subsection shall not apply with respect to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, or American Samoa.

(v)(1) Notwithstanding the preceding provisions of this section, except as provided in paragraphs (2) and (4), no payment may be made to a State under this section for medical assistance furnished to an alien who is not lawfully admitted for permanent residence or otherwise permanently residing in the United States under color of law.

(2) Payment shall be made under this section for care and services that are furnished to an alien described in paragraph (1) only if—

(A) such care and services are necessary for the treatment of an emergency medical condition of the alien,

(B) such alien otherwise meets the eligibility requirements for medical assistance under the State plan approved under this title (other than the requirement of the receipt of aid or assistance under title IV, supplemental security income benefits under title XVI, or a State supplementary payment), and

(C) such care and services are not related to an organ transplant procedure.

(3) For purposes of this subsection, the term "emergency medical condition" means a medical condition (including emergency labor and delivery) manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(A) placing the patient's health in serious jeopardy,
(B) serious impairment to bodily functions, or
(C) serious dysfunction of any bodily organ or part.

(4)(A) A State may elect (in a plan amendment under this title) to provide medical assistance under this title, notwithstanding sections 401(a), 402(b), 403, and 421 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, to children and pregnant women who are lawfully residing in the United States (including battered individuals described in section 431(c) of such Act) and who are otherwise eligible for such assistance, within either or both of the following eligibility categories:

(i) PREGNANT WOMEN.—Women during pregnancy (and during the 60-day period beginning on the last day of the pregnancy).

(ii) CHILDREN.—Individuals under 21 years of age, including optional targeted low-income children described in section 1905(u)(2)(B).

(B) In the case of a State that has elected to provide medical assistance to a category of aliens under subparagraph (A), no debt shall accrue under an affidavit of support against any sponsor of such an alien on the basis of provision of assistance to such category and the cost of such assistance shall not be considered as an unreimbursed cost.

(C) As part of the State's ongoing eligibility redetermination requirements and procedures for an individual provided medical assistance as a result of an election by the State under subparagraph (A), a State shall verify that the individual continues to lawfully reside in the United States using the documentation presented to the State by the individual on initial enrollment. If the State cannot successfully verify that the individual is lawfully residing in the United States in this manner, it shall require that the individual provide the State with further documentation or other evidence to verify that the individual is lawfully residing in the United States.

(w)(1)(A) Notwithstanding the previous provisions of this section, for purposes of determining the amount to be paid to a State (as defined in paragraph (7)(D)) under subsection (a)(1) for quarters in any fiscal year, the total amount expended during such fiscal year as medical assistance under the State plan (as determined without regard to this subsection) shall be reduced by the sum of any revenues received by the State (or by a unit of local government in the State) during the fiscal year—

(i) from provider-related donations (as defined in paragraph (2)(A)), other than—
(I) bona fide provider-related donations (as defined in paragraph (2)(B)), and
(II) donations described in paragraph (2)(C);

(ii) from health care related taxes (as defined in paragraph (3)(A)), other than broad-based health care related taxes (as defined in paragraph (3)(B));

(iii) from a broad-based health care related tax, if there is in effect a hold harmless provision (described in paragraph (4)) with respect to the tax; or

(iv) only with respect to State fiscal years (or portions thereof) occurring on or after January 1, 1992, and before October 1, 1995, from broad-based health care related taxes to the extent the amount of such taxes collected exceeds the limit established under paragraph (5).

(B) Notwithstanding the previous provisions of this section, for purposes of determining the amount to be paid to a State under subsection (a)(7) for all quarters in a Federal fiscal year (beginning with fiscal year 1993), the total amount expended during the fiscal year for administrative expenditures under the State plan (as determined without regard to this subsection) shall be reduced by the sum of any revenues received by the State (or by a unit of local government in the State) during such quarters from donations described in paragraph (2)(C), to the extent the amount of such donations exceeds 10 percent of the amounts expended under the State plan under this title during the fiscal year for purposes described in paragraphs (2), (3), (4), (6), and (7) of subsection (a).

(C)(i) Except as otherwise provided in clause (ii), subparagraph (A)(i) shall apply to donations received on or after January 1, 1992.

(ii) Subject to the limits described in clause (iii) and subparagraph (E), subparagraph (A)(i) shall not apply to donations received before the effective date specified in subparagraph (F) if such donations are received under programs in effect or as described in State plan amendments or related documents submitted to the Secretary by September 30, 1991, and applicable to State fiscal year 1992, as demonstrated by State plan amendments, written agreements, State budget documentation, or other documentary evidence in existence on that date.

(iii) In applying clause (ii) in the case of donations received in State fiscal year 1993, the maximum amount of such donations to which such clause may be applied may not exceed the total

amount of such donations received in the corresponding period in State fiscal year 1992 (or not later than 5 days after the last day of the corresponding period).

(D)(i) Except as otherwise provided in clause (ii), subparagraphs (A)(ii) and (A)(iii) shall apply to taxes received on or after January 1, 1992.

(ii) Subparagraphs (A)(ii) and (A)(iii) shall not apply to impermissible taxes (as defined in clause (iii)) received before the effective date specified in subparagraph (F) to the extent the taxes (including the tax rate or base) were in effect, or the legislation or regulations imposing such taxes were enacted or adopted, as of November 22, 1991.

(iii) In this subparagraph and subparagraph (E), the term "impermissible tax" means a health care related tax for which a reduction may be made under clause (ii) or (iii) of subparagraph (A).

(E)(i) In no case may the total amount of donations and taxes permitted under the exception provided in subparagraphs (C)(ii) and (D)(ii) for the portion of State fiscal year 1992 occurring during calendar year 1992 exceed the limit under paragraph (5) minus the total amount of broad-based health care related taxes received in the portion of that fiscal year.

(ii) In no case may the total amount of donations and taxes permitted under the exception provided in subparagraphs (C)(ii) and (D)(ii) for State fiscal year 1993 exceed the limit under paragraph (5) minus the total amount of broad-based health care related taxes received in that fiscal year.

(F) In this paragraph in the case of a State—

(i) except as provided in clause (iii), with a State fiscal year beginning on or before July 1, the effective date is October 1, 1992,

(ii) except as provided in clause (iii), with a State fiscal year that begins after July 1, the effective date is January 1, 1993, or

(iii) with a State legislature which is not scheduled to have a regular legislative session in 1992, with a State legislature which is not scheduled to have a regular legislative session in 1993, or with a provider-specific tax enacted on November 4, 1991, the effective date is July 1, 1993.

(2)(A) In this subsection (except as provided in paragraph (6)), the term "provider-related donation" means any donation or other voluntary payment (whether in cash or in kind) made (directly or indirectly) to a State or unit of local government by—

(i) a health care provider (as defined in paragraph (7)(B)),

(ii) an entity related to a health care provider (as defined in paragraph (7)(C)), or

(iii) an entity providing goods or services under the State plan for which payment is made to the State under paragraph (2), (3), (4), (6), or (7) of subsection (a).

(B) For purposes of paragraph (1)(A)(i)(I), the term "bona fide provider-related donation" means a provider-related donation that has no direct or indirect relationship (as determined by the Secretary) to payments made under this title to that provider, to providers furnishing the same class of items and services as that provider, or to any related entity, as established by the State to the satisfaction of the Secretary. The Secretary may by regulation specify types of provider-related donations described in the previous sentence that will be considered to be bona fide provider-related donations.

(C) For purposes of paragraph (1)(A)(i)(II), donations described in this subparagraph are funds expended by a hospital, clinic, or similar entity for the direct cost (including costs of training and of preparing and distributing outreach materials) of State or local agency personnel who are stationed at the hospital, clinic, or entity to determine the eligibility of individuals for medical assistance under this title and to provide outreach services to eligible or potentially eligible individuals.

(3)(A) In this subsection (except as provided in paragraph (6)), the term "health care related tax" means a tax (as defined in paragraph (7)(F)) that—

(i) is related to health care items or services, or to the provision of, the authority to provide, or payment for, such items or services, or

(ii) is not limited to such items or services but provides for treatment of individuals or entities that are providing or paying for such items or services that is different from the treatment provided to other individuals or entities.

In applying clause (i), a tax is considered to relate to health care items or services if at least 85 percent of the burden of such tax falls on health care providers.

(B) In this subsection, the term "broad-based health care related tax" means a health care related tax which is imposed with respect to a class of health care items or services (as described in paragraph (7)(A)) or with respect to providers of such items or services and which, except as provided in subparagraphs (D), (E), and (F)—

(i) is imposed at least with respect to all items or services in the class furnished by all non-Federal, nonpublic providers in the State (or, in the case of a tax imposed by a unit of local government, the area over which the unit has jurisdiction) or is imposed with respect to all non-Federal, nonpublic providers in the class; and

(ii) is imposed uniformly (in accordance with subparagraph (C)).

(C)(i) Subject to clause (ii), for purposes of subparagraph (B)(ii), a tax is considered to be imposed uniformly if—

(I) in the case of a tax consisting of a licensing fee or similar tax on a class of health care items or services (or providers of such items or services), the amount of the tax imposed is the same for every provider providing items or services within the class;

(II) in the case of a tax consisting of a licensing fee or similar tax imposed on a class of health care items or services (or providers of such services) on the basis of the number of beds (licensed or otherwise) of the provider, the amount of the tax is the same for each bed of each provider of such items or services in the class;

(III) in the case of a tax based on revenues or receipts with respect to a class of items or services (or providers of items or services) the tax is imposed at a uniform rate for all items and services (or providers of such items of services) in the class on all the gross revenues or receipts, or net operating revenues, relating to the provision of all such items or services (or all such providers) in the State (or, in the case of a tax imposed by a unit of local government within the State, in the area over which the unit has jurisdiction); or

(IV) in the case of any other tax, the State establishes to the satisfaction of the Secretary that the tax is imposed uniformly.

(ii) Subject to subparagraphs (D) and (E), a tax imposed with respect to a class of health care items and services is not considered to be imposed uniformly if the tax provides for any credits, exclusions, or deductions which have as their purpose or effect the return to providers of all or a portion of the tax paid in a manner that is inconsistent with subclauses (I) and (II) of subparagraph (E)(ii) or provides for a hold harmless provision described in paragraph (4).

(D) A tax imposed with respect to a class of health care items and services is considered to be imposed uniformly—

(i) notwithstanding that the tax is not imposed with respect to items or services (or the providers thereof) for which payment is made under a State plan under this title or title XVIII, or

(ii) in the case of a tax described in subparagraph (C)(i)(III), notwithstanding that the tax provides for exclusion (in whole or in part) of revenues or receipts from a State plan under this title or title XVIII.

(E)(i) A State may submit an application to the Secretary requesting that the Secretary treat a tax as a broad-based health care related tax, notwithstanding that the tax does not apply to all health care items or services in class (or all providers of such items and services), provides for a credit, deduction, or exclusion, is not applied uniformly, or otherwise does not meet the requirements of subparagraph (B) or (C). Permissible waivers may include exemptions for rural or sole-community providers.

(ii) The Secretary shall approve such an application if the State establishes to the satisfaction of the Secretary that—

(I) the net impact of the tax and associated expenditures under this title as proposed by the State is generally redistributive in nature, and

(II) the amount of the tax is not directly correlated to payments under this title for items or services with respect to which the tax is imposed.

The Secretary shall by regulation specify types of credits, exclusions, and deductions that will be considered to meet the requirements of this subparagraph.

(F) In no case shall a tax not qualify as a broad-based health care related tax under this paragraph because it does not apply to a hospital that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of such Code and that does not accept payment under the State plan under this title or under title XVIII.

(4) For purposes of paragraph (1)(A)(iii), there is in effect a hold harmless provision with respect to a broad-based health care related tax imposed with respect to a class of items or services if the Secretary determines that any of the following applies:

(A) The State or other unit of government imposing the tax provides (directly or indirectly) for a payment (other than under this title) to taxpayers and the amount of such payment is

positively correlated either to the amount of such tax or to the difference between the amount of the tax and the amount of payment under the State plan.

(B) All or any portion of the payment made under this title to the taxpayer varies based only upon the amount of the total tax paid.

(C)(i) The State or other unit of government imposing the tax provides (directly or indirectly) for any payment, offset, or waiver that guarantees to hold taxpayers harmless for any portion of the costs of the tax.

(ii) For purposes of clause (i), a determination of the existence of an indirect guarantee shall be made under paragraph (3)(i) of section 433.68(f) of title 42, Code of Federal Regulations, as in effect on November 1, 2006, except that for portions of fiscal years beginning on or after January 1, 2008, and before October 1, 2011, "5.5 percent" shall be substituted for "6 percent" each place it appears.

The provisions of this paragraph shall not prevent use of the tax to reimburse health care providers in a class for expenditures under this title nor preclude States from relying on such reimbursement to justify or explain the tax in the legislative process.

(5)(A) For purposes of this subsection, the limit under this subparagraph with respect to a State is an amount equal to 25 percent (or, if greater, the State base percentage, as defined in subparagraph (B)) of the non-Federal share of the total amount expended under the State plan during a State fiscal year (or portion thereof), as it would be determined pursuant to paragraph (1)(A) without regard to paragraph (1)(A)(iv).

(B)(i) In subparagraph (A), the term "State base percentage" means, with respect to a State, an amount (expressed as a percentage) equal to—

(I) the total of the amount of health care related taxes (whether or not broad-based) and the amount of provider-related donations (whether or not bona fide) projected to be collected (in accordance with clause (ii)) during State fiscal year 1992, divided by

(II) the non-Federal share of the total amount estimated to be expended under the State plan during such State fiscal year.

(ii) For purposes of clause (i)(I), in the case of a tax that is not in effect throughout State fiscal year 1992 or the rate (or base) of which is increased during such fiscal year, the Secretary shall project the amount to be collected during such fiscal year as if the tax (or increase) were in effect during the entire State fiscal year.

(C)(i) The total amount of health care related taxes under subparagraph (B)(i)(I) shall be determined by the Secretary based on only those taxes (including the tax rate or base) which were in effect, or for which legislation or regulations imposing such taxes were enacted or adopted, as of November 22, 1991.

(ii) The amount of provider-related donations under subparagraph (B)(i)(I) shall be determined by the Secretary based on programs in effect on September 30, 1991, and applicable to State fiscal year 1992, as demonstrated by State plan amendments, written agreements, State budget documentation, or other documentary evidence in existence on that date.

(iii) The amount of expenditures described in subparagraph (B)(i)(II) shall be determined by the Secretary based on the best data available as of the date of the enactment of this subsection.

(6)(A) Notwithstanding the provisions of this subsection, the Secretary may not restrict States' use of funds where such funds are derived from State or local taxes (or funds appropriated to State university teaching hospitals) transferred from or certified by units of government within a State as the non-Federal share of expenditures under this title, regardless of whether the unit of government is also a health care provider, except as provided in section 1902(a)(2), unless the transferred funds are derived by the unit of government from donations or taxes that would not otherwise be recognized as the non-Federal share under this section.

(B) For purposes of this subsection, funds the use of which the Secretary may not restrict under subparagraph (A) shall not be considered to be a provider-related donation or a health care related tax.

(7) For purposes of this subsection:

(A) Each of the following shall be considered a separate class of health care items and services:

(i) Inpatient hospital services.

(ii) Outpatient hospital services.

(iii) Nursing facility services (other than services of intermediate care facilities for the mentally retarded).

(iv) Services of intermediate care facilities for the mentally retarded.

(v) Physicians' services.
(vi) Home health care services.
(vii) Outpatient prescription drugs.
(viii) Services of managed care organizations (including health maintenance organizations, preferred provider organizations, and such other similar organizations as the Secretary may specify by regulation).
(ix) Such other classification of health care items and services consistent with this subparagraph as the Secretary may establish by regulation.

(B) The term "health care provider" means an individual or person that receives payments for the provision of health care items or services.

(C) An entity is considered to be "related" to a health care provider if the entity—
(i) is an organization, association, corporation or partnership formed by or on behalf of health care providers;
(ii) is a person with an ownership or control interest (as defined in section 1124(a)(3)) in the provider;
(iii) is the employee, spouse, parent, child, or sibling of the provider (or of a person described in clause (ii)); or
(iv) has a similar, close relationship (as defined in regulations) to the provider.

(D) The term "State" means only the 50 States and the District of Columbia but does not include any State whose entire program under this title is operated under a waiver granted under section 1115.

(E) The "State fiscal year" means, with respect to a specified year, a State fiscal year ending in that specified year.

(F) The term "tax" includes any licensing fee, assessment, or other mandatory payment, but does not include payment of a criminal or civil fine or penalty (other than a fine or penalty imposed in lieu of or instead of a fee, assessment, or other mandatory payment).

(G) The term "unit of local government" means, with respect to a State, a city, county, special purpose district, or other governmental unit in the State.

(x)(1) For purposes of section 1902(a)(46)(B)(i), the requirement of this subsection is, with respect to an individual declaring to be a citizen or national of the United States, that, subject to paragraph (2), there is presented satisfactory documentary evidence of citizenship or nationality (as defined in paragraph (3)) of the individual.

(2) The requirement of paragraph (1) shall not apply to an individual declaring to be a citizen or national of the United States who is eligible for medical assistance under this title—
(A) and is entitled to or enrolled for benefits under any part of title XVIII;
(B) and is receiving—
(i) disability insurance benefits under section 223 or monthly insurance benefits under section 202 based on such individual's disability (as defined in section 223(d)); or
(ii) supplemental security income benefits under title XVI;
(C) and with respect to whom—
(i) child welfare services are made available under part B of title IV on the basis of being a child in foster care; or
(ii) adoption or foster care assistance is made available under part E of title IV;
(D) pursuant to the application of section 1902(e)(4) (and, in the case of an individual who is eligible for medical assistance on such basis, the individual shall be deemed to have provided satisfactory documentary evidence of citizenship or nationality and shall not be required to provide further documentary evidence on any date that occurs during or after the period in which the individual is eligible for medical assistance on such basis); or
(E) on such basis as the Secretary may specify under which satisfactory documentary evidence of citizenship or nationality has been previously presented.

(3)(A) For purposes of this subsection, the term "satisfactory documentary evidence of citizenship or nationality" means—
(i) any document described in subparagraph (B); or
(ii) a document described in subparagraph (C) and a document described in subparagraph (D).

(B) The following are documents described in this subparagraph:
(i) A United States passport.
(ii) Form N–550 or N–570 (Certificate of Naturalization).
(iii) Form N–560 or N–561 (Certificate of United States Citizenship).

(iv) A valid State-issued driver's license or other identity document described in section 274A(b)(1)(D) of the Immigration and Nationality Act, but only if the State issuing the license or such document requires proof of United States citizenship before issuance of such license or document or obtains a social security number from the applicant and verifies before certification that such number is valid and assigned to the applicant who is a citizen.

(v)(I) Except as provided in subclause (II), a document issued by a federally recognized Indian tribe evidencing membership or enrollment in, or affiliation with, such tribe (such as a tribal enrollment card or certificate of degree of Indian blood).

(II) With respect to those federally recognized Indian tribes located within States having an international border whose membership includes individuals who are not citizens of the United States, the Secretary shall, after consulting with such tribes, issue regulations authorizing the presentation of such other forms of documentation (including tribal documentation, if appropriate) that the Secretary determines to be satisfactory documentary evidence of citizenship or nationality for purposes of satisfying the requirement of this subsection.

(vi) Such other document as the Secretary may specify, by regulation, that provides proof of United States citizenship or nationality and that provides a reliable means of documentation of personal identity.

(C) The following are documents described in this subparagraph:

(i) A certificate of birth in the United States.

(ii) Form FS–545 or Form DS–1350 (Certification of Birth Abroad).

(iii) Form I–197 (United States Citizen Identification Card).

(iv) Form FS–240 (Report of Birth Abroad of a Citizen of the United States).

(v) Such other document (not described in subparagraph (B)(iv)) as the Secretary may specify that provides proof of United States citizenship or nationality.

(D) The following are documents described in this subparagraph:

(i) Any identity document described in section 274A(b)(1)(D) of the Immigration and Nationality Act.

(ii) Any other documentation of personal identity of such other type as the Secretary finds, by regulation, provides a reliable means of identification.

(E) A reference in this paragraph to a form includes a reference to any successor form.

(4) In the case of an individual declaring to be a citizen or national of the United States with respect to whom a State requires the presentation of satisfactory documentary evidence of citizenship or nationality under section 1902(a)(46)(B)(i), the individual shall be provided at least the reasonable opportunity to present satisfactory documentary evidence of citizenship or nationality under this subsection as is provided under clauses (i) and (ii) of section 1137(d)(4)(A) to an individual for the submittal to the State of evidence indicating a satisfactory immigration status.

(5) Nothing in subparagraph (A) or (B) of section 1902(a)(46), the preceding paragraphs of this subsection, or the Deficit Reduction Act of 2005, including section 6036 of such Act, shall be construed as changing the requirement of section 1902(e)(4) that a child born in the United States to an alien mother for whom medical assistance for the delivery of such child is available as treatment of an emergency medical condition pursuant to subsection (v) shall be deemed eligible for medical assistance during the first year of such child's life.

(y) PAYMENTS FOR ESTABLISHMENT OF ALTERNATE NON-EMERGENCY SERVICES PROVIDERS.—

(1) PAYMENTS.—In addition to the payments otherwise provided under subsection (a), subject to paragraph (2), the Secretary shall provide for payments to States under such subsection for the establishment of alternate non-emergency service providers (as defined in section 1916A(e)(5)(B)), or networks of such providers.

(2) LIMITATION.—The total amount of payments under this subsection shall not exceed $50,000,000 during the 4-year period beginning with 2006. This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this subsection.

(3) PREFERENCE.—In providing for payments to States under this subsection, the Secretary shall provide preference to States that establish, or provide for, alternate non-emergency services providers or networks of such providers that—

(A) serve rural or underserved areas where beneficiaries under this title may not have regular access to providers of primary care services; or

(B) are in partnership with local community hospitals.

(4) FORM AND MANNER OF PAYMENT.—Payment to a State under this subsection shall be made only upon the filing of such application in such form and in such manner as the Sec-

retary shall specify. Payment to a State under this subsection shall be made in the same manner as other payments under section 1903(a).

(z) MEDICAID TRANSFORMATION PAYMENTS.—

(1) IN GENERAL.—In addition to the payments provided under subsection (a), subject to paragraph (4), the Secretary shall provide for payments to States for the adoption of innovative methods to improve the effectiveness and efficiency in providing medical assistance under this title.

(2) PERMISSIBLE USES OF FUNDS.—The following are examples of innovative methods for which funds provided under this subsection may be used:

(A) Methods for reducing patient error rates through the implementation and use of electronic health records, electronic clinical decision support tools, or e-prescribing programs.

(B) Methods for improving rates of collection from estates of amounts owed under this title.

(C) Methods for reducing waste, fraud, and abuse under the program under this title, such as reducing improper payment rates as measured by annual payment error rate measurement (PERM) project rates.

(D) Implementation of a medication risk management program as part of a drug use review program under section 1927(g).

(E) Methods in reducing, in clinically appropriate ways, expenditures under this title for covered outpatient drugs, particularly in the categories of greatest drug utilization, by increasing the utilization of generic drugs through the use of education programs and other incentives to promote greater use of generic drugs.

(F) Methods for improving access to primary and specialty physician care for the uninsured using integrated university-based hospital and clinic systems.

(3) APPLICATION; TERMS AND CONDITIONS.—

(A) IN GENERAL.—No payments shall be made to a State under this subsection unless the State applies to the Secretary for such payments in a form, manner, and time specified by the Secretary.

(B) TERMS AND CONDITIONS.—Such payments are made under such terms and conditions consistent with this subsection as the Secretary prescribes.

(C) ANNUAL REPORT.—Payment to a State under this subsection is conditioned on the State submitting to the Secretary an annual report on the programs supported by such payment. Such report shall include information on—

(i) the specific uses of such payment;

(ii) an assessment of quality improvements and clinical outcomes under such programs; and

(iii) estimates of cost savings resulting from such programs.

(4) FUNDING.—

(A) LIMITATION ON FUNDS.—The total amount of payments under this subsection shall be equal to, and shall not exceed—

(i) $75,000,000 for fiscal year 2007; and

(ii) $75,000,000 for fiscal year 2008.

This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this subsection.

(B) ALLOCATION OF FUNDS.—The Secretary shall specify a method for allocating the funds made available under this subsection among States. Such method shall provide preference for States that design programs that target health providers that treat significant numbers of Medicaid beneficiaries. Such method shall provide that not less than 25 percent of such funds shall be allocated among States the population of which (as determined according to data collected by the United States Census Bureau) as of July 1, 2004, was more than 105 percent of the population of the respective State (as so determined) as of April 1, 2000.

(C) FORM AND MANNER OF PAYMENT.—Payment to a State under this subsection shall be made in the same manner as other payments under section 1903(a). There is no requirement for State matching funds to receive payments under this subsection.

(5) MEDICATION RISK MANAGEMENT PROGRAM.—

(A) IN GENERAL.—For purposes of this subsection, the term "medication risk management program" means a program for targeted beneficiaries that ensures that covered outpatient drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events.

(B) ELEMENTS.—Such program may include the following elements:

(i) The use of established principles and standards for drug utilization review and best practices to analyze prescription drug claims of targeted beneficiaries and identify outlier physicians.

(ii) On an ongoing basis provide outlier physicians—

(I) a comprehensive pharmacy claims history for each targeted beneficiary under their care;

(II) information regarding the frequency and cost of relapses and hospitalizations of targeted beneficiaries under the physician's care; and

(III) applicable best practice guidelines and empirical references.

(iii) Monitor outlier physician's prescribing, such as failure to refill, dosage strengths, and provide incentives and information to encourage the adoption of best clinical practices.

(C) TARGETED BENEFICIARIES.—For purposes of this paragraph, the term "targeted beneficiaries" means Medicaid eligible beneficiaries who are identified as having high prescription drug costs and medical costs, such as individuals with behavioral disorders or multiple chronic diseases who are taking multiple medications.

*(aa) DEMONSTRATION PROJECT TO INCREASE SUBSTANCE USE PROVIDER CAPACITY.—*

*(1) IN GENERAL.—Not later than the date that is 180 days after the date of the enactment of this section, the Secretary shall, in consultation, as appropriate, with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, conduct a 54-month demonstration project for the purpose described in paragraph (2) under which the Secretary shall—*

*(A) for the first 18-month period of such project, award planning grants described in paragraph (3); and*

*(B) for the remaining 36-month period of such project, provide to each State selected under paragraph (4) payments in accordance with paragraph (5).*

*(2) PURPOSE.—The purpose described in this paragraph is for each State selected under paragraph (4) to increase the treatment capacity of providers participating under the State plan (or a waiver of such plan) to provide substance use disorder treatment or recovery services under such plan (or waiver) through the following activities:*

*(A) For the purpose described in paragraph (3)(C)(i), activities that support an ongoing assessment of the behavioral health treatment needs of the State, taking into account the matters described in subclauses (I) through (IV) of such paragraph.*

*(B) Activities that, taking into account the results of the assessment described in subparagraph (A), support the recruitment, training, and provision of technical assistance for providers participating under the State plan (or a waiver of such plan) that offer substance use disorder treatment or recovery services.*

*(C) Improved reimbursement for and expansion of, through the provision of education, training, and technical assistance, the number or treatment capacity of providers participating under the State plan (or waiver) that—*

*(i) are authorized to dispense drugs approved by the Food and Drug Administration for individuals with a substance use disorder who need withdrawal management or maintenance treatment for such disorder;*

*(ii) have in effect a registration or waiver under section 303(g) of the Controlled Substances Act for purposes of dispensing narcotic drugs to individuals for maintenance treatment or detoxification treatment and are in compliance with any regulation promulgated by the Assistant Secretary for Mental Health and Substance Use for purposes of carrying out the requirements of such section 303(g); and*

*(iii) are qualified under applicable State law to provide substance use disorder treatment or recovery services.*

*(D) Improved reimbursement for and expansion of, through the provision of education, training, and technical assistance, the number or treatment capacity of providers participating under the State plan (or waiver) that have the qualifications to address the treatment or recovery needs of—*

*(i) individuals enrolled under the State plan (or a waiver of such plan) who have neonatal abstinence syndrome, in accordance with guidelines issued by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists relating to maternal care and infant care with respect to neonatal abstinence syndrome;*

*(ii) pregnant women, postpartum women, and infants, particularly the concurrent treatment, as appropriate, and comprehensive case management of pregnant women, post–partum women and infants, enrolled under the State plan (or a waiver of such plan);*

*(iii) adolescents and young adults between the ages of 12 and 21 enrolled under the State plan (or a waiver of such plan); or*

*(iv) American Indian and Alaska Native individuals enrolled under the State plan (or a waiver of such plan).*

*(3) PLANNING GRANTS.—*

*(A) IN GENERAL.—The Secretary shall, with respect to the first 18-month period of the demonstration project conducted under paragraph (1), award planning grants to at least 10 States selected in accordance with subparagraph (B) for purposes of preparing an application described in paragraph (4)(C) and carrying out the activities described in subparagraph (C).*

*(B) SELECTION.—In selecting States for purposes of this paragraph, the Secretary shall—*

*(i) select States that have a State plan (or waiver of the State plan) approved under this title;*

*(ii) select States in a manner that ensures geographic diversity; and*

*(iii) give preference to States with a prevalence of substance use disorders (in particular opioid use disorders) that is comparable to or higher than the national average prevalence, as measured by aggregate per capita drug overdoses, or any other measure that the Secretary deems appropriate.*

*(C) ACTIVITIES DESCRIBED.—Activities described in this subparagraph are, with respect to a State, each of the following:*

*(i) Activities that support the development of an initial assessment of the behavioral health treatment needs of the State to determine the extent to which providers are needed (including the types of such providers and geographic area of need) to improve the network of providers that treat substance use disorders under the State plan (or waiver), including the following:*

*(I) An estimate of the number of individuals enrolled under the State plan (or a waiver of such plan) who have a substance use disorder.*

*(II) Information on the capacity of providers to provide substance use disorder treatment or recovery services to individuals enrolled under the State plan (or waiver), including information on providers who provide such services and their participation under the State plan (or waiver).*

*(III) Information on the gap in substance use disorder treatment or recovery services under the State plan (or waiver) based on the information described in subclauses (I) and (II).*

*(IV) Projections regarding the extent to which the State participating under the demonstration project would increase the number of providers offering substance use disorder treatment or recovery services under the State plan (or waiver) during the period of the demonstration project.*

*(ii) Activities that, taking into account the results of the assessment described in clause (i), support the development of State infrastructure to, with respect to the provision of substance use disorder treatment or recovery services under the State plan (or a waiver of such plan), recruit prospective providers and provide training and technical assistance to such providers.*

*(D) FUNDING.—For purposes of subparagraph (A), there is appropriated, out of any funds in the Treasury not otherwise appropriated, $50,000,000, to remain available until expended.*

*(4) POST-PLANNING STATES.—*

*(A) IN GENERAL.—The Secretary shall, with respect to the remaining 36-month period of the demonstration project conducted under paragraph (1), select not more than 5 States*

*in accordance with subparagraph (B) for purposes of carrying out the activities described in paragraph (2) and receiving payments in accordance with paragraph (5).*

*(B) SELECTION.—In selecting States for purposes of this paragraph, the Secretary shall—*

*(i) select States that received a planning grant under paragraph (3);*

*(ii) select States that submit to the Secretary an application in accordance with the requirements in subparagraph (C), taking into consideration the quality of each such application;*

*(iii) select States in a manner that ensures geographic diversity; and*

*(iv) give preference to States with a prevalence of substance use disorders (in particular opioid use disorders) that is comparable to or higher than the national average prevalence, as measured by aggregate per capita drug overdoses, or any other measure that the Secretary deems appropriate.*

*(C) APPLICATIONS.—*

*(i) IN GENERAL.—A State seeking to be selected for purposes of this paragraph shall submit to the Secretary, at such time and in such form and manner as the Secretary requires, an application that includes such information, provisions, and assurances, as the Secretary may require, in addition to the following:*

*(I) A proposed process for carrying out the ongoing assessment described in paragraph (2)(A), taking into account the results of the initial assessment described in paragraph (3)(C)(i).*

*(II) A review of reimbursement methodologies and other policies related to substance use disorder treatment or recovery services under the State plan (or waiver) that may create barriers to increasing the number of providers delivering such services.*

*(III) The development of a plan, taking into account activities carried out under paragraph (3)(C)(ii), that will result in long-term and sustainable provider networks under the State plan (or waiver) that will offer a continuum of care for substance use disorders. Such plan shall include the following:*

*(aa) Specific activities to increase the number of providers (including providers that specialize in providing substance use disorder treatment or recovery services, hospitals, health care systems, Federally qualified health centers, and, as applicable, certified community behavioral health clinics) that offer substance use disorder treatment, recovery, or support services, including short-term detoxification services, outpatient substance use disorder services, and evidence-based peer recovery services.*

*(bb) Strategies that will incentivize providers described in subparagraphs (C) and (D) of paragraph (2) to obtain the necessary training, education, and support to deliver substance use disorder treatment or recovery services in the State.*

*(cc) Milestones and timeliness for implementing activities set forth in the plan.*

*(dd) Specific measurable targets for increasing the substance use disorder treatment and recovery provider network under the State plan (or a waiver of such plan).*

*(IV) A proposed process for reporting the information required under paragraph (6)(A), including information to assess the effectiveness of the efforts of the State to expand the capacity of providers to deliver substance use disorder treatment or recovery services during the period of the demonstration project under this subsection.*

*(V) The expected financial impact of the demonstration project under this subsection on the State.*

*(VI) A description of all funding sources available to the State to provide substance use disorder treatment or recovery services in the State.*

*(VII) A preliminary plan for how the State will sustain any increase in the capacity of providers to deliver substance use disorder treatment or recovery services resulting from the demonstration project under this subsection after the termination of such demonstration project.*

*(VIII) A description of how the State will coordinate the goals of the demonstration project with any waiver granted (or submitted by the State and pending) pursuant to section 1115 for the delivery of substance use services under the State plan, as applicable.*

*(ii) CONSULTATION.—In completing an application under clause (i), a State shall consult with relevant stakeholders, including Medicaid managed care plans, health care providers, and Medicaid beneficiary advocates, and include in such application a description of such consultation.*

*(5) PAYMENT.—*

*(A) IN GENERAL.—For each quarter occurring during the period for which the demonstration project is conducted (after the first 18 months of such period), the Secretary shall pay under this subsection, subject to subparagraph (C), to each State selected under paragraph (4) an amount equal to 80 percent of so much of the qualified sums expended during such quarter.*

*(B) QUALIFIED SUMS DEFINED.—For purposes of subparagraph (A), the term "qualified sums" means, with respect to a State and a quarter, the amount equal to the amount (if any) by which the sums expended by the State during such quarter attributable to substance use treatment or recovery services furnished by providers participating under the State plan (or a waiver of such plan) exceeds 1/4 of such sums expended by the State during fiscal year 2018 attributable to substance use treatment or recovery services.*

*(C) NON-DUPLICATION OF PAYMENT.—In the case that payment is made under subparagraph (A) with respect to expenditures for substance use treatment or recovery services furnished by providers participating under the State plan (or a waiver of such plan), payment may not also be made under subsection (a) with respect to expenditures for the same services so furnished.*

*(6) REPORTS.—*

*(A) STATE REPORTS.—A State receiving payments under paragraph (5) shall, for the period of the demonstration project under this subsection, submit to the Secretary a quarterly report, with respect to expenditures for substance use treatment or recovery services for which payment is made to the State under this subsection, on the following:*

*(i) The specific activities with respect to which payment under this subsection was provided.*

*(ii) The number of providers that delivered substance use disorder treatment or recovery services in the State under the demonstration project compared to the estimated number of providers that would have otherwise delivered such services in the absence of such demonstration project.*

*(iii) The number of individuals enrolled under the State plan (or a waiver of such plan) who received substance use disorder treatment or recovery services under the demonstration project compared to the estimated number of such individuals who would have otherwise received such services in the absence of such demonstration project.*

*(iv) Other matters as determined by the Secretary.*

*(B) CMS REPORTS.—*

*(i) INITIAL REPORT.—Not later than October 1, 2020, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress an initial report on—*

*(I) the States awarded planning grants under paragraph (3);*

*(II) the criteria used in such selection; and*

*(III) the activities carried out by such States under such planning grants.*

*(ii) INTERIM REPORT.—Not later than October 1, 2022, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress an interim report—*

*(I) on activities carried out under the demonstration project under this subsection;*

*(II) on the extent to which States selected under paragraph (4) have achieved the stated goals submitted in their applications under subparagraph (C) of such paragraph;*

*(III) with a description of the strengths and limitations of such demonstration project; and*

*(IV) with a plan for the sustainability of such project.*

*(iii) FINAL REPORT.—Not later than October 1, 2024, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress a final report—*

*(I) providing updates on the matters reported in the interim report under clause (ii);*

*(II) including a description of any changes made with respect to the demonstration project under this subsection after the submission of such interim report; and*

*(III) evaluating such demonstration project.*

*(C) AHRQ REPORT.—Not later than three years after the date of the enactment of this subsection, the Director of the Agency for Healthcare Research and Quality, on consultation with the Administrator of the Centers for Medicare & Medicaid Services, shall submit to Congress a summary on the experiences of States awarded planning grants under paragraph (3) and States selected under paragraph (4).*

*(7) DATA SHARING AND BEST PRACTICES.—During the period of the demonstration project under this subsection, the Secretary shall, in collaboration with States selected under paragraph (4), facilitate data sharing and the development of best practices between such States and States that were not so selected.*

*(8) CMS FUNDING.—There is appropriated, out of any funds in the Treasury not otherwise appropriated, $5,000,000 to the Centers for Medicare & Medicaid Services for purposes of implementing this subsection. Such amount shall remain available until expended.*

* * * * * * *

DEFINITIONS

SEC. 1905. For purposes of this title—

(a) The term "medical assistance" means payment of part or all of the cost of the following care and services or the care and services themselves, or both (if provided in or after the third month before the month in which the recipient makes application for assistance or, in the case of medicare cost-sharing with respect to a qualified medicare beneficiary described in subsection (p)(1), if provided after the month in which the individual becomes such a beneficiary) for individuals, and, with respect to physicians' or dentists' services, at the option of the State, to individuals (other than individuals with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them a State supplementary payment and are eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1902(a)(10)(A)) not receiving aid or assistance under any plan of the State approved under title I, X, XIV, or XVI, or part A of title IV, and with respect to whom supplemental security income benefits are not being paid under title XVI, who are—

(i) under the age of 21, or, at the option of the State, under the age of 20, 19, or 18 as the State may choose,

(ii) relatives specified in section 406(b)(1) with whom a child is living if such child is (or would, if needy, be) a dependent child under part A of title IV,

(iii) 65 years of age or older,

(iv) blind, with respect to States eligible to participate in the State plan program established under title XVI,

(v) 18 years of age or older and permanently and totally disabled, with respect to States eligible to participate in the State plan program established under title XVI,

(vi) persons essential (as described in the second sentence of this subsection) to individuals receiving aid or assistance under State plans approved under title I, X, XIV, or XVI,

(vii) blind or disabled as defined in section 1614, with respect to States not eligible to participate in the State plan program established under title XVI,

(viii) pregnant women,

(ix) individuals provided extended benefits under section 1925,
(x) individuals described in section 1902(u)(1),
(xi) individuals described in section 1902(z)(1),
(xii) employed individuals with a medically improved disability (as defined in subsection (v)),
(xiii) individuals described in section 1902(aa),
(xiv) individuals described in section 1902(a)(10)(A)(i)(VIII) or 1902(a)(10)(A)(i)(IX),
(xv) individuals described in section 1902(a)(10)(A)(ii)(XX),
(xvi) individuals described in section 1902(ii), or
(xvii) individuals who are eligible for home and community-based services under needs-based criteria established under paragraph (1)(A) of section 1915(i), or who are eligible for home and community-based services under paragraph (6) of such section, and who will receive home and community-based services pursuant to a State plan amendment under such subsection,

but whose income and resources are insufficient to meet all of such cost—

(1) inpatient hospital services (other than services in an institution for mental diseases);
(2)(A) outpatient hospital services, (B) consistent with State law permitting such services, rural health clinic services (as defined in subsection (l)(1)) and any other ambulatory services which are offered by a rural health clinic (as defined in subsection (l)(1)) and which are otherwise included in the plan, and (C) Federally-qualified health center services (as defined in subsection (l)(2)) and any other ambulatory services offered by a Federally-qualified health center and which are otherwise included in the plan;
(3) other laboratory and X-ray services;
(4)(A) nursing facility services (other than services in an institution for mental diseases) for individuals 21 years of age or older; (B) early and periodic screening, diagnostic, and treatment services (as defined in subsection (r)) for individuals who are eligible under the plan and are under the age of 21; (C) family planning services and supplies furnished (directly or under arrangements with others) to individuals of child-bearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies; and (D) counseling and pharmacotherapy for cessation of tobacco use by pregnant women (as defined in subsection (bb));
(5)(A) physicians' services furnished by a physician (as defined in section 1861(r)(1)), whether furnished in the office, the patient's home, a hospital, or a nursing facility, or elsewhere, and (B) medical and surgical services furnished by a dentist (described in section 1861(r)(2)) to the extent such services may be performed under State law either by a doctor of medicine or by a doctor of dental surgery or dental medicine and would be described in clause (A) if furnished by a physician (as defined in section 1861(r)(1));
(6) medical care, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law;
(7) home health care services;
(8) private duty nursing services;
(9) clinic services furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician, including such services furnished outside the clinic by clinic personnel to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address;
(10) dental services;
(11) physical therapy and related services;
(12) prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist, whichever the individual may select;
(13) other diagnostic, screening, preventive, and rehabilitative services, including—
(A) any clinical preventive services that are assigned a grade of A or B by the United States Preventive Services Task Force;
(B) with respect to an adult individual, approved vaccines recommended by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention) and their administration; and
(C) any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the

scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level;

(14) inpatient hospital services and nursing facility services for individuals 65 years of age or over in an institution for mental diseases;

(15) services in an intermediate care facility for the mentally retarded (other than in an institution for mental diseases) for individuals who are determined, in accordance with section 1902(a)(31), to be in need of such care;

(16) (A) effective January 1, 1973, inpatient psychiatric hospital services for individuals under age 21, as defined in subsection (h), and, (B) for individuals receiving services described in subparagraph (A), early and periodic screening, diagnostic, and treatment services (as defined in subsection (r)), whether or not such screening, diagnostic, and treatment services are furnished by the provider of the services described in such subparagraph;

(17) services furnished by a nurse-midwife (as defined in section 1861(gg)) which the nurse-midwife is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), whether or not the nurse-midwife is under the supervision of, or associated with, a physician or other health care provider, and without regard to whether or not the services are performed in the area of management of the care of mothers and babies throughout the maternity cycle;

(18) hospice care (as defined in subsection (o));

(19) case management services (as defined in section 1915(g)(2)) and TB-related services described in section 1902(z)(2)(F);

(20) respiratory care services (as defined in section 1902(e)(9)(C));

(21) services furnished by a certified pediatric nurse practitioner or certified family nurse practitioner (as defined by the Secretary) which the certified pediatric nurse practitioner or certified family nurse practitioner is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), whether or not the certified pediatric nurse practitioner or certified family nurse practitioner is under the supervision of, or associated with, a physician or other health care provider;

(22) home and community care (to the extent allowed and as defined in section 1929) for functionally disabled elderly individuals;

(23) community supported living arrangements services (to the extent allowed and as defined in section 1930);

(24) personal care services furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility for the mentally retarded, or institution for mental disease that are (A) authorized for the individual by a physician in accordance with a plan of treatment or (at the option of the State) otherwise authorized for the individual in accordance with a service plan approved by the State, (B) provided by an individual who is qualified to provide such services and who is not a member of the individual's family, and (C) furnished in a home or other location;

(25) primary care case management services (as defined in subsection (t));

(26) services furnished under a PACE program under section 1934 to PACE program eligible individuals enrolled under the program under such section;

(27) subject to subsection (x), primary and secondary medical strategies and treatment and services for individuals who have Sickle Cell Disease;

(28) freestanding birth center services (as defined in subsection (l)(3)(A)) and other ambulatory services that are offered by a freestanding birth center (as defined in subsection (l)(3)(B)) and that are otherwise included in the plan; **[**and**]**

*(29) subject to paragraph (2) of subsection (ee), for the period beginning October 1, 2020, and ending September 30, 2025, medication-assisted treatment (as defined in paragraph (1) of such subsection); and*

**[**(29)**]** *(30)* any other medical care, and any other type of remedial care recognized under State law, specified by the Secretary,

except as otherwise provided in paragraph (16), such term does not include—

(A) any such payments with respect to care or services for any individual who is an inmate of a public institution (except as a patient in a medical institution); or

(B) any such payments with respect to care or services for any individual who has not attained 65 years of age and who is a patient in an institution for mental diseases.

For purposes of clause (vi) of the preceding sentence, a person shall be considered essential to another individual if such person is the spouse of and is living with such individual, the needs of

such person are taken into account in determining the amount of aid or assistance furnished to such individual (under a State plan approved under title I, X, XIV, or XVI), and such person is determined, under such a State plan, to be essential to the well-being of such individual. The payment described in the first sentence may include expenditures for medicare cost-sharing and for premiums under part B of title XVIII for individuals who are eligible for medical assistance under the plan and (A) are receiving aid or assistance under any plan of the State approved under title I, X, XIV, or XVI, or part A of title IV, or with respect to whom supplemental security income benefits are being paid under title XVI, or (B) with respect to whom there is being paid a State supplementary payment and are eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1902(a)(10)(A), and, except in the case of individuals 65 years of age or older and disabled individuals entitled to health insurance benefits under title XVIII who are not enrolled under part B of title XVIII, other insurance premiums for medical or any other type of remedial care or the cost thereof. No service (including counseling) shall be excluded from the definition of "medical assistance" solely because it is provided as a treatment service for alcoholism or drug dependency.

(b) Subject to subsections (y), (z), and (aa) and section 1933(d), the term "Federal medical assistance percentage" for any State shall be 100 per centum less the State percentage; and the State percentage shall be that percentage which bears the same ratio to 45 per centum as the square of the per capita income of such State bears to the square of the per capita income of the continental United States (including Alaska) and Hawaii; except that (1) the Federal medical assistance percentage shall in no case be less than 50 per centum or more than 83 per centum, (2) the Federal medical assistance percentage for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be 55 percent, (3) for purposes of this title and title XXI, the Federal medical assistance percentage for the District of Columbia shall be 70 percent, (4) the Federal medical assistance percentage shall be equal to the enhanced FMAP described in section 2105(b) with respect to medical assistance provided to individuals who are eligible for such assistance only on the basis of section 1902(a)(10)(A)(ii)(XVIII), and (5) in the case of a State that provides medical assistance for services and vaccines described in subparagraphs (A) and (B) of subsection (a)(13), and prohibits cost-sharing for such services and vaccines, the Federal medical assistance percentage, as determined under this subsection and subsection (y) (without regard to paragraph (1)(C) of such subsection), shall be increased by 1 percentage point with respect to medical assistance for such services and vaccines and for items and services described in subsection (a)(4)(D). The Federal medical assistance percentage for any State shall be determined and promulgated in accordance with the provisions of section 1101(a)(8)(B). Notwithstanding the first sentence of this section, the Federal medical assistance percentage shall be 100 per centum with respect to amounts expended as medical assistance for services which are received through an Indian Health Service facility whether operated by the Indian Health Service or by an Indian tribe or tribal organization (as defined in section 4 of the Indian Health Care Improvement Act). Notwithstanding the first sentence of this subsection, in the case of a State plan that meets the condition described in subsection (u)(1), with respect to expenditures (other than expenditures under section 1923) described in subsection (u)(2)(A) or subsection (u)(3) for the State for a fiscal year, and that do not exceed the amount of the State's available allotment under section 2104, the Federal medical assistance percentage is equal to the enhanced FMAP described in section 2105(b).

(c) For definition of the term "nursing facility", see section 1919(a).

(d) The term "intermediate care facility for the mentally retarded" means an institution (or distinct part thereof) for the mentally retarded or persons with related conditions if—

(1) the primary purpose of such institution (or distinct part thereof) is to provide health or rehabilitative services for mentally retarded individuals and the institution meets such standards as may be prescribed by the Secretary;

(2) the mentally retarded individual with respect to whom a request for payment is made under a plan approved under this title is receiving active treatment under such a program; and

(3) in the case of a public institution, the State or political subdivision responsible for the operation of such institution has agreed that the non-Federal expenditures in any calendar quarter prior to January 1, 1975, with respect to services furnished to patients in such institution (or distinct part thereof) in the State will not, because of payments made under this title, be reduced below the average amount expended for such services in such institution in the four quarters immediately preceding the quarter in which the State in which such institution is located elected to make such services available under its plan approved under this title.

(e) In the case of any State the State plan of which (as approved under this title)—

(1) does not provide for the payment of services (other than services covered under section 1902(a)(12)) provided by an optometrist; but

(2) at a prior period did provide for the payment of services referred to in paragraph (1); the term "physicians' services" (as used in subsection (a)(5)) shall include services of the type which an optometrist is legally authorized to perform where the State plan specifically provides that the term "physicians' services", as employed in such plan, includes services of the type which an optometrist is legally authorized to perform, and shall be reimbursed whether furnished by a physician or an optometrist.

(f) For purposes of this title, the term "nursing facility services" means services which are or were required to be given an individual who needs or needed on a daily basis nursing care (provided directly by or requiring the supervision of nursing personnel) or other rehabilitation services which as a practical matter can only be provided in a nursing facility on an inpatient basis.

(g) If the State plan includes provision of chiropractors' services, such services include only—

(1) services provided by a chiropractor (A) who is licensed as such by the State and (B) who meets uniform minimum standards promulgated by the Secretary under section 1861(r)(5); and

(2) services which consist of treatment by means of manual manipulation of the spine which the chiropractor is legally authorized to perform by the State.

(h)(1) For purposes of paragraph (16) of subsection (a), the term "inpatient psychiatric hospital services for individuals under age 21" includes only—

(A) inpatient services which are provided in an institution (or distinct part thereof) which is a psychiatric hospital as defined in section 1861(f) or in another inpatient setting that the Secretary has specified in regulations;

(B) inpatient services which, in the case of any individual (i) involve active treatment which meets such standards as may be prescribed in regulations by the Secretary, and (ii) a team, consisting of physicians and other personnel qualified to make determinations with respect to mental health conditions and the treatment thereof, has determined are necessary on an inpatient basis and can reasonably be expected to improve the condition, by reason of which such services are necessary, to the extent that eventually such services will no longer be necessary; and

(C) inpatient services which, in the case of any individual, are provided prior to (i) the date such individual attains age 21, or (ii) in the case of an individual who was receiving such services in the period immediately preceding the date on which he attained age 21, (I) the date such individual no longer requires such services, or (II) if earlier, the date such individual attains age 22;

(2) Such term does not include services provided during any calendar quarter under the State plan of any State if the total amount of the funds expended, during such quarter, by the State (and the political subdivisions thereof) from non-Federal funds for inpatient services included under paragraph (1), and for active psychiatric care and treatment provided on an outpatient basis for eligible mentally ill children, is less than the average quarterly amount of the funds expended, during the 4-quarter period ending December 31, 1971, by the State (and the political subdivisions thereof) from non-Federal funds for such services.

(i) The term "institution for mental diseases" means a hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services.

(j) The term "State supplementary payment" means any cash payment made by a State on a regular basis to an individual who is receiving supplemental security income benefits under title XVI or who would but for his income be eligible to receive such benefits, as assistance based on need in supplementation of such benefits (as determined by the Commissioner of Social Security), but only to the extent that such payments are made with respect to an individual with respect to whom supplemental security income benefits are payable under title XVI, or would but for his income be payable under that title.

(k) Increased supplemental security income benefits payable pursuant to section 211 of Public Law 93-66 shall not be considered supplemental security income benefits payable under title XVI.

(l)(1) The terms "rural health clinic services" and "rural health clinic" have the meanings given such terms in section 1861(aa), except that (A) clause (ii) of section 1861(aa)(2) shall not apply to such terms, and (B) the physician arrangement required under section 1861(aa)(2)(B) shall only apply with respect to rural health clinic services and, with respect to other ambulatory care serv-

ices, the physician arrangement required shall be only such as may be required under the State plan for those services.

(2)(A) The term "Federally-qualified health center services" means services of the type described in subparagraphs (A) through (C) of section 1861(aa)(1) when furnished to an individual as an patient of a Federally-qualified health center and, for this purpose, any reference to a rural health clinic or a physician described in section 1861(aa)(2)(B) is deemed a reference to a Federally-qualified health center or a physician at the center, respectively.

(B) The term "Federally-qualified health center" means an entity which—

(i) is receiving a grant under section 330 of the Public Health Service Act,

(ii)(I) is receiving funding from such a grant under a contract with the recipient of such a grant, and

(II) meets the requirements to receive a grant under section 330 of such Act,

(iii) based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant, including requirements of the Secretary that an entity may not be owned, controlled, or operated by another entity, or

(iv) was treated by the Secretary, for purposes of part B of title XVIII, as a comprehensive Federally funded health center as of January 1, 1990;

and includes an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act (Public Law 93-638) or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services. In applying clause (ii), the Secretary may waive any requirement referred to in such clause for up to 2 years for good cause shown.

(3)(A) The term "freestanding birth center services" means services furnished to an individual at a freestanding birth center (as defined in subparagraph (B)) at such center.

(B) The term "freestanding birth center" means a health facility—

(i) that is not a hospital;

(ii) where childbirth is planned to occur away from the pregnant woman's residence;

(iii) that is licensed or otherwise approved by the State to provide prenatal labor and delivery or postpartum care and other ambulatory services that are included in the plan; and

(iv) that complies with such other requirements relating to the health and safety of individuals furnished services by the facility as the State shall establish.

(C) A State shall provide separate payments to providers administering prenatal labor and delivery or postpartum care in a freestanding birth center (as defined in subparagraph (B)), such as nurse midwives and other providers of services such as birth attendants recognized under State law, as determined appropriate by the Secretary. For purposes of the preceding sentence, the term "birth attendant" means an individual who is recognized or registered by the State involved to provide health care at childbirth and who provides such care within the scope of practice under which the individual is legally authorized to perform such care under State law (or the State regulatory mechanism provided by State law), regardless of whether the individual is under the supervision of, or associated with, a physician or other health care provider. Nothing in this subparagraph shall be construed as changing State law requirements applicable to a birth attendant.

(m)(1) Subject to paragraph (2), the term "qualified family member" means an individual (other than a qualified pregnant woman or child, as defined in subsection (n)) who is a member of a family that would be receiving aid under the State plan under part A of title IV pursuant to section 407 if the State had not exercised the option under section 407(b)(2)(B)(i).

(2) No individual shall be a qualified family member for any period after September 30, 1998.

(n) The term "qualified pregnant woman or child" means—

(1) a pregnant woman who—

(A) would be eligible for aid to families with dependent children under part A of title IV (or would be eligible for such aid if coverage under the State plan under part A of title IV included aid to families with dependent children of unemployed parents pursuant to section 407) if her child had been born and was living with her in the month such aid would be paid, and such pregnancy has been medically verified;

(B) is a member of a family which would be eligible for aid under the State plan under part A of title IV pursuant to section 407 if the plan required the payment of aid pursuant to such section; or

(C) otherwise meets the income and resources requirements of a State plan under part A of title IV; and

(2) a child who has not attained the age of 19, who was born after September 30, 1983 (or such earlier date as the State may designate), and who meets the income and resources requirements of the State plan under part A of title IV.

(o)(1)(A) Subject to subparagraphs (B) and (C), the term "hospice care" means the care described in section 1861(dd)(1) furnished by a hospice program (as defined in section 1861(dd)(2)) to a terminally ill individual who has voluntarily elected (in accordance with paragraph (2)) to have payment made for hospice care instead of having payment made for certain benefits described in section 1812(d)(2)(A) and for which payment may otherwise be made under title XVIII and intermediate care facility services under the plan. For purposes of such election, hospice care may be provided to an individual while such individual is a resident of a skilled nursing facility or intermediate care facility, but the only payment made under the State plan shall be for the hospice care.

(B) For purposes of this title, with respect to the definition of hospice program under section 1861(dd)(2), the Secretary may allow an agency or organization to make the assurance under subparagraph (A)(iii) of such section without taking into account any individual who is afflicted with acquired immune deficiency syndrome (AIDS).

(C) A voluntary election to have payment made for hospice care for a child (as defined by the State) shall not constitute a waiver of any rights of the child to be provided with, or to have payment made under this title for, services that are related to the treatment of the child's condition for which a diagnosis of terminal illness has been made.

(2) An individual's voluntary election under this subsection —

(A) shall be made in accordance with procedures that are established by the State and that are consistent with the procedures established under section 1812(d)(2);

(B) shall be for such a period or periods (which need not be the same periods described in section 1812(d)(1)) as the State may establish; and

(C) may be revoked at any time without a showing of cause and may be modified so as to change the hospice program with respect to which a previous election was made.

(3) In the case of an individual—

(A) who is residing in a nursing facility or intermediate care facility for the mentally retarded and is receiving medical assistance for services in such facility under the plan,

(B) who is entitled to benefits under part A of title XVIII and has elected, under section 1812(d), to receive hospice care under such part, and

(C) with respect to whom the hospice program under such title and the nursing facility or intermediate care facility for the mentally retarded have entered into a written agreement under which the program takes full responsibility for the professional management of the individual's hospice care and the facility agrees to provide room and board to the individual,

instead of any payment otherwise made under the plan with respect to the facility's services, the State shall provide for payment to the hospice program of an amount equal to the additional amount determined in section 1902(a)(13)(B) and, if the individual is an individual described in section 1902(a)(10)(A), shall provide for payment of any coinsurance amounts imposed under section 1813(a)(4).

(p)(1) The term "qualified medicare beneficiary" means an individual—

(A) who is entitled to hospital insurance benefits under part A of title XVIII (including an individual entitled to such benefits pursuant to an enrollment under section 1818, but not including an individual entitled to such benefits only pursuant to an enrollment under section 1818A),

(B) whose income (as determined under section 1612 for purposes of the supplemental security income program, except as provided in paragraph (2)(D)) does not exceed an income level established by the State consistent with paragraph (2), and

(C) whose resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed twice the maximum amount of resources that an individual may have and obtain benefits under that program or, effective beginning with January 1, 2010, whose resources (as so determined) do not exceed the maximum resource level applied for the year under subparagraph (D) of section 1860D–14(a)(3) (determined without regard to the life insurance policy exclusion provided under subparagraph (G) of such section) applicable to an individual or to the individual and the individual's spouse (as the case may be).

(2)(A) The income level established under paragraph (1)(B) shall be at least the percent provided under subparagraph (B) (but not more than 100 percent) of the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section

673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

(B) Except as provided in subparagraph (C), the percent provided under this clause, with respect to eligibility for medical assistance on or after—

(i) January 1, 1989, is 85 percent,

(ii) January 1, 1990, is 90 percent, and

(iii) January 1, 1991, is 100 percent.

(C) In the case of a State which has elected treatment under section 1902(f) and which, as of January 1, 1987, used an income standard for individuals age 65 or older which was more restrictive than the income standard established under the supplemental security income program under title XVI, the percent provided under subparagraph (B), with respect to eligibility for medical assistance on or after—

(i) January 1, 1989, is 80 percent,

(ii) January 1, 1990, is 85 percent,

(iii) January 1, 1991, is 95 percent, and

(iv) January 1, 1992, is 100 percent.

(D)(i) In determining under this subsection the income of an individual who is entitled to monthly insurance benefits under title II for a transition month (as defined in clause (ii)) in a year, such income shall not include any amounts attributable to an increase in the level of monthly insurance benefits payable under such title which have occurred pursuant to section 215(i) for benefits payable for months beginning with December of the previous year.

(ii) For purposes of clause (i), the term "transition month" means each month in a year through the month following the month in which the annual revision of the official poverty line, referred to in subparagraph (A), is published.

(3) The term "medicare cost-sharing" means (subject to section 1902(n)(2)) the following costs incurred with respect to a qualified medicare beneficiary, without regard to whether the costs incurred were for items and services for which medical assistance is otherwise available under the plan:

(A)(i) premiums under section 1818 or 1818A, and

(ii) premiums under section 1839,

(B) Coinsurance under title XVIII (including coinsurance described in section 1813).

(C) Deductibles established under title XVIII (including those described in section 1813 and section 1833(b)).

(D) The difference between the amount that is paid under section 1833(a) and the amount that would be paid under such section if any reference to "80 percent" therein were deemed a reference to "100 percent".

Such term also may include, at the option of a State, premiums for enrollment of a qualified medicare beneficiary with an eligible organization under section 1876.

(4) Notwithstanding any other provision of this title, in the case of a State (other than the 50 States and the District of Columbia)—

(A) the requirement stated in section 1902(a)(10)(E) shall be optional, and

(B) for purposes of paragraph (2), the State may substitute for the percent provided under subparagraph (B) of such paragraph or 1902(a)(10)(E)(iii) any percent.

In the case of any State which is providing medical assistance to its residents under a waiver granted under section 1115, the Secretary shall require the State to meet the requirement of section 1902(a)(10)(E) in the same manner as the State would be required to meet such requirement if the State had in effect a plan approved under this title.

(5)(A) The Secretary shall develop and distribute to States a simplified application form for use by individuals (including both qualified medicare beneficiaries and specified low-income medicare beneficiaries) in applying for medical assistance for medicare cost-sharing under this title in the States which elect to use such form. Such form shall be easily readable by applicants and uniform nationally. The Secretary shall provide for the translation of such application form into at least the 10 languages (other than English) that are most often used by individuals applying for hospital insurance benefits under section 226 or 226A and shall make the translated forms available to the States and to the Commissioner of Social Security.

(B) In developing such form, the Secretary shall consult with beneficiary groups and the States.

(6) For provisions relating to outreach efforts to increase awareness of the availability of medicare cost-sharing, see section 1144.

(q) The term "qualified severely impaired individual" means an individual under age 65—

(1) who for the month preceding the first month to which this subsection applies to such individual—

(A) received (i) a payment of supplemental security income benefits under section 1611(b) on the basis of blindness or disability, (ii) a supplementary payment under section 1616 of this Act or under section 212 of Public Law 93-66 on such basis, (iii) a payment of monthly benefits under section 1619(a), or (iv) a supplementary payment under section 1616(c)(3), and

(B) was eligible for medical assistance under the State plan approved under this title; and

(2) with respect to whom the Commissioner of Social Security determines that—

(A) the individual continues to be blind or continues to have the disabling physical or mental impairment on the basis of which he was found to be under a disability and, except for his earnings, continues to meet all non-disability-related requirements for eligibility for benefits under title XVI,

(B) the income of such individual would not, except for his earnings, be equal to or in excess of the amount which would cause him to be ineligible for payments under section 1611(b) (if he were otherwise eligible for such payments),

(C) the lack of eligibility for benefits under this title would seriously inhibit his ability to continue or obtain employment, and

(D) the individual's earnings are not sufficient to allow him to provide for himself a reasonable equivalent of the benefits under title XVI (including any federally administered State supplementary payments), this title, and publicly funded attendant care services (including personal care assistance) that would be available to him in the absence of such earnings.

In the case of an individual who is eligible for medical assistance pursuant to section 1619(b) in June, 1987, the individual shall be a qualified severely impaired individual for so long as such individual meets the requirements of paragraph (2).

(r) The term "early and periodic screening, diagnostic, and treatment services" means the following items and services:

(1) Screening services—

(A) which are provided—

(i) at intervals which meet reasonable standards of medical and dental practice, as determined by the State after consultation with recognized medical and dental organizations involved in child health care and, with respect to immunizations under subparagraph (B)(iii), in accordance with the schedule referred to in section 1928(c)(2)(B)(i) for pediatric vaccines, and

(ii) at such other intervals, indicated as medically necessary, to determine the existence of certain physical or mental illnesses or conditions; and

(B) which shall at a minimum include—

(i) a comprehensive health and developmental history (including assessment of both physical and mental health development),

(ii) a comprehensive unclothed physical exam,

(iii) appropriate immunizations (according to the schedule referred to in section 1928(c)(2)(B)(i) for pediatric vaccines) according to age and health history,

(iv) laboratory tests (including lead blood level assessment appropriate for age and risk factors), and

(v) health education (including anticipatory guidance).

(2) Vision services—

(A) which are provided—

(i) at intervals which meet reasonable standards of medical practice, as determined by the State after consultation with recognized medical organizations involved in child health care, and

(ii) at such other intervals, indicated as medically necessary, to determine the existence of a suspected illness or condition; and

(B) which shall at a minimum include diagnosis and treatment for defects in vision, including eyeglasses.

(3) Dental services—

(A) which are provided—

(i) at intervals which meet reasonable standards of dental practice, as determined by the State after consultation with recognized dental organizations involved in child health care, and

(ii) at such other intervals, indicated as medically necessary, to determine the existence of a suspected illness or condition; and

(B) which shall at a minimum include relief of pain and infections, restoration of teeth, and maintenance of dental health.

(4) Hearing services—

(A) which are provided—

(i) at intervals which meet reasonable standards of medical practice, as determined by the State after consultation with recognized medical organizations involved in child health care, and

(ii) at such other intervals, indicated as medically necessary, to determine the existence of a suspected illness or condition; and

(B) which shall at a minimum include diagnosis and treatment for defects in hearing, including hearing aids.

(5) Such other necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan.

Nothing in this title shall be construed as limiting providers of early and periodic screening, diagnostic, and treatment services to providers who are qualified to provide all of the items and services described in the previous sentence or as preventing a provider that is qualified under the plan to furnish one or more (but not all) of such items or services from being qualified to provide such items and services as part of early and periodic screening, diagnostic, and treatment services. The Secretary shall, not later than July 1, 1990, and every 12 months thereafter, develop and set annual participation goals for each State for participation of individuals who are covered under the State plan under this title in early and periodic screening, diagnostic, and treatment services.

(s) The term "qualified disabled and working individual" means an individual—

(1) who is entitled to enroll for hospital insurance benefits under part A of title XVIII under section 1818A (as added by 6012 of the Omnibus Budget Reconciliation Act of 1989);

(2) whose income (as determined under section 1612 for purposes of the supplemental security income program) does not exceed 200 percent of the official poverty line (as defined by the Office of Management and Budget and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved;

(3) whose resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed twice the maximum amount of resources that an individual or a couple (in the case of an individual with a spouse) may have and obtain benefits for supplemental security income benefits under title XVI; and

(4) who is not otherwise eligible for medical assistance under this title.

(t)(1) The term "primary care case management services" means case-management related services (including locating, coordinating, and monitoring of health care services) provided by a primary care case manager under a primary care case management contract.

(2) The term "primary care case manager" means any of the following that provides services of the type described in paragraph (1) under a contract referred to in such paragraph:

(A) A physician, a physician group practice, or an entity employing or having other arrangements with physicians to provide such services.

(B) At State option—

(i) a nurse practitioner (as described in section 1905(a)(21));

(ii) a certified nurse-midwife (as defined in section 1861(gg)); or

(iii) a physician assistant (as defined in section 1861(aa)(5)).

(3) The term "primary care case management contract" means a contract between a primary care case manager and a State under which the manager undertakes to locate, coordinate, and monitor covered primary care (and such other covered services as may be specified under the contract) to all individuals enrolled with the manager, and which—

(A) provides for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment with respect to medical emergencies;

(B) restricts enrollment to individuals residing sufficiently near a service delivery site of the manager to be able to reach that site within a reasonable time using available and affordable modes of transportation;

(C) provides for arrangements with, or referrals to, sufficient numbers of physicians and other appropriate health care professionals to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care;

(D) prohibits discrimination on the basis of health status or requirements for health care services in enrollment, disenrollment, or reenrollment of individuals eligible for medical assistance under this title;

(E) provides for a right for an enrollee to terminate enrollment in accordance with section 1932(a)(4); and

(F) complies with the other applicable provisions of section 1932.

(4) For purposes of this subsection, the term "primary care" includes all health care services customarily provided in accordance with State licensure and certification laws and regulations, and all laboratory services customarily provided by or through, a general practitioner, family medicine physician, internal medicine physician, obstetrician/gynecologist, or pediatrician.

(u)(1) The conditions described in this paragraph for a State plan are as follows:

(A) The State is complying with the requirement of section 2105(d)(1).

(B) The plan provides for such reporting of information about expenditures and payments attributable to the operation of this subsection as the Secretary deems necessary in order to carry out the fourth sentence of subsection (b).

(2)(A) For purposes of subsection (b), the expenditures described in this subparagraph are expenditures for medical assistance for optional targeted low-income children described in subparagraph (B).

(B) For purposes of this paragraph, the term "optional targeted low-income child" means a targeted low-income child as defined in section 2110(b)(1) (determined without regard to that portion of subparagraph (C) of such section concerning eligibility for medical assistance under this title) who would not qualify for medical assistance under the State plan under this title as in effect on March 31, 1997 (but taking into account the expansion of age of eligibility effected through the operation of section 1902(l)(1)(D)). Such term excludes any child eligible for medical assistance only by reason of section 1902(a)(10)(A)(ii)(XIX).

(3) For purposes of subsection (b), the expenditures described in this paragraph are expenditures for medical assistance for children who are born before October 1, 1983, and who would be described in section 1902(l)(1)(D) if they had been born on or after such date, and who are not eligible for such assistance under the State plan under this title based on such State plan as in effect as of March 31, 1997.

(4) The limitations on payment under subsections (f) and (g) of section 1108 shall not apply to Federal payments made under section 1903(a)(1) based on an enhanced FMAP described in section 2105(b).

(v)(1) The term "employed individual with a medically improved disability" means an individual who—

(A) is at least 16, but less than 65, years of age;

(B) is employed (as defined in paragraph (2));

(C) ceases to be eligible for medical assistance under section 1902(a)(10)(A)(ii)(XV) because the individual, by reason of medical improvement, is determined at the time of a regularly scheduled continuing disability review to no longer be eligible for benefits under section 223(d) or 1614(a)(3); and

(D) continues to have a severe medically determinable impairment, as determined under regulations of the Secretary.

(2) For purposes of paragraph (1), an individual is considered to be "employed" if the individual—

(A) is earning at least the applicable minimum wage requirement under section 6 of the Fair Labor Standards Act (29 U.S.C. 206) and working at least 40 hours per month; or

(B) is engaged in a work effort that meets substantial and reasonable threshold criteria for hours of work, wages, or other measures, as defined by the State and approved by the Secretary.'

(w)(1) For purposes of this title, the term "independent foster care adolescent" means an individual—

(A) who is under 21 years of age;

(B) who, on the individual's 18th birthday, was in foster care under the responsibility of a State; and

(C) whose assets, resources, and income do not exceed such levels (if any) as the State may establish consistent with paragraph (2).

(2) The levels established by a State under paragraph (1)(C) may not be less than the corresponding levels applied by the State under section 1931(b).

(3) A State may limit the eligibility of independent foster care adolescents under section 1902(a)(10)(A)(ii)(XVII) to those individuals with respect to whom foster care maintenance payments or independent living services were furnished under a program funded under part E of title IV before the date the individuals attained 18 years of age.

(x) For purposes of subsection (a)(27), the strategies, treatment, and services described in that subsection include the following:

(1) Chronic blood transfusion (with deferoxamine chelation) to prevent stroke in individuals with Sickle Cell Disease who have been identified as being at high risk for stroke.

(2) Genetic counseling and testing for individuals with Sickle Cell Disease or the sickle cell trait to allow health care professionals to treat such individuals and to prevent symptoms of Sickle Cell Disease.

(3) Other treatment and services to prevent individuals who have Sickle Cell Disease and who have had a stroke from having another stroke.

(y) INCREASED FMAP FOR MEDICAL ASSISTANCE FOR NEWLY ELIGIBLE MANDATORY INDIVIDUALS.—

(1) AMOUNT OF INCREASE.—Notwithstanding subsection (b), the Federal medical assistance percentage for a State that is one of the 50 States or the District of Columbia, with respect to amounts expended by such State for medical assistance for newly eligible individuals described in subclause (VIII) of section 1902(a)(10)(A)(i), shall be equal to—

(A) 100 percent for calendar quarters in 2014, 2015, and 2016;

(B) 95 percent for calendar quarters in 2017;

(C) 94 percent for calendar quarters in 2018;

(D) 93 percent for calendar quarters in 2019; and

(E) 90 percent for calendar quarters in 2020 and each year thereafter.

(2) DEFINITIONS.—In this subsection:

(A) NEWLY ELIGIBLE.—The term "newly eligible" means, with respect to an individual described in subclause (VIII) of section 1902(a)(10)(A)(i), an individual who is not under 19 years of age (or such higher age as the State may have elected) and who, as of December 1, 2009, is not eligible under the State plan or under a waiver of the plan for full benefits or for benchmark coverage described in subparagraph (A), (B), or (C) of section 1937(b)(1) or benchmark equivalent coverage described in section 1937(b)(2) that has an aggregate actuarial value that is at least actuarially equivalent to benchmark coverage described in subparagraph (A), (B), or (C) of section 1937(b)(1), or is eligible but not enrolled (or is on a waiting list) for such benefits or coverage through a waiver under the plan that has a capped or limited enrollment that is full.

(B) FULL BENEFITS.—The term "full benefits" means, with respect to an individual, medical assistance for all services covered under the State plan under this title that is not less in amount, duration, or scope, or is determined by the Secretary to be substantially equivalent, to the medical assistance available for an individual described in section 1902(a)(10)(A)(i).

(z) EQUITABLE SUPPORT FOR CERTAIN STATES.—

(1)(A) During the period that begins on January 1, 2014, and ends on December 31, 2015, notwithstanding subsection (b), the Federal medical assistance percentage otherwise determined under subsection (b) with respect to a fiscal year occurring during that period shall be increased by 2.2 percentage points for any State described in subparagraph (B) for amounts expended for medical assistance for individuals who are not newly eligible (as defined in subsection (y)(2)) individuals described in subclause (VIII) of section 1902(a)(10)(A)(i).

(B) For purposes of subparagraph (A), a State described in this subparagraph is a State that—

(i) is an expansion State described in paragraph (3);

(ii) the Secretary determines will not receive any payments under this title on the basis of an increased Federal medical assistance percentage under subsection (y) for expenditures for medical assistance for newly eligible individuals (as so defined); and

(iii) has not been approved by the Secretary to divert a portion of the DSH allotment for a State to the costs of providing medical assistance or other health benefits coverage under a waiver that is in effect on July 2009.

(2)(A) For calendar quarters in 2014 and each year thereafter, the Federal medical assistance percentage otherwise determined under subsection (b) for an expansion State described in paragraph (3) with respect to medical assistance for individuals described in section 1902(a)(10)(A)(i)(VIII) who are nonpregnant childless adults with respect to whom the State may require enrollment in benchmark coverage under section 1937 shall be equal to the percent specified in subparagraph (B)(i) for such year.

(B)(i) The percent specified in this subparagraph for a State for a year is equal to the Federal medical assistance percentage (as defined in the first sentence of subsection (b)) for the State increased by a number of percentage points equal to the transition percentage (specified in clause (ii) for the year) of the number of percentage points by which—

(I) such Federal medical assistance percentage for the State, is less than

(II) the percent specified in subsection (y)(1) for the year.

(ii) The transition percentage specified in this clause for—

(I) 2014 is 50 percent;

(II) 2015 is 60 percent;

(III) 2016 is 70 percent;

(IV) 2017 is 80 percent;

(V) 2018 is 90 percent; and

(VI) 2019 and each subsequent year is 100 percent.

(3) A State is an expansion State if, on the date of the enactment of the Patient Protection and Affordable Care Act, the State offers health benefits coverage statewide to parents and nonpregnant, childless adults whose income is at least 100 percent of the poverty line, that includes inpatient hospital services, is not dependent on access to employer coverage, employer contribution, or employment and is not limited to premium assistance, hospital-only benefits, a high deductible health plan, or alternative benefits under a demonstration program authorized under section 1938. A State that offers health benefits coverage to only parents or only nonpregnant childless adults described in the preceding sentence shall not be considered to be an expansion State.

(aa)(1) Notwithstanding subsection (b), beginning January 1, 2011, the Federal medical assistance percentage for a fiscal year for a disaster-recovery FMAP adjustment State shall be equal to the following:

(A) In the case of the first fiscal year (or part of a fiscal year) for which this subsection applies to the State, the State's regular FMAP shall be increased by 50 percent of the number of percentage points by which the State's regular FMAP for such fiscal year is less than the Federal medical assistance percentage determined for the State for the preceding fiscal year after the application of only subsection (a) of section 5001 of Public Law 111–5 (if applicable to the preceding fiscal year) and without regard to this subsection, subsections (y) and (z), and subsections (b) and (c) of section 5001 of Public Law 111–5.

(B) In the case of the second or any succeeding fiscal year for which this subsection applies to the State, the State's regular FMAP for such fiscal year shall be increased by 25 percent (or 50 percent in the case of fiscal year 2013) of the number of percentage points by which the State's regular FMAP for such fiscal year is less than the Federal medical assistance percentage received by the State during the preceding fiscal year.

(2) In this subsection, the term "disaster-recovery FMAP adjustment State" means a State that is one of the 50 States or the District of Columbia, for which, at any time during the preceding 7 fiscal years, the President has declared a major disaster under section 401 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act and determined as a result of such disaster that every county or parish in the State warrant individual and public assistance or public assistance from the Federal Government under such Act and for which—

(A) in the case of the first fiscal year (or part of a fiscal year) for which this subsection applies to the State, the State's regular FMAP for the fiscal year is less than the Federal medical assistance percentage determined for the State for the preceding fiscal year after the application of only subsection (a) of section 5001 of Public Law 111–5 (if applicable to the preceding fiscal year) and without regard to this subsection, subsections (y) and (z), and subsections (b) and (c) of section 5001 of Public Law 111–5, by at least 3 percentage points; and

(B) in the case of the second or any succeeding fiscal year for which this subsection applies to the State, the State's regular FMAP for the fiscal year is less than the Federal medical assistance percentage determined for the State for the preceding fiscal year under this subsection by at least 3 percentage points.

(3) In this subsection, the term "regular FMAP" means, for each fiscal year for which this subsection applies to a State, the Federal medical assistance percentage that would otherwise apply to the State for the fiscal year, as determined under subsection (b) and without regard to this subsection, subsections (y) and (z), and section 10202 of the Patient Protection and Affordable Care Act.

(4) The Federal medical assistance percentage determined for a disaster-recovery FMAP adjustment State under paragraph (1) shall apply for purposes of this title (other than with respect to disproportionate share hospital payments described in section 1923 and payments under this title that are based on the enhanced FMAP described in 2105(b)) and shall not apply with respect to payments under title IV (other than under part E of title IV) or payments under title XXI.

(bb)(1) For purposes of this title, the term "counseling and pharmacotherapy for cessation of tobacco use by pregnant women" means diagnostic, therapy, and counseling services and pharmacotherapy (including the coverage of prescription and nonprescription tobacco cessation agents approved by the Food and Drug Administration) for cessation of tobacco use by pregnant women who use tobacco products or who are being treated for tobacco use that is furnished—

(A) by or under the supervision of a physician; or

(B) by any other health care professional who—

(i) is legally authorized to furnish such services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished; and

(ii) is authorized to receive payment for other services under this title or is designated by the Secretary for this purpose.

(2) Subject to paragraph (3), such term is limited to—

(A) services recommended with respect to pregnant women in "Treating Tobacco Use and Dependence: 2008 Update: A Clinical Practice Guideline", published by the Public Health Service in May 2008, or any subsequent modification of such Guideline; and

(B) such other services that the Secretary recognizes to be effective for cessation of tobacco use by pregnant women.

(3) Such term shall not include coverage for drugs or biologicals that are not otherwise covered under this title.

(cc) REQUIREMENT FOR CERTAIN STATES.—Notwithstanding subsections (y), (z), and (aa), in the case of a State that requires political subdivisions within the State to contribute toward the non-Federal share of expenditures required under the State plan under section 1902(a)(2), the State shall not be eligible for an increase in its Federal medical assistance percentage under such subsections if it requires that political subdivisions pay a greater percentage of the non-Federal share of such expenditures, or a greater percentage of the non-Federal share of payments under section 1923, than the respective percentages that would have been required by the State under the State plan under this title, State law, or both, as in effect on December 31, 2009, and without regard to any such increase. Voluntary contributions by a political subdivision to the non-Federal share of expenditures under the State plan under this title or to the non-Federal share of payments under section 1923, shall not be considered to be required contributions for purposes of this subsection. The treatment of voluntary contributions, and the treatment of contributions required by a State under the State plan under this title, or State law, as provided by this subsection, shall also apply to the increases in the Federal medical assistance percentage under section 5001 of the American Recovery and Reinvestment Act of 2009.

(dd) INCREASED FMAP FOR ADDITIONAL EXPENDITURES FOR PRIMARY CARE SERVICES.—Notwithstanding subsection (b), with respect to the portion of the amounts expended for medical assistance for services described in section 1902(a)(13)(C) furnished on or after January 1, 2013, and before January 1, 2015, that is attributable to the amount by which the minimum payment rate required under such section (or, by application, section 1932(f)) exceeds the payment rate applicable to such services under the State plan as of July 1, 2009, the Federal medical assistance percentage for a State that is one of the 50 States or the District of Columbia shall be equal to 100 percent. The preceding sentence does not prohibit the payment of Federal financial participation based on the Federal medical assistance percentage for amounts in excess of those specified in such sentence.

*(ee) MEDICATION-ASSISTED TREATMENT.—*

*(1) DEFINITION.—For purposes of subsection (a)(29), the term "medication-assisted treatment"—*

*(A) means all drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), including methadone, and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) to treat opioid use disorders; and*

*(B) includes, with respect to the provision of such drugs and biological products, counseling services and behavioral therapy.*

*(2) EXCEPTION.—The provisions of paragraph (29) of subsection (a) shall not apply with respect to a State for the period specified in such paragraph, if before the beginning of such period the State certifies to the satisfaction of the Secretary that implementing such provisions statewide for all individuals eligible to enroll in the State plan (or waiver of the State plan) would not be feasible by reason of a shortage of qualified providers of medication-assisted treatment, or facilities providing such treatment, that will contract with the State or a managed care entity with which the State has a contract under section 1903(m) or under section 1905(t)(3).*

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PAYMENT FOR COVERED OUTPATIENT DRUGS

SEC. 1927. (a) REQUIREMENT FOR REBATE AGREEMENT.—

(1) IN GENERAL.—In order for payment to be available under section 1903(a) or under part B of title XVIII for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of title VI of the Veterans Health Care Act of 1992) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(2) EFFECTIVE DATE.—Paragraph (1) shall first apply to drugs dispensed under this title on or after January 1, 1991.

(3) AUTHORIZING PAYMENT FOR DRUGS NOT COVERED UNDER REBATE AGREEMENTS.—Paragraph (1), and section 1903(i)(10)(A), shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d), or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

(4) EFFECT ON EXISTING AGREEMENTS.—In the case of a rebate agreement in effect between a State and a manufacturer on the date of the enactment of this section, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this title. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on the date of the enactment of this section provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under

the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

(5) LIMITATION ON PRICES OF DRUGS PURCHASED BY COVERED ENTITIES.—

(A) AGREEMENT WITH SECRETARY.—A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 340B of the Public Health Service Act with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this paragraph.

(B) COVERED ENTITY DEFINED.—In this subsection, the term "covered entity" means an entity described in section 340B(a)(4) of the Public Health Service Act.

(C) ESTABLISHMENT OF ALTERNATIVE MECHANISM TO ENSURE AGAINST DUPLICATE DISCOUNTS OR REBATES.—If the Secretary does not establish a mechanism under section 340B(a)(5)(A) of the Public Health Service Act within 12 months of the date of the enactment of such section, the following requirements shall apply:

(i) ENTITIES.—Each covered entity shall inform the single State agency under section 1902(a)(5) when it is seeking reimbursement from the State plan for medical assistance described in section 1905(a)(12) with respect to a unit of any covered outpatient drug which is subject to an agreement under section 340B(a) of such Act.

(ii) STATE AGENCY.—Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 340B of such Act, and not submit to any manufacturer a claim for a rebate payment under subsection (b) with respect to such a drug.

(D) EFFECT OF SUBSEQUENT AMENDMENTS.—In determining whether an agreement under subparagraph (A) meets the requirements of section 340B of the Public Health Service Act, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992.

(E) DETERMINATION OF COMPLIANCE.—A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 340B of the Public Health Service Act (as in effect immediately after the enactment of this paragraph, and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after the date of the enactment of this paragraph.

(6) REQUIREMENTS RELATING TO MASTER AGREEMENTS FOR DRUGS PROCURED BY DEPARTMENT OF VETERANS AFFAIRS AND CERTAIN OTHER FEDERAL AGENCIES.—

(A) IN GENERAL.—A manufacturer meets the requirements of this paragraph if the manufacturer complies with the provisions of section 8126 of title 38, United States Code, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

(B) EFFECT OF SUBSEQUENT AMENDMENTS.—In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of title 38, United States Code, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992.

(C) DETERMINATION OF COMPLIANCE.—A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of title 38, United States Code (as in effect immediately after the enactment of this paragraph) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after the date of the enactment of this paragraph.

(7) REQUIREMENT FOR SUBMISSION OF UTILIZATION DATA FOR CERTAIN PHYSICIAN ADMINISTERED DRUGS.—

(A) SINGLE SOURCE DRUGS.—In order for payment to be available under section 1903(a) for a covered outpatient drug that is a single source drug that is physician administered under this title (as determined by the Secretary), and that is administered on or after January 1, 2006, the State shall provide for the collection and submission of such

utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section for drugs administered for which payment is made under this title.

(B) MULTIPLE SOURCE DRUGS.—

(i) IDENTIFICATION OF MOST FREQUENTLY PHYSICIAN ADMINISTERED MULTIPLE SOURCE DRUGS.—Not later than January 1, 2007, the Secretary shall publish a list of the 20 physician administered multiple source drugs that the Secretary determines have the highest dollar volume of physician administered drugs dispensed under this title. The Secretary may modify such list from year to year to reflect changes in such volume.

(ii) REQUIREMENT.—In order for payment to be available under section 1903(a) for a covered outpatient drug that is a multiple source drug that is physician administered (as determined by the Secretary), that is on the list published under clause (i), and that is administered on or after January 1, 2008, the State shall provide for the submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section.

(C) USE OF NDC CODES.—Not later than January 1, 2007, the information shall be submitted under subparagraphs (A) and (B)(ii) using National Drug Code codes unless the Secretary specifies that an alternative coding system should be used.

(D) HARDSHIP WAIVER.—The Secretary may delay the application of subparagraph (A) or (B)(ii), or both, in the case of a State to prevent hardship to States which require additional time to implement the reporting system required under the respective subparagraph.

(b) TERMS OF REBATE AGREEMENT.—

(1) PERIODIC REBATES.—

(A) IN GENERAL.—A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title, a rebate for a rebate period in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period, including such drugs dispensed to individuals enrolled with a medicaid managed care organization if the organization is responsible for coverage of such drugs. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) OFFSET AGAINST MEDICAL ASSISTANCE.—Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) or an agreement described in subsection (a)(4)) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1).

(C) SPECIAL RULE FOR INCREASED MINIMUM REBATE PERCENTAGE.—

(i) IN GENERAL.—In addition to the amounts applied as a reduction under subparagraph (B), for rebate periods beginning on or after January 1, 2010, during a fiscal year, the Secretary shall reduce payments to a State under section 1903(a) in the manner specified in clause (ii), in an amount equal to the product of—

(I) 100 percent minus the Federal medical assistance percentage applicable to the rebate period for the State; and

(II) the amounts received by the State under such subparagraph that are attributable (as estimated by the Secretary based on utilization and other data) to the increase in the minimum rebate percentage effected by the amendments made by subsections (a)(1), (b), and (d) of section 2501 of the Patient Protection and Affordable Care Act, taking into account the additional drugs included under the amendments made by subsection (c) of section 2501 of such Act.

The Secretary shall adjust such payment reduction for a calendar quarter to the extent the Secretary determines, based upon subsequent utilization and other data, that the reduction for such quarter was greater or less than the amount of payment reduction that should have been made.

(ii) MANNER OF PAYMENT REDUCTION.—The amount of the payment reduction under clause (i) for a State for a quarter shall be deemed an overpayment to the State

under this title to be disallowed against the State's regular quarterly draw for all Medicaid spending under section 1903(d)(2). Such a disallowance is not subject to a reconsideration under section 1116(d).

(2) STATE PROVISION OF INFORMATION.—

(A) STATE RESPONSIBILITY.—Each State agency under this title shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, including such information reported by each medicaid managed care organization, and shall promptly transmit a copy of such report to the Secretary.

(B) AUDITS.—A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) MANUFACTURER PROVISION OF PRICE INFORMATION.—

(A) IN GENERAL.—Each manufacturer with an agreement in effect under this section shall report to the Secretary—

(i) not later than 30 days after the last day of each rebate period under the agreement—

(I) on the average manufacturer price (as defined in subsection (k)(1)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and

(II) for single source drugs and innovator multiple source drugs (including all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), on the manufacturer's best price (as defined in subsection (c)(1)(C)) for such drugs for the rebate period under the agreement;

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1)) as of October 1, 1990 for each of the manufacturer's covered outpatient drugs (including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and

(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size)—

(I) the manufacturer's average sales price (as defined in section 1847A(c)) and the total number of units specified under section 1847A(b)(2)(A);

(II) if required to make payment under section 1847A, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

(III) information on those sales that were made at a nominal price or otherwise described in section 1847A(c)(2)(B);

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1842(o)(1) or section 1881(b)(13)(A)(ii), and, for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs.

(iv) not later than 30 days after the last day of each month of a rebate period under the agreement, on the manufacturer's total number of units that are used to calculate the monthly average manufacturer price for each covered outpatient drug;

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services. Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v) (relating to the weighted average of the most recently reported monthly average manufacturer prices).

(B) VERIFICATION SURVEYS OF AVERAGE MANUFACTURER PRICE AND MANUFACTURER'S AVERAGE SALES PRICE.—The Secretary may survey wholesalers and manufacturers that di-

rectly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(C) PENALTIES.—

(i) FAILURE TO PROVIDE TIMELY INFORMATION.—In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

(ii) FALSE INFORMATION.—Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(D) CONFIDENTIALITY OF INFORMATION.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) (other than the wholesale acquisition cost for purposes of carrying out section 1847A) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section, to carry out section 1847A (including the determination and implementation of the payment amount), or to carry out section 1847B,

(ii) to permit the Comptroller General to review the information provided,

(iii) to permit the Director of the Congressional Budget Office to review the information provided,

(iv) to States to carry out this title, and

(v) to the Secretary to disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug in accordance with subsection (f).

The previous sentence shall also apply to information disclosed under section 1860D–2(d)(2) or 1860D–4(c)(2)(E) and drug pricing data reported under the first sentence of section 1860D–31(i)(1).

(4) LENGTH OF AGREEMENT.—

(A) IN GENERAL.—A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

(B) TERMINATION.—

(i) BY THE SECRETARY.—The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer

with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(ii) BY A MANUFACTURER.—A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

(iv) NOTICE TO STATES.—In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

(v) APPLICATION TO TERMINATIONS OF OTHER AGREEMENTS.—The provisions of this subparagraph shall apply to the terminations of agreements described in section 340B(a)(1) of the Public Health Service Act and master agreements described in section 8126(a) of title 38, United States Code.

(C) DELAY BEFORE REENTRY.—In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

(c) DETERMINATION OF AMOUNT OF REBATE.—

(1) BASIC REBATE FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS.—

(A) IN GENERAL.—Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8)) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of—

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of—

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

of or the rebate period.

(B) RANGE OF REBATES REQUIRED.—

(i) MINIMUM REBATE PERCENTAGE.—For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning—

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent;

(V) after December 31, 1995, and before January 1, 2010 is 15.1 percent;and

(VI) except as provided in clause (iii), after December 31, 2009, 23.1 percent.

(ii) TEMPORARY LIMITATION ON MAXIMUM REBATE AMOUNT.—In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning—

(I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

(iii) MINIMUM REBATE PERCENTAGE FOR CERTAIN DRUGS.—

(I) IN GENERAL.—In the case of a single source drug or an innovator multiple source drug described in subclause (II), the minimum rebate percentage for rebate periods specified in clause (i)(VI) is 17.1 percent.

(II) DRUG DESCRIBED.—For purposes of subclause (I), a single source drug or an innovator multiple source drug described in this subclause is any of the following drugs:

(aa) A clotting factor for which a separate furnishing payment is made under section 1842(o)(5) and which is included on a list of such factors specified and updated regularly by the Secretary.

(bb) A drug approved by the Food and Drug Administration exclusively for pediatric indications.

(C) BEST PRICE DEFINED.—For purposes of this section—

(i) IN GENERAL.—The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program;

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1860D–31; and

(VI) any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by an MA–PD plan under part C of such title with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A.

(ii) SPECIAL RULES.—The term "best price"—

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package;

(III) shall not take into account prices that are merely nominal in amount; and

(IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding those prices described in subclauses (I) through (IV) of clause (i).

(iii) APPLICATION OF AUDITING AND RECORDKEEPING REQUIREMENTS.—With respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 340B(a)(5)(C) of the Public Health Service Act.

(D) LIMITATION ON SALES AT A NOMINAL PRICE.—

(i) IN GENERAL.—For purposes of subparagraph (C)(ii)(III) and subsection (b)(3)(A)(iii)(III), only sales by a manufacturer of covered outpatient drugs at nominal prices to the following shall be considered to be sales at a nominal price or merely nominal in amount:

(I) A covered entity described in section 340B(a)(4) of the Public Health Service Act.

(II) An intermediate care facility for the mentally retarded.

(III) A State-owned or operated nursing facility.

(IV) An entity that—

(aa) is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Act or is State-owned or operated; and

(bb) would be a covered entity described in section 340(B)(a)(4) of the Public Health Service Act insofar as the entity provides the same type of services to the same type of populations as a covered entity described in such section provides, but does not receive funding under a provision of law referred to in such section;

(V) A public or nonprofit entity, or an entity based at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, that provides a service or services described under section 1001(a) of the Public Health Service Act, 42 U.S.C. 300.

(VI) Any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate based on the factors described in clause (ii).

(ii) FACTORS.—The factors described in this clause with respect to a facility or entity are the following:

(I) The type of facility or entity.

(II) The services provided by the facility or entity.

(III) The patient population served by the facility or entity.

(IV) The number of other facilities or entities eligible to purchase at nominal prices in the same service area.

(iii) NONAPPLICATION.—Clause (i) shall not apply with respect to sales by a manufacturer at a nominal price of covered outpatient drugs pursuant to a master agreement under section 8126 of title 38, United States Code.

(iv) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to alter any existing statutory or regulatory prohibition on services with respect to an entity described in clause (i)(IV), including the prohibition set forth in section 1008 of the Public Health Service Act.

(2) ADDITIONAL REBATE FOR SINGLE SOURCE AND INNOVATOR MULTIPLE SOURCE DRUGS.—

(A) IN GENERAL.—The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of—

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which—

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

(B) TREATMENT OF SUBSEQUENTLY APPROVED DRUGS.—In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting "the first full calendar quarter after the day on which the drug was first marketed" for "the calendar quarter beginning July 1, 1990" and "the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed" for "September 1990".

(C) TREATMENT OF NEW FORMULATIONS.—

(i) IN GENERAL.—In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation for a rebate period with respect to such drug under this subsection shall be the greater of the amount described in clause (ii) for such drug or the amount described in clause (iii) for such drug.

(ii) AMOUNT 1.—For purposes of clause (i), the amount described in this clause with respect to a drug described in clause (i) and rebate period is the amount computed under paragraph (1) for such drug, increased by the amount computed under subparagraph (A) and, as applicable, subparagraph (B) for such drug and rebate period.

(iii) AMOUNT 2.—For purposes of clause (i), the amount described in this clause with respect to a drug described in clause (i) and rebate period is the amount computed under paragraph (1) for such drug, increased by the product of—

(I) the average manufacturer price for the rebate period of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form;

(II) the highest additional rebate (calculated as a percentage of average manufacturer price) under this paragraph for the rebate period for any strength of the original single source drug or innovator multiple source drug; and

(III) the total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

In this subparagraph, the term "line extension" means, with respect to a drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation.

(D) MAXIMUM REBATE AMOUNT.—In no case shall the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator multiple source drug for a rebate period beginning after December 31, 2009, exceed 100 percent of the average manufacturer price of the drug.

(3) REBATE FOR OTHER DRUGS.—

(A) IN GENERAL.—Except as provided in subparagraph (C), the amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of—

(i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and

(ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

(B) APPLICABLE PERCENTAGE DEFINED.—For purposes of subparagraph (A)(i), the "applicable percentage" for rebate periods beginning—

(i) before January 1, 1994, is 10 percent,

(ii) after December 31, 1993, and before January 1, 2010, is 11 percent; and

(iii) after December 31, 2009, is 13 percent.

(C) ADDITIONAL REBATE.—

(i) IN GENERAL.—The amount of the rebate specified in this paragraph for a rebate period, with respect to each dosage form and strength of a covered outpatient drug other than a single source drug or an innovator multiple source drug of a manufacturer, shall be increased in the manner that the rebate for a dosage form and strength of a single source drug or an innovator multiple source drug is increased under subparagraphs (A) and (D) of paragraph (2), except as provided in clause (ii).

(ii) SPECIAL RULES FOR APPLICATION OF PROVISION.—In applying subparagraphs (A) and (D) of paragraph (2) under clause (i)—

(I) the reference in subparagraph (A)(i) of such paragraph to "1990" shall be deemed a reference to "2014";

(II) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to "the calendar quarter beginning July 1, 1990" shall be deemed a reference to "the calendar quarter beginning July 1, 2014"; and

(III) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to "September 1990" shall be deemed a reference to "September 2014";

(IV) the references in subparagraph (D) of such paragraph to "paragraph (1)(A)(ii)", "this paragraph", and "December 31, 2009" shall be deemed references to "subparagraph (A)", "this subparagraph", and "December 31, 2014", respectively; and

(V) any reference in such paragraph to a "single source drug or an innovator multiple source drug" shall be deemed to be a reference to a drug to which clause (i) applies.

(iii) SPECIAL RULE FOR CERTAIN NONINNOVATOR MULTIPLE SOURCE DRUGS.—In applying paragraph (2)(A)(ii)(II) under clause (i) with respect to a covered outpatient drug that is first marketed as a drug other than a single source drug or an innovator multiple source drug after April 1, 2013, such paragraph shall be applied—

(I) by substituting "the applicable quarter" for "the calendar quarter beginning July 1, 1990"; and

(II) by substituting "the last month in such applicable quarter" for "September 1990".

(iv) APPLICABLE QUARTER DEFINED.—In this subsection, the term "applicable quarter" means, with respect to a drug described in clause (iii), the fifth full calendar quarter after which the drug is marketed as a drug other than a single source drug or an innovator multiple source drug.

(d) LIMITATIONS ON COVERAGE OF DRUGS.—

(1) PERMISSIBLE RESTRICTIONS.—(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) LIST OF DRUGS SUBJECT TO RESTRICTION.—The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(F) Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1905(bb)(2)(A), agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(G) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(H) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

(3) UPDATE OF DRUG LISTINGS.—The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review pro-

grams of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) REQUIREMENTS FOR FORMULARIES.—A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3)).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) REQUIREMENTS OF PRIOR AUTHORIZATION PROGRAMS.—A State plan under this title may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval—

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) OTHER PERMISSIBLE RESTRICTIONS.—A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this Act.

(7) NON-EXCLUDABLE DRUGS.—The following drugs or classes of drugs, or their medical uses, shall not be excluded from coverage:

(A) Agents when used to promote smoking cessation, including agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(B) Barbiturates.

(C) Benzodiazepines.

(e) TREATMENT OF PHARMACY REIMBURSEMENT LIMITS.—

(1) IN GENERAL.—During the period beginning on January 1, 1991, and ending on December 31, 1994—

(A) a State may not reduce the payment limits established by regulation under this title or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph (2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Fed-

eral Regulations, in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

(2) SPECIAL RULE.—If a State is not in compliance with the regulations described in paragraph (1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

(3) EFFECT ON STATE MAXIMUM ALLOWABLE COST LIMITATIONS.—This section shall not supersede or affect provisions in effect prior to January 1, 1991, or after December 31, 1994, relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation.

(4) ESTABLISHMENT OF UPPER PAYMENT LIMITS.—Subject to paragraph (5), the Secretary shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.

(5) USE OF AMP IN UPPER PAYMENT LIMITS.—The Secretary shall calculate the Federal upper reimbursement limit established under paragraph (4) as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. The Secretary shall implement a smoothing process for average manufacturer prices. Such process shall be similar to the smoothing process used in determining the average sales price of a drug or biological under section 1847A.

(f) SURVEY OF RETAIL PRICES; STATE PAYMENT AND UTILIZATION RATES; AND PERFORMANCE RANKINGS.—

(1) SURVEY OF RETAIL PRICES.—

(A) USE OF VENDOR.—The Secretary may contract services for—

(i) with respect to a retail community pharmacy, the determination on a monthly basis of retail survey prices for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available); and

(ii) the notification of the Secretary when a drug product that is therapeutically and pharmaceutically equivalent and bioequivalent becomes generally available.

(B) SECRETARY RESPONSE TO NOTIFICATION OF AVAILABILITY OF MULTIPLE SOURCE PRODUCTS.—If contractor notifies the Secretary under subparagraph (A)(ii) that a drug product described in such subparagraph has become generally available, the Secretary shall make a determination, within 7 days after receiving such notification, as to whether the product is now described in subsection (e)(4).

(C) USE OF COMPETITIVE BIDDING.—In contracting for such services, the Secretary shall competitively bid for an outside vendor that has a demonstrated history in—

(i) surveying and determining, on a representative nationwide basis, retail prices for ingredient costs of prescription drugs;

(ii) working with retail community pharmacies, commercial payers, and States in obtaining and disseminating such price information; and

(iii) collecting and reporting such price information on at least a monthly basis.

In contracting for such services, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this subsection, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) ADDITIONAL PROVISIONS.—A contract with a vendor under this paragraph shall include such terms and conditions as the Secretary shall specify, including the following:

(i) The vendor must monitor the marketplace and report to the Secretary each time there is a new covered outpatient drug generally available.

(ii) The vendor must update the Secretary no less often than monthly on the retail survey prices for covered outpatient drugs.

(iii) The contract shall be effective for a term of 2 years.

(E) AVAILABILITY OF INFORMATION TO STATES.—Information on retail survey prices obtained under this paragraph, including applicable information on single source drugs, shall be provided to States on at least a monthly basis. The Secretary shall devise and implement a means for providing access to each State agency designated under section 1902(a)(5) with responsibility for the administration or supervision of the administration of the State plan under this title of the retail survey price determined under this paragraph.

(2) ANNUAL STATE REPORT.—Each State shall annually report to the Secretary information on—

(A) the payment rates under the State plan under this title for covered outpatient drugs;

(B) the dispensing fees paid under such plan for such drugs; and

(C) utilization rates for noninnovator multiple source drugs under such plan.

(3) ANNUAL STATE PERFORMANCE RANKINGS.—

(A) COMPARATIVE ANALYSIS.—The Secretary annually shall compare, for the 50 most widely prescribed drugs identified by the Secretary, the national retail sales price data (collected under paragraph (1)) for such drugs with data on prices under this title for each such drug for each State.

(B) AVAILABILITY OF INFORMATION.—The Secretary shall submit to Congress and the States full information regarding the annual rankings made under subparagraph (A).

(4) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary of Health and Human Services $5,000,000 for each of fiscal years 2006 through 2010 to carry out this subsection.

(g) DRUG USE REVIEW.—

(1) IN GENERAL.—

(A) In order to meet the requirement [of section 1903(i)(10)(B)] *of section 1902(a)(54)*, a State shall provide[, by not later than January 1, 1993,] for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, *excessive utilization,* [or inappropriate or medically unnecessary care] *inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization*, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information (or its successor publications); and

(III) the DRUGDEX Information System; and

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1903, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1919, currently at section 483.60 of title 42, Code of Federal Regulations.

(2) DESCRIPTION OF PROGRAM.—Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) PROSPECTIVE DRUG REVIEW.—(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this title, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with non-prescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this title by pharmacists which includes at least the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this title or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this title:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this title or caregiver of such individual refuses such consultation, or to require verification of the offer to provide consultation or a refusal of such offer.

(B) RETROSPECTIVE DRUG USE REVIEW.—The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1903(r)) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, *excessive utilization,* ❲or inappropriate or medically unnecessary care❳ *inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization*, among physicians, pharmacists and individuals receiving benefits under this title, or associated with specific drugs or groups of drugs.

(C) APPLICATION OF STANDARDS.—The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) EDUCATIONAL PROGRAM.—The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

(3) STATE DRUG USE REVIEW BOARD.—

(A) ESTABLISHMENT.—Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the "DUR Board") either directly or through a contract with a private organization.

(B) MEMBERSHIP.—The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs.

(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

(iii) Drug use review, evaluation, and intervention.

(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least ⅓ but no more than 51 percent licensed and actively practicing physicians and at least ⅓ licensed and actively practicing pharmacists.

(C) ACTIVITIES.—The activities of the DUR Board shall include but not be limited to the following:

(i) Retrospective DUR as defined in section (2)(B).

(ii) Application of standards as defined in section (2)(C).

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) ANNUAL REPORT.—Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

(h) ELECTRONIC CLAIMS MANAGEMENT.—

(1) IN GENERAL.—In accordance with chapter 35 of title 44, United States Code (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this title, a point-of-sale electronic claims management system, for the purpose of performing on-

line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

(2) ENCOURAGEMENT.—In order to carry out paragraph (1)—

(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1903(a)(3)(A)(i) (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

(i) ANNUAL REPORT.—

(1) IN GENERAL.—Not later than May 1 of each year the Secretary shall transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives a report on the operation of this section in the preceding fiscal year.

(2) DETAILS.—Each report shall include information on—

(A) ingredient costs paid under this title for single source drugs, multiple source drugs, and nonprescription covered outpatient drugs;

(B) the total value of rebates received and number of manufacturers providing such rebates;

(C) how the size of such rebates compare with the size or rebates offered to other purchasers of covered outpatient drugs;

(D) the effect of inflation on the value of rebates required under this section;

(E) trends in prices paid under this title for covered outpatient drugs; and

(F) Federal and State administrative costs associated with compliance with the provisions of this title.

(j) EXEMPTION OF ORGANIZED HEALTH CARE SETTINGS.—

(1) Covered outpatient drugs are not subject to the requirements of this section if such drugs are—

(A) dispensed by health maintenance organizations, including Medicaid managed care organizations that contract under section 1903(m); and

(B) subject to discounts under section 340B of the Public Health Service Act.

(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c).

(k) DEFINITIONS.—In the section—

(1) AVERAGE MANUFACTURER PRICE.—

(A) IN GENERAL.—Subject to subparagraph (B), the term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by—

(i) wholesalers for drugs distributed to retail community pharmacies; and

(ii) retail community pharmacies that purchase drugs directly from the manufacturer.

(B) EXCLUSION OF CUSTOMARY PROMPT PAY DISCOUNTS AND OTHER PAYMENTS.—

(i) IN GENERAL.—The average manufacturer price for a covered outpatient drug shall exclude—

(I) customary prompt pay discounts extended to wholesalers;

(II) bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with ad-

ministrative services agreements and patient care programs (such as medication compliance programs and patient education programs);

(III) reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;

(IV) payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy; and

(V) discounts provided by manufacturers under section 1860D–14A.

(ii) INCLUSION OF OTHER DISCOUNTS AND PAYMENTS.—Notwithstanding clause (i), any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the average manufacturer price for a covered outpatient drug.

(C) INCLUSION OF SECTION 505(c) DRUGS.—In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.

(2) COVERED OUTPATIENT DRUG.—Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which—

(i) may only be dispensed upon prescription,

(ii) is licensed under section 351 of the Public Health Service Act, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

(3) LIMITING DEFINITION.—The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.

(4) NONPRESCRIPTION DRUGS.—If a State plan for medical assistance under this title includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of drugs which may be sold without a prescription (commonly referred to as "over-the-counter" drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

(5) MANUFACTURER.—The term "manufacturer" means any entity which is engaged in—

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) MEDICALLY ACCEPTED INDICATION.—The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

(7) MULTIPLE SOURCE DRUG; INNOVATOR MULTIPLE SOURCE DRUG; NONINNOVATOR MULTIPLE SOURCE DRUG; SINGLE SOURCE DRUG.—

(A) DEFINED.—

(i) MULTIPLE SOURCE DRUG.—The term "multiple source drug" means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which there at least 1 other drug product which—

(I) is rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (B), is pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) is sold or marketed in the United States during the period.

(ii) INNOVATOR MULTIPLE SOURCE DRUG.—The term "innovator multiple source drug" means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(iii) NONINNOVATOR MULTIPLE SOURCE DRUG.—The term "noninnovator multiple source drug" means a multiple source drug that is not an innovator multiple source drug.

(iv) SINGLE SOURCE DRUG.—The term "single source drug" means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(B) EXCEPTION.—Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication de-

scribed in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) DEFINITIONS.—For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

(8) REBATE PERIOD.—The term "rebate period" means, with respect to an agreement under subsection (a), a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) STATE AGENCY.—The term "State agency" means the agency designated under section 1902(a)(5) to administer or supervise the administration of the State plan for medical assistance.

(10) RETAIL COMMUNITY PHARMACY.—The term "retail community pharmacy" means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

(11) WHOLESALER.—The term "wholesaler" means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses) independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

***SEC. 1927A. DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.***

*(a) IN GENERAL.—Beginning January 1, 2020, a State shall operate a qualified drug management program under which a State may enroll certain at-risk beneficiaries identified by the State under the program.*

*(b) QUALIFIED DRUG MANAGEMENT PROGRAM.—For purposes of this section, the term "qualified drug management program" means, with respect to a State, a program carried out by the State (including through a contract with a pharmacy benefit manager) that provides at least for the following:*

*(1) IDENTIFICATION OF AT-RISK INDIVIDUALS.—Under the program, the State identifies, in accordance with subsection (c), individuals enrolled under the State plan (or waiver of the State plan) who are at-risk beneficiaries.*

*(2) ELEMENTS OF PROGRAM.—*

*(A) IN GENERAL.—Under the program, the State, with respect to each individual identified under paragraph (1) and enrolled under the program under paragraph (5)—*

*(i) subject to subparagraphs (B) and (C), selects at least one, but not more than three, health care providers and at least one, but not more than three, pharmacies for each such individual for purposes of clause (ii), in accordance with a selection process that takes into account reasonable factors such as the individual's previous utilization of items and services from health care providers and pharmacies, geographic proximity of the individual to such health care providers and pharmacies, access of the individual to health care, reasonable travel time, information regarding housing status, and any known preference of the individual for a certain health care provider or pharmacy; and*

*(ii) requires that any controlled substance furnished to such individual during the period for which such individual is enrolled under the program be prescribed by a health care provider selected under clause (i) for such individual and dispensed by a pharmacy selected under clause (i) for such individual in order for such controlled substance to be covered under the State plan (or waiver).*

*(B) BENEFICIARY PREFERENCE.—In the case of an individual receiving a notice under paragraph (3)(A) of being identified as potentially being an at-risk beneficiary described in such paragraph, such individual may submit, during the 30-day period following receipt of such notice, preferences for which health care providers and pharmacies the individual would prefer the State to select under subparagraph (A). The State shall select or change the selection of health care providers and pharmacies under subparagraph (A) for the individuals based on such preferences, except that in the case that State determines that such selection (or change of selection) of a health care provider or pharmacy under subparagraph (A) is contributing or would contribute to prescription drug abuse or drug diversion by the individual, the State may select or change the selection of health care provider or pharmacy for the individual without regard to the preferences of the individual described in this subparagraph. If the State selects or changes the selection pursuant to the preceding sentence without regard to the preferences of the individual, the State shall provide the individual with at least 30 days written notice of the selection or change of selection and a rationale for the selection or change.*

*(C) TREATMENT OF PHARMACY WITH MULTIPLE LOCATIONS.—For purposes of subparagraph (A)(i), in the case of a pharmacy that has multiple locations that share real-time electronic prescription data, all such locations of the pharmacy shall collectively be treated as one pharmacy.*

*(D) TREATMENT OF EXISTING FFS DRUG MANAGEMENT PROGRAMS.—In the case of a patient review and restriction program (as identified in the annual report submitted to the Secretary under section 1927(g)(3)(D)) operated by a State pursuant to section 1915(a)(2) before the date of the enactment of this section, such program shall be treated as a qualified drug management program.*

*(E) REASONABLE ACCESS.—The program shall ensure, including through waiver of elements of the program (including under subparagraph (A)(ii)), reasonable access to health care (including access to health care providers and pharmacies with respect to prescription drugs described in subparagraph (A)) in the case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services (as defined for purposes of section 1860D–4(c)(5)(D)(ii)(II)).*

*(3) NOTIFICATION TO IDENTIFIED INDIVIDUALS.—Under the program, the State provides each individual who is identified under paragraph (1), prior to enrolling such individual under the program, at least one notification of each of the following:*

*(A) Notice that the State has identified the individual as potentially being an at-risk beneficiary for abuse or misuse of a controlled substance.*

*(B) The name, address, and contact information of each health care provider and pharmacy that may be selected for the individual under paragraph (2)(A).*

*(C) Information describing all State and Federal public health resources that are designed to address such abuse or misuse to which the individual has access, including mental health services, substance use disorder and recovery services, and other counseling services.*

*(D) Notice of, and information about, the right of the individual to—*

*(i) submit preferences of the individual for health care providers and pharmacies to be selected under paragraph (2)(A), including as described in paragraph (2)(B);*

*(ii) appeal under paragraph (4)—*

*(I) such identification described in subparagraph (A); and*

*(II) the selection of health care providers and pharmacies under paragraph (2)(A).*

*(E) An explanation of the meaning and consequences of the identification of the individual as potentially being an at-risk beneficiary for abuse or misuse of a controlled substance, including an explanation of the program.*

*(F) Information, including a contact list and clear instructions, that explain how the individual can contact the appropriate entities administering the program in order to submit preferences described in paragraph (2)(B) and any other communications relating to the program.*

*(4) APPEALS PROCESS.—Under the program, the State provides for an appeals process under which, with respect to an individual identified under paragraph (1)—*

*(A) such individual may appeal—*

*(i) such identification; and*

*(ii) the selection of a health care provider or pharmacy under paragraph (2)(A);*

*(B) in the case of an appeal described in subparagraph (A)(ii), the State shall accommodate the health care provider or pharmacy preferred by the individual for selection for purposes of paragraph (2)(A), unless the State determines that a change to the selection of health care provider or pharmacy under such paragraph is contributing or would contribute to prescription drug abuse or drug diversion by the individual;*

*(C) such individual is provided a period of not less than 30 days following the date of receipt of the notice described in paragraph (3) to submit such appeal; and*

*(D) the State must make a determination with respect to an appeal described in subparagraph (A), and notify the individual of such determination, prior to enrollment of such individual in the program.*

*(5) ENROLLMENT.—Under the program, the State initially enrolls individuals who are identified under paragraph (1) in the program for a 12-month period—*

*(A) in the case of such an individual who does not submit an appeal under paragraph (4) within the period applied by the State pursuant to subparagraph (C) of such paragraph, beginning on the day after the last day of such period; and*

*(B) in the case of such an individual who does submit an appeal under paragraph (4) within the period applied by the State pursuant to subparagraph (C) of such paragraph but such appeal is denied, beginning not later than 30 days after the date of such denial.*

*(6) NOTIFICATION OF HEALTH CARE PROVIDERS AND PHARMACIES.—Under the program, the State provides to each health care provider and pharmacy selected for an individual under paragraph (2)—*

*(A) notification that the individual is an at-risk beneficiary enrolled under the program and that the provider or pharmacy has been selected for the individual under paragraph (2);*

*(B) information on such program and the role of being so selected; and*

*(C) a process through which the provider or pharmacy can submit a concern or complaint with respect to being so selected.*

*(7) CONTINUATION OF ENROLLMENT.—Under the program, the State, with respect to an individual enrolled under the program, provides for a process to—*

*(A) not later than 30 days before the end of the 12-month period for which the individual is so enrolled pursuant to paragraph (5)—*

*(i) assess, in accordance with publicly available evidence-based guidelines, whether or not such individual should continue to be enrolled under the program; and*

*(ii) notify such individual of the results of the assessment under clause (i);*

*(B) continue, subject to subparagraph (C), enrollment of such individual if such assessment recommends such continuation; and*

*(C) appeal the continuation of enrollment in accordance with the appeals process described in paragraph (4).*

*(c) AT-RISK BENEFICIARY.—*

*(1) IDENTIFICATION.—For purposes of this section, a State shall identify an individual enrolled under the State plan (or waiver of the State plan) as an at-risk beneficiary if the individual is not an exempted individual described in paragraph (2) and—*

*(A) is identified as such an at-risk beneficiary through the use of publicly available evidence-based guidelines that indicate misuse or abuse of a controlled substance; or*

*(B) the State received notification from a PDP sponsor or Medicare Advantage organization that such individual was identified as being an at-risk beneficiary for prescription drug abuse for enrollment in a drug management program established by the sponsor or organization pursuant to section 1860D–4(c)(5) and such identification has not been terminated under subparagraph (F) of such section.*

*(2) EXEMPTED INDIVIDUAL DESCRIBED.—For purposes of paragraph (1), an exempted individual described in this paragraph is an individual who—*

*(A) is receiving—*

*(i) hospice or palliative care; or*

*(ii) treatment for cancer;*

*(B) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or*

*(C) the State elects to treat as an exempted individual for purposes of paragraph (1).*

*(d) APPLICATION OF PRIVACY RULES CLARIFICATION.—The Secretary shall clarify privacy requirements, including requirements under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), related to the sharing of data under subsection (b)(6) in the same manner as the Secretary is required under subparagraph (J) of section 1860D–4(c)(5) to clarify privacy requirements related to the sharing of data described in such subparagraph.*

*(e) REPORTS.—*

*(1) ANNUAL REPORTS.—A State operating a qualified drug management program shall include in the annual report submitted to the Secretary under section 1927(g)(3)(D), beginning with such reports submitted for 2021, the following information:*

*(A) The number of individuals enrolled under the State plan (or waiver of the State plan) who are enrolled under the program and the percentage of individuals enrolled under the State plan (or waiver) who are enrolled under such program.*

*(B) The number of prescriptions for controlled substances that were dispensed per month during each such year per individual enrolled under the program, including the daily morphine milligram equivalents and the quantity prescribed for each such prescription.*

*(C) The number of pharmacies filling prescriptions for controlled substances for individuals enrolled under such program.*

*(D) The number of health care providers writing prescriptions for controlled substances (other than prescriptions for a refill) for individuals enrolled under such program.*

*(E) Any other data that the Secretary may require.*

*(F) Any report submitted by a managed care entity under subsection (f)(1)(B) with respect to the year involved.*

*For each such report for a year after 2021, the information described in this paragraph shall be provided in a manner that compares such information with respect to the prior calendar year to such information with respect to the second prior calendar year.*

*(2) MACPAC REPORTS AND REVIEW.—Not later than two years after the date of the enactment of this section, the Medicaid and CHIP Payment and Access Commission (in this section referred to as "MACPAC"), in consultation with the National Association of Medicaid Directors, pharmacy benefit managers, managed care organizations, health care providers (including pharmacists), beneficiary advocates, and other stakeholders, shall publish a report that includes—*

*(A) best practices for operating drug management programs, based on a review of a representative sample of States administering such a program;*

*(B) a summary of the experience of the appeals process under drug management programs operated by several States, such as the frequency at which individuals appealed the identification of being an at-risk individual, the frequency at which individuals appealed the selection of a health care provider or pharmacy under such a program, the timeframes for such appeals, a summary of the reasons for such appeals, and the design of such appeals processes;*

*(C) a summary of trends and the effectiveness of qualified drug management programs operated under this section; and*

*(D) recommendations to States on how improvements can be made with respect to the operation of such programs.*

*In reporting on State practices, the MACPAC shall consider how such programs have been implemented in rural areas, under fee-for-service as well as managed care arrangements, and the extent to which such programs have resulted in increased efficiencies to such States or to the Federal Government under this title.*

*(3) REPORT ON PLAN FOR COORDINATED CARE.—Not later than January 1, 2021, each State operating a qualified drug management program shall submit to the Administrator of the Centers for Medicare & Medicaid Services a report on how such State plans to provide coordinated care for individuals enrolled under the State plan (or waiver of the State plan) and—*

*(A) who are enrolled under the program; or*

*(B) who are enrolled with a managed care entity and enrolled under such a qualified drug management program operated by such entity.*

*(f) APPLICABILITY TO MANAGED CARE ENTITIES.—*

*(1) IN GENERAL.—With respect to any contract that a State enters into on or after January 1, 2020, with a managed care entity (as defined in section 1932(a)(1)(B)) pursuant to section 1903(m), the State shall, as a condition of the contract, require the managed care entity—*

*(A) to operate a qualified drug management program (as defined in subsection (b)) for at-risk beneficiaries who are enrolled with such entity and identified by the managed care entity by means of application of paragraph (2);*

*(B) to submit to the State an annual report on the matters described in subparagraphs (A) through (E) of subsection (e)(1); and*

*(C) to submit to the State a list (and as necessary update such list) of individuals enrolled with such entity under the qualified drug management program operated by such entity under subparagraph (A) for purposes of allowing State plans for which medical assistance is paid on a fee-for-service basis to have access to such information.*

*(2) APPLICATION.—For purposes of applying, with respect to a managed care entity—*

*(A) under paragraph (1)(A)—*

*(i) the definition of the term "qualified drug management program" under subsection (b), other than paragraph (2)(D) of such subsection; and*

*(ii) the provisions of paragraphs (1) and (2) of subsection (c); and*

*(B) under paragraph (1)(B), the report requirements described in subparagraphs (A) through (E) of subsection (e)(1);*

*each reference in such subsection (b) and paragraphs of subsection (c) to "a State" or "the State" (other than to "a State plan" or "the State plan") shall be deemed a reference to the managed care entity, each reference under such subsection, paragraphs, or subparagraphs to individuals enrolled under the State plan (or waiver of the State plan) shall be deemed a reference to individuals enrolled with such entity, and each reference under such subsection, paragraphs, or subparagraphs to individuals enrolled under the qualified drug management program operated by the State shall be deemed a reference to individuals enrolled under the qualified drug management program operated by the managed care entity.*

*(g) CONTROLLED SUBSTANCE DEFINED.—For purposes of this section, the term "controlled substance" means a drug that is included in schedule II, III, or IV of section 202(c) of the Controlled Substances Act, or any combination thereof, as specified by the State.*

* * * * * * *

PROVISIONS RELATING TO MANAGED CARE

SEC. 1932. (a) STATE OPTION TO USE MANAGED CARE.—

(1) USE OF MEDICAID MANAGED CARE ORGANIZATIONS AND PRIMARY CARE CASE MANAGERS.—

(A) IN GENERAL.—Subject to the succeeding provisions of this section, and notwithstanding paragraph (1), (10)(B), or (23)(A) of section 1902(a), a State—

(i) may require an individual who is eligible for medical assistance under the State plan under this title to enroll with a managed care entity as a condition of receiving such assistance (and, with respect to assistance furnished by or under arrangements with such entity, to receive such assistance through the entity), if—

(I) the entity and the contract with the State meet the applicable requirements of this section and section 1903(m) or section 1905(t), and

(II) the requirements described in the succeeding paragraphs of this subsection are met; and

(ii) may restrict the number of provider agreements with managed care entities under the State plan if such restriction does not substantially impair access to services.

(B) DEFINITION OF MANAGED CARE ENTITY.—In this section, the term "managed care entity" means—

(i) a medicaid managed care organization, as defined in section 1903(m)(1)(A), that provides or arranges for services for enrollees under a contract pursuant to section 1903(m); and

(ii) a primary care case manager, as defined in section 1905(t)(2).

(2) SPECIAL RULES.—

(A) EXEMPTION OF CERTAIN CHILDREN WITH SPECIAL NEEDS.—A State may not require under paragraph (1) the enrollment in a managed care entity of an individual under 19 years of age who—

(i) is eligible for supplemental security income under title XVI;
(ii) is described in section 501(a)(1)(D);
(iii) is described in section 1902(e)(3);
(iv) is receiving foster care or adoption assistance under part E of title IV; or
(v) is in foster care or otherwise in an out-of-home placement.

(B) EXEMPTION OF MEDICARE BENEFICIARIES.—A State may not require under paragraph (1) the enrollment in a managed care entity of an individual who is a qualified medicare beneficiary (as defined in section 1905(p)(1)) or an individual otherwise eligible for benefits under title XVIII.

(C) INDIAN ENROLLMENT.—A State may not require under paragraph (1) the enrollment in a managed care entity of an individual who is an Indian (as defined in section 4(c) of the Indian Health Care Improvement Act of 1976 (25 U.S.C. 1603(c)) unless the entity is one of the following (and only if such entity is participating under the plan):

(i) The Indian Health Service.

(ii) An Indian health program operated by an Indian tribe or tribal organization pursuant to a contract, grant, cooperative agreement, or compact with the Indian Health Service pursuant to the Indian Self-Determination Act (25 U.S.C. 450 et seq.).

(iii) An urban Indian health program operated by an urban Indian organization pursuant to a grant or contract with the Indian Health Service pursuant to title V of the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

(3) CHOICE OF COVERAGE.—

(A) IN GENERAL.—A State must permit an individual to choose a managed care entity from not less than two such entities that meet the applicable requirements of this section, and of section 1903(m) or section 1905(t).

(B) STATE OPTION.—At the option of the State, a State shall be considered to meet the requirements of subparagraph (A) in the case of an individual residing in a rural area, if the State requires the individual to enroll with a managed care entity if such entity—

(i) permits the individual to receive such assistance through not less than two physicians or case managers (to the extent that at least two physicians or case managers are available to provide such assistance in the area), and

(ii) permits the individual to obtain such assistance from any other provider in appropriate circumstances (as established by the State under regulations of the Secretary).

(C) TREATMENT OF CERTAIN COUNTY-OPERATED HEALTH INSURING ORGANIZATIONS.—A State shall be considered to meet the requirement of subparagraph (A) if—

(i) the managed care entity in which the individual is enrolled is a health-insuring organization which—

(I) first became operational prior to January 1, 1986, or

(II) is described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as added by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990), and

(ii) the individual is given a choice between at least two providers within such entity.

(4) PROCESS FOR ENROLLMENT AND TERMINATION AND CHANGE OF ENROLLMENT.—As conditions under paragraph (1)(A)—

(A) IN GENERAL.—The State, enrollment broker (if any), and managed care entity shall permit an individual eligible for medical assistance under the State plan under this title who is enrolled with the entity under this title to terminate (or change) such enrollment—

(i) for cause at any time (consistent with section 1903(m)(2)(A)(vi)), and

(ii) without cause—

(I) during the 90-day period beginning on the date the individual receives notice of such enrollment, and

(II) at least every 12 months thereafter.

(B) NOTICE OF TERMINATION RIGHTS.—The State shall provide for notice to each such individual of the opportunity to terminate (or change) enrollment under such conditions. Such notice shall be provided at least 60 days before each annual enrollment opportunity described in subparagraph (A)(ii)(II).

(C) ENROLLMENT PRIORITIES.—In carrying out paragraph (1)(A), the State shall establish a method for establishing enrollment priorities in the case of a managed care entity

that does not have sufficient capacity to enroll all such individuals seeking enrollment under which individuals already enrolled with the entity are given priority in continuing enrollment with the entity.

(D) DEFAULT ENROLLMENT PROCESS.—In carrying out paragraph (1)(A), the State shall establish a default enrollment process—

(i) under which any such individual who does not enroll with a managed care entity during the enrollment period specified by the State shall be enrolled by the State with such an entity which has not been found to be out of substantial compliance with the applicable requirements of this section and of section 1903(m) or section 1905(t); and

(ii) that takes into consideration—

(I) maintaining existing provider-individual relationships or relationships with providers that have traditionally served beneficiaries under this title; and

(II) if maintaining such provider relationships is not possible, the equitable distribution of such individuals among qualified managed care entities available to enroll such individuals, consistent with the enrollment capacities of the entities.

(5) PROVISION OF INFORMATION.—

(A) INFORMATION IN EASILY UNDERSTOOD FORM.—Each State, enrollment broker, or managed care entity shall provide all enrollment notices and informational and instructional materials relating to such an entity under this title in a manner and form which may be easily understood by enrollees and potential enrollees of the entity who are eligible for medical assistance under the State plan under this title.

(B) INFORMATION TO ENROLLEES AND POTENTIAL ENROLLEES.—Each managed care entity that is a medicaid managed care organization shall, upon request, make available to enrollees and potential enrollees in the organization's service area information concerning the following:

(i) PROVIDERS.—The identity, locations, qualifications, and availability of health care providers that participate with the organization.

(ii) ENROLLEE RIGHTS AND RESPONSIBILITIES.—The rights and responsibilities of enrollees.

(iii) GRIEVANCE AND APPEAL PROCEDURES.—The procedures available to an enrollee and a health care provider to challenge or appeal the failure of the organization to cover a service.

(iv) INFORMATION ON COVERED ITEMS AND SERVICES.—All items and services that are available to enrollees under the contract between the State and the organization that are covered either directly or through a method of referral and prior authorization. Each managed care entity that is a primary care case manager shall, upon request, make available to enrollees and potential enrollees in the organization's service area the information described in clause (iii).

(C) COMPARATIVE INFORMATION.—A State that requires individuals to enroll with managed care entities under paragraph (1)(A) shall annually (and upon request) provide, directly or through the managed care entity, to such individuals a list identifying the managed care entities that are (or will be) available and information (presented in a comparative, chart-like form) relating to the following for each such entity offered:

(i) BENEFITS AND COST-SHARING.—The benefits covered and cost-sharing imposed by the entity.

(ii) SERVICE AREA.—The service area of the entity.

(iii) QUALITY AND PERFORMANCE.—To the extent available, quality and performance indicators for the benefits under the entity.

(D) INFORMATION ON BENEFITS NOT COVERED UNDER MANAGED CARE ARRANGEMENT.—A State, directly or through managed care entities, shall, on or before an individual enrolls with such an entity under this title, inform the enrollee in a written and prominent manner of any benefits to which the enrollee may be entitled to under this title but which are not made available to the enrollee through the entity. Such information shall include information on where and how such enrollees may access benefits not made available to the enrollee through the entity.

(b) BENEFICIARY PROTECTIONS.—

(1) SPECIFICATION OF BENEFITS.—Each contract with a managed care entity under section 1903(m) or under section 1905(t)(3) shall specify the benefits the provision (or arrangement) for which the entity is responsible.

(2) ASSURING COVERAGE TO EMERGENCY SERVICES.—

(A) IN GENERAL.—Each contract with a medicaid managed care organization under section 1903(m) and each contract with a primary care case manager under section 1905(t)(3) shall require the organization or manager—

(i) to provide coverage for emergency services (as defined in subparagraph (B)) without regard to prior authorization or the emergency care provider's contractual relationship with the organization or manager, and

(ii) to comply with guidelines established under section 1852(d)(2) (respecting coordination of post-stabilization care) in the same manner as such guidelines apply to Medicare+Choice plans offered under part C of title XVIII.

The requirement under clause (ii) shall first apply 30 days after the date of promulgation of the guidelines referred to in such clause.

(B) EMERGENCY SERVICES DEFINED.—In subparagraph (A)(i), the term "emergency services" means, with respect to an individual enrolled with an organization, covered inpatient and outpatient services that—

(i) are furnished by a provider that is qualified to furnish such services under this title, and

(ii) are needed to evaluate or stabilize an emergency medical condition (as defined in subparagraph (C)).

(C) EMERGENCY MEDICAL CONDITION DEFINED.—In subparagraph (B)(ii), the term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

(ii) serious impairment to bodily functions, or

(iii) serious dysfunction of any bodily organ or part.

(D) EMERGENCY SERVICES FURNISHED BY NON-CONTRACT PROVIDERS.—Any provider of emergency services that does not have in effect a contract with a Medicaid managed care entity that establishes payment amounts for services furnished to a beneficiary enrolled in the entity's Medicaid managed care plan must accept as payment in full no more than the amounts (less any payments for indirect costs of medical education and direct costs of graduate medical education) that it could collect if the beneficiary received medical assistance under this title other than through enrollment in such an entity. In a State where rates paid to hospitals under the State plan are negotiated by contract and not publicly released, the payment amount applicable under this subparagraph shall be the average contract rate that would apply under the State plan for general acute care hospitals or the average contract rate that would apply under such plan for tertiary hospitals.

(3) PROTECTION OF ENROLLEE-PROVIDER COMMUNICATIONS.—

(A) IN GENERAL.—Subject to subparagraphs (B) and (C), under a contract under section 1903(m) a medicaid managed care organization (in relation to an individual enrolled under the contract) shall not prohibit or otherwise restrict a covered health care professional (as defined in subparagraph (D)) from advising such an individual who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the contract, if the professional is acting within the lawful scope of practice.

(B) CONSTRUCTION.—Subparagraph (A) shall not be construed as requiring a medicaid managed care organization to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization—

(i) objects to the provision of such service on moral or religious grounds; and

(ii) in the manner and through the written instrumentalities such organization deems appropriate, makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days

after the date that the organization adopts a change in policy regarding such a counseling or referral service.

Nothing in this subparagraph shall be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

(C) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this paragraph, the term "health care professional" means a physician (as defined in section 1861(r)) or other health care professional if coverage for the professional's services is provided under the contract referred to in subparagraph (A) for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

(4) GRIEVANCE PROCEDURES.—Each medicaid managed care organization shall establish an internal grievance procedure under which an enrollee who is eligible for medical assistance under the State plan under this title, or a provider on behalf of such an enrollee, may challenge the denial of coverage of or payment for such assistance.

(5) DEMONSTRATION OF ADEQUATE CAPACITY AND SERVICES.—Each medicaid managed care organization shall provide the State and the Secretary with adequate assurances (in a time and manner determined by the Secretary) that the organization, with respect to a service area, has the capacity to serve the expected enrollment in such service area, including assurances that the organization—

(A) offers an appropriate range of services and access to preventive and primary care services for the population expected to be enrolled in such service area, and

(B) maintains a sufficient number, mix, and geographic distribution of providers of services.

(6) PROTECTING ENROLLEES AGAINST LIABILITY FOR PAYMENT.—Each medicaid managed care organization shall provide that an individual eligible for medical assistance under the State plan under this title who is enrolled with the organization may not be held liable—

(A) for the debts of the organization, in the event of the organization's insolvency,

(B) for services provided to the individual—

(i) in the event of the organization failing to receive payment from the State for such services; or

(ii) in the event of a health care provider with a contractual, referral, or other arrangement with the organization failing to receive payment from the State or the organization for such services, or

(C) for payments to a provider that furnishes covered services under a contractual, referral, or other arrangement with the organization in excess of the amount that would be owed by the individual if the organization had directly provided the services.

(7) ANTIDISCRIMINATION.—A medicaid managed care organization shall not discriminate with respect to participation, reimbursement, or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification. This paragraph shall not be construed to prohibit an organization from including providers only to the extent necessary to meet the needs of the organization's enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the organization.

(8) COMPLIANCE WITH CERTAIN MATERNITY AND MENTAL HEALTH REQUIREMENTS.—Each medicaid managed care organization shall comply with the requirements of subpart 2 of part A of title XXVII of the Public Health Service Act insofar as such requirements apply and are effective with respect to a health insurance issuer that offers group health insurance coverage.

(c) QUALITY ASSURANCE STANDARDS.—

(1) QUALITY ASSESSMENT AND IMPROVEMENT STRATEGY.—

(A) IN GENERAL.—If a State provides for contracts with medicaid managed care organizations under section 1903(m), the State shall develop and implement a quality assessment and improvement strategy consistent with this paragraph. Such strategy shall include the following:

(i) ACCESS STANDARDS.—Standards for access to care so that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialized services capacity.

(ii) OTHER MEASURES.—Examination of other aspects of care and service directly related to the improvement of quality of care (including grievance procedures and marketing and information standards).

(iii) MONITORING PROCEDURES.—Procedures for monitoring and evaluating the quality and appropriateness of care and services to enrollees that reflect the full spectrum of populations enrolled under the contract and that includes requirements for provision of quality assurance data to the State using the data and information set that the Secretary has specified for use under part C of title XVIII or such alternative data as the Secretary approves, in consultation with the State.

(iv) PERIODIC REVIEW.—Regular, periodic examinations of the scope and content of the strategy.

(B) STANDARDS.—The strategy developed under subparagraph (A) shall be consistent with standards that the Secretary first establishes within 1 year after the date of the enactment of this section. Such standards shall not preempt any State standards that are more stringent than such standards. Guidelines relating to quality assurance that are applied under section 1915(b)(1) shall apply under this subsection until the effective date of standards for quality assurance established under this subparagraph.

(C) MONITORING.—The Secretary shall monitor the development and implementation of strategies under subparagraph (A).

(D) CONSULTATION.—The Secretary shall conduct activities under subparagraphs (B) and (C) in consultation with the States.

(2) EXTERNAL INDEPENDENT REVIEW OF MANAGED CARE ACTIVITIES.—

(A) REVIEW OF CONTRACTS.—

(i) IN GENERAL.—Each contract under section 1903(m) with a medicaid managed care organization shall provide for an annual (as appropriate) external independent review conducted by a qualified independent entity of the quality outcomes and timeliness of, and access to, the items and services for which the organization is responsible under the contract. The requirement for such a review shall not apply until after the date that the Secretary establishes the identification method described in clause (ii).

(ii) QUALIFICATIONS OF REVIEWER.—The Secretary, in consultation with the States, shall establish a method for the identification of entities that are qualified to conduct reviews under clause (i).

(iii) USE OF PROTOCOLS.—The Secretary, in coordination with the National Governors' Association, shall contract with an independent quality review organization (such as the National Committee for Quality Assurance) to develop the protocols to be used in external independent reviews conducted under this paragraph on and after January 1, 1999.

(iv) AVAILABILITY OF RESULTS.—The results of each external independent review conducted under this subparagraph shall be available to participating health care providers, enrollees, and potential enrollees of the organization, except that the results may not be made available in a manner that discloses the identity of any individual patient.

(B) NONDUPLICATION OF ACCREDITATION.—A State may provide that, in the case of a medicaid managed care organization that is accredited by a private independent entity (such as those described in section 1852(e)(4)) or that has an external review conducted under section 1852(e)(3), the external review activities conducted under subparagraph (A) with respect to the organization shall not be duplicative of review activities conducted as part of the accreditation process or the external review conducted under such section.

(C) DEEMED COMPLIANCE FOR MEDICARE MANAGED CARE ORGANIZATIONS.—At the option of a State, the requirements of subparagraph (A) shall not apply with respect to a medicaid managed care organization if the organization is an eligible organization with a contract in effect under section 1876 or a Medicare+Choice organization with a contract in effect under part C of title XVIII and the organization has had a contract in effect under section 1903(m) at least during the previous 2-year period.

(d) PROTECTIONS AGAINST FRAUD AND ABUSE.—

(1) PROHIBITING AFFILIATIONS WITH INDIVIDUALS DEBARRED BY FEDERAL AGENCIES.—

(A) IN GENERAL.—A managed care entity may not knowingly—

(i) have a person described in subparagraph (C) as a director, officer, partner, or person with beneficial ownership of more than 5 percent of the entity's equity, or

(ii) have an employment, consulting, or other agreement with a person described in such subparagraph for the provision of items and services that are significant and material to the entity's obligations under its contract with the State.

(B) EFFECT OF NONCOMPLIANCE.—If a State finds that a managed care entity is not in compliance with clause (i) or (ii) of subparagraph (A), the State—

(i) shall notify the Secretary of such noncompliance;

(ii) may continue an existing agreement with the entity unless the Secretary (in consultation with the Inspector General of the Department of Health and Human Services) directs otherwise; and

(iii) may not renew or otherwise extend the duration of an existing agreement with the entity unless the Secretary (in consultation with the Inspector General of the Department of Health and Human Services) provides to the State and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement.

(C) PERSONS DESCRIBED.—A person is described in this subparagraph if such person—

(i) is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in nonprocurement activities under regulations issued pursuant to Executive Order No. 12549 or under guidelines implementing such order; or

(ii) is an affiliate (as defined in such Regulation) of a person described in clause (i).

(2) RESTRICTIONS ON MARKETING.—

(A) DISTRIBUTION OF MATERIALS.—

(i) IN GENERAL.—A managed care entity, with respect to activities under this title, may not distribute directly or through any agent or independent contractor marketing materials within any State—

(I) without the prior approval of the State, and

(II) that contain false or materially misleading information.

The requirement of subclause (I) shall not apply with respect to a State until such date as the Secretary specifies in consultation with such State.

(ii) CONSULTATION IN REVIEW OF MARKET MATERIALS.—In the process of reviewing and approving such materials, the State shall provide for consultation with a medical care advisory committee.

(B) SERVICE MARKET.—A managed care entity shall distribute marketing materials to the entire service area of such entity covered under the contract under section 1903(m) or section 1905(t)(3).

(C) PROHIBITION OF TIE-INS.—A managed care entity, or any agency of such entity, may not seek to influence an individual's enrollment with the entity in conjunction with the sale of any other insurance.

(D) PROHIBITING MARKETING FRAUD.—Each managed care entity shall comply with such procedures and conditions as the Secretary prescribes in order to ensure that, before an individual is enrolled with the entity, the individual is provided accurate oral and written information sufficient to make an informed decision whether or not to enroll.

(E) PROHIBITION OF "COLD-CALL" MARKETING.—Each managed care entity shall not, directly or indirectly, conduct door-to-door, telephonic, or other "cold-call" marketing of enrollment under this title.

(3) STATE CONFLICT-OF-INTEREST SAFEGUARDS IN MEDICAID RISK CONTRACTING.—A medicaid managed care organization may not enter into a contract with any State under section 1903(m) unless the State has in effect conflict-of-interest safeguards with respect to officers and employees of the State with responsibilities relating to contracts with such organizations or to the default enrollment process described in subsection (a)(4)(C)(ii) that are at least as effective as the Federal safeguards provided under section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423), against conflicts of interest that apply with respect to Federal procurement officials with comparable responsibilities with respect to such contracts.

(4) USE OF UNIQUE PHYSICIAN IDENTIFIER FOR PARTICIPATING PHYSICIANS.—Each medicaid managed care organization shall require each physician providing services to enrollees eligible

for medical assistance under the State plan under this title to have a unique identifier in accordance with the system established under section 1173(b).

(5) CONTRACT REQUIREMENT FOR MANAGED CARE ENTITIES.—With respect to any contract with a managed care entity under section 1903(m) or 1905(t)(3) (as applicable), no later than July 1, 2018, such contract shall include a provision that providers of services or persons terminated (as described in section 1902(kk)(8)) from participation under this title, title XVIII, or title XXI shall be terminated from participating under this title as a provider in any network of such entity that serves individuals eligible to receive medical assistance under this title.

(6) ENROLLMENT OF PARTICIPATING PROVIDERS.—

(A) IN GENERAL.—Beginning not later than January 1, 2018, a State shall require that, in order to participate as a provider in the network of a managed care entity that provides services to, or orders, prescribes, refers, or certifies eligibility for services for, individuals who are eligible for medical assistance under the State plan under this title (or under a waiver of the plan) and who are enrolled with the entity, the provider is enrolled consistent with section 1902(kk) with the State agency administering the State plan under this title. Such enrollment shall include providing to the State agency the provider's identifying information, including the name, specialty, date of birth, Social Security number, national provider identifier, Federal taxpayer identification number, and the State license or certification number of the provider.

(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) shall be construed as requiring a provider described in such subparagraph to provide services to individuals who are not enrolled with a managed care entity under this title.

(e) SANCTIONS FOR NONCOMPLIANCE.—

(1) USE OF INTERMEDIATE SANCTIONS BY THE STATE TO ENFORCE REQUIREMENTS.—

(A) IN GENERAL.—A State may not enter into or renew a contract under section 1903(m) unless the State has established intermediate sanctions, which may include any of the types described in paragraph (2), other than the termination of a contract with a medicaid managed care organization, which the State may impose against a medicaid managed care organization with such a contract, if the organization—

(i) fails substantially to provide medically necessary items and services that are required (under law or under such organization's contract with the State) to be provided to an enrollee covered under the contract;

(ii) imposes premiums or charges on enrollees in excess of the premiums or charges permitted under this title;

(iii) acts to discriminate among enrollees on the basis of their health status or requirements for health care services, including expulsion or refusal to reenroll an individual, except as permitted by this title, or engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment with the organization by eligible individuals whose medical condition or history indicates a need for substantial future medical services;

(iv) misrepresents or falsifies information that is furnished—

(I) to the Secretary or the State under this title; or

(II) to an enrollee, potential enrollee, or a health care provider under such title; or

(v) fails to comply with the applicable requirements of section 1903(m)(2)(A)(x).

The State may also impose such intermediate sanction against a managed care entity if the State determines that the entity distributed directly or through any agent or independent contractor marketing materials in violation of subsection (d)(2)(A)(i)(II).

(B) RULE OF CONSTRUCTION.—Clause (i) of subparagraph (A) shall not apply to the provision of abortion services, except that a State may impose a sanction on any medicaid managed care organization that has a contract to provide abortion services if the organization does not provide such services as provided for under the contract.

(2) INTERMEDIATE SANCTIONS.—The sanctions described in this paragraph are as follows:

(A) Civil money penalties as follows:

(i) Except as provided in clause (ii), (iii), or (iv), not more than $25,000 for each determination under paragraph (1)(A).

(ii) With respect to a determination under clause (iii) or (iv)(I) of paragraph (1)(A), not more than $100,000 for each such determination.

(iii) With respect to a determination under paragraph (1)(A)(ii), double the excess amount charged in violation of such subsection (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned).

(iv) Subject to clause (ii), with respect to a determination under paragraph (1)(A)(iii), $15,000 for each individual not enrolled as a result of a practice described in such subsection.

(B) The appointment of temporary management—

(i) to oversee the operation of the medicaid managed care organization upon a finding by the State that there is continued egregious behavior by the organization or there is a substantial risk to the health of enrollees; or

(ii) to assure the health of the organization's enrollees, if there is a need for temporary management while—

(I) there is an orderly termination or reorganization of the organization; or

(II) improvements are made to remedy the violations found under paragraph (1),

except that temporary management under this subparagraph may not be terminated until the State has determined that the medicaid managed care organization has the capability to ensure that the violations shall not recur.

(C) Permitting individuals enrolled with the managed care entity to terminate enrollment without cause, and notifying such individuals of such right to terminate enrollment.

(D) Suspension or default of all enrollment of individuals under this title after the date the Secretary or the State notifies the entity of a determination of a violation of any requirement of section 1903(m) or this section.

(E) Suspension of payment to the entity under this title for individuals enrolled after the date the Secretary or State notifies the entity of such a determination and until the Secretary or State is satisfied that the basis for such determination has been corrected and is not likely to recur.

(3) TREATMENT OF CHRONIC SUBSTANDARD ENTITIES.—In the case of a medicaid managed care organization which has repeatedly failed to meet the requirements of section 1903(m) and this section, the State shall (regardless of what other sanctions are provided) impose the sanctions described in subparagraphs (B) and (C) of paragraph (2).

(4) AUTHORITY TO TERMINATE CONTRACT.—

(A) IN GENERAL.—In the case of a managed care entity which has failed to meet the requirements of this part or a contract under section 1903(m) or 1905(t)(3), the State shall have the authority to terminate such contract with the entity and to enroll such entity's enrollees with other managed care entities (or to permit such enrollees to receive medical assistance under the State plan under this title other than through a managed care entity).

(B) AVAILABILITY OF HEARING PRIOR TO TERMINATION OF CONTRACT.—A State may not terminate a contract with a managed care entity under subparagraph (A) unless the entity is provided with a hearing prior to the termination.

(C) NOTICE AND RIGHT TO DISENROLL IN CASES OF TERMINATION HEARING.—A State may—

(i) notify individuals enrolled with a managed care entity which is the subject of a hearing to terminate the entity's contract with the State of the hearing, and

(ii) in the case of such an entity, permit such enrollees to disenroll immediately with the entity without cause.

(5) OTHER PROTECTIONS FOR MANAGED CARE ENTITIES AGAINST SANCTIONS IMPOSED BY STATE.—Before imposing any sanction against a managed care entity other than termination of the entity's contract, the State shall provide the entity with notice and such other due process protections as the State may provide, except that a State may not provide a managed care entity with a pre-termination hearing before imposing the sanction described in paragraph (2)(B).

(f) TIMELINESS OF PAYMENT; ADEQUACY OF PAYMENT FOR PRIMARY CARE SERVICES.—A contract under section 1903(m) with a medicaid managed care organization shall provide that the organization shall make payment to health care providers for items and services which are subject to the contract and that are furnished to individuals eligible for medical assistance under the State plan under this title who are enrolled with the organization on a timely basis consistent with the claims payment procedures described in section 1902(a)(37)(A), unless the health care provider and the

organization agree to an alternate payment schedule and, in the case of primary care services described in section 1902(a)(13)(C), consistent with the minimum payment rates specified in such section (regardless of the manner in which such payments are made, including in the form of capitation or partial capitation).

(g) IDENTIFICATION OF PATIENTS FOR PURPOSES OF MAKING DSH PAYMENTS.—Each contract with a managed care entity under section 1903(m) or under section 1905(t)(3) shall require the entity either—

(1) to report to the State information necessary to determine the hospital services provided under the contract (and the identity of hospitals providing such services) for purposes of applying sections 1886(d)(5)(F) and 1923; or

(2) to include a sponsorship code in the identification card issued to individuals covered under this title in order that a hospital may identify a patient as being entitled to benefits under this title.

(h) SPECIAL RULES WITH RESPECT TO INDIAN ENROLLEES, INDIAN HEALTH CARE PROVIDERS, AND INDIAN MANAGED CARE ENTITIES.—

(1) ENROLLEE OPTION TO SELECT AN INDIAN HEALTH CARE PROVIDER AS PRIMARY CARE PROVIDER.—In the case of a non-Indian Medicaid managed care entity that—

(A) has an Indian enrolled with the entity; and

(B) has an Indian health care provider that is participating as a primary care provider within the network of the entity,

insofar as the Indian is otherwise eligible to receive services from such Indian health care provider and the Indian health care provider has the capacity to provide primary care services to such Indian, the contract with the entity under section 1903(m) or under section 1905(t)(3) shall require, as a condition of receiving payment under such contract, that the Indian shall be allowed to choose such Indian health care provider as the Indian's primary care provider under the entity.

(2) ASSURANCE OF PAYMENT TO INDIAN HEALTH CARE PROVIDERS FOR PROVISION OF COVERED SERVICES.—Each contract with a managed care entity under section 1903(m) or under section 1905(t)(3) shall require any such entity, as a condition of receiving payment under such contract, to satisfy the following requirements:

(A) DEMONSTRATION OF ACCESS TO INDIAN HEALTH CARE PROVIDERS AND APPLICATION OF ALTERNATIVE PAYMENT ARRANGEMENTS.—Subject to subparagraph (C), to—

(i) demonstrate that the number of Indian health care providers that are participating providers with respect to such entity are sufficient to ensure timely access to covered Medicaid managed care services for those Indian enrollees who are eligible to receive services from such providers; and

(ii) agree to pay Indian health care providers, whether such providers are participating or nonparticipating providers with respect to the entity, for covered Medicaid managed care services provided to those Indian enrollees who are eligible to receive services from such providers at a rate equal to the rate negotiated between such entity and the provider involved or, if such a rate has not been negotiated, at a rate that is not less than the level and amount of payment which the entity would make for the services if the services were furnished by a participating provider which is not an Indian health care provider.

The Secretary shall establish procedures for applying the requirements of clause (i) in States where there are no or few Indian health providers.

(B) PROMPT PAYMENT.—To agree to make prompt payment (consistent with rule for prompt payment of providers under section 1932(f)) to Indian health care providers that are participating providers with respect to such entity or, in the case of an entity to which subparagraph (A)(ii) or (C) applies, that the entity is required to pay in accordance with that subparagraph.

(C) APPLICATION OF SPECIAL PAYMENT REQUIREMENTS FOR FEDERALLY-QUALIFIED HEALTH CENTERS AND FOR SERVICES PROVIDED BY CERTAIN INDIAN HEALTH CARE PROVIDERS.—

(i) FEDERALLY-QUALIFIED HEALTH CENTERS.—

(I) MANAGED CARE ENTITY PAYMENT REQUIREMENT.—To agree to pay any Indian health care provider that is a federally-qualified health center under this title but not a participating provider with respect to the entity, for the provision of covered Medicaid managed care services by such provider to an Indian enrollee

of the entity at a rate equal to the amount of payment that the entity would pay a federally-qualified health center that is a participating provider with respect to the entity but is not an Indian health care provider for such services.

(II) CONTINUED APPLICATION OF STATE REQUIREMENT TO MAKE SUPPLEMENTAL PAYMENT.—Nothing in subclause (I) or subparagraph (A) or (B) shall be construed as waiving the application of section 1902(bb)(5) regarding the State plan requirement to make any supplemental payment due under such section to a federally-qualified health center for services furnished by such center to an enrollee of a managed care entity (regardless of whether the federally-qualified health center is or is not a participating provider with the entity).

(ii) PAYMENT RATE FOR SERVICES PROVIDED BY CERTAIN INDIAN HEALTH CARE PROVIDERS.—If the amount paid by a managed care entity to an Indian health care provider that is not a federally-qualified health center for services provided by the provider to an Indian enrollee with the managed care entity is less than the rate that applies to the provision of such services by the provider under the State plan, the plan shall provide for payment to the Indian health care provider, whether the provider is a participating or nonparticipating provider with respect to the entity, of the difference between such applicable rate and the amount paid by the managed care entity to the provider for such services.

(D) CONSTRUCTION.—Nothing in this paragraph shall be construed as waiving the application of section 1902(a)(30)(A) (relating to application of standards to assure that payments are consistent with efficiency, economy, and quality of care).

(3) SPECIAL RULE FOR ENROLLMENT FOR INDIAN MANAGED CARE ENTITIES.—Regarding the application of a Medicaid managed care program to Indian Medicaid managed care entities, an Indian Medicaid managed care entity may restrict enrollment under such program to Indians in the same manner as Indian Health Programs may restrict the delivery of services to Indians.

(4) DEFINITIONS.—For purposes of this subsection:

(A) INDIAN HEALTH CARE PROVIDER.—The term "Indian health care provider" means an Indian Health Program or an Urban Indian Organization.

(B) INDIAN MEDICAID MANAGED CARE ENTITY.—The term "Indian Medicaid managed care entity" means a managed care entity that is controlled (within the meaning of the last sentence of section 1903(m)(1)(C)) by the Indian Health Service, a Tribe, Tribal Organization, or Urban Indian Organization, or a consortium, which may be composed of 1 or more Tribes, Tribal Organizations, or Urban Indian Organizations, and which also may include the Service.

(C) NON-INDIAN MEDICAID MANAGED CARE ENTITY.—The term "non-Indian Medicaid managed care entity" means a managed care entity that is not an Indian Medicaid managed care entity.

(D) COVERED MEDICAID MANAGED CARE SERVICES.—The term "covered Medicaid managed care services" means, with respect to an individual enrolled with a managed care entity, items and services for which benefits are available with respect to the individual under the contract between the entity and the State involved.

(E) MEDICAID MANAGED CARE PROGRAM.—The term "Medicaid managed care program" means a program under sections 1903(m), 1905(t), and 1932 and includes a managed care program operating under a waiver under section 1915(b) or 1115 or otherwise.

*(i) DRUG UTILIZATION REVIEW ACTIVITIES AND REQUIREMENTS.—Beginning not later than October 1, 2019, each contract under a State plan with a managed care entity (other than a primary care case manager) under section 1903(m) shall provide that the entity is in compliance with the applicable provisions of section 438.3(s)(2) of title 42 of the Code of Federal Regulations, section 483.3(s)(4)) of such title, and section 483.3(s)(5) of such title, as such provisions were in effect on March 31, 2018.*

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***SEC. 1944. REQUIREMENTS RELATING TO QUALIFIED PRESCRIPTION DRUG MONITORING PROGRAMS AND PRESCRIBING CERTAIN CONTROLLED SUBSTANCES.***

*(a) IN GENERAL.—Beginning October 1, 2021, a State shall, subject to subsection (d), require each covered provider to check, in accordance with such timing, manner, and form as specified by the State, the prescription drug history of a covered individual being treated by the covered provider*

*through a qualified prescription drug monitoring program described in subsection (b) before prescribing to such individual a controlled substance.*

*(b) QUALIFIED PRESCRIPTION DRUG MONITORING PROGRAM DESCRIBED.—A qualified prescription drug monitoring program described in this subsection is, with respect to a State, a prescription drug monitoring program administered by the State that, at a minimum, satisfies each of the following criteria:*

*(1) The program facilitates access by a covered provider to, at a minimum, the following information with respect to a covered individual, in as close to real-time as possible:*

*(A) Information regarding the prescription drug history of a covered individual with respect to controlled substances.*

*(B) The number and type of controlled substances prescribed to and filled for the covered individual during at least the most recent 12-month period.*

*(C) The name, location, and contact information (or other identifying number selected by the State, such as a national provider identifier issued by the National Plan and Provider Enumeration System of the Centers for Medicare & Medicaid Services) of each covered provider who prescribed a controlled substance to the covered individual during at least the most recent 12-month period.*

*(2) The program facilitates the integration of information described in paragraph (1) into the workflow of a covered provider, which may include the electronic system the covered provider uses to prescribe controlled substances.*

*A qualified prescription drug monitoring program described in this subsection, with respect to a State, may have in place, in accordance with applicable State and Federal law, a data sharing agreement with the State Medicaid program that allows the medical director and pharmacy director of such program (and any designee of such a director who reports directly to such director) to access the information described in paragraph (1) in an electronic format. The State Medicaid program under this title may facilitate reasonable and limited access, as determined by the State and ensuring documented beneficiary protections regarding the use of such data, to such qualified prescription drug monitoring program for the medical director or pharmacy director of any managed care entity (as defined under section 1932(a)(1)(B)) that has a contract with the State under section 1903(m) or under section 1905(t)(3), or the medical director or pharmacy director of any entity has a contract to manage the pharmaceutical benefit with respect to individuals enrolled in the State plan (or waiver of the State plan). All applicable State and Federal security and privacy laws shall apply to the directors or designees of such directors of any State Medicaid program or entity accessing a qualified prescription drug monitoring program under this section.*

*(c) APPLICATION OF PRIVACY RULES CLARIFICATION.—The Secretary shall clarify privacy requirements, including requirements under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), related to the sharing of data under subsection (b) in the same manner as the Secretary is required under subparagraph (J) of section 1860D–4(c)(5) to clarify privacy requirements related to the sharing of data described in such subparagraph.*

*(d) ENSURING ACCESS.—In order to ensure reasonable access to health care, the Secretary shall waive the application of the requirement under subsection (a), with respect to a State, in the case of natural disasters and similar situations, and in the case of the provision of emergency services (as defined for purposes of section 1860D–4(c)(5)(D)(ii)(II)).*

*(e) REPORTS.—*

*(1) STATE REPORTS.—Each State shall include in the annual report submitted to the Secretary under section 1927(g)(3)(D), beginning with such reports submitted for 2023, information including, at a minimum, the following information for the most recent 12-month period:*

*(A) The percentage of covered providers (as determined pursuant to a process established by the State) who checked the prescription drug history of a covered individual through a qualified prescription drug monitoring program described in subsection (b) before prescribing to such individual a controlled substance.*

*(B) Aggregate trends with respect to prescribing controlled substances such as—*

*(i) the quantity of daily morphine milligram equivalents prescribed for controlled substances;*

*(ii) the number and quantity of daily morphine milligram equivalents prescribed for controlled substances per covered individual; and*

*(iii) the types of controlled substances prescribed, including the dates of such prescriptions, the supplies authorized (including the duration of such supplies), and the*

*period of validity of such prescriptions, in different populations (such as individuals who are elderly, individuals with disabilities, and individuals who are enrolled under both this title and title XVIII).*

*(C) Whether or not the State requires (and a detailed explanation as to why the State does or does not require) pharmacists to check the prescription drug history of a covered individual through a qualified drug management program before dispensing a controlled substance to such individual.*

*(2) REPORT BY CMS.—Not later than October 1, 2023, the Administrator of the Centers for Medicare & Medicaid Services shall publish on the publicly available website of the Centers for Medicare & Medicaid Services a report including the following information:*

*(A) Guidance for States on how States can increase the percentage of covered providers who use qualified prescription drug monitoring programs described in subsection (b).*

*(B) Best practices for how States and covered providers should use such qualified prescription drug monitoring programs to reduce the occurrence of abuse of controlled substances.*

*(f) INCREASE TO FEDERAL MATCHING RATE FOR CERTAIN EXPENDITURES RELATING TO QUALIFIED PRESCRIPTION DRUG MANAGEMENT PROGRAMS.—The Secretary shall increase the Federal medical assistance percentage or Federal matching rate that would otherwise apply to a State under section 1903(a) for a calendar quarter occurring during the period beginning October 1, 2018, and ending September 30, 2021, for expenditures by the State for activities under the State plan (or waiver of the State plan) to implement a prescription drug management program that satisfies the criteria described in paragraphs (1) and (2) of subsection (b) if the State (in this subsection referred to as the "administering State") has in place agreements with all States that are contiguous to such administering State that, when combined, enable covered providers in all such contiguous States to access, through the prescription drug management program, the information that is described in subsection (b)(1) of covered individuals of such administering State and that covered providers in such administering State are able to access through such program. In no case shall an increase under this subsection result in a Federal medical assistance percentage or Federal matching rate that exceeds 100 percent.*

*(g) RULE OF CONSTRUCTION.—Nothing in this section prevents a State from requiring pharmacists to check the prescription drug history of covered individuals through a qualified drug management program before dispensing controlled substances to such individuals.*

*(h) DEFINITIONS.—In this section:*

*(1) CONTROLLED SUBSTANCE.—The term "controlled substance" means a drug that is included in schedule II of section 202(c) of the Controlled Substances Act and, at the option of the State involved, a drug included in schedule III or IV of such section.*

*(2) COVERED INDIVIDUAL.—The term "covered individual" means, with respect to a State, an individual who is enrolled in the State plan (or under a waiver of such plan). Such term does not include an individual who—*

*(A) is receiving—*

*(i) hospice or palliative care; or*

*(ii) treatment for cancer;*

*(B) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or*

*(C) the State elects to treat as exempted from such term.*

*(3) COVERED PROVIDER.—*

*(A) IN GENERAL.—The term "covered provider" means, subject to subparagraph (B), with respect to a State, a health care provider who is participating under the State plan (or waiver of the State plan) and licensed, registered, or otherwise permitted by the State to prescribe a controlled substance (or the designee of such provider).*

*(B) EXCEPTIONS.—*

*(i) IN GENERAL.—Beginning October 1, 2021, for purposes of this section, such term does not include a health care provider included in any type of health care provider determined by the Secretary to be exempt from application of this section under clause (ii).*

*(ii) EXCEPTIONS PROCESS.—Not later than October 1, 2020, the Secretary, after consultation with the National Association of Medicaid Directors, national health care provider associations, Medicaid beneficiary advocates, and advocates for individuals with*

*rare diseases, shall determine, based on such consultations, the types of health care providers (if any) that should be exempted from the definition of the term "covered provider" for purposes of this section.*

SEC. 1945. STATE OPTION TO PROVIDE COORDINATED CARE THROUGH A HEALTH HOME FOR INDIVIDUALS WITH CHRONIC CONDITIONS.—

(a) IN GENERAL.—Notwithstanding section 1902(a)(1) (relating to statewideness), section 1902(a)(10)(B) (relating to comparability), and any other provision of this title for which the Secretary determines it is necessary to waive in order to implement this section, beginning January 1, 2011, a State, at its option as a State plan amendment, may provide for medical assistance under this title to eligible individuals with chronic conditions who select a designated provider (as described under subsection (h)(5)), a team of health care professionals (as described under subsection (h)(6)) operating with such a provider, or a health team (as described under subsection (h)(7)) as the individual's health home for purposes of providing the individual with health home services.

(b) HEALTH HOME QUALIFICATION STANDARDS.—The Secretary shall establish standards for qualification as a designated provider for the purpose of being eligible to be a health home for purposes of this section.

(c) PAYMENTS.—

(1) IN GENERAL.—A State shall provide a designated provider, a team of health care professionals operating with such a provider, or a health team with payments for the provision of health home services to each eligible individual with chronic conditions that selects such provider, team of health care professionals, or health team as the individual's health home. Payments made to a designated provider, a team of health care professionals operating with such a provider, or a health team for such services shall be treated as medical assistance for purposes of section 1903(a), except that, *subject to paragraph (4),* during the first 8 fiscal year quarters that the State plan amendment is in effect, the Federal medical assistance percentage applicable to such payments shall be equal to 90 percent.

(2) METHODOLOGY.—

(A) IN GENERAL.—The State shall specify in the State plan amendment the methodology the State will use for determining payment for the provision of health home services. Such methodology for determining payment—

(i) may be tiered to reflect, with respect to each eligible individual with chronic conditions provided such services by a designated provider, a team of health care professionals operating with such a provider, or a health team, as well as the severity or number of each such individual's chronic conditions or the specific capabilities of the provider, team of health care professionals, or health team; and

(ii) shall be established consistent with section 1902(a)(30)(A).

(B) ALTERNATE MODELS OF PAYMENT.—The methodology for determining payment for provision of health home services under this section shall not be limited to a per-member per-month basis and may provide (as proposed by the State and subject to approval by the Secretary) for alternate models of payment.

(3) PLANNING GRANTS.—

(A) IN GENERAL.—Beginning January 1, 2011, the Secretary may award planning grants to States for purposes of developing a State plan amendment under this section. A planning grant awarded to a State under this paragraph shall remain available until expended.

(B) STATE CONTRIBUTION.—A State awarded a planning grant shall contribute an amount equal to the State percentage determined under section 1905(b) (without regard to section 5001 of Public Law 111–5) for each fiscal year for which the grant is awarded.

(C) LIMITATION.—The total amount of payments made to States under this paragraph shall not exceed $25,000,000.

*(4) SPECIAL RULE RELATING TO SUBSTANCE USE DISORDER HEALTH HOMES.—*

*(A) IN GENERAL.—In the case of a State with an SUD-focused State plan amendment approved by the Secretary on or after October 1, 2018, the Secretary may, at the request of the State, extend the application of the Federal medical assistance percentage described in paragraph (1) to payments for the provision of health home services to SUD-eligible individuals under such State plan amendment, in addition to the first 8 fiscal year quarters the State plan amendment is in effect, for the subsequent 2 fiscal year quarters that the State plan amendment is in effect. Nothing in this section shall be construed as prohibiting*

*a State with a State plan amendment that is approved under this section and that is not an SUD-focused State plan amendment from additionally having approved on or after such date an SUD-focused State plan amendment under this section, including for purposes of application of this paragraph.*

*(B) REPORT REQUIREMENTS.—In the case of a State with an SUD-focused State plan amendment for which the application of the Federal medical assistance percentage has been extended under subparagraph (A), such State shall, at the end of the period of such State plan amendment, submit to the Secretary a report on the following, with respect to SUD-eligible individuals provided health home services under such State plan amendment:*

*(i) The quality of health care provided to such individuals, with a focus on outcomes relevant to the recovery of each such individual.*

*(ii) The access of such individuals to health care.*

*(iii) The total expenditures of such individuals for health care.*

*For purposes of this subparagraph, the Secretary shall specify all applicable measures for determining quality, access, and expenditures.*

*(C) BEST PRACTICES.—Not later than October 1, 2020, the Secretary shall make publicly available on the Internet website of the Centers for Medicare & Medicaid Services best practices for designing and implementing an SUD-focused State plan amendment, based on the experiences of States that have State plan amendments approved under this section that include SUD-eligible individuals.*

*(D) DEFINITIONS.—For purposes of this paragraph:*

*(i) SUD-ELIGIBLE INDIVIDUALS.—The term "SUD-eligible individual" means, with respect to a State, an individual who satisfies all of the following:*

*(I) The individual is an eligible individual with chronic conditions.*

*(II) The individual is an individual with a substance use disorder.*

*(III) The individual has not previously received health home services under any other State plan amendment approved for the State under this section by the Secretary.*

*(ii) SUD-FOCUSED STATE PLAN AMENDMENT.—The term "SUD-focused State plan amendment" means a State plan amendment under this section that is designed to provide health home services primarily to SUD-eligible individuals.*

(d) HOSPITAL REFERRALS.—A State shall include in the State plan amendment a requirement for hospitals that are participating providers under the State plan or a waiver of such plan to establish procedures for referring any eligible individuals with chronic conditions who seek or need treatment in a hospital emergency department to designated providers.

(e) COORDINATION.—A State shall consult and coordinate, as appropriate, with the Substance Abuse and Mental Health Services Administration in addressing issues regarding the prevention and treatment of mental illness and substance abuse among eligible individuals with chronic conditions.

(f) MONITORING.—A State shall include in the State plan amendment—

(1) a methodology for tracking avoidable hospital readmissions and calculating savings that result from improved chronic care coordination and management under this section; and

(2) a proposal for use of health information technology in providing health home services under this section and improving service delivery and coordination across the care continuum (including the use of wireless patient technology to improve coordination and management of care and patient adherence to recommendations made by their provider).

(g) REPORT ON QUALITY MEASURES.—As a condition for receiving payment for health home services provided to an eligible individual with chronic conditions, a designated provider shall report to the State, in accordance with such requirements as the Secretary shall specify, on all applicable measures for determining the quality of such services. When appropriate and feasible, a designated provider shall use health information technology in providing the State with such information.

(h) DEFINITIONS.—In this section:

(1) ELIGIBLE INDIVIDUAL WITH CHRONIC CONDITIONS.—

(A) IN GENERAL.—Subject to subparagraph (B), the term "eligible individual with chronic conditions" means an individual who—

(i) is eligible for medical assistance under the State plan or under a waiver of such plan; and

(ii) has at least—

(I) 2 chronic conditions;

(II) 1 chronic condition and is at risk of having a second chronic condition; or

(III) 1 serious and persistent mental health condition.

(B) RULE OF CONSTRUCTION.—Nothing in this paragraph shall prevent the Secretary from establishing higher levels as to the number or severity of chronic or mental health conditions for purposes of determining eligibility for receipt of health home services under this section.

(2) CHRONIC CONDITION.—The term "chronic condition" has the meaning given that term by the Secretary and shall include, but is not limited to, the following:

(A) A mental health condition.

(B) Substance use disorder.

(C) Asthma.

(D) Diabetes.

(E) Heart disease.

(F) Being overweight, as evidenced by having a Body Mass Index (BMI) over 25.

(3) HEALTH HOME.—The term "health home" means a designated provider (including a provider that operates in coordination with a team of health care professionals) or a health team selected by an eligible individual with chronic conditions to provide health home services.

(4) HEALTH HOME SERVICES.—

(A) IN GENERAL.—The term "health home services" means comprehensive and timely high-quality services described in subparagraph (B) that are provided by a designated provider, a team of health care professionals operating with such a provider, or a health team.

(B) SERVICES DESCRIBED.—The services described in this subparagraph are—

(i) comprehensive care management;

(ii) care coordination and health promotion;

(iii) comprehensive transitional care, including appropriate follow-up, from inpatient to other settings;

(iv) patient and family support (including authorized representatives);

(v) referral to community and social support services, if relevant; and

(vi) use of health information technology to link services, as feasible and appropriate.

(5) DESIGNATED PROVIDER.—The term "designated provider" means a physician, clinical practice or clinical group practice, rural clinic, community health center, community mental health center, home health agency, or any other entity or provider (including pediatricians, gynecologists, and obstetricians) that is determined by the State and approved by the Secretary to be qualified to be a health home for eligible individuals with chronic conditions on the basis of documentation evidencing that the physician, practice, or clinic—

(A) has the systems and infrastructure in place to provide health home services; and

(B) satisfies the qualification standards established by the Secretary under subsection (b).

(6) TEAM OF HEALTH CARE PROFESSIONALS.—The term "team of health care professionals" means a team of health professionals (as described in the State plan amendment) that may—

(A) include physicians and other professionals, such as a nurse care coordinator, nutritionist, social worker, behavioral health professional, or any professionals deemed appropriate by the State; and

(B) be free standing, virtual, or based at a hospital, community health center, community mental health center, rural clinic, clinical practice or clinical group practice, academic health center, or any entity deemed appropriate by the State and approved by the Secretary.

(7) HEALTH TEAM.—The term "health team" has the meaning given such term for purposes of section 3502 of the Patient Protection and Affordable Care Act.

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## TITLE XXI—STATE CHILDREN'S HEALTH INSURANCE PROGRAM

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**SEC. 2102. GENERAL CONTENTS OF STATE CHILD HEALTH PLAN; ELIGIBILITY; OUTREACH.**

(a) GENERAL BACKGROUND AND DESCRIPTION.—A State child health plan shall include a description, consistent with the requirements of this title, of—

(1) the extent to which, and manner in which, children in the State, including targeted low-income children and other classes of children classified by income and other relevant factors, currently have creditable health coverage (as defined in section 2110(c)(2));

(2) current State efforts to provide or obtain creditable health coverage for uncovered children, including the steps the State is taking to identify and enroll all uncovered children who are eligible to participate in public health insurance programs and health insurance programs that involve public-private partnerships;

(3) how the plan is designed to be coordinated with such efforts to increase coverage of children under creditable health coverage;

(4) the child health assistance provided under the plan for targeted low-income children, including the proposed methods of delivery, and utilization control systems;

(5) eligibility standards consistent with subsection (b);

(6) outreach activities consistent with subsection (c); and

(7) methods (including monitoring) used—

(A) to assure the quality and appropriateness of care, particularly with respect to well-baby care, well-child care, and immunizations provided under the plan;

(B) to assure access to covered services, including emergency services and services described in ⟦section 2103(c)(5)⟧ *paragraphs (5) and (6) of section 2103(c)*; and

(C) to ensure that the State agency involved is in compliance with subparagraphs (A), (B), and (C) of section 1128K(b)(2).

(b) GENERAL DESCRIPTION OF ELIGIBILITY STANDARDS AND METHODOLOGY.—

(1) ELIGIBILITY STANDARDS.—

(A) IN GENERAL.—The plan shall include a description of the standards used to determine the eligibility of targeted low-income children for child health assistance under the plan. Such standards may include (to the extent consistent with this title) those relating to the geographic areas to be served by the plan, age, income and resources (including any standards relating to spenddowns and disposition of resources), residency, disability status (so long as any standard relating to such status does not restrict eligibility), access to or coverage under other health coverage, and duration of eligibility. Such standards may not discriminate on the basis of diagnosis.

(B) LIMITATIONS ON ELIGIBILITY STANDARDS.—Such eligibility standards—

(i) shall, within any defined group of covered targeted low-income children, not cover such children with higher family income without covering children with a lower family income;

(ii) may not deny eligibility based on a child having a preexisting medical condition;

(iii) may not apply a waiting period (including a waiting period to carry out paragraph (3)(C)) in the case of a targeted low-income pregnant woman provided pregnancy-related assistance under section 2112;

(iv) at State option, may not apply a waiting period in the case of a child provided dental-only supplemental coverage under section 2110(b)(5); and

(v) shall, beginning January 1, 2014, use modified adjusted gross income and household income (as defined in section 36B(d)(2) of the Internal Revenue Code of 1986) to determine eligibility for child health assistance under the State child health plan or under any waiver of such plan and for any other purpose applicable under the plan or waiver for which a determination of income is required, including with respect to the imposition of premiums and cost-sharing, consistent with section 1902(e)(14).

(2) METHODOLOGY.—The plan shall include a description of methods of establishing and continuing eligibility and enrollment.

(3) ELIGIBILITY SCREENING; COORDINATION WITH OTHER HEALTH COVERAGE PROGRAMS.—The plan shall include a description of procedures to be used to ensure—

(A) through both intake and followup screening, that only targeted low-income children are furnished child health assistance under the State child health plan;

(B) that children found through the screening to be eligible for medical assistance under the State medicaid plan under title XIX are enrolled for such assistance under such plan;

(C) that the insurance provided under the State child health plan does not substitute for coverage under group health plans;

(D) the provision of child health assistance to targeted low-income children in the State who are Indians (as defined in section 4(c) of the Indian Health Care Improvement Act, 25 U.S.C. 1603(c)); and

(E) coordination with other public and private programs providing creditable coverage for low-income children.

(4) REDUCTION OF ADMINISTRATIVE BARRIERS TO ENROLLMENT.—

(A) IN GENERAL.—Subject to subparagraph (B), the plan shall include a description of the procedures used to reduce administrative barriers to the enrollment of children and pregnant women who are eligible for medical assistance under title XIX or for child health assistance or health benefits coverage under this title. Such procedures shall be established and revised as often as the State determines appropriate to take into account the most recent information available to the State identifying such barriers.

(B) DEEMED COMPLIANCE IF JOINT APPLICATION AND RENEWAL PROCESS THAT PERMITS APPLICATION OTHER THAN IN PERSON.—A State shall be deemed to comply with subparagraph (A) if the State's application and renewal forms and supplemental forms (if any) and information verification process is the same for purposes of establishing and renewing eligibility for children and pregnant women for medical assistance under title XIX and child health assistance under this title, and such process does not require an application to be made in person or a face-to-face interview.

(5) NONENTITLEMENT.—Nothing in this title shall be construed as providing an individual with an entitlement to child health assistance under a State child health plan.

(c) OUTREACH AND COORDINATION.—A State child health plan shall include a description of the procedures to be used by the State to accomplish the following:

(1) OUTREACH.—Outreach (through community health workers and others) to families of children likely to be eligible for child health assistance under the plan or under other public or private health coverage programs to inform these families of the availability of, and to assist them in enrolling their children in, such a program.

(2) COORDINATION WITH OTHER HEALTH INSURANCE PROGRAMS.—Coordination of the administration of the State program under this title with other public and private health insurance programs.

(3) PREMIUM ASSISTANCE SUBSIDIES.—In the case of a State that provides for premium assistance subsidies under the State child health plan in accordance with paragraph (2)(B), (3), or (10) of section 2105(c), or a waiver approved under section 1115, outreach, education, and enrollment assistance for families of children likely to be eligible for such subsidies, to inform such families of the availability of, and to assist them in enrolling their children in, such subsidies, and for employers likely to provide coverage that is eligible for such subsidies, including the specific, significant resources the State intends to apply to educate employers about the availability of premium assistance subsidies under the State child health plan.

**SEC. 2103. COVERAGE REQUIREMENTS FOR CHILDREN'S HEALTH INSURANCE.**

(a) REQUIRED SCOPE OF HEALTH INSURANCE COVERAGE.—The child health assistance provided to a targeted low-income child under the plan in the form described in paragraph (1) of section 2101(a) shall consist, consistent with **[**paragraphs (5), (6), and (7)**]** *paragraphs (5), (6), (7), and (8)* of subsection (c), of any of the following:

(1) BENCHMARK COVERAGE.—Health benefits coverage that is at least equivalent to the benefits coverage in a benchmark benefit package described in subsection (b).

(2) BENCHMARK-EQUIVALENT COVERAGE.—Health benefits coverage that meets the following requirements:

(A) INCLUSION OF BASIC SERVICES.—The coverage includes benefits for items and services within each of the categories of basic services described in subsection (c)(1).

(B) AGGREGATE ACTUARIAL VALUE EQUIVALENT TO BENCHMARK PACKAGE.—The coverage has an aggregate actuarial value that is at least actuarially equivalent to one of the benchmark benefit packages.

(C) SUBSTANTIAL ACTUARIAL VALUE FOR ADDITIONAL SERVICES INCLUDED IN BENCHMARK PACKAGE.—With respect to each of the categories of additional services described in subsection (c)(2) for which coverage is provided under the benchmark benefit package used

under subparagraph (B), the coverage has an actuarial value that is equal to at least 75 percent of the actuarial value of the coverage of that category of services in such package.

(3) EXISTING COMPREHENSIVE STATE-BASED COVERAGE.—Health benefits coverage under an existing comprehensive State-based program, described in subsection (d)(1).

(4) SECRETARY-APPROVED COVERAGE.—Any other health benefits coverage that the Secretary determines, upon application by a State, provides appropriate coverage for the population of targeted low-income children proposed to be provided such coverage.

(b) BENCHMARK BENEFIT PACKAGES.—The benchmark benefit packages are as follows:

(1) FEHBP-EQUIVALENT CHILDREN'S HEALTH INSURANCE COVERAGE.—The standard Blue Cross/Blue Shield preferred provider option service benefit plan, described in and offered under section 8903(1) of title 5, United States Code.

(2) STATE EMPLOYEE COVERAGE.—A health benefits coverage plan that is offered and generally available to State employees in the State involved.

(3) COVERAGE OFFERED THROUGH HMO.—The health insurance coverage plan that—

(A) is offered by a health maintenance organization (as defined in section 2791(b)(3) of the Public Health Service Act), and

(B) has the largest insured commercial, non-medicaid enrollment of covered lives of such coverage plans offered by such a health maintenance organization in the State involved.

(c) CATEGORIES OF SERVICES; DETERMINATION OF ACTUARIAL VALUE OF COVERAGE.—

(1) CATEGORIES OF BASIC SERVICES.—For purposes of this section, the categories of basic services described in this paragraph are as follows:

(A) Inpatient and outpatient hospital services.

(B) Physicians' surgical and medical services.

(C) Laboratory and x-ray services.

(D) Well-baby and well-child care, including age-appropriate immunizations.

*(E) Mental health and substance use disorder services (as defined in paragraph (5)).*

(2) CATEGORIES OF ADDITIONAL SERVICES.—For purposes of this section, the categories of additional services described in this paragraph are as follows:

(A) Coverage of prescription drugs.

(B) Vision services.

(C) Hearing services.

(3) TREATMENT OF OTHER CATEGORIES.—Nothing in this subsection shall be construed as preventing a State child health plan from providing coverage of benefits that are not within a category of services described in paragraph (1) or (2).

(4) DETERMINATION OF ACTUARIAL VALUE.—The actuarial value of coverage of benchmark benefit packages, coverage offered under the State child health plan, and coverage of any categories of additional services under benchmark benefit packages and under coverage offered by such a plan, shall be set forth in an actuarial opinion in an actuarial report that has been prepared—

(A) by an individual who is a member of the American Academy of Actuaries;

(B) using generally accepted actuarial principles and methodologies;

(C) using a standardized set of utilization and price factors;

(D) using a standardized population that is representative of privately insured children of the age of children who are expected to be covered under the State child health plan;

(E) applying the same principles and factors in comparing the value of different coverage (or categories of services);

(F) without taking into account any differences in coverage based on the method of delivery or means of cost control or utilization used; and

(G) taking into account the ability of a State to reduce benefits by taking into account the increase in actuarial value of benefits coverage offered under the State child health plan that results from the limitations on cost sharing under such coverage.

The actuary preparing the opinion shall select and specify in the memorandum the standardized set and population to be used under subparagraphs (C) and (D).

*(5) MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES.—Regardless of the type of coverage elected by a State under subsection (a), child health assistance provided under such coverage for targeted low-income children and, in the case that the State elects to provide preg-*

*nancy-related assistance under such coverage pursuant to section 2112, such pregnancy-related assistance for targeted low-income women (as defined in section 2112(d)) shall—*

*(A) include coverage of mental health services (including behavioral health treatment) necessary to prevent, diagnose, and treat a broad range of mental health symptoms and disorders, including substance use disorders; and*

*(B) be delivered in a culturally and linguistically appropriate manner.*

**[**(5)**]** *(6)* DENTAL BENEFITS.—

(A) IN GENERAL.—The child health assistance provided to a targeted low-income child shall include coverage of dental services necessary to prevent disease and promote oral health, restore oral structures to health and function, and treat emergency conditions.

(B) PERMITTING USE OF DENTAL BENCHMARK PLANS BY CERTAIN STATES.—A State may elect to meet the requirement of subparagraph (A) through dental coverage that is equivalent to a benchmark dental benefit package described in subparagraph (C).

(C) BENCHMARK DENTAL BENEFIT PACKAGES.—The benchmark dental benefit packages are as follows:

(i) FEHBP CHILDREN'S DENTAL COVERAGE.—A dental benefits plan under chapter 89A of title 5, United States Code, that has been selected most frequently by employees seeking dependent coverage, among such plans that provide such dependent coverage, in either of the previous 2 plan years.

(ii) STATE EMPLOYEE DEPENDENT DENTAL COVERAGE.—A dental benefits plan that is offered and generally available to State employees in the State involved and that has been selected most frequently by employees seeking dependent coverage, among such plans that provide such dependent coverage, in either of the previous 2 plan years.

(iii) COVERAGE OFFERED THROUGH COMMERCIAL DENTAL PLAN.—A dental benefits plan that has the largest insured commercial, non-medicaid enrollment of dependent covered lives of such plans that is offered in the State involved.

**[**(6)**]** *(7)* MENTAL HEALTH SERVICES PARITY.—

**[**(A) IN GENERAL.—In the case of a State child health plan that provides both medical and surgical benefits and mental health or substance use disorder benefits, such plan shall ensure that the financial requirements and treatment limitations applicable to such mental health or substance use disorder benefits comply with the requirements of section 2705(a) of the Public Health Service Act in the same manner as such requirements apply to a group health plan.**]**

*(A) IN GENERAL.—A State child health plan shall ensure that the financial requirements and treatment limitations applicable to mental health and substance use disorder services (as described in paragraph (5)) provided under such plan comply with the requirements of section 2726(a) of the Public Health Service Act in the same manner as such requirements or limitations apply to a group health plan under such section.*

(B) DEEMED COMPLIANCE.—To the extent that a State child health plan includes coverage with respect to an individual described in section 1905(a)(4)(B) and covered under the State plan under section 1902(a)(10)(A) of the services described in section 1905(a)(4)(B) (relating to early and periodic screening, diagnostic, and treatment services defined in section 1905(r)) and provided in accordance with section 1902(a)(43), such plan shall be deemed to satisfy the requirements of subparagraph (A).

**[**(7)**]** *(8)* CONSTRUCTION ON PROHIBITED COVERAGE.—Nothing in this section shall be construed as requiring any health benefits coverage offered under the plan to provide coverage for items or services for which payment is prohibited under this title, notwithstanding that any benchmark benefit package includes coverage for such an item or service.

**[**(8)**]** *(9)* AVAILABILITY OF COVERAGE FOR ITEMS AND SERVICES FURNISHED THROUGH SCHOOL-BASED HEALTH CENTERS.—Nothing in this title shall be construed as limiting a State's ability to provide child health assistance for covered items and services that are furnished through school-based health centers (as defined in section 2110(c)(9)).

(d) DESCRIPTION OF EXISTING COMPREHENSIVE STATE-BASED COVERAGE.—

(1) IN GENERAL.—A program described in this paragraph is a child health coverage program that—

(A) includes coverage of a range of benefits;

(B) is administered or overseen by the State and receives funds from the State;

(C) is offered in New York, Florida, or Pennsylvania; and

(D) was offered as of the date of the enactment of this title.

(2) MODIFICATIONS.—A State may modify a program described in paragraph (1) from time to time so long as it continues to meet the requirement of subparagraph (A) and does not reduce the actuarial value of the coverage under the program below the lower of—

(A) the actuarial value of the coverage under the program as of the date of the enactment of this title, or

(B) the actuarial value described in subsection (a)(2)(B),

evaluated as of the time of the modification.

(e) COST-SHARING.—

(1) DESCRIPTION; GENERAL CONDITIONS.—

(A) DESCRIPTION.—A State child health plan shall include a description, consistent with this subsection, of the amount (if any) of premiums, deductibles, coinsurance, and other cost sharing imposed. Any such charges shall be imposed pursuant to a public schedule.

(B) PROTECTION FOR LOWER INCOME CHILDREN.—The State child health plan may only vary premiums, deductibles, coinsurance, and other cost sharing based on the family income of targeted low-income children in a manner that does not favor children from families with higher income over children from families with lower income.

(2) NO COST SHARING ON BENEFITS FOR PREVENTIVE SERVICES OR PREGNANCY-RELATED ASSISTANCE.—The State child health plan may not impose deductibles, coinsurance, or other cost sharing with respect to benefits for services within the category of services described in subsection (c)(1)(D) or for pregnancy-related assistance.

(3) LIMITATIONS ON PREMIUMS AND COST-SHARING.—

(A) CHILDREN IN FAMILIES WITH INCOME BELOW 150 PERCENT OF POVERTY LINE.—In the case of a targeted low-income child whose family income is at or below 150 percent of the poverty line, the State child health plan may not impose—

(i) an enrollment fee, premium, or similar charge that exceeds the maximum monthly charge permitted consistent with standards established to carry out section 1916(b)(1) (with respect to individuals described in such section); and

(ii) a deductible, cost sharing, or similar charge that exceeds an amount that is nominal (as determined consistent with regulations referred to in section 1916(a)(3), with such appropriate adjustment for inflation or other reasons as the Secretary determines to be reasonable).

(B) OTHER CHILDREN.—For children not described in subparagraph (A), subject to paragraphs (1)(B) and (2), any premiums, deductibles, cost sharing or similar charges imposed under the State child health plan may be imposed on a sliding scale related to income, except that the total annual aggregate cost-sharing with respect to all targeted low-income children in a family under this title may not exceed 5 percent of such family's income for the year involved.

(C) PREMIUM GRACE PERIOD.—The State child health plan—

(i) shall afford individuals enrolled under the plan a grace period of at least 30 days from the beginning of a new coverage period to make premium payments before the individual's coverage under the plan may be terminated; and

(ii) shall provide to such an individual, not later than 7 days after the first day of such grace period, notice—

(I) that failure to make a premium payment within the grace period will result in termination of coverage under the State child health plan; and

(II) of the individual's right to challenge the proposed termination pursuant to the applicable Federal regulations.

For purposes of clause (i), the term "new coverage period" means the month immediately following the last month for which the premium has been paid.

(4) RELATION TO MEDICAID REQUIREMENTS.—Nothing in this subsection shall be construed as affecting the rules relating to the use of enrollment fees, premiums, deductions, cost sharing, and similar charges in the case of targeted low-income children who are provided child health assistance in the form of coverage under a medicaid program under section 2101(a)(2).

(f) APPLICATION OF CERTAIN REQUIREMENTS.—

(1) RESTRICTION ON APPLICATION OF PREEXISTING CONDITION EXCLUSIONS.—

(A) IN GENERAL.—Subject to subparagraph (B), the State child health plan shall not permit the imposition of any preexisting condition exclusion for covered benefits under the plan.

(B) GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.—If the State child health plan provides for benefits through payment for, or a contract with, a group health plan or group health insurance coverage, the plan may permit the imposition of a preexisting condition exclusion but only insofar as it is permitted under the applicable provisions of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 and title XXVII of the Public Health Service Act.

(2) COMPLIANCE WITH OTHER REQUIREMENTS.—Coverage offered under this section shall comply with the requirements of subpart 2 of part A of title XXVII of the Public Health Service Act insofar as such requirements apply with respect to a health insurance issuer that offers group health insurance coverage.

(3) COMPLIANCE WITH MANAGED CARE REQUIREMENTS.—The State child health plan shall provide for the application of subsections (a)(4), (a)(5), (b), (c), (d), and (e) of section 1932 (relating to requirements for managed care) to coverage, State agencies, enrollment brokers, managed care entities, and managed care organizations under this title in the same manner as such subsections apply to coverage and such entities and organizations under title XIX.

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**SEC. 2110. DEFINITIONS.**

(a) CHILD HEALTH ASSISTANCE.—For purposes of this title, the term "child health assistance" means payment for part or all of the cost of health benefits coverage for targeted low-income children that includes any of the following (and includes, in the case described in section 2105(a)(1)(D)(i), payment for part or all of the cost of providing any of the following), as specified under the State plan:

(1) Inpatient hospital services.

(2) Outpatient hospital services.

(3) Physician services.

(4) Surgical services.

(5) Clinic services (including health center services) and other ambulatory health care services.

(6) Prescription drugs and biologicals and the administration of such drugs and biologicals, only if such drugs and biologicals are not furnished for the purpose of causing, or assisting in causing, the death, suicide, euthanasia, or mercy killing of a person.

(7) Over-the-counter medications.

(8) Laboratory and radiological services.

(9) Prenatal care and prepregnancy family planning services and supplies.

(10) Inpatient mental health services, other than services described in paragraph (18) but including services furnished in a State-operated mental hospital and including residential or other 24-hour therapeutically planned structured services.

(11) Outpatient mental health services, other than services described in paragraph (19) but including services furnished in a State-operated mental hospital and including community-based services.

(12) Durable medical equipment and other medically-related or remedial devices (such as prosthetic devices, implants, eyeglasses, hearing aids, dental devices, and adaptive devices).

(13) Disposable medical supplies.

(14) Home and community-based health care services and related supportive services (such as home health nursing services, home health aide services, personal care, assistance with activities of daily living, chore services, day care services, respite care services, training for family members, and minor modifications to the home).

(15) Nursing care services (such as nurse practitioner services, nurse midwife services, advanced practice nurse services, private duty nursing care, pediatric nurse services, and respiratory care services) in a home, school, or other setting.

(16) Abortion only if necessary to save the life of the mother or if the pregnancy is the result of an act of rape or incest.

(17) Dental services.

(18) Inpatient [substance abuse] *substance use* treatment services and residential [substance abuse] *substance use* treatment services.

(19) Outpatient [substance abuse] *substance use* treatment services.
(20) Case management services.
(21) Care coordination services.
(22) Physical therapy, occupational therapy, and services for individuals with speech, hearing, and language disorders.
(23) Hospice care (concurrent, in the case of an individual who is a child, with care related to the treatment of the child's condition with respect to which a diagnosis of terminal illness has been made.
(24) Any other medical, diagnostic, screening, preventive, restorative, remedial, therapeutic, or rehabilitative services (whether in a facility, home, school, or other setting) if recognized by State law and only if the service is—
(A) prescribed by or furnished by a physician or other licensed or registered practitioner within the scope of practice as defined by State law,
(B) performed under the general supervision or at the direction of a physician, or
(C) furnished by a health care facility that is operated by a State or local government or is licensed under State law and operating within the scope of the license.
(25) Premiums for private health care insurance coverage.
(26) Medical transportation.
(27) Enabling services (such as transportation, translation, and outreach services) only if designed to increase the accessibility of primary and preventive health care services for eligible low-income individuals.
(28) Any other health care services or items specified by the Secretary and not excluded under this section.
(b) TARGETED LOW-INCOME CHILD DEFINED.—For purposes of this title—
(1) IN GENERAL.—Subject to paragraph (2), the term "targeted low-income child" means a child—
(A) who has been determined eligible by the State for child health assistance under the State plan;
(B)(i) who is a low-income child, or
(ii) is a child—
(I) whose family income (as determined under the State child health plan) exceeds the medicaid applicable income level (as defined in paragraph (4)), but does not exceed 50 percentage points above the medicaid applicable income level;
(II) whose family income (as so determined) does not exceed the medicaid applicable income level (as defined in paragraph (4) but determined as if "June 1, 1997" were substituted for "March 31, 1997"); or
(III) who resides in a State that does not have a medicaid applicable income level (as defined in paragraph (4)); and
(C) who is not found to be eligible for medical assistance under title XIX or, subject to paragraph (5), covered under a group health plan or under health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act).
(2) CHILDREN EXCLUDED.—Such term does not include—
(A) a child who is an inmate of a public institution or a patient in an institution for mental diseases; or
(B) except as provided in paragraph (6), a child who is a member of a family that is eligible for health benefits coverage under a State health benefits plan on the basis of a family member's employment with a public agency in the State.
(3) SPECIAL RULE.—A child shall not be considered to be described in paragraph (1)(C) notwithstanding that the child is covered under a health insurance coverage program that has been in operation since before July 1, 1997, and that is offered by a State which receives no Federal funds for the program's operation.
(4) MEDICAID APPLICABLE INCOME LEVEL.—The term "medicaid applicable income level" means, with respect to a child, the effective income level (expressed as a percent of the poverty line) that has been specified under the State plan under title XIX (including under a waiver authorized by the Secretary or under section 1902(r)(2)), as of March 31, 1997, for the child to be eligible for medical assistance under section 1902(l)(2) or 1905(n)(2) (as selected by a State) for the age of such child.
(5) OPTION FOR STATES WITH A SEPARATE CHIP PROGRAM TO PROVIDE DENTAL-ONLY SUPPLEMENTAL COVERAGE.—

(A) IN GENERAL.—Subject to subparagraphs (B) and (C), in the case of any child who is enrolled in a group health plan or health insurance coverage offered through an employer who would, but for the application of paragraph (1)(C), satisfy the requirements for being a targeted low-income child under a State child health plan that is implemented under this title, a State may waive the application of such paragraph to the child in order to provide—

(i) dental coverage consistent with the requirements of ⟦subsection (c)(5)⟧ *subsection (c)(6)* of section 2103; or

(ii) cost-sharing protection for dental coverage consistent with such requirements and the requirements of subsection (e)(3)(B) of such section.

(B) LIMITATION.—A State may limit the application of a waiver of paragraph (1)(C) to children whose family income does not exceed a level specified by the State, so long as the level so specified does not exceed the maximum income level otherwise established for other children under the State child health plan.

(C) CONDITIONS.—A State may not offer dental-only supplemental coverage under this paragraph unless the State satisfies the following conditions:

(i) INCOME ELIGIBILITY.—The State child health plan under this title—

(I) has the highest income eligibility standard permitted under this title (or a waiver) as of January 1, 2009;

(II) does not limit the acceptance of applications for children or impose any numerical limitation, waiting list, or similar limitation on the eligibility of such children for child health assistance under such State plan; and

(III) provides benefits to all children in the State who apply for and meet eligibility standards.

(ii) NO MORE FAVORABLE TREATMENT.—The State child health plan may not provide more favorable dental coverage or cost-sharing protection for dental coverage to children provided dental-only supplemental coverage under this paragraph than the dental coverage and cost-sharing protection for dental coverage provided to targeted low-income children who are eligible for the full range of child health assistance provided under the State child health plan.

(6) EXCEPTIONS TO EXCLUSION OF CHILDREN OF EMPLOYEES OF A PUBLIC AGENCY IN THE STATE.—

(A) IN GENERAL.—A child shall not be considered to be described in paragraph (2)(B) if—

(i) the public agency that employs a member of the child's family to which such paragraph applies satisfies subparagraph (B); or

(ii) subparagraph (C) applies to such child.

(B) MAINTENANCE OF EFFORT WITH RESPECT TO AGENCY CONTRIBUTION FOR FAMILY COVERAGE.—For purposes of subparagraph (A)(i), a public agency satisfies this subparagraph if the amount of annual agency expenditures made on behalf of employees enrolled in health coverage paid for by the agency that includes dependent coverage for the most recent State fiscal year is not less than the amount of such expenditures made by the agency for the 1997 State fiscal year, increased by the percentage increase in the medical care expenditure category of the Consumer Price Index for All-Urban Consumers (all items: U.S. City Average) for such preceding fiscal year.

(C) HARDSHIP EXCEPTION.—For purposes of subparagraph (A)(ii), this subparagraph applies to a child if the State determines that the annual aggregate amount of premiums and cost-sharing imposed for coverage of the family of the child would exceed 5 percent of such family's income for the year involved.

(c) ADDITIONAL DEFINITIONS.—For purposes of this title:

(1) CHILD.—The term "child" means an individual under 19 years of age.

(2) CREDITABLE HEALTH COVERAGE.—The term "creditable health coverage" has the meaning given the term "creditable coverage" under section 2701(c) of the Public Health Service Act (42 U.S.C. 300gg(c)) and includes coverage that meets the requirements of section 2103 provided to a targeted low-income child under this title or under a waiver approved under section 2105(c)(2)(B) (relating to a direct service waiver).

(3) GROUP HEALTH PLAN; HEALTH INSURANCE COVERAGE; ETC.—The terms "group health plan", "group health insurance coverage", and "health insurance coverage" have the meanings given such terms in section 2791 of the Public Health Service Act.

(4) LOW-INCOME.—The term "low-income child" means a child whose family income is at or below 200 percent of the poverty line for a family of the size involved.

(5) POVERTY LINE DEFINED.—The term "poverty line" has the meaning given such term in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)), including any revision required by such section.

(6) PREEXISTING CONDITION EXCLUSION.—The term "preexisting condition exclusion" has the meaning given such term in section 2701(b)(1)(A) of the Public Health Service Act (42 U.S.C. 300gg(b)(1)(A)).

(7) STATE CHILD HEALTH PLAN; PLAN.—Unless the context otherwise requires, the terms "State child health plan" and "plan" mean a State child health plan approved under section 2106.

(8) UNCOVERED CHILD.—The term "uncovered child" means a child that does not have creditable health coverage.

(9) SCHOOL-BASED HEALTH CENTER.—

(A) IN GENERAL.—The term "school-based health center" means a health clinic that—

(i) is located in or near a school facility of a school district or board or of an Indian tribe or tribal organization;

(ii) is organized through school, community, and health provider relationships;

(iii) is administered by a sponsoring facility;

(iv) provides through health professionals primary health services to children in accordance with State and local law, including laws relating to licensure and certification; and

(v) satisfies such other requirements as a State may establish for the operation of such a clinic.

(B) SPONSORING FACILITY.—For purposes of subparagraph (A)(iii), the term "sponsoring facility" includes any of the following:

(i) A hospital.

(ii) A public health department.

(iii) A community health center.

(iv) A nonprofit health care agency.

(v) A local educational agency (as defined under section 8101 of the Elementaryand Secondary Education Act of 1965.

(vi) A program administered by the Indian Health Service or the Bureau of Indian Affairs or operated by an Indian tribe or a tribal organization.

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## PUBLIC HEALTH SERVICE ACT

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### TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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### PART B—FEDERAL-STATE COOPERATION

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[SURVEILLANCE AND EDUCATION REGARDING HEPATITIS C VIRUS

[SEC. 317N. (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may (directly and through grants to public and nonprofit private entities) provide for programs to carry out the following:

[(1) To cooperate with the States in implementing a national system to determine the incidence of hepatitis C virus infection (in this section referred to as "HCV infection") and to assist the States in determining the prevalence of such infection, including the reporting of chronic HCV cases.

[(2) To identify, counsel, and offer testing to individuals who are at risk of HCV infection as a result of receiving blood transfusions prior to July 1992, or as a result of other risk factors.

[(3) To provide appropriate referrals for counseling, testing, and medical treatment of individuals identified under paragraph (2) and to ensure, to the extent practicable, the provision of appropriate follow-up services.

[(4) To develop and disseminate public information and education programs for the detection and control of HCV infection, with priority given to high risk populations as determined by the Secretary.

[(5) To improve the education, training, and skills of health professionals in the detection and control of HCV infection, with priority given to pediatricians and other primary care physicians, and obstetricians and gynecologists.

[(b) LABORATORY PROCEDURES.—The Secretary may (directly and through grants to public and nonprofit private entities) carry out programs to provide for improvements in the quality of clinical-laboratory procedures regarding hepatitis C, including reducing variability in laboratory results on hepatitis C antibody and PCR testing.

[(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.]

***SEC. 317N. Surveillance and education regarding infections associated with illicit drug use and other risk factors.***

*(a) IN GENERAL.—The Secretary may (directly and through grants to public and nonprofit private entities) provide for programs for the following:*

*(1) To cooperate with the States and Indian tribes in implementing or maintaining a surveillance system to determine the incidence of infections commonly associated with illicit drug use, including infections commonly associated with injection drug use such as viral hepatitis, human immunodeficiency virus, and infective endocarditis, and to assist the States in determining the prevalence of such infections, which may include the reporting of cases of such infections.*

*(2) To identify, counsel, and offer testing to individuals who are at risk of infections as a result of injection drug use, receiving blood transfusions prior to July 1992, or other risk factors.*

*(3) To provide appropriate referrals for counseling, testing, and medical treatment of individuals identified under paragraph (2) and to ensure, to the extent practicable, the provision of appropriate follow-up services.*

*(4) To develop and disseminate public information and education programs for the detection and control of infections described in paragraph (1), with priority given to high-risk populations as determined by the Secretary.*

*(5) To improve the education, training, and skills of health professionals in the detection and control of infections and the coordination of treatment of addiction and infectious diseases described in paragraph (1), with priority given to substance use disorder treatment providers, pediatricians and other primary care providers, obstetrician-gynecologists, infectious diseases clinicians, and HIV clinicians.*

*(b) LABORATORY PROCEDURES.—The Secretary may (directly or through grants to public and nonprofit private entities) carry out programs to provide for improvements in the quality of clinical-laboratory procedures regarding infections described in subsection (a)(1).*

*(c) DEFINITIONS.—In this section:*

*(1) The term "Indian tribe" has the meaning given that term in section 4 of the Indian Self-Determination and Education Assistance Act.*

*(2) The term "injection drug use" means—*

*(A) intravenous administration of a substance in schedule I under section 202 of the Controlled Substances Act;*

*(B) intravenous administration of a substance in schedule II, III, IV, or V under section 202 of the Controlled Substances Act that has not been approved for intravenous use under—*

*(i) section 505 of the Federal Food, Drug and Cosmetic Act; or*

*(ii) section 351 of the Public Health Service Act; or*

*(C) intravenous administration of a substance in schedule II, III, IV, or V under section 202 of the Controlled Substances Act that has not been prescribed to the person using the substance.*

*(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $40,000,000 for each of the fiscal years 2019 through 2023.*

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[GRANTS FOR LEAD POISONING RELATED ACTIVITIES

[SEC. 317O. (a) AUTHORITY TO MAKE GRANTS.—

[(1) IN GENERAL.—The Secretary shall make grants to States to support public health activities in States and localities where data suggests that at least 5 percent of preschool-age children have an elevated blood lead level through—

[(A) effective, ongoing outreach and community education targeted to families most likely to be at risk for lead poisoning;

[(B) individual family education activities that are designed to reduce ongoing exposures to lead for children with elevated blood lead levels, including through home visits and coordination with other programs designed to identify and treat children at risk for lead poisoning; and

[(C) the development, coordination and implementation of community-based approaches for comprehensive lead poisoning prevention from surveillance to lead hazard control.

[(2) STATE MATCH.—A State is not eligible for a grant under this section unless the State agrees to expend (through State or local funds) $1 for every $2 provided under the grant to carry out the activities described in paragraph (1).

[(3) APPLICATION.—To be eligible to receive a grant under this section, a State shall submit an application to the Secretary in such form and manner and containing such information as the Secretary may require.

[(b) COORDINATION WITH OTHER CHILDREN'S PROGRAMS.—A State shall identify in the application for a grant under this section how the State will coordinate operations and activities under the grant with—

[(1) other programs operated in the State that serve children with elevated blood lead levels, including any such programs operated under title V, XIX, or XXI of the Social Security Act; and

[(2) one or more of the following—

[(A) the child welfare and foster care and adoption assistance programs under parts B and E of title IV of such Act;

[(B) the head start program established under the Head Start Act (42 U.S.C. 9831 et seq.);

[(C) the program of assistance under the special supplemental nutrition program for women, infants and children (WIC) under section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786);

[(D) local public and private elementary or secondary schools; or

[(E) public housing agencies, as defined in section 3 of the United States Housing Act of 1937 (42 U.S.C. 1437a).

[(c) PERFORMANCE MEASURES.—The Secretary shall establish needs indicators and performance measures to evaluate the activities carried out under grants awarded under this section. Such indicators shall be commensurate with national measures of maternal and child health programs and shall be developed in consultation with the Director of the Centers for Disease Control and Prevention.

[(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.]

***SEC. 399O. Prescription drug monitoring program.***

*(a) PROGRAM.—*

*(1) IN GENERAL.—Each fiscal year, the Secretary, in consultation with the Director of National Drug Control Policy, acting through the Director of the Centers for Disease Control and Prevention, the Assistant Secretary for Mental Health and Substance Use, and the National Co-*

*ordinator for Health Information Technology, shall support States for the purpose of improving the efficiency and use of PDMPs, including—*

*(A) establishment and implementation of a PDMP;*

*(B) maintenance of a PDMP;*

*(C) improvements to a PDMP by—*

*(i) enhancing functional components to work toward—*

*(I) universal use of PDMPs among providers and their delegates, to the extent that State laws allow, within a State;*

*(II) more timely inclusion of data within a PDMP;*

*(III) active management of the PDMP, in part by sending proactive or unsolicited reports to providers to inform prescribing; and*

*(IV) ensuring the highest level of ease in use and access of PDMPs by providers and their delegates, to the extent that State laws allow;*

*(ii) improving the intrastate interoperability of PDMPs by—*

*(I) making PDMPs more actionable by integrating PDMPs within electronic health records and health information technology infrastructure; and*

*(II) linking PDMP data to other data systems within the State, including—*

*(aa) the data of pharmacy benefit managers, medical examiners and coroners, and the State's Medicaid program;*

*(bb) worker's compensation data; and*

*(cc) prescribing data of providers of the Department of Veterans Affairs and the Indian Health Service within the State;*

*(iii) improving the interstate interoperability of PDMPs through—*

*(I) sharing of dispensing data in near-real time across State lines; and*

*(II) integration of automated queries for multistate PDMP data and analytics into clinical workflow to improve the use of such data and analytics by practitioners and dispensers; or*

*(iv) improving the ability to include treatment availability resources and referral capabilities within the PDMP.*

*(2) STATE LEGISLATION.—As a condition on the receipt of support under this section, the Secretary shall require a State to demonstrate that the State has enacted legislation or regulations—*

*(A) to provide for the implementation of the PDMP; and*

*(B) to permit the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained by the PDMP.*

*(b) PDMP STRATEGIES.—The Secretary shall encourage a State, in establishing, improving, or maintaining a PDMP, to implement strategies that improve—*

*(1) the reporting of dispensing in the State of a controlled substance to an ultimate user so the reporting occurs not later than 24 hours after the dispensing event;*

*(2) the consultation of the PDMP by each prescribing practitioner, or their designee, in the State before initiating treatment with a controlled substance, or any substance as required by the State to be reported to the PDMP, and over the course of ongoing treatment for each prescribing event;*

*(3) the consultation of the PDMP before dispensing a controlled substance, or any substance as required by the State to be reported to the PDMP;*

*(4) the proactive notification to a practitioner when patterns indicative of controlled substance misuse by a patient, including opioid misuse, are detected;*

*(5) the availability of data in the PDMP to other States, as allowable under State law; and*

*(6) the availability of nonidentifiable information to the Centers for Disease Control and Prevention for surveillance, epidemiology, statistical research, or educational purposes.*

*(c) DRUG MISUSE AND ABUSE.—In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving support under this section—*

*(1) shall establish a program to notify practitioners and dispensers of information that will help to identify and prevent the unlawful diversion or misuse of controlled substances; and*

*(2) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the PDMP maintained by the State indicates an unlawful diversion or abuse of a controlled substance.*

*(d) EVALUATION AND REPORTING.—As a condition on receipt of support under this section, the State shall report on interoperability with PDMPs of other States and Federal agencies, where appropriate, intrastate interoperability with health information technology systems such as electronic health records, health information exchanges, and e-prescribing, where appropriate, and whether or not the State provides automatic, up-to-date, or daily information about a patient when a practitioner (or the designee of a practitioner, where permitted) requests information about such patient.*

*(e) EVALUATION AND REPORTING.—A State receiving support under this section shall provide the Secretary with aggregate nonidentifiable information, as permitted by State law, to enable the Secretary—*

*(1) to evaluate the success of the State's program in achieving the purpose described in subsection (a); or*

*(2) to prepare and submit to the Congress the report required by subsection (i)(2).*

*(f) EDUCATION AND ACCESS TO THE MONITORING SYSTEM.—A State receiving support under this section shall take steps to—*

*(1) facilitate prescribers and dispensers, and their delegates, as permitted by State law, to use the PDMP, to the extent practicable; and*

*(2) educate prescribers and dispensers, and their delegates on the benefits of the use of PDMPs.*

*(g) ELECTRONIC FORMAT.—The Secretary may issue guidelines specifying a uniform electronic format for the reporting, sharing, and disclosure of information pursuant to PDMPs.*

*(h) RULES OF CONSTRUCTION.—*

*(1) FUNCTIONS OTHERWISE AUTHORIZED BY LAW.—Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.*

*(2) ADDITIONAL PRIVACY PROTECTIONS.—Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.*

*(3) FEDERAL PRIVACY REQUIREMENTS.—Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 543 of this Act.*

*(4) NO FEDERAL PRIVATE CAUSE OF ACTION.—Nothing in this section shall be construed to create a Federal private cause of action.*

*(i) PROGRESS REPORT.—Not later than 3 years after the date of enactment of the CONNECTIONS Act, the Secretary shall—*

*(1) complete a study that—*

*(A) determines the progress of States in establishing and implementing PDMPs consistent with this section;*

*(B) provides an analysis of the extent to which the operation of PDMPs has—*

*(i) reduced inappropriate use, abuse, diversion of, and overdose with, controlled substances;*

*(ii) established or strengthened initiatives to ensure linkages to substance use disorder treatment services; or*

*(iii) affected patient access to appropriate care in States operating PDMPs;*

*(C) determine the progress of States in achieving interstate interoperability and intrastate interoperability of PDMPs, including an assessment of technical, legal, and financial barriers to such progress and recommendations for addressing these barriers;*

*(D) determines the progress of States in implementing near real-time electronic PDMPs;*

*(E) provides an analysis of the privacy protections in place for the information reported to the PDMP in each State receiving support under this section and any recommendations of the Secretary for additional Federal or State requirements for protection of this information;*

*(F) determines the progress of States in implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in PDMPs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and*

*(G) evaluates the penalties that States have enacted for the unauthorized use and disclosure of information maintained in PDMPs, and the criteria used by the Secretary to determine whether such penalties qualify as appropriate for purposes of subsection (a)(2); and*

*(2) submit a report to the Congress on the results of the study.*

*(j) ADVISORY COUNCIL.—*

*(1) ESTABLISHMENT.—A State may establish an advisory council to assist in the establishment, improvement, or maintenance of a PDMP consistent with this section.*

*(2) LIMITATION.—A State may not use Federal funds for the operations of an advisory council to assist in the establishment, improvement, or maintenance of a PDMP.*

*(3) SENSE OF CONGRESS.—It is the sense of the Congress that, in establishing an advisory council to assist in the establishment, improvement, or maintenance of a PDMP, a State should consult with appropriate professional boards and other interested parties.*

*(k) DEFINITIONS.—For purposes of this section:*

*(1) The term "controlled substance" means a controlled substance (as defined in section 102 of the Controlled Substances Act) in schedule II, III, or IV of section 202 of such Act.*

*(2) The term "dispense" means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the internet or other means to effect such delivery.*

*(3) The term "dispenser" means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.*

*(4) The term "interstate interoperability" with respect to a PDMP means the ability of the PDMP to electronically share reported information with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.*

*(5) The term "intrastate interoperability" with respect to a PDMP means the integration of PDMP data within electronic health records and health information technology infrastructure or linking of a PDMP to other data systems within the State, including the State's Medicaid program, workers' compensation programs, and medical examiners or coroners.*

*(6) The term "nonidentifiable information" means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.*

*(7) The term "PDMP" means a prescription drug monitoring program that is State-controlled.*

*(8) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which the individual practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.*

*(9) The term "State" means each of the 50 States, the District of Columbia, and any commonwealth or territory of the United States.*

*(10) The term "ultimate user" means a person who has obtained from a dispenser, and who possesses, a controlled substance for the person's own use, for the use of a member of the person's household, or for the use of an animal owned by the person or by a member of the person's household.*

*(11) The term "clinical workflow" means the integration of automated queries for prescription drug monitoring programs data and analytics into health information technologies such as electronic health record systems, health information exchanges, and/or pharmacy dispensing software systems, thus streamlining provider access through automated queries.*

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***SEC. 317U. ENHANCED FENTANYL SURVEILLANCE.***

*(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall enhance its drug surveillance program by—*

*(1) expanding its surveillance program to include all 50 States and the territories of the United States;*

*(2) increasing and accelerating the collection of data on fentanyl, its analogues, and other synthetic opioids and new emerging drugs of abuse, including related overdose data from medical examiners and drug treatment admissions; and*

*(3) utilizing available and emerging information on fentanyl, its analogues, and other synthetic opioids and new emerging drugs of abuse, including information from—*

*(A) the National Drug Early Warning System;*
*(B) State and local public health authorities; and*
*(C) Federal, State, and local public health laboratories.*

*(b) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $10,000,000 for each of fiscal years 2019 through 2023.*

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PART FLICENSING—BIOLOGICAL PRODUCTS ***, clinical laboratories, and public health laboratories*—Licensing—Biological Products [and Clinical Laboratories] *, Clinical Laboratories, and Public Health Laboratories***

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## *Subpart 4—Public Health Laboratories*

***SEC. 355. PUBLIC HEALTH LABORATORIES TO DETECT FENTANYL.***

*(a) IN GENERAL.—The Secretary shall establish a program to award grants to Federal, State, and local agencies to support the establishment or operation of public health laboratories to detect fentanyl, its analogues, and other synthetic opioids, as described in subsection (b).*

*(b) STANDARDS.—The Secretary, in consultation with the Director of the National Institute of Standards and Technology, shall—*

*(1) develop standards for safely and effectively handling and testing fentanyl, its analogues, and other synthetic opioids;*

*(2) develop fentanyl and fentanyl analog reference materials and quality control standards and protocols to calibrate instrumentation for clinical diagnostics and postmortem surveillance; and*

*(3) include in the standards developed pursuant to paragraph (1) procedures for encountering new and emerging synthetic opioid formulations and reporting those findings to other Federal, State, and local public health laboratories.*

*(c) LABORATORIES.—The Secretary shall require grantees under subsection (a) to—*

*(1) follow the standards established under subsection (b) and be capable of providing systematic and routine laboratory testing of drugs for the purposes of obtaining and disseminating public health information to Federal, State, and local public health officials, laboratories, and other entities the Secretary deems appropriate;*

*(2) work with law enforcement agencies and public health authorities, as feasible, to develop real-time information on the purity and movement of fentanyl, its analogues, and other synthetic opioids;*

*(3) assist State and local law enforcement agencies in testing seized drugs when State and local forensic laboratories request additional assistance;*

*(4) provide early warning information and advice to Federal, State, and local law enforcement agencies and public health authorities regarding potential significant changes in the supply of fentanyl, its analogues, and other synthetic opioids;*

*(5) provide biosurveillance for non-fatal exposures; and*

*(6) provide diagnostic testing for non-fatal exposures of emergency personnel.*

*(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $15,000,000 for each of fiscal years 2019 through 2023.*

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# PART P—ADDITIONAL PROGRAMS

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***SEC. 399V-7. PILOT PROGRAM FOR POINT-OF-USE TESTING OF ILLICIT DRUGS FOR DANGEROUS CONTAMINANTS.***

*(a) IN GENERAL.—The Secretary shall—*

*(1) establish a pilot program through which 5 State or local agencies conduct, in 5 States, point-of-use testing of illicit drugs for dangerous contaminants;*

*(2) establish metrics to evaluate the success of the pilot program in reducing drug overdose rates; and*

*(3) based on such metrics, conduct an annual evaluation of the pilot program and submit an annual report to the Congress containing the results of such evaluation.*

*(b) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2019 through 2023.*

***SEC. 399V–7. NATIONAL RECOVERY HOUSING BEST PRACTICES.***

*(a) BEST PRACTICES.—The Secretary of Health and Human Services, in consultation with the Secretary for Housing and Urban Development, patients with a history of opioid use disorder, and other stakeholders, which may include State accrediting entities and reputable providers, analysts, and stakeholders of recovery housing services, such as the National Alliance for Recovery Residences, shall identify or facilitate the development of best practices, which may include model laws for implementing suggested minimum standards, for operating recovery housing.*

*(b) DISSEMINATION.—The Secretary shall disseminate the best practices identified or developed under subsection (a) to—*

*(1) State agencies, which may include the provision of technical assistance to State agencies seeking to adopt or implement such best practices;*

*(2) recovery housing entities; and*

*(3) the public, as appropriate.*

*(c) DEFINITIONS.—In this section:*

*(1) The term "recovery housing" means a shared living environment free from alcohol and illicit drug use and centered on peer support and connection to services, including medication-assisted treatment services, that promote sustained recovery from substance use disorders.*

*(2) The term "State" includes any of the several States, the District of Columbia, each Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), and any territory or possession of the United States.*

*(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $3,000,000 for the period of fiscal years 2019 through 2021.*

***SEC. 399V–7. PREVENTING OVERDOSES OF CONTROLLED SUBSTANCES.***

*(a) EVIDENCE-BASED PREVENTION GRANTS.—*

*(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention may—*

*(A) to the extent practicable, carry out any evidence-based prevention activity described in paragraph (2);*

*(B) provide training and technical assistance to States, localities, and Indian tribes for purposes of carrying out any such activity; and*

*(C) award grants to States, localities, and Indian tribes for purposes of carrying out any such activity.*

*(2) EVIDENCE-BASED PREVENTION ACTIVITIES.—An evidence-based prevention activity described in this paragraph is any of the following activities:*

*(A) With respect to a State, improving the efficiency and use of the State prescription drug monitoring program by—*

*(i) encouraging all authorized users (as specified by the State) to register with and use the program and making the program easier to use;*

*(ii) enabling such users to access any updates to information collected by the program in as close to real-time as possible;*

*(iii) providing for a mechanism for the program to automatically flag any potential misuse or abuse of controlled substances and any detection of inappropriate prescribing practices relating to such substances;*

*(iv) enhancing interoperability between the program and any electronic health records system, including by integrating the use of electronic health records into the program for purposes of improving clinical decisionmaking;*

*(v) continually updating program capabilities to respond to technological innovation for purposes of appropriately addressing a controlled substance overdose epidemic as such epidemic may occur and evolve;*

*(vi) facilitating data sharing between the program and the prescription drug monitoring programs of neighboring States; and*

*(vii) meeting the purpose of the program established under section 399O, as described in section 399O(a).*

*(B) Achieving community or health system interventions through activities such as—*

*(i) establishing or improving controlled substances prescribing interventions for insurers and health systems;*

*(ii) enhancing the use of evidence-based controlled substances prescribing guidelines across sectors and health care settings; and*

*(iii) implementing strategies to align the prescription of controlled substances with the guidelines described in clause (ii).*

*(C) Evaluating interventions to better understand what works to prevent overdoses, including those involving prescription and illicit controlled substances.*

*(D) Implementing projects to advance an innovative prevention approach with respect to new and emerging public health crises and opportunities to address such crises, such as enhancing public education and awareness on the risks associated with opioids.*

*(b) ENHANCED SURVEILLANCE OF CONTROLLED SUBSTANCE OVERDOSE GRANTS.—*

*(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention may—*

*(A) to the extent practicable, carry out any controlled substance overdose surveillance activity described in paragraph (2);*

*(B) provide training and technical assistance to States for purposes of carrying out any such activity;*

*(C) award grants to States for purposes of carrying out any such activity; and*

*(D) coordinate with the Assistant Secretary for Mental Health and Substance Use to collect data pursuant to section 505(d)(1)(A) (relating to the number of individuals admitted to the emergency rooms of hospitals as a result of the abuse of alcohol or other drugs).*

*(2) CONTROLLED SUBSTANCE OVERDOSE SURVEILLANCE ACTIVITIES.—A controlled substance overdose surveillance activity described in this paragraph is any of the following activities:*

*(A) Enhancing the timeliness of reporting data to the public, including data on fatal and nonfatal overdoses of controlled substances.*

*(B) Enhancing comprehensiveness of data on controlled substances overdoses by collecting information on such overdoses from appropriate sources such as toxicology reports, autopsy reports, death scene investigations, and other risk factors.*

*(C) Using data to help identify risk factors associated with controlled substances overdoses.*

*(D) With respect to a State, supporting entities involved in providing information to inform efforts within the State, such as by coroners and medical examiners, to improve accurate testing and reporting of causes and contributing factors to controlled substances overdoses.*

*(E) Working to enable information sharing regarding controlled substances overdoses among data sources.*

*(c) DEFINITIONS.—In this section:*

*(1) CONTROLLED SUBSTANCE.—The term "controlled substance" has the meaning given that term in section 102 of the Controlled Substances Act.*

*(2) INDIAN TRIBE.—The term "Indian tribe" has the meaning given that term in section 4 of the Indian Self-Determination and Education Assistance Act.*

*(d) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section and section 399O, there is authorized to be appropriated $486,000,000 for each of fiscal years 2019 through 2023.*

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## TITLE IV—NATIONAL RESEARCH INSTITUTES

### PART A—NATIONAL INSTITUTES OF HEALTH

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#### APPOINTMENT AND AUTHORITY OF DIRECTOR OF NIH

SEC. 402. (a) The National Institutes of Health shall be headed by the Director of NIH who shall be appointed by the President by and with the advice and consent of the Senate. The Director of NIH shall perform functions as provided under subsection (b) and as the Secretary may otherwise prescribe.

(b) In carrying out the purposes of section 301, the Secretary, acting through the Director of NIH—

(1) shall carry out this title, including being responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

(2) shall coordinate and oversee the operation of the national research institutes, national centers, and administrative entities within the National Institutes of Health;

(3) shall, in consultation with the heads of the national research institutes and national centers, be responsible for program coordination across the national research institutes and national centers, including conducting priority-setting reviews, to ensure that the research portfolio of the National Institutes of Health is balanced and free of unnecessary duplication, and takes advantage of collaborative, cross-cutting research;

(4) shall assemble accurate data to be used to assess research priorities, including—

(A) information to better evaluate scientific opportunity, public health burdens, and progress in reducing health disparities; and

(B) data on study populations of clinical research, funded by or conducted at each national research institute and national center, which—

(i) specifies the inclusion of—

(I) women;

(II) members of minority groups;

(III) relevant age categories, including pediatric subgroups; and

(IV) other demographic variables as the Director of the National Institutes of Health determines appropriate;

(ii) is disaggregated by research area, condition, and disease categories; and

(iii) is to be made publicly available on the Internet website of the National Institutes of Health;

(5) shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health, and through the development, implementation, and updating of the strategic plan developed under subsection (m);

(6) shall ensure that the resources of the National Institutes of Health are sufficiently allocated for research projects identified in strategic plans;

(7)(A) shall, through the Division of Program Coordination, Planning, and Strategic Initiatives—

(i) identify research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between 2 or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning;

(ii) include information on such research in reports under section 403; and

(iii) in the case of such research supported with funds referred to in subparagraph (B)—

(I) require as appropriate that proposals include milestones and goals for the research;

(II) require that the proposals include timeframes for funding of the research; and

(III) ensure appropriate consideration of proposals for which the principal investigator is an individual who has not previously served as the principal investigator of research conducted or supported by the National Institutes of Health;

(B)(i) may, with respect to funds reserved under section 402A(c)(1) for the Common Fund, allocate such funds to the national research institutes and national centers for conducting and supporting research that is identified under subparagraph (A); and

(ii) shall, with respect to funds appropriated to the Common Fund pursuant to section 402A(a)(2), allocate such funds to the national research institutes and national centers for making grants for pediatric research that is identified under subparagraph (A); and

(C) may assign additional functions to the Division in support of responsibilities identified in subparagraph (A), as determined appropriate by the Director;

(8) shall, in coordination with the heads of the national research institutes and national centers, ensure that such institutes and centers—

(A) preserve an emphasis on investigator-initiated research project grants, including with respect to research involving collaboration between 2 or more such institutes or centers;

(B) when appropriate, maximize investigator-initiated research project grants in their annual research portfolios;

(C) foster collaboration between clinical research projects funded by the respective national research institutes and national centers that—

(i) conduct research involving human subjects; and

(ii) collect similar data; and

(D) encourage the collaboration described in subparagraph (C) to—

(i) allow for an increase in the number of subjects studied; and

(ii) utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities;

(9) shall ensure that research conducted or supported by the National Institutes of Health is subject to review in accordance with section 492 and that, after such review, the research is reviewed in accordance with section 492A(a)(2) by the appropriate advisory council under section 406 before the research proposals are approved for funding;

(10) shall have authority to review and approve the establishment of all centers of excellence recommended by the national research institutes;

(11)(A) shall oversee research training for all of the national research institutes and National Research Service Awards in accordance with section 487; and

(B) may conduct and support research training—

(i) for which fellowship support is not provided under section 487; and

(ii) that does not consist of residency training of physicians or other health professionals;

(12) may, from funds appropriated under section 402A(b), reserve funds to provide for research on matters that have not received significant funding relative to other matters, to respond to new issues and scientific emergencies, and to act on research opportunities of high priority;

(13) may, subject to appropriations Acts, collect and retain registration fees obtained from third parties to defray expenses for scientific, educational, and research-related conferences;

(14) for the national research institutes and administrative entities within the National Institutes of Health—

(A) may acquire, construct, improve, repair, operate, and maintain, at the site of such institutes and entities, laboratories, and other research facilities, other facilities, equipment, and other real or personal property, and

(B) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed ten years;

(15) may secure resources for research conducted by or through the National Institutes of Health;

(16) may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific peer review groups and scientific program advisory committees as are needed to carry out the requirements of this title and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups;

(17) may secure for the National Institutes of Health consultation services and advice of persons from the United States or abroad;

(18) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(19) may, for purposes of study, admit and treat at facilities of the National Institutes of Health individuals not otherwise eligible for such treatment;

(20) may accept voluntary and uncompensated services;

(21) may perform such other administrative functions as the Secretary determines are needed to effectively carry out this title;

(22) may appoint physicians, dentists, and other health care professionals, subject to the provisions of title 5, United States Code, relating to appointments and classifications in the competitive service, and may compensate such professionals subject to the provisions of chapter 74 of title 38, United States Code;

(23) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development;

(24) implement the Cures Acceleration Network described in section 480; and

(25) may require recipients of National Institutes of Health awards to share scientific data, to the extent feasible, generated from such National Institutes of Health awards in a manner that is consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

(A) human research participants, including with respect to privacy, security, informed consent, and protected health information; and

(B) proprietary interests, confidential commercial information, and the intellectual property rights of the funding recipient.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (16). The members of such a group shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of such group. Not more than one-fourth of the members of any such group shall be officers or employees of the United States.

(c) The Director of NIH may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(d)(1) The Director of NIH may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than 220 experts or consultants, with scientific or other professional qualifications, for the National Institutes of Health.

(2)(A) Except as provided in subparagraph (B), experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment.

(B) Expenses specified in subparagraph (A) shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(e) The Director of NIH shall—

(1) advise the agencies of the National Institutes of Health on medical applications of research;

(2) coordinate, review, and facilitate the systematic identification and evaluation of, clinically relevant information from research conducted by or through the national research institutes;

(3) promote the effective transfer of the information described in paragraph (2) to the health care community and to entities that require such information;

(4) monitor the effectiveness of the activities described in paragraph (3); and

(5) ensure that, after January 1, 1994, all new or revised health education and promotion materials developed or funded by the National Institutes of Health and intended for the general public are in a form that does not exceed a level of functional literacy, as defined in the National Literacy Act of 1991 (Public Law 102–73).

(f) There shall be in the National Institutes of Health an Associate Director for Prevention. The Director of NIH shall delegate to the Associate Director for Prevention the functions of the Director relating to the promotion of the disease prevention research programs of the national research institutes and the coordination of such programs among the national research institutes and between the national research institutes and other public and private entities, including elementary, secondary, and post-secondary schools. The Associate Director shall—

(1) annually review the efficacy of existing policies and techniques used by the national research institutes to disseminate the results of disease prevention and behavioral research programs; and

(2) recommend, coordinate, and oversee the modification or reconstruction of such policies and techniques to ensure maximum dissemination, using advanced technologies to the maximum extent practicable, of research results to such entities.

[(g) Transferred to section 461, redesignated as subsection (b) of such section, and amended (as so redesignated) by section 221(b)(5) of division F of Public Law 112–74.]

(h) The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research.

(i)(1)(A) The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (in this subsection referred to as the "data bank"). The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

(B) The Secretary shall establish the data bank after consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention.

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

(3) The data bank shall include the following:

(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act, which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria for participation in the clinical trials, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

(i) under a treatment investigational new drug application that has been submitted to the Secretary under section 561(c) of the Federal Food, Drug, and Cosmetic Act; or

(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that such disclosure would not substantially interfere with such enrollment.

(5) Fees collected under section 736 of the Federal Food, Drug, and Cosmetic Act shall not be used in carrying out this subsection.

(j) EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.—

(1) DEFINITIONS; REQUIREMENT.—

(A) DEFINITIONS.—In this subsection:

(i) APPLICABLE CLINICAL TRIAL.—The term "applicable clinical trial" means an applicable device clinical trial or an applicable drug clinical trial.

(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The term "applicable device clinical trial" means—

(I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and

(II) a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

(iii) APPLICABLE DRUG CLINICAL TRIAL.—

(I) IN GENERAL.—The term "applicable drug clinical trial" means a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act.

(II) CLINICAL INVESTIGATION.—For purposes of subclause (I), the term "clinical investigation" has the meaning given that term in section 312.3 of title 21, Code of Federal Regulations (or any successor regulation).

(III) PHASE I.—For purposes of subclause (I), the term "phase I" has the meaning given that term in section 312.21 of title 21, Code of Federal Regulations (or any successor regulation).

(iv) CLINICAL TRIAL INFORMATION.—The term "clinical trial information" means, with respect to an applicable clinical trial, those data elements that the responsible party is required to submit under paragraph (2) or under paragraph (3).

(v) COMPLETION DATE.—The term "completion date" means, with respect to an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated.

(vi) DEVICE.—The term "device" means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

(vii) DRUG.—The term "drug" means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act or a biological product as defined in section 351 of this Act.

(viii) ONGOING.—The term "ongoing" means, with respect to a clinical trial of a drug or a device and to a date, that—

(I) 1 or more patients is enrolled in the clinical trial; and

(II) the date is before the completion date of the clinical trial.

(ix) RESPONSIBLE PARTY.—The term "responsible party", with respect to a clinical trial of a drug or device, means—

(I) the sponsor of the clinical trial (as defined in section 50.3 of title 21, Code of Federal Regulations (or any successor regulation)); or

(II) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this subsection for the submission of clinical trial information.

(B) REQUIREMENT.—The Secretary shall develop a mechanism by which the responsible party for each applicable clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information under paragraph (2).

(2) EXPANSION OF CLINICAL TRIAL REGISTRY DATA BANK WITH RESPECT TO CLINICAL TRIAL INFORMATION.—

(A) IN GENERAL.—

(i) EXPANSION OF DATA BANK.—To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials, the Secretary, acting through the Director of NIH, shall expand, in accordance with this subsection, the clinical trials registry of the data bank described under subsection (i)(1) (referred to

in this subsection as the "registry data bank"). The Director of NIH shall ensure that the registry data bank is made publicly available through the Internet.

(ii) CONTENT.—The clinical trial information required to be submitted under this paragraph for an applicable clinical trial shall include—

(I) descriptive information, including—

(aa) a brief title, intended for the lay public;

(bb) a brief summary, intended for the lay public;

(cc) the primary purpose;

(dd) the study design;

(ee) for an applicable drug clinical trial, the study phase;

(ff) study type;

(gg) the primary disease or condition being studied, or the focus of the study;

(hh) the intervention name and intervention type;

(ii) the study start date;

(jj) the expected completion date;

(kk) the target number of subjects; and

(ll) outcomes, including primary and secondary outcome measures;

(II) recruitment information, including—

(aa) eligibility criteria;

(bb) gender;

(cc) age limits;

(dd) whether the trial accepts healthy volunteers;

(ee) overall recruitment status;

(ff) individual site status; and

(gg) in the case of an applicable drug clinical trial, if the drug is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act, specify whether or not there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act for those who do not qualify for enrollment in the clinical trial and how to obtain information about such access;

(III) location and contact information, including—

(aa) the name of the sponsor;

(bb) the responsible party, by official title; and

(cc) the facility name and facility contact information (including the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed); and

(IV) administrative data (which the Secretary may make publicly available as necessary), including—

(aa) the unique protocol identification number;

(bb) other protocol identification numbers, if any; and

(cc) the Food and Drug Administration IND/IDE protocol number and the record verification date.

(iii) MODIFICATIONS.—The Secretary may by regulation modify the requirements for clinical trial information under this paragraph, if the Secretary provides a rationale for why such a modification improves and does not reduce such clinical trial information.

(B) FORMAT AND STRUCTURE.—

(i) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the public may, in addition to keyword searching, search the entries in the registry data bank by 1 or more of the following criteria:

(I) The disease or condition being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.

(II) The name of the intervention, including any drug or device being studied in the clinical trial.

(III) The location of the clinical trial.

(IV) The age group studied in the clinical trial, including pediatric subpopulations.

(V) The study phase of the clinical trial.

(VI) The sponsor of the clinical trial, which may be the National Institutes of Health or another Federal agency, a private industry source, or a university or other organization.

(VII) The recruitment status of the clinical trial.

(VIII) The National Clinical Trial number or other study identification for the clinical trial.

(ii) ADDITIONAL SEARCHABLE CATEGORY.—Not later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Director of NIH shall ensure that the public may search the entries of the registry data bank by the safety issue, if any, being studied in the clinical trial as a primary or secondary outcome.

(iii) OTHER ELEMENTS.—The Director of NIH shall also ensure that the public may search the entries of the registry data bank by such other elements as the Director deems necessary on an ongoing basis.

(iv) FORMAT.—The Director of the NIH shall ensure that the registry data bank is easily used by the public, and that entries are easily compared.

(C) DATA SUBMISSION.—The responsible party for an applicable clinical trial, including an applicable drug clinical trial for a serious or life-threatening disease or condition, that is initiated after, or is ongoing on the date that is 90 days after, the date of the enactment of the Food and Drug Administration Amendments Act of 2007, shall submit to the Director of NIH for inclusion in the registry data bank the clinical trial information described in of subparagraph (A)(ii) not later than the later of—

(i) 90 days after such date of enactment;

(ii) 21 days after the first patient is enrolled in such clinical trial; or

(iii) in the case of a clinical trial that is not for a serious or life-threatening disease or condition and that is ongoing on such date of enactment, 1 year after such date of enactment.

(D) POSTING OF DATA.—

(i) APPLICABLE DRUG CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable drug clinical trial submitted in accordance with this paragraph is posted in the registry data bank not later than 30 days after such submission.

(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable device clinical trial submitted in accordance with this paragraph is posted publicly in the registry data bank—

(I) not earlier than the date of clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act, or approval under section 515 or 520(m) of such Act, as applicable, for a device that was not previously cleared or approved, and not later than 30 days after such date, unless the responsible party affirmatively requests that the Director of the National Institutes of Health publicly post such clinical trial information for an applicable device clinical trial prior to such date of clearance or approval; or

(II) for a device that was previously cleared or approved, not later than 30 days after the clinical trial information under paragraph (3)(C) is required to be posted by the Secretary.

(iii) OPTION TO MAKE CERTAIN CLINICAL TRIAL INFORMATION AVAILABLE EARLIER.—The Director of the National Institutes of Health shall inform responsible parties of the option to request that clinical trial information for an applicable device clinical trial be publicly posted prior to the date of clearance or approval, in accordance with clause (ii)(I).

(iv) COMBINATION PRODUCTS.—An applicable clinical trial for a product that is a combination of drug, device, or biological product shall be considered—

(I) an applicable drug clinical trial, if the Secretary determines under section 503(g) of the Federal Food, Drug, and Cosmetic Act that the primary mode of action of such product is that of a drug or biological product; or

(II) an applicable device clinical trial, if the Secretary determines under such section that the primary mode of action of such product is that of a device.

(3) EXPANSION OF REGISTRY DATA BANK TO INCLUDE RESULTS OF CLINICAL TRIALS.—

(A) LINKING REGISTRY DATA BANK TO EXISTING RESULTS.—

(i) IN GENERAL.—Beginning not later than 90 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, for those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug involved is approved or after the device involved is cleared or approved, the Secretary shall ensure that the registry data bank includes links to results information as described in clause (ii) for such clinical trial—

(I) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

(II) not later than 30 days after the results information described in clause (ii) becomes publicly available.

(ii) REQUIRED INFORMATION.—

(I) FDA INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

(aa) If an advisory committee considered at a meeting an applicable clinical trial, any posted Food and Drug Administration summary document regarding such applicable clinical trial.

(bb) If an applicable drug clinical trial was conducted under section 505A or 505B of the Federal Food, Drug, and Cosmetic Act, a link to the posted Food and Drug Administration assessment of the results of such trial.

(cc) Food and Drug Administration public health advisories regarding the drug or device that is the subject of the applicable clinical trial, if any.

(dd) For an applicable drug clinical trial, the Food and Drug Administration action package for approval document required under section 505(l)(2) of the Federal Food, Drug, and Cosmetic Act.

(ee) For an applicable device clinical trial, in the case of a premarket application under section 515 of the Federal Food, Drug, and Cosmetic Act, the detailed summary of information respecting the safety and effectiveness of the device required under section 520(h)(1) of such Act, or, in the case of a report under section 510(k) of such Act, the section 510(k) summary of the safety and effectiveness data required under section 807.95(d) of title 21, Code of Federal Regulations (or any successor regulation).

(II) NIH INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

(aa) Medline citations to any publications focused on the results of an applicable clinical trial.

(bb) The entry for the drug that is the subject of an applicable drug clinical trial in the National Library of Medicine database of structured product labels, if available.

(iii) RESULTS FOR EXISTING DATA BANK ENTRIES.—The Secretary may include the links described in clause (ii) for data bank entries for clinical trials submitted to the data bank prior to enactment of the Food and Drug Administration Amendments Act of 2007, as available.

(B) INCLUSION OF RESULTS.—The Secretary, acting through the Director of NIH, shall—

(i) expand the registry data bank to include the results of applicable clinical trials (referred to in this subsection as the "registry and results data bank");

(ii) ensure that such results are made publicly available through the Internet;

(iii) post publicly a glossary for the lay public explaining technical terms related to the results of clinical trials; and

(iv) in consultation with experts on risk communication, provide information with the information included under subparagraph (C) in the registry and results data bank to help ensure that such information does not mislead the patients or the public.

(C) BASIC RESULTS.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall include in the registry and results data bank for each applicable clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act or a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act, the following elements:

(i) DEMOGRAPHIC AND BASELINE CHARACTERISTICS OF PATIENT SAMPLE.—A table of the demographic and baseline data collected overall and for each arm of the clinical trial to describe the patients who participated in the clinical trial, including the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any.

(ii) PRIMARY AND SECONDARY OUTCOMES.—The primary and secondary outcome measures as submitted under paragraph (2)(A)(ii)(I)(ll), and a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial, including the results of scientifically appropriate tests of the statistical significance of such outcome measures.

(iii) POINT OF CONTACT.—A point of contact for scientific information about the clinical trial results.

(iv) CERTAIN AGREEMENTS.—Whether there exists an agreement (other than an agreement solely to comply with applicable provisions of law protecting the privacy of participants) between the sponsor or its agent and the principal investigator (unless the sponsor is an employer of the principal investigator) that restricts in any manner the ability of the principal investigator, after the completion date of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial.

(D) EXPANDED REGISTRY AND RESULTS DATA BANK.—

(i) EXPANSION BY RULEMAKING.—To provide more complete results information and to enhance patient access to and understanding of the results of clinical trials, not later than 3 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall by regulation expand the registry and results data bank as provided under this subparagraph.

(ii) CLINICAL TRIALS.—

(I) APPROVED PRODUCTS.—The regulations under this subparagraph shall require the inclusion of the results information described in clause (iii) for—

(aa) each applicable drug clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; and

(bb) each applicable device clinical trial for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act.

(II) UNAPPROVED PRODUCTS.—The regulations under this subparagraph shall establish whether or not the results information described in clause (iii) shall be required for—

(aa) an applicable drug clinical trial for a drug that is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act and not licensed under section 351 of this Act (whether approval or licensure was sought or not); and

(bb) an applicable device clinical trial for a device that is not cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act and not approved under section 515 or section 520(m) of such Act (whether clearance or approval was sought or not).

(iii) REQUIRED ELEMENTS.—The regulations under this subparagraph shall require, in addition to the elements described in subparagraph (C), information within each of the following categories:

(I) A summary of the clinical trial and its results that is written in non-technical, understandable language for patients, if the Secretary determines that such types of summary can be included without being misleading or promotional.

(II) A summary of the clinical trial and its results that is technical in nature, if the Secretary determines that such types of summary can be included without being misleading or promotional.

(III) The full protocol or such information on the protocol for the trial as may be necessary to help to evaluate the results of the trial.

(IV) Such other categories as the Secretary determines appropriate.

(iv) RESULTS SUBMISSION.—The results information described in clause (iii) shall be submitted to the Director of NIH for inclusion in the registry and results data bank as provided by subparagraph (E), except that the Secretary shall by regulation determine—

(I) whether the 1-year period for submission of clinical trial information described in subparagraph (E)(i) should be increased from 1 year to a period not to exceed 18 months;

(II) whether the clinical trial information described in clause (iii) should be required to be submitted for an applicable clinical trial for which the clinical trial information described in subparagraph (C) is submitted to the registry and results data bank before the effective date of the regulations issued under this subparagraph; and

(III) in the case when the clinical trial information described in clause (iii) is required to be submitted for the applicable clinical trials described in clause (ii)(II), the date by which such clinical trial information shall be required to be submitted, taking into account—

(aa) the certification process under subparagraph (E)(iii) when approval, licensure, or clearance is sought; and

(bb) whether there should be a delay of submission when approval, licensure, or clearance will not be sought.

(v) ADDITIONAL PROVISIONS.—The regulations under this subparagraph shall also establish—

(I) a standard format for the submission of clinical trial information under this paragraph to the registry and results data bank;

(II) additional information on clinical trials and results that is written in non-technical, understandable language for patients;

(III) considering the experience under the pilot quality control project described in paragraph (5)(C), procedures for quality control, including using representative samples, with respect to completeness and content of clinical trial information under this subsection, to help ensure that data elements are not false or misleading and are non-promotional;

(IV) the appropriate timing and requirements for updates of clinical trial information, and whether and, if so, how such updates should be tracked;

(V) a statement to accompany the entry for an applicable clinical trial when the primary and secondary outcome measures for such clinical trial are submitted under paragraph (4)(A) after the date specified for the submission of such information in paragraph (2)(C); and

(VI) additions or modifications to the manner of reporting of the data elements established under subparagraph (C).

(vi) CONSIDERATION OF WORLD HEALTH ORGANIZATION DATA SET.—The Secretary shall consider the status of the consensus data elements set for reporting clinical trial results of the World Health Organization when issuing the regulations under this subparagraph.

(vii) PUBLIC MEETING.—The Secretary shall hold a public meeting no later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 to provide an opportunity for input from interested parties with regard to the regulations to be issued under this subparagraph.

(E) SUBMISSION OF RESULTS INFORMATION.—

(i) IN GENERAL.—Except as provided in clauses (iii), (iv), (v), and (vi) the responsible party for an applicable clinical trial that is described in clause (ii) shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraph (C) not later than 1 year, or such other period as may be provided by regulation under subparagraph (D), after the earlier of—

(I) the estimated completion date of the trial as described in paragraph (2)(A)(ii)(I)(jj)); or

(II) the actual date of completion.

(ii) CLINICAL TRIALS DESCRIBED.—An applicable clinical trial described in this clause is an applicable clinical trial subject to—

(I) paragraph (2)(C); and

(II)(aa) subparagraph (C); or

(bb) the regulations issued under subparagraph (D).

(iii) DELAYED SUBMISSION OF RESULTS WITH CERTIFICATION.—If the responsible party for an applicable clinical trial submits a certification that clause (iv) or (v) applies to such clinical trial, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) as required under the applicable clause.

(iv) SEEKING INITIAL APPROVAL OF A DRUG OR DEVICE.—With respect to an applicable clinical trial that is completed before the drug is initially approved under section 505 of the Federal Food, Drug, and Cosmetic Act or initially licensed under section 351 of this Act, or the device is initially cleared under section 510(k) or initially approved under section 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) not later than 30 days after the drug or device is approved under such section 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515 or 520(m), as applicable.

(v) SEEKING APPROVAL OF A NEW USE FOR THE DRUG OR DEVICE.—

(I) IN GENERAL.—With respect to an applicable clinical trial where the manufacturer of the drug or device is the sponsor of an applicable clinical trial, and such manufacturer has filed, or will file within 1 year, an application seeking approval under section 505 of the Federal Food, Drug, and Cosmetic Act, licensing under section 351 of this Act, or clearance under section 510(k), or approval under section 515 or 520(m), of the Federal Food, Drug, and Cosmetic Act for the use studied in such clinical trial (which use is not included in the labeling of the approved drug or device), then the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) on the earlier of the date that is 30 days after the date—

(aa) the new use of the drug or device is approved under such section 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515 or 520(m);

(bb) the Secretary issues a letter, such as a complete response letter, not approving the submission or not clearing the submission, a not approvable letter, or a not substantially equivalent letter for the new use of the drug or device under such section 505, 351, 510(k), 515, or 520(m); or

(cc) except as provided in subclause (III), the application or premarket notification under such section 505, 351, 510(k), 515, or 520(m) is withdrawn without resubmission for no less than 210 days.

(II) REQUIREMENT THAT EACH CLINICAL TRIAL IN APPLICATION BE TREATED THE SAME.—If a manufacturer makes a certification under clause (iii) that this clause applies with respect to a clinical trial, the manufacturer shall make such a certification with respect to each applicable clinical trial that is required to be submitted in an application or report for licensure, approval, or clearance (under section 351 of this Act or section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act, as applicable) of the use studied in the clinical trial.

(III) TWO-YEAR LIMITATION.—The responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information subject to subclause (I) on the date that is 2 years after the date a certification under clause (iii) was made to the Director of NIH, if an action referred to in item (aa), (bb), or (cc) of subclause (I) has not occurred by such date.

(vi) EXTENSIONS.—The Director of NIH may provide an extension of the deadline for submission of clinical trial information under clause (i) if the responsible party for the trial submits to the Director a written request that demonstrates good cause for the extension and provides an estimate of the date on which the information will be submitted. The Director of NIH may grant more than one such extension for a clinical trial.

(F) NOTICE TO DIRECTOR OF NIH.—The Commissioner of Food and Drugs shall notify the Director of NIH when there is an action described in subparagraph (E)(iv) or item (aa),

(bb), or (cc) of subparagraph (E)(v)(I) with respect to an application or a report that includes a certification required under paragraph (5)(B) of such action not later than 30 days after such action.

(G) POSTING OF DATA.—The Director of NIH shall ensure that the clinical trial information described in subparagraphs (C) and (D) for an applicable clinical trial submitted in accordance with this paragraph is posted publicly in the registry and results database not later than 30 days after such submission.

(H) WAIVERS REGARDING CERTAIN CLINICAL TRIAL RESULTS.—The Secretary may waive any applicable requirements of this paragraph for an applicable clinical trial, upon a written request from the responsible party, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is consistent with the protection of public health, or in the interest of national security. Not later than 30 days after any part of a waiver is granted, the Secretary shall notify, in writing, the appropriate committees of Congress of the waiver and provide an explanation for why the waiver was granted.

(I) ADVERSE EVENTS.—

(i) REGULATIONS.—Not later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall by regulation determine the best method for including in the registry and results data bank appropriate results information on serious adverse and frequent adverse events for applicable clinical trials described in subparagraph (C) in a manner and form that is useful and not misleading to patients, physicians, and scientists.

(ii) DEFAULT.—If the Secretary fails to issue the regulation required by clause (i) by the date that is 24 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, clause (iii) shall take effect.

(iii) ADDITIONAL ELEMENTS.—Upon the application of clause (ii), the Secretary shall include in the registry and results data bank for applicable clinical trials described in subparagraph (C), in addition to the clinical trial information described in subparagraph (C), the following elements:

(I) SERIOUS ADVERSE EVENTS.—A table of anticipated and unanticipated serious adverse events grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

(II) FREQUENT ADVERSE EVENTS.—A table of anticipated and unanticipated adverse events that are not included in the table described in subclause (I) that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

(iv) POSTING OF OTHER INFORMATION.—In carrying out clause (iii), the Secretary shall, in consultation with experts in risk communication, post with the tables information to enhance patient understanding and to ensure such tables do not mislead patients or the lay public.

(v) RELATION TO SUBPARAGRAPH (C).—Clinical trial information included in the registry and results data bank pursuant to this subparagraph is deemed to be clinical trial information included in such data bank pursuant to subparagraph (C).

(4) ADDITIONAL SUBMISSIONS OF CLINICAL TRIAL INFORMATION.—

(A) VOLUNTARY SUBMISSIONS.—A responsible party for a clinical trial that is not an applicable clinical trial, or that is an applicable clinical trial that is not subject to paragraph (2)(C), may submit complete clinical trial information described in paragraph (2) or paragraph (3) provided the responsible party submits clinical trial information for each applicable clinical trial that is required to be submitted under section 351 or under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act in an application or report for licensure, approval, or clearance of the drug or device for the use studied in the clinical trial.

(B) REQUIRED SUBMISSIONS.—

(i) IN GENERAL.—Notwithstanding paragraphs (2) and (3) and subparagraph (A), in any case in which the Secretary determines for a specific clinical trial described in clause (ii) that posting in the registry and results data bank of clinical trial information for such clinical trial is necessary to protect the public health—

(I) the Secretary may require by notification that such information be submitted to the Secretary in accordance with paragraphs (2) and (3) except with regard to timing of submission;

(II) unless the responsible party submits a certification under paragraph (3)(E)(iii), such information shall be submitted not later than 30 days after the date specified by the Secretary in the notification; and

(III) failure to comply with the requirements under subclauses (I) and (II) shall be treated as a violation of the corresponding requirement of such paragraphs.

(ii) CLINICAL TRIALS DESCRIBED.—A clinical trial described in this clause is—

(I) an applicable clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act or for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or section 520(m) of such Act, whose completion date is on or after the date 10 years before the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

(II) an applicable clinical trial that is described by both by paragraph (2)(C) and paragraph (3)(D)(ii)(II)).

(C) UPDATES TO CLINICAL TRIAL DATA BANK.—

(i) SUBMISSION OF UPDATES.—The responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the registry and results data bank updates to reflect changes to the clinical trial information submitted under paragraph (2). Such updates—

(I) shall be provided not less than once every 12 months, unless there were no changes to the clinical trial information during the preceding 12-month period;

(II) shall include identification of the dates of any such changes;

(III) not later than 30 days after the recruitment status of such clinical trial changes, shall include an update of the recruitment status; and

(IV) not later than 30 days after the completion date of the clinical trial, shall include notification to the Director that such clinical trial is complete.

(ii) PUBLIC AVAILABILITY OF UPDATES.—The Director of NIH shall make updates submitted under clause (i) publicly available in the registry data bank. Except with regard to overall recruitment status, individual site status, location, and contact information, the Director of NIH shall ensure that updates to elements required under subclauses (I) to (V) of paragraph (2)(A)(ii) do not result in the removal of any information from the original submissions or any preceding updates, and information in such databases is presented in a manner that enables users to readily access each original element submission and to track the changes made by the updates. The Director of NIH shall provide a link from the table of primary and secondary outcomes required under paragraph (3)(C)(ii) to the tracked history required under this clause of the primary and secondary outcome measures submitted under paragraph (2)(A)(ii)(I)(ll).

(5) COORDINATION AND COMPLIANCE.—

(A) CLINICAL TRIALS SUPPORTED BY GRANTS FROM FEDERAL AGENCIES.—

(i) GRANTS FROM CERTAIN FEDERAL AGENCIES.—If an applicable clinical trial is funded in whole or in part by a grant from any agency of the Department of Health and Human Services, including the Food and Drug Administration, the National Institutes of Health, or the Agency for Healthcare Research and Quality, any grant or progress report forms required under such grant shall include a certification that the responsible party has made all required submissions to the Director of NIH under paragraphs (2) and (3).

(ii) VERIFICATION BY FEDERAL AGENCIES.—The heads of the agencies referred to in clause (i), as applicable, shall verify that the clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted under paragraphs (2) and (3) before releasing any remaining funding for a grant or funding for a future grant to such grantee.

(iii) NOTICE AND OPPORTUNITY TO REMEDY.—If the head of an agency referred to in clause (i), as applicable, verifies that a grantee has not submitted clinical trial information as described in clause (ii), such agency head shall provide notice to such

grantee of such non-compliance and allow such grantee 30 days to correct such noncompliance and submit the required clinical trial information.

(iv) CONSULTATION WITH OTHER FEDERAL AGENCIES.—The Secretary shall—

(I) consult with other agencies that conduct research involving human subjects in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulations), to determine if any such research is an applicable clinical trial; and

(II) develop with such agencies procedures comparable to those described in clauses (i), (ii), and (iii) to ensure that clinical trial information for such applicable clinical trial is submitted under paragraphs (2) and (3).

(B) CERTIFICATION TO ACCOMPANY DRUG, BIOLOGICAL PRODUCT, AND DEVICE SUBMISSIONS.—At the time of submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, section 520(m) of such Act, or section 351 of this Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of this subsection have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

(C) QUALITY CONTROL.—

(i) PILOT QUALITY CONTROL PROJECT.—Until the effective date of the regulations issued under paragraph (3)(D), the Secretary, acting through the Director of NIH and the Commissioner of Food and Drugs, shall conduct a pilot project to determine the optimal method of verification to help to ensure that the clinical trial information submitted under paragraph (3)(C) is non-promotional and is not false or misleading in any particular under subparagraph (D). The Secretary shall use the publicly available information described in paragraph (3)(A) and any other information available to the Secretary about applicable clinical trials to verify the accuracy of the clinical trial information submitted under paragraph (3)(C).

(ii) NOTICE OF COMPLIANCE.—If the Secretary determines that any clinical trial information was not submitted as required under this subsection, or was submitted but is false or misleading in any particular, the Secretary shall notify the responsible party and give such party an opportunity to remedy such noncompliance by submitting the required revised clinical trial information not later than 30 days after such notification.

(D) TRUTHFUL CLINICAL TRIAL INFORMATION.—

(i) IN GENERAL.—The clinical trial information submitted by a responsible party under this subsection shall not be false or misleading in any particular.

(ii) EFFECT.—Clause (i) shall not have the effect of—

(I) requiring clinical trial information with respect to an applicable clinical trial to include information from any source other than such clinical trial involved; or

(II) requiring clinical trial information described in paragraph (3)(D) to be submitted for purposes of paragraph (3)(C).

(E) PUBLIC NOTICES.—

(i) NOTICE OF VIOLATIONS.—If the responsible party for an applicable clinical trial fails to submit clinical trial information for such clinical trial as required under paragraphs (2) or (3), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice—

(I) that the responsible party is not in compliance with this Act by—

(aa) failing to submit required clinical trial information; or

(bb) submitting false or misleading clinical trial information;

(II) of the penalties imposed for the violation, if any; and

(III) whether the responsible party has corrected the clinical trial information in the registry and results data bank.

(ii) NOTICE OF FAILURE TO SUBMIT PRIMARY AND SECONDARY OUTCOMES.—If the responsible party for an applicable clinical trial fails to submit the primary and secondary outcomes as required under section 2(A)(ii)(I)(ll), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice that the responsible party is not in compliance by failing to register the primary and sec-

ondary outcomes in accordance with this act, and that the primary and secondary outcomes were not publicly disclosed in the database before conducting the clinical trial.

(iii) FAILURE TO SUBMIT STATEMENT.—The notice under clause (i) for a violation described in clause (i)(I)(aa) shall include the following statement: "The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.".

(iv) SUBMISSION OF FALSE INFORMATION STATEMENT.—The notice under clause (i) for a violation described in clause (i)(I)(bb) shall include the following statement: "The entry for this clinical trial was found to be false or misleading and therefore not in compliance with the law.".

(v) NON-SUBMISSION OF STATEMENT.—The notice under clause (ii) for a violation described in clause (ii) shall include the following statement: "The entry for this clinical trial did not contain information on the primary and secondary outcomes at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.".

(vi) COMPLIANCE SEARCHES.—The Director of NIH shall provide that the public may easily search the registry and results data bank for entries that include notices required under this subparagraph.

(6) LIMITATION ON DISCLOSURE OF CLINICAL TRIAL INFORMATION.—

(A) IN GENERAL.—Nothing in this subsection (or under section 552 of title 5, United States Code) shall require the Secretary to publicly disclose, by any means other than the registry and results data bank, information described in subparagraph (B).

(B) INFORMATION DESCRIBED.—Information described in this subparagraph is—

(i) information submitted to the Director of NIH under this subsection, or information of the same general nature as (or integrally associated with) the information so submitted; and

(ii) information not otherwise publicly available, including because it is protected from disclosure under section 552 of title 5, United States Code.

(7) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $10,000,000 for each fiscal year.

(k)(1) The Director of NIH may establish a program to provide day care services for the employees of the National Institutes of Health similar to those services provided by other Federal agencies (including the availability of day care service on a 24-hour-a-day basis).

(2) Any day care provider at the National Institutes of Health shall establish a sliding scale of fees that takes into consideration the income and needs of the employee.

(3) For purposes regarding the provision of day care services, the Director of NIH may enter into rental or lease purchase agreements.

(l) COUNCIL OF COUNCILS.—

(1) ESTABLISHMENT.—Not later than 90 days after the date of the enactment of the National Institutes of Health Reform Act of 2006, the Director of NIH shall establish within the Office of the Director an advisory council to be known as the "Council of Councils" (referred to in this subsection as the "Council") for the purpose of advising the Director on matters related to the policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives, including making recommendations with respect to the conduct and support of research described in subsection (b)(7).

(2) MEMBERSHIP.—

(A) IN GENERAL.—The Council shall be composed of 27 members selected by the Director of NIH with approval from the Secretary from among the list of nominees under subparagraph (C).

(B) CERTAIN REQUIREMENTS.—In selecting the members of the Council, the Director of NIH shall ensure—

(i) the representation of a broad range of disciplines and perspectives; and

(ii) the ongoing inclusion of at least 1 representative from each national research institute whose budget is substantial relative to a majority of the other institutes.

(C) NOMINATION.—The Director of NIH shall maintain an updated list of individuals who have been nominated to serve on the Council, which list shall consist of the following:

(i) For each national research institute and national center, 3 individuals nominated by the head of such institute or center from among the members of the advisory council of the institute or center, of which—

(I) two shall be scientists; and

(II) one shall be from the general public or shall be a leader in the field of public policy, law, health policy, economics, or management.

(ii) For each office within the Division of Program Coordination, Planning, and Strategic Initiatives, 1 individual nominated by the head of such office.

(iii) Members of the Council of Public Representatives.

(3) TERMS.—

(A) IN GENERAL.—The term of service for a member of the Council shall be 6 years, except as provided in subparagraphs (B) and (C).

(B) TERMS OF INITIAL APPOINTEES.—Of the initial members selected for the Council, the Director of NIH shall designate—

(i) nine for a term of 6 years;

(ii) nine for a term of 4 years; and

(iii) nine for a term of 2 years.

(C) VACANCIES.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office.

(m) NATIONAL INSTITUTES OF HEALTH STRATEGIC PLAN.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of the 21st Century Cures Act, and at least every 6 years thereafter, the Director of the National Institutes of Health shall develop and submit to the appropriate committees of Congress and post on the Internet website of the National Institutes of Health, a coordinated strategy (to be known as the "National Institutes of Health Strategic Plan") to provide direction to the biomedical research investments made by the National Institutes of Health, to facilitate collaboration across the institutes and centers, to leverage scientific opportunity, and to advance biomedicine.

(2) REQUIREMENTS.—The strategy under paragraph (1) shall—

(A) identify strategic research priorities and objectives across biomedical research, including—

(i) an assessment of the state of biomedical and behavioral research, including areas of opportunity with respect to basic, clinical, and translational research;

(ii) priorities and objectives to advance the treatment, cure, and prevention of health conditions;

(iii) emerging scientific opportunities, rising public health challenges, and scientific knowledge gaps; and

(iv) the identification of near-, mid-, and long-term scientific needs;

(B) consider, in carrying out subparagraph (A)—

(i) disease burden in the United States and the potential for return on investment to the United States;

(ii) rare diseases and conditions;

(iii) biological, social, and other determinants of health that contribute to health disparities; and

(iv) other factors the Director of National Institutes of Health determines appropriate;

(C) include multi-institute priorities, including coordination of research among institutes and centers;

(D) include strategic priorities for funding research through the Common Fund, in accordance with section 402A(c)(1)(C);

(E) address the National Institutes of Health's proposed and ongoing activities related to training and the biomedical workforce; and

(F) describe opportunities for collaboration with other agencies and departments, as appropriate.

(3) USE OF PLANS.—Strategic plans developed and updated by the national research institutes and national centers of the National Institutes of Health shall be prepared regularly and in such a manner that such plans will be informed by the strategic plans developed and updated under this subsection. Such plans developed by and updated by the national research institutes and national centers shall have a common template.

(4) CONSULTATION.—The Director of National Institutes of Health shall develop the strategic plan under paragraph (1) in consultation with the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders.

(n) UNIQUE RESEARCH INITIATIVES.—

(1) IN GENERAL.—The Director of NIH may approve, after consideration of a proposal under paragraph (2)(A), requests by the national research institutes and centers, or program officers within the Office of the Director to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects that carry out—

(A) the Precision Medicine Initiative under section 498E; **[**or**]**

(B) section 402(b)(7), except that not more than 50 percent of the funds available for a fiscal year through the Common Fund under section 402A(c)(1) for purposes of carrying out such section 402(b)(7) may be used to engage in such other transactions**[**.**]***; or*

*(C) high impact cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, or treatment of diseases and disorders, or research urgently required to respond to a public health threat.*

(2) REQUIREMENTS.—The authority provided under this subsection may be used to conduct or support high impact cutting-edge research described in paragraph (1) using the other transactions authority described in such paragraph if the institute, center, or office—

(A) submits a proposal to the Director of NIH for the use of such authority before conducting or supporting the research, including why the use of such authority is essential to promoting the success of the project;

(B) receives approval for the use of such authority from the Director of NIH; and

(C) for each year in which the institute, center, or office has used such authority in accordance with this subsection, submits a report to the Director of NIH on the activities of the institute, center, or office relating to such research.

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## TITLE V—SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

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### PART A—ORGANIZATION AND GENERAL AUTHORITIES

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**SEC. 501A. NATIONAL MENTAL HEALTH AND SUBSTANCE USE POLICY LABORATORY.**

(a) IN GENERAL.—There shall be established within the Administration a National Mental Health and Substance Use Policy Laboratory (referred to in this section as the "Laboratory").

(b) RESPONSIBILITIES.—The Laboratory shall—

(1) continue to carry out the authorities and activities that were in effect for the Office of Policy, Planning, and Innovation as such Office existed prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016;

(2) identify, coordinate, and facilitate the implementation of policy changes likely to have a significant effect on mental health, mental illness, recovery supports, and the prevention and treatment of substance use disorder services;

(3) work with the Center for Behavioral Health Statistics and Quality to collect, as appropriate, information from grantees under programs operated by the Administration in order to evaluate and disseminate information on evidence-based practices, including culturally and linguistically appropriate services, as appropriate, and service delivery models;

(4) provide leadership in identifying and coordinating policies and programs, including evidence-based programs, related to mental and substance use disorders;

(5) periodically review programs and activities operated by the Administration relating to the diagnosis or prevention of, treatment for, and recovery from, mental and substance use disorders to—

(A) identify any such programs or activities that are duplicative;

(B) identify any such programs or activities that are not evidence-based, effective, or efficient; and

(C) formulate recommendations for coordinating, eliminating, or improving programs or activities identified under subparagraph (A) or (B) and merging such programs or activities into other successful programs or activities; **[**and**]**

(6) carry out other activities as deemed necessary to continue to encourage innovation and disseminate evidence-based programs and practices**[**.**]***; and*

*(7) issue and periodically update guidance for entities applying for grants from the Substance Abuse and Mental Health Services Administration in order to—*

*(A) encourage the funding of evidence-based practices;*

*(B) encourage the replication of promising or effective practices; and*

*(C) inform applicants on how to best articulate the rationale for the funding of a program or activity.*

(c) EVIDENCE-BASED PRACTICES AND SERVICE DELIVERY MODELS.—

(1) IN GENERAL.—In carrying out subsection (b)(3), the Laboratory—

(A) may give preference to models that improve—

(i) the coordination between mental health and physical health providers;

(ii) the coordination among such providers and the justice and corrections system; and

(iii) the cost effectiveness, quality, effectiveness, and efficiency of health care services furnished to adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis; and

(B) may include clinical protocols and practices that address the needs of individuals with early serious mental illness.

(2) CONSULTATION.—In carrying out this section, the Laboratory shall consult with—

(A) the Chief Medical Officer appointed under section 501(g);

(B) representatives of the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, on an ongoing basis;

(C) other appropriate Federal agencies;

(D) clinical and analytical experts with expertise in psychiatric medical care and clinical psychological care, health care management, education, corrections health care, and mental health court systems, as appropriate; and

(E) other individuals and agencies as determined appropriate by the Assistant Secretary.

(d) DEADLINE FOR BEGINNING IMPLEMENTATION.—The Laboratory shall begin implementation of this section not later than January 1, 2018.

(e) PROMOTING INNOVATION.—

(1) IN GENERAL.—The Assistant Secretary, in coordination with the Laboratory, may award grants to States, local governments, Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), educational institutions, and nonprofit organizations to develop evidence-based interventions, including culturally and linguistically appropriate services, as appropriate, for—

(A) evaluating a model that has been scientifically demonstrated to show promise, but would benefit from further applied development, for—

(i) enhancing the prevention, diagnosis, intervention, and treatment of, and recovery from, mental illness, serious emotional disturbances, substance use disorders, and co-occurring illness or disorders; or

(ii) integrating or coordinating physical health services and mental and substance use disorders services; and

(B) expanding, replicating, or scaling evidence-based programs across a wider area to enhance effective screening, early diagnosis, intervention, and treatment with respect to mental illness, serious mental illness, serious emotional disturbances, and substance use disorders, primarily by—

(i) applying such evidence-based programs to the delivery of care, including by training staff in effective evidence-based treatments; or

(ii) integrating such evidence-based programs into models of care across specialties and jurisdictions.

(2) CONSULTATION.—In awarding grants under this subsection, the Assistant Secretary shall, as appropriate, consult with the Chief Medical Officer, appointed under section 501(g), the advisory councils described in section 502, the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, as appropriate.

(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

(A) to carry out paragraph (1)(A), $7,000,000 for the period of fiscal years 2018 through 2020; and

(B) to carry out paragraph (1)(B), $7,000,000 for the period of fiscal years 2018 through 2020.

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PART D—MISCELLANEOUS PROVISIONS RELATING TO SUBSTANCE ABUSE AND MENTAL HEALTH

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**SEC. 547. BUILDING COMMUNITIES OF RECOVERY.**

(a) [DEFINITION] *DEFINITIONS.*—[In this section, the term "recovery community organization" means an independent nonprofit organization that—] *In this section:*

*(1) RECOVERY COMMUNITY ORGANIZATION.—The term "recovery community organization" means an independent nonprofit organization that—*

[(1)] *(A)* mobilizes resources within and outside of the recovery community to increase the prevalence and quality of long-term recovery from substance use disorders; and

[(2)] *(B)* is wholly or principally governed by people in recovery for substance use disorders who reflect the community served.

*(2) ELIGIBLE ENTITY.—The term "eligible entity" means—*

*(A) a national nonprofit entity focused on substance use disorder with a network of local affiliates and partners that are geographically and organizationally diverse; or*

*(B) a nonprofit organization—*

*(i) focused on substance use disorder;*

*(ii) established by individuals in personal or family recovery; and*

*(iii) serving prevention, treatment, recovery, payor, faith-based, and criminal justice stakeholders in the implementation of local addiction and recovery initiatives.*

(b) GRANTS AUTHORIZED.—[The Secretary shall award grants to recovery community organizations] *The Secretary—*

*(1) shall award grants to recovery community organizations* to enable such organizations to develop, expand, and enhance recovery [services.] *services and allow such organizations to use such grant funds to carry out the activities described in subparagraphs (A) through (C) of subsection (c)(2); and*

*(2) may award grants to eligible entities for purposes of establishing regional technical assistance centers, in accordance with subsection (c)(2)(D).*

[(c) FEDERAL SHARE.—The Federal share of the costs of a program funded by a grant under this section may not exceed 50 percent.

[(d)] *(c)* USE OF FUNDS.—Grants awarded under subsection (b)—

(1) [shall be used] *to a recovery community organization shall be used* to develop, expand, and enhance community and statewide recovery support services; and

(2) may be used to—

(A) *in the case of a grant awarded to a recovery community organization,* build connections between recovery networks, between recovery community organizations, and with other recovery support services, including—

(i) behavioral health providers;

(ii) primary care providers and physicians;

(iii) the criminal justice system;

(iv) employers;

(v) housing services;

(vi) child welfare agencies; and

(vii) other recovery support services that facilitate recovery from substance use disorders;

(B) *in the case of a grant awarded to a recovery community organization,* reduce the stigma associated with substance use disorders; [and]

(C) *in the case of a grant awarded to a recovery community organization,* conduct outreach on issues relating to substance use disorders and recovery, including—

(i) identifying the signs of addiction;

(ii) the resources available to individuals struggling with addiction and to families with a family member struggling with, or being treated for, addiction, including programs that mentor and provide support services to children;

(iii) the resources available to help support individuals in recovery; and

(iv) related medical outcomes of substance use disorders, the potential of acquiring an infectious disease from intravenous drug use, and neonatal abstinence syndrome among infants exposed to opioids during pregnancy**[**.**]***; and*

*(D) in the case of a grant awarded to an eligible entity, provide for the establishment of regional technical assistance centers to provide regional technical assistance for the following:*

*(i) Implementation of regionally driven, peer-delivered addiction recovery support services before, during, after, or in conjunction with addiction treatment.*

*(ii) Establishment of recovery community organizations.*

*(iii) Establishment of recovery community centers.*

**[**(e)**]** *(d)* AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $1,000,000 for each of fiscal years 2017 through 2021*, and $15,000,000 for each of fiscal years 2019 through 2023*.

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***SEC. 550. REGIONAL CENTERS OF EXCELLENCE IN SUBSTANCE USE DISORDER EDUCATION.***

*(a) IN GENERAL.—The Secretary, in consultation with such other agencies as are appropriate, shall, subject to the availability of appropriations, establish a solicitation process and award cooperative agreements to eligible entities for the designation of such entities as Regional Centers of Excellence in Substance Use Disorder Education and support of such regional centers of excellence to enhance and improve how health professionals are educated in substance use disorder prevention, treatment, and recovery through development, evaluation, and distribution of evidence-based curricula for health profession schools. An eligible entity designated by the Secretary as a Regional Center of Excellence in Substance Use Disorder Education shall carry out the activities described in subsection (b).*

*(b) SELECTION OF CENTERS OF EXCELLENCE.—*

*(1) ELIGIBLE ENTITIES.—To be eligible to receive a cooperative agreement under subsection (a), an entity shall—*

*(A) be an entity specified by the Secretary that offers education to students in various health professions, which may include—*

*(i) a health system;*

*(ii) a teaching hospital;*

*(iii) a medical school;*

*(iv) a certified behavioral health clinic; or*

*(v) any other health profession school, school of public health, or Cooperative Extension Program at institutions of higher education engaged in an aspect of the prevention, treatment, or recovery of substance use disorders;*

*(B) be accredited by the appropriate educational accreditation body;*

*(C) demonstrate an existing strategy, and have in place a plan for continuing such strategy, or a proposed strategy to implement a curriculum based on best practices for substance use disorder prevention, treatment, and recovery;*

*(D) demonstrate community engagement and participation through community partners, including other health profession schools, mental health counselors, social workers, peer recovery specialists, substance use treatment programs, community health centers, physicians' offices, certified behavioral health clinics, law enforcement, and the business community; and*

*(E) provide to the Secretary such information, at such time, and in such manner, as the Secretary may require.*

*(2) DIVERSITY.—In awarding cooperative agreements under subsection (a), the Secretary shall take into account regional differences among eligible entities and shall make an effort to ensure geographic diversity.*

*(c) DISSEMINATION OF INFORMATION.—*

*(1) PUBLIC POSTING.—The Secretary shall make information provided to the Secretary under subsection (b)(1)(E) publically available on the Internet website of the Department of Health and Human Services.*

*(2) EVALUATION.—The Secretary shall evaluate each project carried out by a Regional Center of Excellence in Substance Use Disorder Education under this section and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.*

*(d) FUNDING.—There is authorized to be appropriated to carry out this section, $4,000,000 for each of fiscal years 2019 through 2023.*

***SEC. 550. COMPREHENSIVE OPIOID RECOVERY CENTERS.***

*(a) IN GENERAL.—The Secretary shall award grants on a competitive basis to eligible entities to establish or operate a comprehensive opioid recovery center (referred to in this section as a "Center").*

*(b) GRANT PERIOD.—*

*(1) IN GENERAL.—A grant awarded under subsection (a) shall be for a period not less than three years and not more than five years.*

*(2) RENEWAL.—A grant awarded under subsection (a) may be renewed, on a competitive basis, for additional periods of time, as determined by the Secretary. In determining whether to renew a grant under this paragraph, the Secretary shall consider the data submitted under subsection (h).*

*(c) MINIMUM NUMBER OF CENTERS.—The Secretary shall allocate the amounts made available under subsection (i) in such amounts that not fewer than 10 Centers will be established across the United States.*

*(d) APPLICATION.—In order to be eligible for a grant under subsection (a), an entity shall submit an application to the Secretary at such time and in such manner as the Secretary may require. Such application shall include—*

*(1) evidence that such entity carries out, or is capable of coordinating with other entities to carry out, the activities described in subsection (g); and*

*(2) such other information as the Secretary may require.*

*(e) PRIORITY.—In awarding grants under subsection (a), the Secretary shall give priority to eligible entities located in a State or Indian country (as defined in section 1151 of title 18, United States Code)—*

*(1) with a high per capita drug overdose mortality rate, as determined by the Director of the Centers for Disease Control and Prevention; or*

*(2) based on any other criteria or need, as determined by the Secretary.*

*(f) USE OF GRANT FUNDS.—An eligible entity awarded a grant under subsection (a) shall use the grant funds to establish or operate a Center to carry out the activities described in subsection (g).*

*(g) CENTER ACTIVITIES AND SERVICES.—Each Center shall, at a minimum, carry out the activities described in this subsection. In the case of a Center that determines that a service described in paragraph (2) cannot reasonably be carried out by the Center, such Center shall contract with such other entities as may be necessary to ensure that patients have access to the full range of services described in such paragraph.*

*(1) COMMUNITY OUTREACH.—Each Center shall carry out the following outreach activities:*

*(A) Train and supervise outreach staff to work with schools, workplaces, faith-based organizations, State and local health departments, law enforcement, and first responders to ensure that such institutions are aware of the services of the Center.*

*(B) Disseminate and make available online evidence-based resources that educate professionals and the public on opioid use disorder and other substance use disorders.*

*(2) TREATMENT AND RECOVERY SERVICES.—Each Center shall provide the following treatment and recovery services:*

*(A) Ensure that intake evaluations meet the clinical needs of patients.*

*(B) Periodically conduct patient assessments to ensure continued and meaningful recovery, as defined by the Assistant Secretary for Mental Health and Substance Use.*

*(C) Provide the full continuum of treatment services, including—*

*(i) all drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act and all biological products licensed under section 351 of this Act, including methadone, to treat substance use disorders, including opioid use disorder and alcohol use disorder;*

*(ii) withdrawal management, which shall include medically supervised detoxification that includes patient evaluation, stabilization, and readiness for and entry into treatment;*

*(iii) counseling and case management, including counseling and recovery services for any possible co-occurring mental illness;*

*(iv) residential rehabilitation;*

*(v) recovery housing;*

*(vi) community-based and peer recovery support services;*

*(vii) job training and placement assistance to support reintegration into the workforce; and*

*(viii) other best practices, as determined by the Secretary.*

*(D) Administer an onsite pharmacy and provide toxicology services.*

*(E) Establish and operate a secure and confidential electronic health information system.*

*(F) Offer family support services such as child care, family counseling, and parenting interventions to help stabilize families impacted by substance use disorder.*

*(h) DATA REPORTING AND PROGRAM OVERSIGHT.—With respect to a grant awarded under subsection (a) to an eligible entity for a Center, not later than 90 days after the end of the first year of the grant period, and annually thereafter for the duration of the grant period (including the duration of any renewal period for such grant), the entity shall submit data, as appropriate, to the Secretary regarding—*

*(1) the programs and activities funded by the grant;*

*(2) health outcomes of individuals with a substance use disorder who received services from the Center;*

*(3) the effectiveness of interventions designed, tested, and evaluated by the Center; and*

*(4) any other information that the Secretary may require for the purpose of—*

*(A) evaluating the effectiveness of the Center; and*

*(B) ensuring that the Center is complying with all the requirements of the grant, including providing the full continuum of services described in subsection (g)(2)(C) and providing drugs and devices for overdose reversal under such subsection.*

*(i) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $10,000,000 for each of fiscal years 2019 through 2023 for purposes of carrying out this section.*

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# TITLE VII—HEALTH PROFESSIONS EDUCATION

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## *PART F—SUBSTANCE USE DISORDER TREATMENT EMPLOYEES*

***SEC. 781. LOAN REPAYMENT PROGRAM FOR SUBSTANCE USE DISORDER TREATMENT EMPLOYEES.***

*(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall carry out a program under which—*

*(1) the Secretary enters into agreements with individuals to make payments in accordance with subsection (b) on the principal of and interest on any eligible loan; and*

*(2) the individuals each agree to complete a period of service in a substance use disorder treatment job, as described in subsection (d).*

*(b) PAYMENTS.—For each year of obligated service by an individual pursuant to an agreement under subsection (a), the Secretary shall make a payment to such individual as follows:*

*(1) SERVICE IN A SHORTAGE AREA.—The Secretary shall pay—*

*(A) for each year of obligated service by an individual pursuant to an agreement under subsection (a), 1/6 of the principal of and interest on each eligible loan of the individual which is outstanding on the date the individual began service pursuant to the agreement; and*

*(B) for completion of the sixth and final year of such service, the remainder of such principal and interest.*

*(2) MAXIMUM AMOUNT.—The total amount of payments under this section to any individual shall not exceed $250,000.*

*(c) ELIGIBLE LOANS.—The loans eligible for repayment under this section are each of the following:*

*(1) Any loan for education or training for a substance use disorder treatment job.*

*(2) Any loan under part E of title VIII (relating to nursing student loans).*

*(3) Any Federal Direct Stafford Loan, Federal Direct PLUS Loan, or Federal Direct Unsubsidized Stafford Loan, or Federal Direct Consolidation Loan (as such terms are used in section 455 of the Higher Education Act of 1965).*

*(4) Any Federal Perkins Loan under part E of title I of the Higher Education Act of 1965.*

*(5) Any other Federal loan as determined appropriate by the Secretary.*

*(d) PERIOD OF SERVICE.—The period of service required by an agreement under subsection (a) shall consist of up to 6 years of full-time employment, with no more than one year passing between any two years of covered employment, in a substance use disorder treatment job in the United States in—*

*(1) a Mental Health Professional Shortage Area, as designated under section 332; or*

*(2) a county (or a municipality, if not contained within any county) where the mean drug overdose death rate per 100,000 people over the past 3 years for which official data is available from the State, is higher than the most recent available national average overdose death rate per 100,000 people, as reported by the Centers for Disease Control and Prevention.*

*(e) INELIGIBILITY FOR DOUBLE BENEFITS.—No borrower may, for the same service, receive a reduction of loan obligations or a loan repayment under both—*

*(1) this subsection; and*

*(2) any Federally supported loan forgiveness program, including under section 338B, 338I, or 846 of this Act, or section 428J, 428 L, 455(m), or 460 of the Higher Education Act of 1965.*

*(f) BREACH.—*

*(1) LIQUIDATED DAMAGES FORMULA.—The Secretary may establish a liquidated damages formula to be used in the event of a breach of an agreement entered into under subsection (a).*

*(2) LIMITATION.—The failure by an individual to complete the full period of service obligated pursuant to such an agreement, taken alone, shall not constitute a breach of the agreement, so long as the individual completed in good faith the years of service for which payments were made to the individual under this section.*

*(g) ADDITIONAL CRITERIA.—The Secretary—*

*(1) may establish such criteria and rules to carry out this section as the Secretary determines are needed and in addition to the criteria and rules specified in this section; and*

*(2) shall give notice to the committees specified in subsection (h) of any criteria and rules so established.*

*(h) REPORT TO CONGRESS.—Not later than 5 years after the date of enactment of the Substance Use Disorder Workforce Loan Repayment Act of 2018, and every other year thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on—*

*(1) the number and location of borrowers who have qualified for loan repayments under this section; and*

*(2) the impact of this section on the availability of substance use disorder treatment employees nationally and in shortage areas and counties described in subsection (d).*

*(i) DEFINITION.—In this section:*

*(1) The term "municipality" means a city, town, or other public body created by or pursuant to State law, or an Indian Tribe.*

*(2) The term "substance use disorder treatment job" means a full-time job (including a fellowship)—*

*(A) where the primary intent and function of the job is the direct treatment or recovery support of patients with or in recovery from a substance use disorder, such as a physician, physician assistant, registered nurse, nurse practitioner, advanced practice registered nurse, social worker, recovery coach, mental health counselor, addictions counselor, psychologist or other behavioral health professional, or any other relevant professional as determine by the Secretary; and*

*(B) which is located at a substance use disorder treatment program, private physician practice, hospital or health system-affiliated inpatient treatment center or outpatient clinic (including an academic medical center-affiliated treatment program), correctional facility or program, youth detention center or program, inpatient psychiatric facility, crisis stabilization unit, community health center, community mental health or other specialty community behavioral health center, recovery center, school, community-based organization, telehealth platform, migrant health center, health program or facility operated by a tribe or tribal or-*

*ganization, Federal medical facility, or any other facility as determined appropriate for purposes of this section by the Secretary.*

*(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $25,000,000 for each of fiscal years 2019 through 2028.*

## PART [F] *G*—GENERAL PROVISIONS

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### TITLE XII—TRAUMA CARE

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### PART G—POISON CONTROL

**[SEC. 1271. MAINTENANCE OF THE NATIONAL TOLL-FREE NUMBER.**

[(a) IN GENERAL.—The Secretary shall provide coordination and assistance to poison control centers for the establishment of a nationwide toll-free phone number, and the maintenance of such number, to be used to access such centers.

[(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $700,000 for each of fiscal years 2015 through 2019 for the maintenance of the nationwide toll free phone number under subsection (a).

**[SEC. 1272. NATIONWIDE MEDIA CAMPAIGN TO PROMOTE POISON CONTROL CENTER UTILIZATION.**

[(a) IN GENERAL.—The Secretary shall carry out, and expand upon, a national media campaign to educate the public and health care providers about poison prevention and the availability of poison control center resources in local communities and to conduct advertising campaigns concerning the nationwide toll-free number established under section 1271(a).

[(b) CONTRACT WITH ENTITY.—The Secretary may carry out subsection (a) by entering into contracts with one or more public or private entities, including nationally recognized organizations in the field of poison control and national media firms, for the development and implementation of a nationwide poison prevention and poison control center awareness campaign, which may include—

[(1) the development and distribution of poison prevention and poison control center awareness materials;

[(2) television, radio, Internet, and newspaper public service announcements; and

[(3) other activities to provide for public and professional awareness and education.

[(c) EVALUATION.—The Secretary shall—

[(1) establish baseline measures and benchmarks to quantitatively evaluate the impact of the nationwide media campaign carried out under this section; and

[(2) on an annual basis, prepare and submit to the appropriate committees of Congress an evaluation of the nationwide media campaign.

[(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $800,000 for each of fiscal years 2015 through 2019.

**[SEC. 1273. MAINTENANCE OF THE POISON CONTROL CENTER GRANT PROGRAM.**

[(a) AUTHORIZATION OF PROGRAM.—The Secretary shall award grants to poison control centers accredited under subsection (c) (or granted a waiver under subsection (d)) and professional organizations in the field of poison control for the purposes of preventing, and providing treatment recommendations for, poisonings and complying with the operational requirements needed to sustain the accreditation of the center under subsection (c).

[(b) ADDITIONAL USES OF FUNDS.—In addition to the purposes described in subsection (a), a poison center or professional organization awarded a grant, contract, or cooperative agreement under such subsection may also use amounts received under such grant, contract, or cooperative agreement—

[(1) to research, establish, implement, and evaluate best practices in the United States for poison prevention, poison control center outreach, and emergency and preparedness programs;

[(2) to research, develop, implement, revise, and communicate standard patient management guidelines for commonly encountered toxic exposures;

[(3) to improve national toxic exposure surveillance by enhancing cooperative activities between poison control centers in the United States and the Centers for Disease Control and Prevention;

[(4) to research, improve, and enhance the communications and response capability and capacity of the nation's network of poison control centers to facilitate increased access to the centers through the integration and modernization of the current poison control centers communications and data system, including enhancing the network's telephony, Internet, data and social networking technologies;

[(5) to develop, support, and enhance technology and capabilities of professional organizations in the field of poison control to collect national poisoning, toxic occurrence, and related public health data;

[(6) to develop initiatives to foster the enhanced public health utilization of national poison data collected by organizations described in paragraph (5);

[(7) to support and expand the toxicologic expertise within poison control centers; and

[(8) to improve the capacity of poison control centers to answer high volumes of calls and Internet communications, and to sustain and enhance the poison control center's network capability to respond during times of national crisis or other public health emergencies.

[(c) ACCREDITATION.—Except as provided in subsection (d), the Secretary may award a grant to a poison control center under subsection (a) only if—

[(1) the center has been accredited by a professional organization in the field of poison control, and the Secretary has approved the organization as having in effect standards for accreditation that reasonably provide for the protection of the public health with respect to poisoning; or

[(2) the center has been accredited by a State government, and the Secretary has approved the State government as having in effect standards for accreditation that reasonably provide for the protection of the public health with respect to poisoning.

[(d) WAIVER OF ACCREDITATION REQUIREMENTS.—

[(1) IN GENERAL.—The Secretary may grant a waiver of the accreditation requirements of subsection (c) with respect to a nonaccredited poison control center that applies for a grant under this section if such center can reasonably demonstrate that the center will obtain such an accreditation within a reasonable period of time as determined appropriate by the Secretary.

[(2) RENEWAL.—The Secretary may renew a waiver under paragraph (1).

[(3) LIMITATION.—In no case may the sum of the number of years for a waiver under paragraph (1) and a renewal under paragraph (2) exceed—

[(A) 5 years; or

[(B) in the case of a nonaccredited poison control center operating pursuant to a waiver under this subsection as of October 1, 2014, 6 years.

[(e) SUPPLEMENT NOT SUPPLANT.—Amounts made available to a poison control center under this section shall be used to supplement and not supplant other Federal, State or local funds provided for such center.

[(f) MAINTENANCE OF EFFORT.—A poison control center, in utilizing the proceeds of a grant under this section, shall maintain the expenditures of the center for its activities at a level that is not less than the level of expenditures maintained by the center for the fiscal year preceding the fiscal year for which the grant is received.

[(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $28,600,000 for each of fiscal years 2015 through 2019. The Secretary may utilize an amount not to exceed 6 percent of the amount appropriated under this preceding sentence in each fiscal year for coordination, dissemination, technical assistance, program evaluation, data activities, and other program administration functions, which are determined by the Secretary to be appropriate for carrying out the program under this section.]

***SEC. 1271. ESTABLISHMENT AND MAINTENANCE OF THE NATIONAL TOLL-FREE NUMBER AND ENHANCED COMMUNICATIONS CAPABILITIES.***

*(a) IN GENERAL.—The Secretary shall provide coordination and assistance to poison control centers for—*

*(1) the development, establishment, implementation, and maintenance of a nationwide toll-free phone number; and*

*(2) the enhancement of communications capabilities, which may include text capabilities.*

*(b) CONSULTATION.—The Secretary may consult with nationally recognized professional organizations in the field of poison control to determine the best and most effective means of achieving the goals described in paragraphs (1) and (2) of subsection (a).*

*(c) RULE OF CONSTRUCTION.—In assisting with public health emergencies, responses, or preparedness, nothing in this section shall be construed to restrict the work of poison control centers or the use of their resources by the Secretary or other governmental agencies.*

*(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $700,000 for each of fiscal years 2019 through 2023.*

***SEC. 1272. NATIONWIDE PUBLIC AWARENESS CAMPAIGN TO PROMOTE POISON CONTROL CENTER UTILIZATION AND THEIR PUBLIC HEALTH EMERGENCY RESPONSE CAPABILITIES.***

*(a) IN GENERAL.—The Secretary shall—*

*(1) carry out, and expand upon, a national public awareness campaign to educate the public and health care providers about—*

*(A) poisoning, toxic exposure, and drug misuse prevention; and*

*(B) the availability of poison control center resources in local communities; and*

*(2) as part of such campaign, highlight the nationwide toll-free number and enhanced communications capabilities supported under section 1271.*

*(b) CONSULTATION.—In carrying out and expanding upon the national campaign under subsection (a), the Secretary may consult with nationally recognized professional organizations in the field of poison control response for the purpose of determining the best and most effective methods for achieving public awareness.*

*(c) CONTRACT WITH ENTITY.—The Secretary may carry out subsection (a) by entering into contracts with one or more public or private entities, including nationally recognized professional organizations in the field of poison control and national media firms, for the development and implementation of the awareness campaign under subsection (a), which may include—*

*(1) the development and distribution of poisoning and toxic exposure prevention, poison control center, and public health emergency awareness and response materials;*

*(2) television, radio, internet, and newspaper public service announcements; and*

*(3) other means and activities to provide for public and professional awareness and education.*

*(d) EVALUATION.—The Secretary shall—*

*(1) establish baseline measures and benchmarks to quantitatively evaluate the impact of the nationwide public awareness campaign carried out under this section; and*

*(2) on a biennial basis, prepare and submit to the appropriate committees of Congress an evaluation of the nationwide public awareness campaign.*

*(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $800,000 for each of fiscal years 2019 through 2023.*

***SEC. 1273. MAINTENANCE OF THE POISON CONTROL CENTER GRANT PROGRAM.***

*(a) AUTHORIZATION OF PROGRAM.—The Secretary shall award grants to poison control centers accredited under subsection (c) (or granted a waiver under subsection (d)) and nationally recognized professional organizations in the field of poison control for the purposes of—*

*(1) preventing, and providing treatment recommendations for, poisonings and toxic exposures including opioid and drug misuse;*

*(2) assisting with public health emergencies, responses, and preparedness; and*

*(3) complying with the operational requirements needed to sustain the accreditation of the center under subsection (c).*

*(b) ADDITIONAL USES OF FUNDS.—In addition to the purposes described in subsection (a), a poison center or professional organization awarded a grant under such subsection may also use amounts received under such grant—*

*(1) to research, establish, implement, and evaluate best practices in the United States for poisoning prevention, poison control center outreach, opioid and drug misuse information and response, and public health emergency, response, and preparedness programs;*

*(2) to research, develop, implement, revise, and communicate standard patient management guidelines for commonly encountered toxic exposures;*

*(3) to improve national toxic exposure and opioid misuse surveillance by enhancing cooperative activities between poison control centers in the United States and the Centers for Disease Control and Prevention and other governmental agencies;*

*(4) to research, improve, and enhance the communications and response capability and capacity of the Nation's network of poison control centers to facilitate increased access to the centers through the integration and modernization of the current poison control centers communications and data system, including enhancing the network's telephony, internet, data, and social networking technologies;*

*(5) to develop, support, and enhance technology and capabilities of nationally recognized professional organizations in the field of poison control to collect national poisoning, toxic occurrence, and related public health data;*

*(6) to develop initiatives to foster the enhanced public health utilization of national poison data collected by such organizations;*

*(7) to support and expand the toxicologic expertise within poison control centers; and*

*(8) to improve the capacity of poison control centers to answer high volumes of contacts and internet communications, and to sustain and enhance the poison control center's network capability to respond during times of national crisis or other public health emergencies.*

*(c) ACCREDITATION.—Except as provided in subsection (d), the Secretary may award a grant to a poison control center under subsection (a) only if—*

*(1) the center has been accredited by a nationally recognized professional organization in the field of poison control, and the Secretary has approved the organization as having in effect standards for accreditation that reasonably provide for the protection of the public health with respect to poisoning; or*

*(2) the center has been accredited by a State government, and the Secretary has approved the State government as having in effect standards for accreditation that reasonably provide for the protection of the public health with respect to poisoning.*

*(d) WAIVER OF ACCREDITATION REQUIREMENTS.—*

*(1) IN GENERAL.—The Secretary may grant a waiver of the accreditation requirements of subsection (c) with respect to a nonaccredited poison control center that applies for a grant under this section if such center can reasonably demonstrate that the center will obtain such an accreditation within a reasonable period of time as determined appropriate by the Secretary.*

*(2) RENEWAL.—The Secretary may renew a waiver under paragraph (1).*

*(3) LIMITATION.—The Secretary may not, after the date of enactment of the Poison Control Network Enhancement Act of 2018, grant to a poison control center waivers or renewals that total more than 5 years.*

*(e) SUPPLEMENT NOT SUPPLANT.—Amounts made available to a poison control center under this section shall be used to supplement and not supplant other Federal, State, or local funds provided for such center.*

*(f) MAINTENANCE OF EFFORT.—A poison control center, in utilizing the proceeds of a grant under this section, shall maintain the annual recurring expenditures of the center for its activities at a level that is not less than 80 percent of the average level of such recurring expenditures maintained by the center for the preceding 3 fiscal years for which a grant is received.*

*(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $28,600,000 for each of fiscal years 2019 through 2023. The Secretary may utilize an amount not to exceed 6 percent of the amount appropriated pursuant to the preceding sentence for each fiscal year for coordination, dissemination, technical assistance, program evaluation, data activities, and other program administration functions, which are determined by the Secretary to be appropriate for carrying out the program under this section.*

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## TITLE XVII—HEALTH INFORMATION AND HEALTH PROMOTION

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***SEC. 1711. ESTABLISHMENT OF SUBSTANCE USE DISORDER INFORMATION DASHBOARD.***

*(a) IN GENERAL.—Not later than six months after the date of the enactment of this section, the Secretary of Health and Human Services shall, in consultation with the Director of National Drug Control Policy, establish and periodically update a public information dashboard that—*

*(1) coordinates information on programs within the Department of Health and Human Services related to the reduction of opioid abuse and other substance use disorders;*

*(2) provides access to publicly available data from other Federal agencies; State, local, and Tribal governments; nonprofit organizations; law enforcement; medical experts; public health*

*educators; and research institutions regarding prevention, treatment, recovery, and other services for opioid use disorder and other substance use disorders;*

*(3) provides comparable data on substance use disorder prevention and treatment strategies in different regions and population of the United States;*

*(4) provides recommendations for health care providers on alternatives to controlled substances for pain management, including approaches studied by the National Institutes of Health Pain Consortium and the National Center for Complimentary and Integrative Health; and*

*(5) provides guidelines and best practices for health care providers regarding treatment of substance use disorders.*

*(b) CONTROLLED SUBSTANCE DEFINED.—In this section, the term "controlled substance" has the meaning given that term in section 102 of the Controlled Substances Act (21 U.S.C. 802).*

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## CONTROLLED SUBSTANCES ACT

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### TITLE II—CONTROL AND ENFORCEMENT

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### PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

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#### PERSONS REQUIRED TO REGISTER

SEC. 302. (a)(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event; however, shall such registrations be issued for less than one year nor for more than three years.

(b) Persons registered by the Attorney General under this title to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this title.

(c) The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this title:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 102(25).

(d) The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e)(1) A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(2) Notwithstanding paragraph (1), a registrant who is a veterinarian shall not be required to have a separate registration in order to transport and dispense controlled substances in the usual course of veterinary practice at a site other than the registrant's registered principal place of business or professional practice, so long as the site of transporting and dispensing is located in a State where the veterinarian is licensed to practice veterinary medicine and is not a principal place of business or professional practice.

(f) The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

(g)(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this title may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if—

(A) the person receiving the controlled substance is authorized under this title to engage in such activity; and

(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

(2) In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

(3) The Attorney General may, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at such long-term care facilities in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

(4) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.

*(5)(A) In the case of a person receiving hospice care, an employee of a qualified hospice program, acting within the scope of employment, may handle, without being registered under this section, any controlled substance that was lawfully dispensed to the person receiving hospice care, for the purpose of disposal of the controlled substance after the death of such person, so long as such disposal occurs onsite in accordance with all applicable Federal, State, Tribal, and local law.*

*(B) For the purposes of this paragraph:*

*(i) The terms "hospice care" and "hospice program" have the meanings given to those terms in section 1861(dd) of the Social Security Act.*

*(ii) The term "employee of a qualified hospice program" means a physician, nurse, or other person who—*

*(I) is employed by, or pursuant to arrangements made by, a qualified hospice program;*

*(II)(aa) is licensed to perform medical or nursing services by the jurisdiction in which the person receiving hospice care was located; and*

*(bb) is acting within the scope of such employment in accordance with applicable State law; and*

*(III) has completed training through the qualified hospice program regarding the disposal of controlled substances in a secure and responsible manner so as to discourage abuse, misuse, or diversion.*

*(iii) The term "qualified hospice program" means a hospice program that—*

*(I) has written policies and procedures for assisting in the disposal of the controlled substances of a person receiving hospice care after the person's death;*

*(II) at the time when the controlled substances are first ordered—*

*(aa) provides a copy of the written policies and procedures to the patient or patient representative and family;*

*(bb) discusses the policies and procedures with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe disposal of controlled substances; and*

*(cc) documents in the patient's clinical record that the written policies and procedures were provided and discussed; and*

*(III) at the time following the disposal of the controlled substances—*

*(aa) documents in the patient's clinical record the type of controlled substance, dosage, route of administration, and quantity so disposed; and*
*(bb) the time, date, and manner in which that disposal occurred.*

REGISTRATION REQUIREMENTS

SEC. 303. (a) The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 306.

(d) The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent

with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Seretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 304(a). Article 7 of the Convention on Psychotrophic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this title.

(g)(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)—

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 307) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified

in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying practitioner (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary—

(I) all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention; and

(II) appropriate counseling and other appropriate ancillary services.

(iii)(I) The total number of such patients of the practitioner at any one time will not exceed the applicable number. Except as provided in subclause (II), the applicable number is 30.

**[**(II) The applicable number is 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients.**]**

*(II) The applicable number is—*

*(aa) 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients;*

*(bb) 100 if the practitioner holds additional credentialing, as defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations); or*

*(cc) 100 if the practitioner provides medication-assisted treatment (MAT) using covered medications (as such terms are defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations)) in a qualified practice setting (as described in section 8.615 of title 42, Code of Federal Regulations (or successor regulations)).*

(III) The Secretary may by regulation change such applicable number.

(IV) The Secretary may exclude from the applicable number patients to whom such drugs or combinations of drugs are directly administered by the qualifying practitioner in the office setting.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f).

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f).

(ii) Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the

registration issued for the practitioner pursuant to subsection (f). The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B) and shall forward such determination to the Attorney General. If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the practitioner an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 304(a)(4), consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term "group practice" has the meaning given such term in section 1877(h)(4) of the Social Security Act.

(ii) The term "qualifying physician" means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

(II) The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.

(III) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause. Such training shall include—

(aa) opioid maintenance and detoxification;

(bb) appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;

(cc) initial and periodic patient assessments (including substance use monitoring);

(dd) individualized treatment planning, overdose reversal, and relapse prevention;

(ee) counseling and recovery support services;

(ff) staffing roles and considerations;

(gg) diversion control; and

(hh) other best practices, as identified by the Secretary.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(iii) The term "qualifying practitioner" means—

(I) a qualifying physician, as defined in clause (ii); **[**or**]**

**[**(II) during the period beginning on the date of enactment of the Comprehensive Addiction and Recovery Act of 2016 and ending on October 1, 2021, a qualifying other practitioner, as defined in clause (iv).**]**

*(II) a qualifying other practitioner, as defined in clause (iv), who is a nurse practitioner or physician assistant; or*

*(III) for the period beginning on October 1, 2018, and ending on October 1, 2023, a qualifying other practitioner, as defined in clause (iv), who is a clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife.*

(iv) The term "qualifying other practitioner" means a **[**nurse practitioner or physician assistant**]** *nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant* who satisfies each of the following:

(I) The **[**nurse practitioner or physician assistant**]** *nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant* is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.

(II) The **[**nurse practitioner or physician assistant**]** *nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant* has—

(aa) completed not fewer than 24 hours of initial training addressing each of the topics listed in clause (ii)(IV) (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Assistants, or any other organization that the Secretary determines is appropriate for purposes of this subclause; or

(bb) has such other training or experience as the Secretary determines will demonstrate the ability of the **[**nurse practitioner or physician assistant**]** *nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant* to treat and manage opiate-dependent patients.

(III) The **[**nurse practitioner or physician assistant**]** *nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assist-*

*ant* is supervised by, or works in collaboration with, a qualifying physician, if the [nurse practitioner or physician assistant] *nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant* is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.

The Secretary may, by regulation, revise the requirements for being a qualifying other practitioner under this clause.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

(III) Such other elements of the requirements under this paragraph as the Secretary determines necessary for purposes of implementing such requirements.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 18 months after the date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act, the Secretary shall update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings. The Secretary shall update such protocol in consultation with experts in opioid use disorder research and treatment.

(I) Notwithstanding section 708, nothing in this paragraph shall be construed to preempt any State law that—

(i) permits a qualifying practitioner to dispense narcotic drugs in schedule III, IV, or V, or combinations of such drugs, for maintenance or detoxification treatment in accordance with this paragraph to a total number of patients that is more than 30 or less than the total number applicable to the qualifying practitioner under subparagraph (B)(iii)(II) if a State enacts a law modifying such total number and the Attorney General is notified by the State of such modification; or

(ii) requires a qualifying practitioner to comply with additional requirements relating to the dispensing of narcotic drugs in schedule III, IV, or V, or combinations of such drugs, including requirements relating to the practice setting in which the qualifying practitioner practices and education, training, and reporting requirements.

(h) The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 102(39)(A). In determining the public interest for the purposes of this subsection, the Attorney General shall consider—

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

(i)(1) For purposes of registration to manufacture a controlled substance under subsection (d) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), not later than 180 days after the date on which the application is accepted for filing.

(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursu-

ant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), unless the Attorney General has granted a hearing on the application under section 1008(i) of the Controlled Substances Import and Export Act.

(j) EMERGENCY MEDICAL SERVICES THAT ADMINISTER CONTROLLED SUBSTANCES.—

(1) REGISTRATION.—For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of this subsection, the Attorney General—

(A) shall register an emergency medical services agency if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices; and

(B) may deny an application for such registration if the Attorney General determines that the issuance of such registration would be inconsistent with the requirements of this subsection or the public interest based on the factors listed in subsection (f).

(2) OPTION FOR SINGLE REGISTRATION.—In registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow such agency the option of a single registration in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical services agency.

(3) HOSPITAL-BASED AGENCY.—If a hospital-based emergency medical services agency is registered under subsection (f), the agency may use the registration of the hospital to administer controlled substances in accordance with this subsection without being registered under this subsection.

(4) ADMINISTRATION OUTSIDE PHYSICAL PRESENCE OF MEDICAL DIRECTOR OR AUTHORIZING MEDICAL PROFESSIONAL.—Emergency medical services professionals of a registered emergency medical services agency may administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is—

(A) authorized by the law of the State in which it occurs; and

(B) pursuant to—

(i) a standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State authority; or

(ii) a verbal order that is—

(I) issued in accordance with a policy of the agency; and

(II) provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient—

(aa) in the case of a mass casualty incident; or

(bb) to ensure the proper care and treatment of a specific patient.

(5) DELIVERY.—A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency—

(A) designates the unregistered location for such delivery; and

(B) notifies the Attorney General at least 30 days prior to first delivering controlled substances to the unregistered location.

(6) STORAGE.—A registered emergency medical services agency may store controlled substances—

(A) at a registered location of the agency;

(B) at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or

(C) in an emergency medical services vehicle used by the agency that is—

(i) traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or

(ii) otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General.

(7) NO TREATMENT AS DISTRIBUTION.—The delivery of controlled substances by a registered emergency medical services agency pursuant to this subsection shall not be treated as distribution for purposes of section 308.

(8) RESTOCKING OF EMERGENCY MEDICAL SERVICES VEHICLES AT A HOSPITAL.—Notwithstanding paragraph (13)(J), a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of section 308, provided all of the following conditions are satisfied:

(A) The registered or designated location of the agency where the vehicle is primarily situated maintains a record of such receipt in accordance with paragraph (9).

(B) The hospital maintains a record of such delivery to the agency in accordance with section 307.

(C) If the vehicle is primarily situated at a designated location, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

(9) MAINTENANCE OF RECORDS.—

(A) IN GENERAL.—A registered emergency medical services agency shall maintain records in accordance with subsections (a) and (b) of section 307 of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration, without regard to subsection 307(c)(1)(B).

(B) REQUIREMENTS.—Such records—

(i) shall include records of deliveries of controlled substances between all locations of the agency; and

(ii) shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

(10) OTHER REQUIREMENTS.—A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that—

(A) all emergency medical services professionals who administer controlled substances using the agency's registration act in accordance with the requirements of this subsection;

(B) the recordkeeping requirements of paragraph (9) are met with respect to a registered location and each designated location of the agency;

(C) the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with paragraph (6); and

(D) the agency maintains, at a registered location of the agency, a record of the standing orders issued or adopted in accordance with paragraph (9).

(11) REGULATIONS.—The Attorney General may issue regulations—

(A) specifying, with regard to delivery of controlled substances under paragraph (5)—

(i) the types of locations that may be designated under such paragraph; and

(ii) the manner in which a notification under paragraph (5)(B) must be made;

(B) specifying, with regard to the storage of controlled substances under paragraph (6), the manner in which such substances must be stored at registered and designated locations, including in emergency medical service vehicles; and

(C) addressing the ability of hospitals, emergency medical services agencies, registered locations, and designated locations to deliver controlled substances to each other in the event of—

(i) shortages of such substances;

(ii) a public health emergency; or

(iii) a mass casualty event.

(12) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

(A) to limit the authority vested in the Attorney General by other provisions of this title to take measures to prevent diversion of controlled substances; or

(B) to override the authority of any State to regulate the provision of emergency medical services consistent with this subsection.

(13) DEFINITIONS.—In this section:

(A) The term "authorizing medical professional" means an emergency or other physician, or another medical professional (including an advanced practice registered nurse or physician assistant)—

(i) who is registered under this Act;

(ii) who is acting within the scope of the registration; and

(iii) whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(B) The term "designated location" means a location designated by an emergency medical services agency under paragraph (5).

(C) The term "emergency medical services" means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(D) The term "emergency medical services agency" means an organization providing emergency medical services, including such an organization that—

(i) is governmental (including fire-based and hospital-based agencies), nongovernmental (including hospital-based agencies), private, or volunteer-based;

(ii) provides emergency medical services by ground, air, or otherwise; and

(iii) is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

(E) The term "emergency medical services professional" means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(F) The term "emergency medical services vehicle" means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

(G) The term "hospital-based" means, with respect to an agency, owned or operated by a hospital.

(H) The term "medical director" means a physician who is registered under subsection (f) and provides medical oversight for an emergency medical services agency.

(I) The term "medical oversight" means supervision of the provision of medical care by an emergency medical services agency.

(J) The term "registered emergency medical services agency" means—

(i) an emergency medical services agency that is registered pursuant to this subsection; or

(ii) a hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection (f).

(K) The term "registered location" means a location that appears on the certificate of registration issued to an emergency medical services agency under this subsection or subsection (f), which shall be where the agency receives controlled substances from distributors.

(L) The term "specific State authority" means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(M) The term "standing order" means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(N) The term "verbal order" means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

(k) In this section, the phrase "factors as may be relevant to and consistent with the public health and safety" means factors that are relevant to and consistent with the findings contained in section 101.

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ADDITIONAL REQUIREMENTS RELATING TO ONLINE PHARMACIES AND TELEMEDICINE

SEC. 311. (a) IN GENERAL.—An online pharmacy shall display in a visible and clear manner on its homepage a statement that it complies with the requirements of this section with respect to the delivery or sale or offer for sale of controlled substances and shall at all times display on the homepage of its Internet site a declaration of compliance in accordance with this section.

(b) LICENSURE.—Each online pharmacy shall comply with the requirements of State law concerning the licensure of pharmacies in each State from which it, and in each State to which it, delivers, distributes, or dispenses or offers to deliver, distribute, or dispense controlled substances by means of the Internet, pursuant to applicable licensure requirements, as determined by each such State.

(c) INTERNET PHARMACY SITE DISCLOSURE INFORMATION.—Each online pharmacy shall post in a visible and clear manner on the homepage of each Internet site it operates, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage, the following information for each pharmacy that delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of, that website:

(1) The name and address of the pharmacy as it appears on the pharmacy's Drug Enforcement Administration certificate of registration.

(2) The pharmacy's telephone number and email address.

(3) The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.

(4) A list of the States in which the pharmacy is licensed to dispense controlled substances.

(5) A certification that the pharmacy is registered under this part to deliver, distribute, or dispense by means of the Internet controlled substances.

(6) The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the request of the owner or operator of the website, or any employee or agent thereof.

(7) The following statement, unless revised by the Attorney General by regulation: "This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309.".

(d) NOTIFICATION.—

(1) IN GENERAL.—Thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing, the online pharmacy shall notify the Attorney General, in such form and manner as the Attorney General shall determine, and the State boards of pharmacy in any States in which the online pharmacy offers to sell, deliver, distribute, or dispense controlled substances.

(2) CONTENTS.—The notification required under paragraph (1) shall include—

(A) the information required to be posted on the online pharmacy's Internet site under subsection (c) and shall notify the Attorney General and the applicable State boards of pharmacy, under penalty of perjury, that the information disclosed on its Internet site under subsection (c) is true and accurate;

(B) the online pharmacy's Internet site address and a certification that the online pharmacy shall notify the Attorney General of any change in the address at least 30 days in advance; and

(C) the Drug Enforcement Administration registration numbers of any pharmacies and practitioners referred to in subsection (c), as applicable.

(3) EXISTING ONLINE PHARMACIES.—An online pharmacy that is already operational as of the effective date of this section, shall notify the Attorney General and applicable State boards of pharmacy in accordance with this subsection not later than 30 days after such date.

(e) DECLARATION OF COMPLIANCE.—On and after the date on which it makes the notification under subsection (d), each online pharmacy shall display on the homepage of its Internet site, in such form as the Attorney General shall by regulation require, a declaration that it has made such notification to the Attorney General.

(f) REPORTS.—Any statement, declaration, notification, or disclosure required under this section shall be considered a report required to be kept under this part.

(g) NOTICE AND DESIGNATIONS CONCERNING INDIAN TRIBES.—

(1) IN GENERAL.—For purposes of sections 102(52) and 512(c)(6)(B), the Secretary shall notify the Attorney General, at such times and in such manner as the Secretary and the Attorney General determine appropriate, of the Indian tribes or tribal organizations with which the Secretary has contracted or compacted under the Indian Self-Determination and Education Assistance Act for the tribes or tribal organizations to provide pharmacy services.

(2) DESIGNATIONS.—

(A) IN GENERAL.—The Secretary may designate a practitioner described in subparagraph (B) as an Internet Eligible Controlled Substances Provider. Such designations shall be made only in cases where the Secretary has found that there is a legitimate need for the practitioner to be so designated because the population served by the practitioner is in a sufficiently remote location that access to medical services is limited.

(B) PRACTITIONERS.—A practitioner described in this subparagraph is a practitioner who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact under the Indian Self-Determination and Education Assistance Act with the Indian Health Service.

(h) SPECIAL REGISTRATION FOR TELEMEDICINE.—

(1) IN GENERAL.—The Attorney General may issue to a practitioner a special registration to engage in the practice of telemedicine for purposes of section 102(54)(E) if the practitioner, upon application for such special registration—

(A) demonstrates a legitimate need for the special registration; and

(B) is registered under section 303(f) in the State in which the patient will be located when receiving the telemedicine treatment, unless the practitioner—

(i) is exempted from such registration in all States under section 302(d); or

(ii) is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract and is registered under section 303(f) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f).

(2) REGULATIONS.—[The Attorney General shall, with the concurrence of the Secretary, promulgate regulations] *Not later than 1 year after the date of enactment of the Special Registration for Telemedicine Clarification Act of 2018, the Attorney General shall, with the concurrence of the Secretary, promulgate interim final regulations* specifying the limited circumstances in which a special registration under this subsection may be issued and the procedures for obtaining such a special registration.

(3) DENIALS.—Proceedings to deny an application for registration under this subsection shall be conducted in accordance with section 304(c).

(i) REPORTING OF TELEMEDICINE BY VHA DURING MEDICAL EMERGENCY SITUATIONS.—

(1) IN GENERAL.—Any practitioner issuing a prescription for a controlled substance under the authorization to conduct telemedicine during a medical emergency situation described in section 102(54)(F) shall report to the Secretary of Veterans Affairs the authorization of that emergency prescription, in accordance with such requirements as the Secretary of Veterans Affairs shall, by regulation, establish.

(2) TO ATTORNEY GENERAL.—Not later than 30 days after the date that a prescription described in subparagraph (A) is issued, the Secretary of Veterans Affairs shall report to the Attorney General the authorization of that emergency prescription.

(j) CLARIFICATION CONCERNING PRESCRIPTION TRANSFERS.—Any transfer between pharmacies of information relating to a prescription for a controlled substance shall meet the applicable requirements under regulations promulgated by the Attorney General under this Act.

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## FEDERAL FOOD, DRUG, AND COSMETIC ACT

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### CHAPTER III—PROHIBITED ACTS AND PENALTIES

#### PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404, 415, 505, or 564.

(e) The refusal to permit access to or copying of any record as required by section 412, 414, 417(j), 416, 504, 564, 703, 704(a), 760, or 761; or the failure to establish or maintain any record, or make any report, required under section 412, 414(b), 417, 416, 504, 505 (i) or (k), 512(a)(4)(C), 512 (j), (l) or (m), 572(i), 515(f), 519, 564, 760, 761, 909, or 920 or the refusal to permit access to or verification or copying of any such required record; or the violation of any recordkeeping requirement under section 204 of the FDA Food Safety Modernization Act (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303(c)(2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303(c)(3), which guaranty or undertaking is false.

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404 or 721.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drugs a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 412, 414, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 571, 572, 573, 704, 708, 721, 904, 905, 906, 907, 908, 909, or 920(b) concerning any method or process which as a trade secret is entitled to protection; or the violating of section 408(i)(2) or any regulation issued under that section.. This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of section 407(b) or 407(c).

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 704.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other

printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act.

(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(i)(3).

(q)(1) The failure or refusal—

(A) to comply with any requirement prescribed under section 518, 520(g), 903(b), 907, 908, or 915;

(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, or 920; or

(C) to comply with a requirement under section 522 or 913.

(2) With respect to any device or tobacco product, the submission of any report that is required by or under this Act that is false or misleading in any material respect.

(r) The movement of a device, drug, or tobacco product in violation of an order under section 304(g) or the removal or alteration of any mark or label required by the order to identify the device, drug, or tobacco product as detained.

(s) The failure to provide the notice required by section 412(c) or 412(e), the failure to make the reports required by section 412(f)(1)(B), the failure to retain the records required by section 412(b)(4), or the failure to meet the requirements prescribed under section 412(f)(3).

(t) The importation of a drug in violation of section 801(d)(1), the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c), the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2), the distribution of a drug sample in violation of section 503(d) or the failure to otherwise comply with the requirements of section 503(d), the distribution of drugs in violation of section 503(e), failure to comply with the requirements under section 582, the failure to comply with the requirements under section 584, as applicable, or the failure to otherwise comply with the requirements of section 503(e).

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 512(a)(4)(A), 512(a)(4)(D), or 512(a)(5).

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 413.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 801(d)(3); the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 801(e) or 802, or with section 351(h) of the Public Health Service Act; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 514(c) or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food—

(1) the submission of a report or recommendation by a person accredited under section 523 that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 523 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 523 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act.

(z) The dissemination of information in violation of section 551.

(aa) The importation of a prescription drug in violation of section 804, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

(bb) The transfer of an article of food in violation of an order under section 304(h), or the removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food *or a drug* by, with the assistance of, or at the direction of, a person debarred *from such activity* under section 306(b)(3).

(dd) The failure to register in accordance with section 415.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 801(m).

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 801(o).

(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g); the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under section 416.

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 760 or 761) or the falsification of a serious adverse event report (as defined under section 760 or 761) submitted to the Secretary.

(jj)(1) The failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service Act, or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 402 of the Public Health Service Act.

(3) The submission of clinical trial information under subsection (j) of section 402 of the Public Health Service Act that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) The dissemination of a television advertisement without complying with section 503B.

(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 505, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless—

(1) such drug or such biological product was marketed in food before any approval of the drug under section 505, before licensure of the biological product under such section 351, and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

(A) a regulation issued under section 409 prescribing conditions of safe use in food;

(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

(D) a food contact substance notification that is effective under section 409(h); or

(E) such drug or biological product had been marketed for smoking cessation prior to the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

(4) the drug is a new animal drug whose use is not unsafe under section 512.

(mm) The failure to submit a report or provide a notification required under section 417(d).

(nn) The falsification of a report or notification required under section 417(d).

(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).

(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.

(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(rr) The charitable distribution of tobacco products.

(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that—

(1) the product is approved by the Food and Drug Administration;

(2) the Food and Drug Administration deems the product to be safe for use by consumers;

(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

(4) the product is safe or less harmful by virtue of—

(A) its regulation or inspection by the Food and Drug Administration; or

(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 903.

(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418.

(vv) The failure to comply with the requirements under section 419.

(ww) The failure to comply with section 420.

(xx) The refusal or failure to follow an order under section 423.

(yy) The knowing and willful failure to comply with the notification requirement under section 417(h).

(zz) The importation or offering for importation of a food if the importer (as defined in section 805) does not have in place a foreign supplier verification program in compliance with such section 805.

(aaa) The failure to register in accordance with section 801(s).

(bbb) The failure to notify the Secretary in violation of section 568.

(ccc)(1) The resale of a compounded drug that is labeled "not for resale" in accordance with section 503B.

(2) With respect to a drug to be compounded pursuant to section 503A or 503B, the intentional falsification of a prescription, as applicable.

(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 503B.

(ddd)(1) The manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads.

(2) In this paragraph—

(A) the term "plastic microbead" means any solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body or any part thereof; and

(B) the term "rinse-off cosmetic" includes toothpaste.

*(eee) The failure to comply with any order issued under section 569D.*

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SEIZURE

SEC. 304. (a)(1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section section 301(ll), 404, or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found. No libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (B) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found: (A) Any drug that is a counterfeit drug, (B) Any container of a counterfeit drug, (C) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs, (D) Any adulterated or misbranded device, and (E) Any adulterated or misbranded tobacco product.

(3)(A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any food which—

(i) is misbranded under section 403(a)(2) because of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a food described in subparagraph (A) if—

(i)(I) the food's advertising which resulted in the food being misbranded under section 403(a)(2) was disseminated in the establishment in which the food is being held for sale to the ultimate consumer,

(II) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

(III) all or part of the cost of such advertising was paid by such owner or operator; and

(ii) the owner or operator of such establishment used such advertising in the establishment to promote the sale of the food.

(b) **[**The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury.**]** *The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty rather than the procedure used for civil asset forfeiture proceedings set forth in section 983 of title 18, United States Code. On demand of either party any issue of fact joined in any such a case brought under this section shall be tried by jury. A seizure brought under this section is not governed by Rule G of the Supplemental Rules of Admiralty or Maritime Claims and Asset Forfeiture Actions. Exigent circumstances shall be deemed to exist for all seizures brought under this section, and in such cases, the summons and arrest warrant shall be issued by the clerk of the court without court review.* When libel for condemnation proceedings under this section, involving the same claimant and the same issues of

adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d)(1) Any food, drug, device, tobacco product, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold. After entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the article was imported, and (B) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 801(e) can and will be met. The provisions of this sentence shall not apply where condemnation is based upon violation of section 402(a) (1), (2), or (6), section 501(a)(3), section 502(j), or section 601 (a) or (d). Where such exportation is made to the original foreign supplier, then subparagraphs (A) and (B) of section 801(e)(1) and the preceding sentence shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 801(e) have been met. Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce. Any article condemned by reason of its being an article which may not, under section 404 or 505, be introduced into interstate commerce, shall be disposed of by destruction.

(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a).

(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a), the condemnation of any equipment or thing (other than a drug) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (i) that he has not committed or caused to be committed any prohibited act referred to in such paragraph (2) and has no interest in any drug referred to therein, (ii) that he has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by him in good faith, and (iii) that he at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to counterfeit drugs.

(e) When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

(g)(1) If during an inspection conducted under section 704 of a facility or a vehicle, a device or tobacco product which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device or tobacco product detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) or section 302, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device or tobacco product may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device or tobacco product during the period of its detention for the purpose of identifying the device or tobacco product as detained. Any person who would be entitled to claim a device or tobacco product if it were seized under subsection (a) may appeal to the Secretary a detention of such device or tobacco product under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

(2)(A) Except as authorized by subparagraph (B), a device or tobacco product subject to a detention order issued under paragraph (1) shall not be moved by any person from the place at which it is ordered detained until—

(i) released by the Secretary, or

(ii) the expiration of the detention period applicable to such order,

whichever occurs first.

(B) A device subject to a detention order under paragraph (1) may be moved—

(i) in accordance with regulations prescribed by the Secretary, and

(ii) if not in final form for shipment, at the discretion of the manufacturer of the device for the purpose of completing the work required to put it in such form.

(h) ADMINISTRATIVE DETENTION OF FOODS.—

(1) DETENTION AUTHORITY.—

(A) IN GENERAL.—An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has reason to believe that such article is adulterated or misbranded.

(B) SECRETARY'S APPROVAL.—An article of food may be ordered detained under subparagraph (A) only if the Secretary or an official designated by the Secretary approves the order. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

(2) PERIOD OF DETENTION.—An article of food may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to institute an action under subsection (a) or section 302. The Secretary shall by regulation provide for procedures for instituting such action on an expedited basis with respect to perishable foods.

(3) SECURITY OF DETAINED ARTICLE.—An order under paragraph (1) with respect to an article of food may require that such article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate. An article subject to such an order shall not be transferred by any person from the place at which the article is ordered detained, or from the place to which the article is so removed, as the case may be, until released by the Secretary or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the article pursuant to the execution of a bond while the article is subject to the order, and

section 801(b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is subject to the order.

(4) APPEAL OF DETENTION ORDER.—

(A) IN GENERAL.—With respect to an article of food ordered detained under paragraph (1), any person who would be entitled to be a claimant for such article if the article were seized under subsection (a) may appeal the order to the Secretary. Within five days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such five-day period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

(B) EFFECT OF INSTITUTING COURT ACTION.—The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Secretary institutes an action under subsection (a) or section 302 regarding the article of food involved.

(i) PROCEDURES FOR PROMULGATING REGULATIONS.—

(1) IN GENERAL.—In promulgating a regulation implementing this section, the Secretary shall—

(A) issue a notice of proposed rulemaking that includes the proposed regulation;

(B) provide a period of not less than 60 days for comments on the proposed regulation; and

(C) publish the final regulation not less than 30 days before the regulation's effective date.

(2) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing this section, the Secretary shall only promulgate regulations as described in paragraph (1).

* * * * * * *

DEBARMENT, TEMPORARY DENIAL OF APPROVAL, AND SUSPENSION

SEC. 306. (a) MANDATORY DEBARMENT; CERTAIN DRUG APPLICATIONS.—

(1) CORPORATIONS, PARTNERSHIPS, AND ASSOCIATIONS.—If the Secretary finds that a person other than an individual has been convicted, after the date of the enactment of this section, of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any abbreviated drug application, the Secretary shall debar such person from submitting, or assisting in the submission of, any such application.

(2) INDIVIDUALS.—If the Secretary finds that an individual has been convicted of a felony under Federal law for conduct—

(A) relating to the development or approval, including the process for development or approval, of any drug product, or

(B) otherwise relating to the regulation of any drug product under this Act,

the Secretary shall debar such individual from providing services in any capacity to a person that has an approved or pending drug product application.

(b) PERMISSIVE DEBARMENT; CERTAIN DRUG APPLICATIONS; FOOD IMPORTS.—

(1) IN GENERAL.—The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with **[**paragraph (2)**]** *paragraph (2) or (3)*, debar—

(A) a person other than an individual from submitting or assisting in the submission of any abbreviated drug application,

(B) an individual from providing services in any capacity to a person that has an approved or pending drug product application, **[**or**]**

(C) a person from importing an article of food or offering such an article for import into the United States**[**.**]***, or*

*(D) a person from importing or offering to import into the United States—*

*(i) a controlled substance as defined in section 102(6) of the Controlled Substances Act; or*

*(ii) any drug, if such drug is declared to be valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930), or if such drug is entering the United States by mail.*

(2) PERSONS SUBJECT TO PERMISSIVE DEBARMENT; CERTAIN DRUG APPLICATIONS.—The following persons are subject to debarment under subparagraph (A) or (B) of paragraph (1):

(A) CORPORATIONS, PARTNERSHIPS, AND ASSOCIATIONS.—Any person other than an individual that the Secretary finds has been convicted—

(i) for conduct that—

(I) relates to the development or approval, including the process for the development or approval, of any abbreviated drug application; and

(II) is a felony under Federal law (if the person was convicted before the date of the enactment of this section), a misdemeanor under Federal law, or a felony under State law, or

(ii) of a conspiracy to commit, or aiding or abetting, a criminal offense described in clause (i) or a felony described in subsection (a)(1),

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

(B) INDIVIDUALS.—

(i) Any individual whom the Secretary finds has been convicted of—

(I) a misdemeanor under Federal law or a felony under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under this Act, or

(II) a conspiracy to commit, or aiding or abetting, such criminal offense or a felony described in subsection (a)(2),

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

(ii) Any individual whom the Secretary finds has been convicted of—

(I) a felony which is not described in subsection (a)(2) or clause (i) of this subparagraph and which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, or

(II) a conspiracy to commit, or aiding or abetting, such felony,

if the Secretary finds, on the basis of the conviction of such individual and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this Act relating to drug products.

(iii) Any individual whom the Secretary finds materially participated in acts that were the basis for a conviction for an offense described in subsection (a) or in clause (i) or (ii) for which a conviction was obtained, if the Secretary finds, on the basis of such participation and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this Act relating to drug products.

(iv) Any high managerial agent whom the Secretary finds—

(I) worked for, or worked as a consultant for, the same person as another individual during the period in which such other individual took actions for which a felony conviction was obtained and which resulted in the debarment under subsection (a)(2), or clause (i), of such other individual,

(II) had actual knowledge of the actions described in subclause (I) of such other individual, or took action to avoid such actual knowledge, or failed to take action for the purpose of avoiding such actual knowledge,

(III) knew that the actions described in subclause (I) were violative of law, and

(IV) did not report such actions, or did not cause such actions to be reported, to an officer, employee, or agent of the Department or to an appropriate law enforcement officer, or failed to take other appropriate action that would have ensured that the process for the regulation of drugs was not undermined, within a reasonable time after such agent first knew of such actions,

if the Secretary finds that the type of conduct which served as the basis for such other individual's conviction undermines the process for the regulation of drugs.

(3) PERSONS SUBJECT TO PERMISSIVE DEBARMENT; FOOD *OR DRUG* IMPORTATION.—**[**A person is subject**]**

*(A) FOOD.—A person is subject* to debarment under paragraph (1)(C) if—

**[**(A)**]** *(i)* the person has been convicted of a felony for conduct relating to the importation into the United States of any food; or

**[**(B)**]** *(ii)* the person has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

*(B) IMPORTATION OF DRUGS.—A person is subject to debarment under paragraph (1)(D) if—*

*(i) the person has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance (as defined in section 102 of the Controlled Substances Act); or*

*(ii) the person has engaged in a pattern of importing or offering for import articles of drug that are—*

*(I)(aa) adulterated, misbranded, or in violation of section 505; and*

*(bb) present a threat of serious adverse health consequences or death to humans or animals; or*

*(II) controlled substances whose importation is prohibited pursuant to section 401(m) of the Tariff Act of 1930.*

*(C) DEFINITION.—For purposes of subparagraph (B), the term "pattern of importing or offering for import articles of drug" means importing or offering for import articles of drug described in subclause (I) or (II) of subparagraph (B)(ii) in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer.*

(4) STAY OF CERTAIN ORDERS.—An order of the Secretary under clause (iii) or (iv) of paragraph (2)(B) shall not take effect until 30 days after the order has been issued.

(c) DEBARMENT PERIOD AND CONSIDERATIONS.—

(1) EFFECT OF DEBARMENT.—The Secretary—

(A) shall not accept or review (other than in connection with an audit under this section) any abbreviated drug application submitted by or with the assistance of a person debarred under subsection (a)(1) or (b)(2)(A) during the period such person is debarred,

(B) shall, during the period of a debarment under subsection (a)(2) or (b)(2)(B), debar an individual from providing services in any capacity to a person that has an approved or pending drug product application and shall not accept or review (other than in connection with an audit under this section) an abbreviated drug application from such individual, and

(C) shall, if the Secretary makes the finding described in paragraph (6) or (7) of section 307(a), assess a civil penalty in accordance with section 307.

(2) DEBARMENT PERIODS.—

(A) IN GENERAL.—The Secretary shall debar a person under subsection (a) or (b) for the following periods:

(i) The period of debarment of a person (other than an individual) under subsection (a)(1) shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under subsection (a) occurs within 10 years after such person has been debarred under subsection (a)(1), the period of debarment shall be permanent.

(ii) The debarment of an individual under subsection (a)(2) shall be permanent.

(iii) The period of debarment of any person under paragraph (2) or (3) of subsection (b) shall not be more than 5 years.

The Secretary may determine whether debarment periods shall run concurrently or consecutively in the case of a person debarred for multiple offenses.

(B) NOTIFICATION.—Upon a conviction for an offense described in subsection (a) or (b) or upon execution of an agreement with the United States to plead guilty to such an offense, the person involved may notify the Secretary that the person acquiesces to debarment and such person's debarment shall commence upon such notification.

(3) CONSIDERATIONS.—In determining the appropriateness and the period of a debarment of a person under subsection (b) and any period of debarment beyond the minimum specified in subparagraph (A)(i) of paragraph (2), the Secretary shall consider where applicable—

(A) the nature and seriousness of any offense involved,

(B) the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

(C) the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health,

(D) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,

(E) whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements, and

(F) prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

(d) TERMINATION OF DEBARMENT.—

(1) APPLICATION.—Any person that is debarred under subsection (a) (other than a person permanently debarred) or any person that is debarred under subsection (b) may apply to the Secretary for termination of the debarment under this subsection. Any information submitted to the Secretary under this paragraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

(2) DEADLINE.—The Secretary shall grant or deny any application respecting a debarment which is submitted under paragraph (1) within 180 days of the date the application is submitted.

(3) ACTION BY THE SECRETARY.—

(A) CORPORATIONS.—

(i) CONVICTION REVERSAL.—If the conviction which served as the basis for the debarment of a person under subsection (a)(1) or paragraph (2)(A) or (3) of subsection (b) is reversed, the Secretary shall withdraw the order of debarment.

(ii) APPLICATION.—Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of a person if the Secretary finds that—

(I) changes in ownership, management, or operations have fully corrected the causes of the offense involved and provide reasonable assurances that the offense will not occur in the future, and

(II) in applicable cases, sufficient audits, conducted by the Food and Drug Administration or by independent experts acceptable to the Food and Drug Administration, demonstrate that pending applications and the development of drugs being tested before the submission of an application are free of fraud or material false statements.

In the case of persons debarred under subsection (a)(1), such termination shall take effect no earlier than the expiration of one year from the date of the debarment.

(B) INDIVIDUALS.—

(i) CONVICTION REVERSAL.—If the conviction which served as the basis for the debarment of an individual under subsection (a)(2) or clause (i), (ii), (iii), or (iv) of subsection (b)(2)(B) or subsection (b)(3) is reversed, the Secretary shall withdraw the order of debarment.

(ii) APPLICATION.—Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of an individual who has been debarred under subsection (b)(2)(B) or subsection (b)(3) if such termination serves the interests of justice and adequately protects the integrity of the drug approval process or the food importation process, as the case may be.

(4) SPECIAL TERMINATION.—

(A) APPLICATION.—Any person that is debarred under subsection (a)(1) (other than a person permanently debarred under subsection (c)(2)(A)(i)) or any individual who is debarred under subsection (a)(2) may apply to the Secretary for special termination of debarment under this subsection. Any information submitted to the Secretary under this

subparagraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

(B) CORPORATIONS.—Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that—

(i) the person making the application under subparagraph (A) has demonstrated that the felony conviction which was the basis for such person's debarment involved the commission of an offense which was not authorized, requested, commanded, performed, or recklessly tolerated by the board of directors or by a high managerial agent acting on behalf of the person within the scope of the board's or agent's office or employment,

(ii) all individuals who were involved in the commission of the offense or who knew or should have known of the offense have been removed from employment involving the development or approval of any drug subject to sections 505,

(iii) the person fully cooperated with all investigations and promptly disclosed all wrongdoing to the appropriate authorities, and

(iv) the person acted to mitigate any impact on the public of any offense involved, including the recall, or the discontinuation of the distribution, of any drug with respect to which the Secretary requested a recall or discontinuation of distribution due to concerns about the safety or efficacy of the drug.

(C) INDIVIDUALS.—Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that such individual has provided substantial assistance in the investigations or prosecutions of offenses which are described in subsection (a) or (b) or which relate to any matter under the jurisdiction of the Food and Drug Administration.

(D) SECRETARIAL ACTION.—The action referred to in subparagraphs (B) and (C) is—

(i) in the case of a person other than an individual—

(I) terminating the debarment immediately, or

(II) limiting the period of debarment to less than one year, and

(ii) in the case of an individual, limiting the period of debarment to less than permanent but to no less than 1 year,

whichever best serves the interest of justice and protects the integrity of the drug approval process.

(e) PUBLICATION AND LIST OF DEBARRED PERSONS.—The Secretary shall publish in the Federal Register the name of any person debarred under subsection (a) or (b), the effective date of the debarment, and the period of the debarment. The Secretary shall also maintain and make available to the public a list, updated no less often than quarterly, of such persons, of the effective dates and minimum periods of such debarments, and of the termination of debarments.

(f) TEMPORARY DENIAL OF APPROVAL.—

(1) IN GENERAL.—The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (3), refuse by order, for the period prescribed by paragraph (2), to approve any abbreviated drug application submitted by any person—

(A) if such person is under an active Federal criminal investigation in connection with an action described in subparagraph (B),

(B) if the Secretary finds that such person—

(i) has bribed or attempted to bribe, has paid or attempted to pay an illegal gratuity, or has induced or attempted to induce another person to bribe or pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services or to any other Federal, State, or local official in connection with any abbreviated drug application, or has conspired to commit, or aided or abetted, such actions, or

(ii) has knowingly made or caused to be made a pattern or practice of false statements or misrepresentations with respect to material facts relating to any abbreviated drug application, or the production of any drug subject to an abbreviated drug application, to any officer, employee, or agent of the Department of Health and Human Services, or has conspired to commit, or aided or abetted, such actions, and

(C) if a significant question has been raised regarding—

(i) the integrity of the approval process with respect to such abbreviated drug application, or

(ii) the reliability of data in or concerning such person's abbreviated drug application.

Such an order may be modified or terminated at any time.

(2) APPLICABLE PERIOD.—

(A) IN GENERAL.—Except as provided in subparagraph (B), a denial of approval of an application of a person under paragraph (1) shall be in effect for a period determined by the Secretary but not to exceed 18 months beginning on the date the Secretary finds that the conditions described in subparagraphs (A), (B), and (C) of paragraph (1) exist. The Secretary shall terminate such denial—

(i) if the investigation with respect to which the finding was made does not result in a criminal charge against such person, if criminal charges have been brought and the charges have been dismissed, or if a judgment of acquittal has been entered, or

(ii) if the Secretary determines that such finding was in error.

(B) EXTENSION.—If, at the end of the period described in subparagraph (A), the Secretary determines that a person has been criminally charged for an action described in subparagraph (B) of paragraph (1), the Secretary may extend the period of denial of approval of an application for a period not to exceed 18 months. The Secretary shall terminate such extension if the charges have been dismissed, if a judgment of acquittal has been entered, or if the Secretary determines that the finding described in subparagraph (A) was in error.

(3) INFORMAL HEARING.—Within 10 days of the date an order is issued under paragraph (1), the Secretary shall provide such person with an opportunity for an informal hearing, to be held within such 10 days, on the decision of the Secretary to refuse approval of an abbreviated drug application. Within 60 days of the date on which such hearing is held, the Secretary shall notify the person given such hearing whether the Secretary's refusal of approval will be continued, terminated, or otherwise modified. Such notification shall be final agency action.

(g) SUSPENSION AUTHORITY.—

(1) IN GENERAL.—If—

(A) the Secretary finds—

(i) that a person has engaged in conduct described in subparagraph (B) of subsection (f)(1) in connection with 2 or more drugs under abbreviated drug applications, or

(ii) that a person has engaged in flagrant and repeated, material violations of good manufacturing practice or good laboratory practice in connection with the development, manufacturing, or distribution of one or more drugs approved under an abbreviated drug application during a 2-year period, and—

(I) such violations may undermine the safety and efficacy of such drugs, and

(II) the causes of such violations have not been corrected within a reasonable period of time following notice of such violations by the Secretary, and

(B) such person is under an active investigation by a Federal authority in connection with a civil or criminal action involving conduct described in subparagraph (A),

the Secretary shall issue an order suspending the distribution of all drugs the development or approval of which was related to such conduct described in subparagraph (A) or suspending the distribution of all drugs approved under abbreviated drug applications of such person if the Secretary finds that such conduct may have affected the development or approval of a significant number of drugs which the Secretary is unable to identify. The Secretary shall exclude a drug from such order if the Secretary determines that such conduct was not likely to have influenced the safety or efficacy of such drug.

(2) PUBLIC HEALTH WAIVER.—The Secretary shall, on the Secretary's own initiative or in response to a petition, waive the suspension under paragraph (1) (involving an action described in paragraph (1)(A)(i)) with respect to any drug if the Secretary finds that such waiver is necessary to protect the public health because sufficient quantities of the drug would not otherwise be available. The Secretary shall act on any petition seeking action under this paragraph within 180 days of the date the petition is submitted to the Secretary.

(h) TERMINATION OF SUSPENSION.—The Secretary shall withdraw an order of suspension of the distribution of a drug under subsection (g) if the person with respect to whom the order was issued demonstrates in a petition to the Secretary—

(1)(A) on the basis of an audit by the Food and Drug Administration or by experts acceptable to the Food and Drug Administration, or on the basis of other information, that the development, approval, manufacturing, and distribution of such drug is in substantial compliance with the applicable requirements of this Act, and

(B) changes in ownership, management, or operations—

(i) fully remedy the patterns or practices with respect to which the order was issued, and

(ii) provide reasonable assurances that such actions will not occur in the future, or

(2) the initial determination was in error.

The Secretary shall act on a submission of a petition under this subsection within 180 days of the date of its submission and the Secretary may consider the petition concurrently with the suspension proceeding. Any information submitted to the Secretary under this subsection does not constitute an amendment or supplement to a pending or approved abbreviated drug application.

(i) PROCEDURE.—The Secretary may not take any action under subsection (a), (b), (c), (d)(3), (g), or (h) with respect to any person unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(j) JUDICIAL REVIEW.—

(1) IN GENERAL.—Except as provided in paragraph (2), any person that is the subject of an adverse decision under subsection (a), (b), (c), (d), (f), (g), or (h) may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(2) EXCEPTION.—Any person that is the subject of an adverse decision under clause (iii) or (iv) of subsection (b)(2)(B) may obtain a review of such decision by the United States District Court for the District of Columbia or a district court of the United States for the district in which the person resides, by filing in such court (within 30 days following the date the person is notified of the Secretary's decision) a complaint requesting that the decision be modified or set aside. In such an action, the court shall determine the matter de novo.

(k) CERTIFICATION.—Any application for approval of a drug product shall include—

(1) a certification that the applicant did not and will not use in any capacity the services of any person debarred under subsection (a) or (b), in connection with such application, and

(2) if such application is an abbreviated drug application, a list of all convictions, described in subsections (a) and (b) which occurred within the previous 5 years, of the applicant and affiliated persons responsible for the development or submission of such application.

(l) APPLICABILITY.—

(1) CONVICTION.—For purposes of this section, a person is considered to have been convicted of a criminal offense—

(A) when a judgment of conviction has been entered against the person by a Federal or State court, regardless of whether there is an appeal pending,

(B) when a plea of guilty or nolo contendere by the person has been accepted by a Federal or State court, or

(C) when the person has entered into participation in a first offender, deferred adjudication, or other similar arrangement or program where judgment of conviction has been withheld.

(2) EFFECTIVE DATES.—Subsection (a), subparagraph (A) of subsection (b)(2), clauses (i) and (ii) of subsection (b)(2)(B), and subsection (b)(3)(A) shall not apply to a conviction which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (a) or (b). Clauses (iii) and (iv) of subsection (b)(2)(B), subsection (b)(3)(B), and subsections (f) and (g) shall not apply to an act or action which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (b), (f), or (g). Clause (iv) of subsection (b)(2)(B) shall not apply to an action which occurred before June 1, 1992. Subsection (k) shall not apply to applications submitted to the Secretary before June 1, 1992.

(m) DEVICES; MANDATORY DEBARMENT REGARDING THIRD-PARTY INSPECTIONS AND REVIEWS.—

(1) IN GENERAL.—If the Secretary finds that a person has been convicted of a felony under section 301(gg), the Secretary shall debar such person from being accredited under section 523(b) or 704(g)(2) and from carrying out activities under an agreement described in section 803(b).

(2) DEBARMENT PERIOD.—The Secretary shall debar a person under paragraph (1) for the following periods:

(A) The period of debarment of a person (other than an individual) shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under such paragraph occurs within 10 years after such person has been debarred under such paragraph, the period of debarment shall be permanent.

(B) The debarment of an individual shall be permanent.

(3) TERMINATION OF DEBARMENT; JUDICIAL REVIEW; OTHER MATTERS.—Subsections (c)(3), (d), (e), (i), (j), and (l)(1) apply with respect to a person (other than an individual) or an individual who is debarred under paragraph (1) to the same extent and in the same manner as such subsections apply with respect to a person who is debarred under subsection (a)(1), or an individual who is debarred under subsection (a)(2), respectively.

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## CHAPTER V—DRUGS AND DEVICES

### SUBCHAPTER A—DRUGS AND DEVICES

#### ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated—

(a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 721(a), or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 721(a); or (5) if it is a new animal drug which is unsafe within the meaning of section 512; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 512.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth

in such compendium, if its difference in strength, quality, or purity from such standards is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States it shall be subject to the requirements of the United States Pharmacopeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States and not to those of the United States Pharmacopeia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

(e)(1) If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 514, unless such device is in all respects in conformity with such standard.

(2) If it is declared to be, purports to be, or is represented as, a device that is in conformity with any standard recognized under section 514(c) unless such device is in all respects in conformity with such standard.

(f)(1) If it is a class III device—

(A)(i) which is required by an order issued under subsection (b) of section 515 to have an approval under such section of an application for premarket approval and which is not exempt from section 515 under section 520(g), and

(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the ninety-day period beginning on the date of the issuance of such order, or

(II) for which such an application was filed and approval of the application has been denied, suspended, or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

(B)(i) which was classified under section 513(f) into class III, which under section 515(a) is required to have in effect an approved application for premarket approval, and which is not exempt from section 515 under section 520(g), and

(ii) which has an application which has been suspended or is otherwise not in effect; or

(C) which was classified under section 520(l) into class III, which under such section is required to have in effect an approved application under section 515, and which has an application which has been suspended or is otherwise not in effect.

(2)(A) In the case of a device classified under section 513(f) into class III and intended solely for investigational use, paragraph (1)(B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 520(g)(2).

(B) In the case of a device subject to an order issued under subsection (b) of section 515, paragraph (1) shall not apply with respect to such device during the period ending—

(i) on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 513, or

(ii) on the ninetieth day after the date of the issuance of such order,

whichever occurs later.

(3) In the case of a device with respect to which a regulation was promulgated under section 515(b) prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act, a reference in this subsection to an order issued under section 515(b) shall be deemed to include such regulation.

(g) If it is a banned device.

(h) If it is a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 520(f)(1) or an applicable condition prescribed by an order under section 520(f)(2).

(i) If it is a device for which an exemption has been granted under section 520(g) for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section.

(j) If it is a drug or device and it has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection. For purposes of paragraph (a)(2)(B), the term "current good manufacturing practice" includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, includ-

ing managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.

*(k) If it is a drug approved under a covered application (as defined in section 505–2(e)), the holder of which does not meet the requirements of paragraphs (1) and (2) of subsection (b) of such section.*

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NEW DRUGS

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b)(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 505B. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture use, or sale of the drug. If a application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) RECIPIENTS OF NOTICE.—An applicant required under this paragraph to give notice shall give notice to—

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 351 of the Public Health Service Act, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size—

(i)(I) of clinical trials intended to form the primary basis of an effectiveness claim; or

(II) in the case where human efficacy studies are not ethical or feasible, of animal and any associated clinical trials which, in combination, are intended to form the primary basis of an effectiveness claim; or

(ii) with respect to an application for approval of a biological product under section 351(k) of the Public Health Service Act, of any necessary clinical study or studies.

The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compli-

ance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 351 of the Public Health Service Act (including all scientific and medical matters, chemistry, manufacturing, and controls).

(6) An application submitted under this subsection shall be accompanied by the certification required under section 402(j)(5)(B) of the Public Health Service Act. Such certification shall not be considered an element of such application.

(c)(1) Within one hundred and eighty days after the filing of an application under subsection (b), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary, the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A):

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed—

(I) if the judgment of the district court is appealed, the approval shall be made effective on—

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(D) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of

confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(E)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this clause, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time

(if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of the enactment of this clause and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this clause and the supplement contains reports of new clinical investigations (other than bioavailabilty studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this clause, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from the date of enactment of this clause.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(5)(A) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under subsection (b), if such supplemental application complies with subparagraph (B).

(B) A supplemental application is eligible for review as described in subparagraph (A) only if—

(i) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

(ii) all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.

(C) The Secretary shall post on the Internet website of the Food and Drug Administration and update annually—

(i) the number of applications reviewed solely under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

(ii) the average time for completion of review under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

(iii) the average time for review of supplemental applications where the Secretary did not use review flexibility under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act; and

(iv) the number of applications reviewed under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act for which the Secretary made use of full data sets in addition to the qualified data summary.

(D) In this paragraph—

(i) the term "qualified indication" means an indication for a drug that the Secretary determines to be appropriate for summary level review under this paragraph; and

(ii) the term "qualified data summary" means a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.

(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); ⟦or (7)⟧ *(7)* based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; *or (8) if the drug is or contains a controlled substance for which a listing in any schedule is in effect under the Controlled Substances Act or that is permanently scheduled pursuant to section 201 of such Act, on the basis of information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, the drug is unsafe for use due to the risks of abuse or misuse or there is insufficient information to show that the drug is safe for use considering such risks;* he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through ⟦(6)⟧ *(8)* do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence. The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for marketing approval of a drug.

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) was not filed within thirty days after

the receipt of written notice from the Secretary specifying the failure to file such information; [or (5)] *(5)* that the application contains any untrue statement of a material fact*; or (6) that, in the case of a drug that is or contains a controlled substance for which a listing in any schedule is in effect under the Controlled Substances Act or that is permanently scheduled pursuant to section 201 of such Act, on the basis of new information before him with respect to such drug, evaluated together with the information available to him when the application was approved, that the drug is unsafe for use due to the risks of abuse or misuse*: *Provided,* That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) or to comply with the notice requirements of section 510(k)(2), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based. The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under section 505–1(g)(2)(D).

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with

the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i)(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, or preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b); and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before the date of the enactment of the Food and Drug Administration Modernization Act of 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any

human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs. The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 402 of the Public Health Service Act.

(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; [and]

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the appli-

cant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use**[**.**]***; and*

*(ix) if the drug is or contains an opioid for which a listing in schedule II or III (on a temporary or permanent basis) is in effect under section 202 of the Controlled Substances Act, information to show that the applicant has proposed technologies, controls, or measures related to the packaging or disposal of the drug that provide protections comparable to those provided by the technologies, controls, or measures required for the applicable listed drug under section 505–2, if applicable.*

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insuf-

ficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); **[**or**]**

(K) the application contains an untrue statement of material fact**[**.**]***; or*

*(L) if the drug is a drug described in paragraph (2)(A)(ix) and the applicant has not proposed technologies, controls, or measures related to the packaging or disposal of such drug that the Secretary determines provide protections comparable to those provided by the technologies, controls, or measures required for the applicable listed drug under section 505–2.*

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided

under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-DAY EXCLUSIVITY PERIOD.—

(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) DEFINITIONS.—In this paragraph:

(aa) 180-DAY EXCLUSIVITY PERIOD.—The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) FIRST APPLICANT.—As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) TENTATIVE APPROVAL.—

(AA) IN GENERAL.—The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period

of exclusivity for the listed drug under subparagraph (F) or section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(v) 180-DAY EXCLUSIVITY PERIOD FOR COMPETITIVE GENERIC THERAPIES.—

(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D)(iv), if the application is for a drug that is the same as a competitive generic therapy for which any first approved applicant has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the competitive generic therapy (including the commercial marketing of the listed drug) by any first approved applicant.

(II) LIMITATION.—The exclusivity period under subclause (I) shall not apply with respect to a competitive generic therapy that has previously received an exclusivity period under subclause (I).

(III) DEFINITIONS.—In this clause and subparagraph (D)(iv):

(aa) The term "competitive generic therapy" means a drug—

(AA) that is designated as a competitive generic therapy under section 506H; and

(BB) for which there are no unexpired patents or exclusivities on the list of products described in section 505(j)(7)(A) at the time of submission.

(bb) The term "first approved applicant" means any applicant that has submitted an application that—

(AA) is for a competitive generic therapy that is approved on the first day on which any application for such competitive generic therapy is approved;

(BB) is not eligible for a 180-day exclusivity period under clause (iv) for the drug that is the subject of the application for the competitive generic therapy; and

(CC) is not for a drug for which all drug versions have forfeited eligibility for a 180-day exclusivity period under clause (iv) pursuant to subparagraph (D).

(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subpara-

graph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(iv) SPECIAL FORFEITURE RULE FOR COMPETITIVE GENERIC THERAPY.—The 180-day exclusivity period described in subparagraph (B)(v) shall be forfeited by a first approved applicant if the applicant fails to market the competitive generic therapy within 75 days after the date on which the approval of the first approved applicant's application for the competitive generic therapy is made effective.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) applica-

tion if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of enactment of this subsection and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this subsection and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from the date of enactment of this subsection.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this Act, be eligible for approval and shall not be considered misbranded under section 502 if—

(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

(ii) the labeling revision described under clause (i) does not include a change to the "Warnings" section of the labeling;

(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.

(11)(A) Subject to subparagraph (B), the Secretary shall prioritize the review of, and act within 8 months of the date of the submission of, an original abbreviated new drug application submitted for review under this subsection that is for a drug—

(i) for which there are not more than 3 approved drug products listed under paragraph (7) and for which there are no blocking patents and exclusivities; or

(ii) that has been included on the list under section 506E.

(B) To qualify for priority review under this paragraph, not later than 60 days prior to the submission of an application described in subparagraph (A) or that the Secretary may prioritize pursuant to subparagraph (D), the applicant shall provide complete, accurate information regarding facilities involved in manufacturing processes and testing of the drug that is the subject of the application, including facilities in corresponding Type II active pharmaceutical ingredients drug master files referenced in an application and sites or organizations involved in bioequivalence and clinical studies used to support the application, to enable the Secretary to make a determination regarding whether an inspection of a facility is necessary. Such information shall include the relevant (as determined by the Secretary) sections of such application, which shall be unchanged relative to the date of the submission of such application, except to the extent that a change is made to such information to exclude a facility that was not used to generate data to meet any application requirements for such submission and that is not the only facility intended to conduct one or more unit operations in commercial production. Information provided by an applicant under this subparagraph shall not be considered the submission of an application under this subsection.

(C) The Secretary may expedite an inspection or reinspection under section 704 of an establishment that proposes to manufacture a drug described in subparagraph (A).

(D) Nothing in this paragraph shall prevent the Secretary from prioritizing the review of other applications as the Secretary determines appropriate.

(12) The Secretary shall publish on the internet website of the Food and Drug Administration, and update at least once every 6 months, a list of all drugs approved under subsection (c) for which all patents and periods of exclusivity under this Act have expired and for which no application has been approved under this subsection.

(13) Upon the request of an applicant regarding one or more specified pending applications under this subsection, the Secretary shall, as appropriate, provide review status updates indicating the categorical status of the applications by each relevant review discipline.

(k)(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(3) ACTIVE POSTMARKET RISK IDENTIFICATION.—

(A) DEFINITION.—In this paragraph, the term "data" refers to information with respect to a drug approved under this section or under section 351 of the Public Health Service Act, including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, and any other data deemed appropriate by the Secretary.

(B) DEVELOPMENT OF POSTMARKET RISK IDENTIFICATION AND ANALYSIS METHODS.—The Secretary shall, not later than 2 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, in collaboration with public, academic, and private entities—

(i) develop methods to obtain access to disparate data sources including the data sources specified in subparagraph (C);

(ii) develop validated methods for the establishment of a postmarket risk identification and analysis system to link and analyze safety data from multiple sources, with the goals of including, in aggregate—

(I) at least 25,000,000 patients by July 1, 2010; and

(II) at least 100,000,000 patients by July 1, 2012; and

(iii) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data specified under subparagraph (C), including recommendations on the development of effective research methods for the study of drug safety questions.

(C) ESTABLISHMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

(i) IN GENERAL.—The Secretary shall, not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), establish and maintain procedures—

(I) for risk identification and analysis based on electronic health data, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and in a manner that does not disclose individually identifiable health information in violation of paragraph (4)(B);

(II) for the reporting (in a standardized form) of data on all serious adverse drug experiences (as defined in section 505–1(b)) submitted to the Secretary under paragraph (1), and those adverse events submitted by patients, providers, and drug sponsors, when appropriate;

(III) to provide for active adverse event surveillance using the following data sources, as available:

(aa) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

(bb) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

(cc) other data as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

(IV) to identify certain trends and patterns with respect to data accessed by the system;

(V) to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary determines appropriate, which may include data on comparative national adverse event trends; and

(VI) to enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

(ii) TIMELINESS OF REPORTING.—The procedures established under clause (i) shall ensure that such data are accessed, analyzed, and reported in a timely, routine, and systematic manner, taking into consideration the need for data completeness, coding, cleansing, and standardized analysis and transmission.

(iii) PRIVATE SECTOR RESOURCES.—To ensure the establishment of the active postmarket risk identification and analysis system under this subsection not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), as required under clause (i), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(iv) COMPLEMENTARY APPROACHES.—To the extent the active postmarket risk identification and analysis system under this subsection is not sufficient to gather data and information relevant to a priority drug safety question, the Secretary shall de-

velop, support, and participate in complementary approaches to gather and analyze such data and information, including—

(I) approaches that are complementary with respect to assessing the safety of use of a drug in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and

(II) existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

(v) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

(4) ADVANCED ANALYSIS OF DRUG SAFETY DATA.—

(A) PURPOSE.—The Secretary shall establish collaborations with public, academic, and private entities, which may include the Centers for Education and Research on Therapeutics under section 912 of the Public Health Service Act, to provide for advanced analysis of drug safety data described in paragraph (3)(C) and other information that is publicly available or is provided by the Secretary, in order to—

(i) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

(ii) provide the Secretary with routine access to outside expertise to study advanced drug safety questions; and

(iii) enhance the ability of the Secretary to make timely assessments based on drug safety data.

(B) PRIVACY.—Such analysis shall not disclose individually identifiable health information when presenting such drug safety signals and trends or when responding to inquiries regarding such drug safety signals and trends.

(C) PUBLIC PROCESS FOR PRIORITY QUESTIONS.—At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or any successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on—

(i) priority drug safety questions; and

(ii) mechanisms for answering such questions, including through—

(I) active risk identification under paragraph (3); and

(II) when such risk identification is not sufficient, postapproval studies and clinical trials under subsection (o)(3).

(D) PROCEDURES FOR THE DEVELOPMENT OF DRUG SAFETY COLLABORATIONS.—

(i) IN GENERAL.—Not later than 180 days after the date of the establishment of the active postmarket risk identification and analysis system under this subsection, the Secretary shall establish and implement procedures under which the Secretary may routinely contract with one or more qualified entities to—

(I) classify, analyze, or aggregate data described in paragraph (3)(C) and information that is publicly available or is provided by the Secretary;

(II) allow for prompt investigation of priority drug safety questions, including—

(aa) unresolved safety questions for drugs or classes of drugs; and

(bb) for a newly-approved drugs, safety signals from clinical trials used to approve the drug and other preapproval trials; rare, serious drug side effects; and the safety of use in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children);

(III) perform advanced research and analysis on identified drug safety risks;

(IV) focus postapproval studies and clinical trials under subsection (o)(3) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

(V) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

(ii) REQUEST FOR SPECIFIC METHODOLOGY.—The procedures described in clause (i) shall permit the Secretary to request that a specific methodology be used by the quali-

fied entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

(E) USE OF ANALYSES.—The Secretary shall provide the analyses described in this paragraph, including the methods and results of such analyses, about a drug to the sponsor or sponsors of such drug.

(F) QUALIFIED ENTITIES.—

(i) IN GENERAL.—The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

(ii) QUALIFICATION.—The Secretary shall enter into a contract with an entity under clause (i) only if the Secretary determines that the entity has a significant presence in the United States and has one or more of the following qualifications:

(I) The research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this paragraph, including the capability and expertise to provide the Secretary de-identified data consistent with the requirements of this subsection.

(II) An information technology infrastructure in place to support electronic data and operational standards to provide security for such data.

(III) Experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data.

(IV) An understanding of drug development or risk/benefit balancing in a clinical setting.

(V) Other expertise which the Secretary deems necessary to fulfill the activities under this paragraph.

(G) CONTRACT REQUIREMENTS.—Each contract with a qualified entity under subparagraph (F)(i) shall contain the following requirements:

(i) ENSURING PRIVACY.—The qualified entity shall ensure that the entity will not use data under this subsection in a manner that—

(I) violates the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;

(II) violates sections 552 or 552a of title 5, United States Code, with regard to the privacy of individually-identifiable beneficiary health information; or

(III) discloses individually identifiable health information when presenting drug safety signals and trends or when responding to inquiries regarding drug safety signals and trends.

Nothing in this clause prohibits lawful disclosure for other purposes.

(ii) COMPONENT OF ANOTHER ORGANIZATION.—If a qualified entity is a component of another organization—

(I) the qualified entity shall establish appropriate security measures to maintain the confidentiality and privacy of such data; and

(II) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

(iii) TERMINATION OR NONRENEWAL.—If a contract with a qualified entity under this subparagraph is terminated or not renewed, the following requirements shall apply:

(I) CONFIDENTIALITY AND PRIVACY PROTECTIONS.—The entity shall continue to comply with the confidentiality and privacy requirements under this paragraph with respect to all data disclosed to the entity.

(II) DISPOSITION OF DATA.—The entity shall return any data disclosed to such entity under this subsection to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

(H) COMPETITIVE PROCEDURES.—The Secretary shall use competitive procedures (as defined in section 4(5) of the Federal Procurement Policy Act) to enter into contracts under subparagraph (G).

(I) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review the contract with a qualified entity under this paragraph in the event of a merger or acquisition of the entity in order to ensure that the requirements under this paragraph will continue to be met.

(J) COORDINATION.—In carrying out this paragraph, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and to the extent practicable shall coordinate with the activities of private entities, professional associations, or other entities that may have sources of drug safety data.

(5) The Secretary shall—

(A) conduct regular screenings of the Adverse Event Reporting System database and post a quarterly report on the Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse Event Reporting System within the last quarter; and

(B) on an annual basis, review the entire backlog of postmarket safety commitments to determine which commitments require revision or should be eliminated, report to the Congress on these determinations, and assign start dates and estimated completion dates for such commitments; and

(C) make available on the Internet website of the Food and Drug Administration—

(i) guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System; and

(ii) criteria for public posting of adverse event signals.

(l)(1) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(A) if no work is being or will be undertaken to have the application approved,

(B) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(C) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

(D) if the Secretary has determined that such drug is not a new drug, or

(E) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

(2) ACTION PACKAGE FOR APPROVAL.—

(A) ACTION PACKAGE.—The Secretary shall publish the action package for approval of an application under subsection (b) or section 351 of the Public Health Service Act on the Internet Web site of the Food and Drug Administration—

(i) not later than 30 days after the date of approval of such application for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act; and

(ii) not later than 30 days after the third request for such action package for approval received under section 552 of title 5, United States Code, for any other drug.

(B) IMMEDIATE PUBLICATION OF SUMMARY REVIEW.—Notwithstanding subparagraph (A), the Secretary shall publish, on the Internet Web site of the Food and Drug Administration, the materials described in subparagraph (C)(iv) not later than 48 hours after the date of approval of the drug, except where such materials require redaction by the Secretary.

(C) CONTENTS.—An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:

(i) Documents generated by the Food and Drug Administration related to review of the application.

(ii) Documents pertaining to the format and content of the application generated during drug development.

(iii) Labeling submitted by the applicant.

(iv) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any nonconcurrence with review conclusions.

(v) The Division Director and Office Director's decision document which includes—

(I) a brief statement of concurrence with the summary review;

(II) a separate review or addendum to the review if disagreeing with the summary review; and

(III) a separate review or addendum to the review to add further analysis.

(vi) Identification by name of each officer or employee of the Food and Drug Administration who—

(I) participated in the decision to approve the application; and

(II) consents to have his or her name included in the package.

(D) REVIEW.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final.

(E) CONFIDENTIAL INFORMATION.—This paragraph does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of title 5, United States Code.

(m) For purposes of this section, the term "patent" means a patent issued by the United States Patent and Trademark Office.

(n)(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of enactment of the Food and Drug Administration Modernization Act of 1997, or both.

(2) The Secretary may delegate the appointment and oversight authority granted under section 1004 to a director of a center or successor entity within the Food and Drug Administration.

(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this Act and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(5) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS–15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(6) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(7) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

(o) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING.—

(1) IN GENERAL.—A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under paragraph (3) or (4) with respect to the drug.

(2) DEFINITIONS.—For purposes of this subsection:

(A) RESPONSIBLE PERSON.—The term "responsible person" means a person who—

(i) has submitted to the Secretary a covered application that is pending; or

(ii) is the holder of an approved covered application.

(B) COVERED APPLICATION.—The term "covered application" means—

(i) an application under subsection (b) for a drug that is subject to section 503(b); and

(ii) an application under section 351 of the Public Health Service Act.

(C) NEW SAFETY INFORMATION; SERIOUS RISK.—The terms "new safety information", "serious risk", and "signal of a serious risk" have the meanings given such terms in section 505–1(b).

*(D) NEW EFFECTIVENESS INFORMATION.—The term "new effectiveness information", with respect to a drug that is or contains a controlled substance for which a listing in any schedule is in effect (on a temporary or permanent basis) under section 201 of the Controlled Substances Act, means new information about the effectiveness of the drug, including a new analysis of existing information, derived from—*

*(i) a clinical trial; an adverse event report; a postapproval study or clinical trial (including a study or clinical trial under paragraph (3));*

*(ii) peer-reviewed biomedical literature;*

*(iii) data derived from the postmarket risk identification and analysis system under subsection (k); or*

*(iv) other scientific data determined to be appropriate by the Secretary.*

(3) STUDIES AND CLINICAL TRIALS.—

(A) IN GENERAL.—For any or all of the purposes specified in subparagraph (B), the Secretary may, subject to subparagraph (D), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug, on the basis of scientific data deemed appropriate by the Secretary, including information regarding chemically-related or pharmacologically-related drugs.

(B) PURPOSES OF STUDY OR CLINICAL TRIAL.—The purposes referred to in this subparagraph with respect to a postapproval study or postapproval clinical trial are the following:

(i) To assess a known serious risk related to the use of the drug involved.

(ii) To assess signals of serious risk related to the use of the drug.

(iii) To identify an unexpected serious risk when available data indicates the potential for a serious risk.

*(iv) To assess a potential reduction in effectiveness of the drug for the conditions of use prescribed, recommended, or suggested in the labeling thereof if—*

*(I) the drug involved—*

*(aa) is or contains a substance for which a listing in any schedule is in effect (on a temporary or permanent basis) under section 201 of the Controlled Substances Act; or*

*(bb) is a drug that has not been approved under this section or licensed under section 351 of the Public Health Service Act, for which an application for such approval or licensure is pending or anticipated, and for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act; and*

*(II) the potential reduction in effectiveness could result in the benefits of the drug no longer outweighing the risks.*

(C) ESTABLISHMENT OF REQUIREMENT AFTER APPROVAL OF COVERED APPLICATION.—The Secretary may require a postapproval study or studies or postapproval clinical trial or trials for a drug for which an approved covered application is in effect as of the date on which the Secretary seeks to establish ⟦such requirement only if the Secretary becomes aware of new safety information.⟧ *such requirement—*

*(i) in the case of a purpose described in clause (i), (ii), or (iii) of subparagraph (B), only if the Secretary becomes aware of new safety information; and*

*(ii) in the case of a purpose described in clause (iv) of such subparagraph, if the Secretary determines that new effectiveness information exists.*

(D) DETERMINATION BY SECRETARY.—

(i) POSTAPPROVAL STUDIES.—The Secretary may not require the responsible person to conduct a study under this paragraph, unless the Secretary makes a determination that the reports under subsection (k)(1) and the active postmarket risk identification and analysis system as available under subsection (k)(3) will not be sufficient to meet the purposes set forth in subparagraph (B).

(ii) POSTAPPROVAL CLINICAL TRIALS.—The Secretary may not require the responsible person to conduct a clinical trial under this paragraph, unless the Secretary makes a determination that a postapproval study or studies will not be sufficient to meet the purposes set forth in subparagraph (B).

(E) NOTIFICATION; TIMETABLES; PERIODIC REPORTS.—

(i) NOTIFICATION.—The Secretary shall notify the responsible person regarding a requirement under this paragraph to conduct a postapproval study or clinical trial by the target dates for communication of feedback from the review team to the responsible person regarding proposed labeling and postmarketing study commitments as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

(ii) TIMETABLE; PERIODIC REPORTS.—For each study or clinical trial required to be conducted under this paragraph, the Secretary shall require that the responsible person submit a timetable for completion of the study or clinical trial. With respect to each study required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such study including whether any difficulties in completing the study have been encountered. With respect to each clinical trial required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such clinical trial including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to the requirements under section 402(j) of the Public Health Service Act. If the responsible person fails to comply with such timetable or violates any other requirement of this subparagraph, the responsible person shall be considered in violation of this subsection, unless the responsible person demonstrates good cause for such noncompliance or such other violation. The Secretary shall determine what constitutes good cause under the preceding sentence.

(F) DISPUTE RESOLUTION.—The responsible person may appeal a requirement to conduct a study or clinical trial under this paragraph using dispute resolution procedures established by the Secretary in regulation and guidance.

*(G) APPLICABILITY.—The conduct of a study or clinical trial required pursuant to this paragraph for the purpose specified in subparagraph (B)(iv) shall not be considered a new clinical investigation for the purpose of a period of exclusivity under clause (iii) or (iv) of subsection (c)(3)(E) or clause (iii) or (iv) of subsection (j)(5)(F).*

(4) SAFETY LABELING CHANGES REQUESTED BY SECRETARY.—

(A) NEW SAFETY *OR NEW EFFECTIVENESS* INFORMATION.—If the Secretary becomes aware of new [safety information] *new safety information or new effectiveness information such* that the Secretary [believes should be] *believes changes should be made to* included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under section 505(b) is not currently marketed, the holder of an approved application under 505(j).

(B) RESPONSE TO NOTIFICATION.—Following notification pursuant to subparagraph (A), the responsible person or the holder of the approved application under section 505(j) shall within 30 days—

(i) submit a supplement proposing changes to the approved labeling to reflect the [new safety information] *new safety information or new effectiveness information*, including changes to boxed warnings, *indications,* contraindications, warnings, precautions, or adverse reactions; or

(ii) notify the Secretary that the responsible person or the holder of the approved application under section 505(j) does not believe a labeling change is warranted and submit a statement detailing the reasons why such a change is not warranted.

(C) REVIEW.—Upon receipt of such supplement, the Secretary shall promptly review and act upon such supplement. If the Secretary disagrees with the proposed changes in the supplement or with the statement setting forth the reasons why no labeling change is necessary, the Secretary shall initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new safety information *or new effectiveness information*, and if so, the contents of such labeling changes.

(D) DISCUSSIONS.—Such discussions shall not extend for more than 30 days after the response to the notification under subparagraph (B), unless the Secretary determines an extension of such discussion period is warranted.

(E) ORDER.—Within 15 days of the conclusion of the discussions under subparagraph (D), the Secretary may issue an order directing the responsible person or the holder of the approved application under section 505(j) to make such a labeling change as the Secretary deems appropriate to address the new safety information *or new effectiveness information*. Within 15 days of such an order, the responsible person or the holder of the approved application under section 505(j) shall submit a supplement containing the labeling change.

(F) DISPUTE RESOLUTION.—Within 5 days of receiving an order under subparagraph (E), the responsible person or the holder of the approved application under section 505(j) may appeal using dispute resolution procedures established by the Secretary in regulation and guidance.

(G) VIOLATION.—If the responsible person or the holder of the approved application under section 505(j) has not submitted a supplement within 15 days of the date of such order under subparagraph (E), and there is no appeal or dispute resolution proceeding pending, the responsible person or holder shall be considered to be in violation of this subsection. If at the conclusion of any dispute resolution procedures the Secretary determines that a supplement must be submitted and such a supplement is not submitted within 15 days of the date of that determination, the responsible person or holder shall be in violation of this subsection.

(H) PUBLIC HEALTH THREAT.—Notwithstanding subparagraphs (A) through (F), if the Secretary concludes that such a labeling change is necessary to protect the public health, the Secretary may accelerate the timelines in such subparagraphs.

(I) RULE OF CONSTRUCTION.—This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under section 505(j) to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).

(5) NON-DELEGATION.—Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

(p) RISK EVALUATION AND MITIGATION STRATEGY.—

(1) IN GENERAL.—A person may not introduce or deliver for introduction into interstate commerce a new drug if—

(A)(i) the application for such drug is approved under subsection (b) or (j) and is subject to section 503(b); or

(ii) the application for such drug is approved under section 351 of the Public Health Service Act; and

(B) a risk evaluation and mitigation strategy is required under section 505–1 with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 505–1, including requirements regarding assessments of approved strategies.

(2) CERTAIN POSTMARKET STUDIES.—The failure to conduct a postmarket study under section 506, subpart H of part 314, or subpart E of part 601 of title 21, Code of Federal Regulations (or any successor regulations), is deemed to be a violation of paragraph (1).

(q) PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS.—

(1) IN GENERAL.—

(A) DETERMINATION.—The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public

Health Service Act because of any request to take any form of action relating to the application, either before or during consideration of the request, unless—

(i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and

(ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.

Consideration of the petition shall be separate and apart from review and approval of any application.

(B) NOTIFICATION.—If the Secretary determines under subparagraph (A) that a delay is necessary with respect to an application, the Secretary shall provide to the applicant, not later than 30 days after making such determination, the following information:

(i) Notification of the fact that a determination under subparagraph (A) has been made.

(ii) If applicable, any clarification or additional data that the applicant should submit to the docket on the petition to allow the Secretary to review the petition promptly.

(iii) A brief summary of the specific substantive issues raised in the petition which form the basis of the determination.

(C) FORMAT.—The information described in subparagraph (B) shall be conveyed via either, at the discretion of the Secretary—

(i) a document; or

(ii) a meeting with the applicant involved.

(D) PUBLIC DISCLOSURE.—Any information conveyed by the Secretary under subparagraph (C) shall be considered part of the application and shall be subject to the disclosure requirements applicable to information in such application.

(E) DENIAL BASED ON INTENT TO DELAY.—If the Secretary determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination. The Secretary may issue guidance to describe the factors that will be used to determine under this subparagraph whether a petition is submitted with the primary purpose of delaying the approval of an application.

(F) FINAL AGENCY ACTION.—The Secretary shall take final agency action on a petition not later than 150 days after the date on which the petition is submitted. The Secretary shall not extend such period for any reason, including—

(i) any determination made under subparagraph (A);

(ii) the submission of comments relating to the petition or supplemental information supplied by the petitioner; or

(iii) the consent of the petitioner.

(G) EXTENSION OF 30-MONTH PERIOD.—If the filing of an application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV) and approval of the application was delayed because of a petition, the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such beginning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

(H) CERTIFICATION.—The Secretary shall not consider a petition for review unless the party submitting such petition does so in written form and the subject document is signed and contains the following certification: "I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations:

_____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.", with the date on which such information first became known to such party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(I) VERIFICATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and the subject document is signed and contains the following verification: "I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.", with the date on which such information first became known to the party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(2) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

(A) FINAL AGENCY ACTION WITHIN 150 DAYS.—The Secretary shall be considered to have taken final agency action on a petition if—

(i) during the 150-day period referred to in paragraph (1)(F), the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulation); or

(ii) such period expires without the Secretary having made such a final decision.

(B) DISMISSAL OF CERTAIN CIVIL ACTIONS.—If a civil action is filed against the Secretary with respect to any issue raised in the petition before the Secretary has taken final agency action on the petition within the meaning of subparagraph (A), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.

(C) ADMINISTRATIVE RECORD.—For purposes of judicial review related to the approval of an application for which a petition under paragraph (1) was submitted, the administrative record regarding any issue raised by the petition shall include—

(i) the petition filed under paragraph (1) and any supplements and comments thereto;

(ii) the Secretary's response to such petition, if issued; and

(iii) other information, as designated by the Secretary, related to the Secretary's determinations regarding the issues raised in such petition, as long as the information was considered by the agency no later than the date of final agency action as defined under subparagraph (2)(A), and regardless of whether the Secretary responded to the petition at or before the approval of the application at issue in the petition.

(3) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to the Congress a report that specifies—

(A) the number of applications that were approved during the preceding 12-month period;

(B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period;

(C) the number of days by which such applications were so delayed; and

(D) the number of such petitions that were submitted during such period.

(4) EXCEPTIONS.—

(A) This subsection does not apply to—

(i) a petition that relates solely to the timing of the approval of an application pursuant to subsection (j)(5)(B)(iv); or

(ii) a petition that is made by the sponsor of an application and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

(B) Paragraph (2) does not apply to a petition addressing issues concerning an application submitted pursuant to section 351(k) of the Public Health Service Act.

(5) DEFINITIONS.—

(A) APPLICATION.—For purposes of this subsection, the term "application" means an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act.

(B) PETITION.—For purposes of this subsection, other than paragraph (1)(A)(i), the term "petition" means a request described in paragraph (1)(A)(i).

(r) POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.—

(1) ESTABLISHMENT.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall improve the transparency of information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an Internet Web site that—

(A) provides links to drug safety information listed in paragraph (2) for prescription drugs that are approved under this section or licensed under section 351 of the Public Health Service Act; and

(B) improves communication of drug safety information to patients and providers.

(2) INTERNET WEB SITE.—The Secretary shall carry out paragraph (1) by—

(A) developing and maintaining an accessible, consolidated Internet Web site with easily searchable drug safety information, including the information found on United States Government Internet Web sites, such as the United States National Library of Medicine's Daily Med and Medline Plus Web sites, in addition to other such Web sites maintained by the Secretary;

(B) ensuring that the information provided on the Internet Web site is comprehensive and includes, when available and appropriate—

(i) patient labeling and patient packaging inserts;

(ii) a link to a list of each drug, whether approved under this section or licensed under such section 351, for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

(iii) a link to the registry and results data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act;

(iv) the most recent safety information and alerts issued by the Food and Drug Administration for drugs approved by the Secretary under this section, such as product recalls, warning letters, and import alerts;

(v) publicly available information about implemented RiskMAPs and risk evaluation and mitigation strategies under subsection (o);

(vi) guidance documents and regulations related to drug safety; and

(vii) other material determined appropriate by the Secretary;

(C) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under subsection (k)(3) to provide information of known and serious side-effects for drugs approved under this section or licensed under such section 351;

(D) preparing and making publicly available on the Internet website established under paragraph (1) best practices for drug safety surveillance activities for drugs approved under this section or section 351 of the Public Health Service Act;

(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet Web site;

(F) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet Web site.

(3) POSTING OF DRUG LABELING.—The Secretary shall post on the Internet Web site established under paragraph (1) the approved professional labeling and any required patient labeling of a drug approved under this section or licensed under such section 351 not later than 21 days after the date the drug is approved or licensed, including in a supplemental application with respect to a labeling change.

(4) PRIVATE SECTOR RESOURCES.—To ensure development of the Internet Web site by the date described in paragraph (1), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(5) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subsection.

(6) REVIEW.—The Advisory Committee on Risk Communication under section 567 shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information provided on the Internet Web site established under paragraph (1) and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to patients and providers, and shall recommend ways for the Food and Drug Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.

(s) REFERRAL TO ADVISORY COMMITTEE.—Prior to the approval of a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act, the Secretary shall—

(1) refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee; or

(2) if the Secretary does not refer such a drug to a Food and Drug Administration advisory committee prior to the approval of the drug, provide in the action letter on the application for the drug a summary of the reasons why the Secretary did not refer the drug to an advisory committee prior to approval.

(t) DATABASE FOR AUTHORIZED GENERIC DRUGS.—

(1) IN GENERAL.—

(A) PUBLICATION.—The Commissioner shall—

(i) not later than 9 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, publish a complete list on the Internet Web site of the Food and Drug Administration of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

(B) NOTIFICATION.—The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, when the Commissioner first publishes the information described in subparagraph (A) that the information has been published and that the information will be updated quarterly.

(2) INCLUSION.—The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 1999.

(3) AUTHORIZED GENERIC DRUG.—In this section, the term "authorized generic drug" means a listed drug (as that term is used in subsection (j)) that—

(A) has been approved under subsection (c); and

(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.

(u) CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.—

(1) IN GENERAL.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active ingredient (including any ester or salt of the active ingredient) a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug, if—

(A)(i) the single enantiomer has not been previously approved except in the approved racemic drug; and

(ii) the application submitted under subsection (b) for such non-racemic drug—

(I) includes full reports of new clinical investigations (other than bioavailability studies)—

(aa) necessary for the approval of the application under subsections (c) and (d); and

(bb) conducted or sponsored by the applicant; and

(II) does not rely on any clinical investigations that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use—

(i) in a therapeutic category in which the approved racemic drug has been approved; or

(ii) for which any other enantiomer of the racemic drug has been approved.

(2) LIMITATION.—

(A) NO APPROVAL IN CERTAIN THERAPEUTIC CATEGORIES.—Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

(B) LABELING.—If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

(3) DEFINITION.—

(A) IN GENERAL.—For purposes of this subsection, the term "therapeutic category" means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1860D–4(b)(3)(C)(ii) of the Social Security Act and as in effect on the date of the enactment of this subsection.

(B) PUBLICATION BY SECRETARY.—The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

(4) AVAILABILITY.—The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after the date of the enactment of this subsection and before October 1, 2022.

(v) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997.—

(1) ANTIBIOTIC DRUGS APPROVED BEFORE NOVEMBER 21, 1997.—

(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997, BUT NOT APPROVED.—

(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug—

(i)(I) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

(ii) a patent term extension under section 156 of title 35, United States Code, subject to the requirements of such section.

(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 507 of this Act (as in effect before November 21, 1997), none of which was approved by the Secretary under such section.

(3) LIMITATIONS.—

(A) EXCLUSIVITIES AND EXTENSIONS.—Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an approved application described in subparagraphs (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

(B) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applicable, was approved before the date of the enactment of this subsection.

(4) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A).

(w) DEADLINE FOR DETERMINATION ON CERTAIN PETITIONS.—The Secretary shall issue a final, substantive determination on a petition submitted pursuant to subsection (b) of section 314.161 of title 21, Code of Federal Regulations (or any successor regulations), no later than 270 days after the date the petition is submitted.

(x) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term "date of approval" shall mean the later of—

(A) the date an application under subsection (b) is approved under subsection (c); or

(B) the date of issuance of the interim final rule controlling the drug.

(y) CONTRAST AGENTS INTENDED FOR USE WITH APPLICABLE MEDICAL IMAGING DEVICES.—

(1) IN GENERAL.—The sponsor of a contrast agent for which an application has been approved under this section may submit a supplement to the application seeking approval for a new use following the authorization of a premarket submission for an applicable medical imaging device for that use with the contrast agent pursuant to section 520(p)(1).

(2) REVIEW OF SUPPLEMENT.—In reviewing a supplement submitted under this subsection, the agency center charged with the premarket review of drugs may—

(A) consult with the center charged with the premarket review of devices; and

(B) review information and data submitted to the Secretary by the sponsor of an applicable medical imaging device pursuant to section 515, 510(k), or 513(f)(2) so long as the sponsor of such applicable medical imaging device has provided to the sponsor of the contrast agent a right of reference.

(3) DEFINITIONS.—For purposes of this subsection—

(A) the term "new use" means a use of a contrast agent that is described in the approved labeling of an applicable medical imaging device described in section 520(p), but that is not described in the approved labeling of the contrast agent; and

(B) the terms "applicable medical imaging device" and "contrast agent" have the meanings given such terms in section 520(p).

* * * * * * *

***SEC. 505–2. SAFETY-ENHANCING PACKAGING AND DISPOSAL FEATURES.***

*(a) ORDERS.—*

*(1) IN GENERAL.—The Secretary may issue an order requiring the holder of a covered application to implement or modify one or more technologies, controls, or measures with respect to the packaging or disposal of one or more drugs identified in the covered application, if the Secretary determines such technologies, controls, or measures to be appropriate to help mitigate the risk of abuse or misuse of such drug or drugs, which may include by reducing the availability of unused drugs.*

*(2) PRIOR CONSULTATION.—The Secretary may not issue an order under paragraph (1) unless the Secretary has consulted with relevant stakeholders, through a public meeting, workshop, or otherwise, about matters that are relevant to the subject of the order.*

*(3) ASSURING ACCESS AND MINIMIZING BURDEN.—Technologies, controls, or measures required under paragraph (1) shall—*

*(A) be commensurate with the specific risk of abuse or misuse of the drug listed in the covered application;*

*(B) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular any available evidence regarding the expected or demonstrated public health impact of such technologies, controls, or measures; and*

*(C) reduce the risk of abuse or misuse of such drug.*

*(4) ORDER CONTENTS.—An order issued under paragraph (1) may—*

*(A) provide for a range of options for implementing or modifying the technologies, controls, or measures required to be implemented by such order; and*

*(B) incorporate by reference standards regarding packaging or disposal set forth in an official compendium, established by a nationally or internationally recognized standard development organization, or described on the public website of the Food and Drug Administration, so long as the order includes the rationale for incorporation of such standard.*

*(5) ORDERS APPLICABLE TO DRUG CLASS.—When a concern about the risk of abuse or misuse of a drug relates to a pharmacological class, the Secretary may, after consultation with relevant stakeholders, issue an order under paragraph (1) which applies to the pharmacological class.*

*(b) COMPLIANCE.—The holder of a covered application shall—*

*(1) submit a supplement containing proposed changes to the covered application to comply with an order issued under subsection (a) not later than—*

*(A) 180 calendar days after the date on which the order is issued; or*

*(B)(i) such longer time period as specified by the Secretary in such order; or*

*(ii) if a request for an alternative date is submitted by the holder of such application not later than 60 calendar days after the date on which such order is issued—*

*(I) such requested alternative date if agreed to by the Secretary; or*

*(II) another date as specified by the Secretary; and*

*(2) implement the changes approved pursuant to such supplement not later than the later of—*

*(A) 90 calendar days after the date on which the supplement is approved; or*

*(B) the end of such longer period as is—*

*(i) determined to be appropriate by the Secretary; or*

*(ii) approved by the Secretary pursuant to a request by the holder of the covered application that explains why such longer period is needed, including to satisfy any other applicable Federal statutory or regulatory requirements.*

*(c) ALTERNATIVE MEASURES.—The holder of the covered application may propose, and the Secretary shall approve, technologies, controls, or measures regarding packaging, storage, or disposal other than those specified in the applicable order issued under subsection (a), if such technologies, controls, or measures are supported by data and information demonstrating that such alternative technologies, controls, or measures can be expected to mitigate the risk of abuse or misuse of the drug or drugs involved, including by reducing the availability of unused drugs, to at least the same extent as the technologies, controls, or measures specified in such order.*

*(d) DISPUTE RESOLUTION.—If a dispute arises in connection with a supplement submitted under subsection (b), the holder of the covered application may appeal a determination made with respect to such supplement using applicable dispute resolution procedures specified by the Secretary in regulations or guidance.*

*(e) DEFINITIONS.—In this section—*

*(1) the term "covered application" means an application submitted under subsection (b) or (j) of section 505 for approval under such section or an application submitted under section 351 of Public Health Service Act for approval under such section, with respect to a drug that is or contains an opioid for which a listing in schedule II or III (on a temporary or permanent basis) is in effect under section 202 of the Controlled Substances Act; and*

*(2) the term "relevant stakeholders" may include scientific experts within the drug manufacturing industry; brand and generic drug manufacturers; standard development organizations; wholesalers and distributors; payers; health care providers; pharmacists; pharmacies; manufacturers; poison centers; and representatives of the National Institute on Drug Abuse, the National*

*Institutes of Health, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the Drug Enforcement Agency, the Consumer Product Safety Commission, individuals who specialize in treating addiction, and patient and caregiver groups.*

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SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES

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***SEC. 569D. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.***

*(a) ORDER TO CEASE DISTRIBUTION AND RECALL.—*

*(1) IN GENERAL.—Upon a determination that the use or consumption of, or exposure to, a drug may present an imminent or substantial hazard to the public health, the Secretary shall issue an order requiring any person who distributes the drug to immediately cease distribution of the drug.*

*(2) HEARING.—An order under paragraph (1) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order, on—*

*(A) the actions required by the order; and*

*(B) whether the order should be amended to require a recall of the drug.*

*(3) INADEQUATE GROUNDS.—If, after providing an opportunity for a hearing under paragraph (2), the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.*

*(4) AMENDMENT TO ORDER TO REQUIRE RECALL.—If, after providing an opportunity for an informal hearing under paragraph (2), the Secretary determines that the order should be amended to include a recall of the drug with respect to which the order was issued, the Secretary shall—*

*(A) amend the order to require a recall; and*

*(B) after consultation with the drug sponsor, specify a timetable in which the recall will occur.*

*(5) NOTICE TO PERSONS AFFECTED.—An order under this subsection shall require any person who distributes the drug to provide for notice, including to individuals as appropriate, to persons who may be affected by the order to cease distribution of or recall the drug, as applicable.*

*(6) ACTION FOLLOWING ORDER.—Any person who is subject to an order under paragraph (1) or (4) shall immediately cease distribution of or recall, as applicable, the drug and provide notification as required by such order.*

*(b) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall, as the Secretary determines to be necessary, provide notice of a recall order under this section to—*

*(1) consumers to whom the drug was, or may have been, distributed; and*

*(2) appropriate State and local health officials.*

*(c) ORDER TO RECALL.—*

*(1) CONTENTS.—An order to recall a drug under subsection (a) shall—*

*(A) require periodic reports to the Secretary describing the progress of the recall; and*

*(B) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.*

*(2) ASSISTANCE ALLOWED.—In providing for notice under paragraph (1)(B), the Secretary may allow for the assistance of health professionals, State or local officials, or other individuals designated by the Secretary.*

*(3) NONDELEGATION.—An order under this section shall be ordered by the Secretary or an official designated by the Secretary. An official may not be so designated under this section unless the official is the Director of the Center for Drug Evaluation and Research, is an official senior to such Director, or is so designated by such Director.*

*(d) SAVINGS CLAUSE.—Nothing contained in this section shall be construed as limiting—*

*(1) the authority of the Secretary to issue an order to cease distribution of, or to recall, an drug under any other provision of this Act or the Public Health Service Act; or*

*(2) the ability of the Secretary to request any person to perform a voluntary activity related to any drug subject to this Act or the Public Health Service Act.*

* * * * * * *

## CHAPTER VIII—IMPORTS AND EXPORTS

### IMPORTS AND EXPORTS

SEC. 801. (a) The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, tobacco products, [and cosmetics] *cosmetics, and potential articles of concern (as defined in subsection (u))* which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 or section 905(h) and shall request that if any drugs, devices, or tobacco products manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs, devices, or tobacco products be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505 or the importer (as defined in section 805) is in violation of such section 805, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(ll), or (4) the recordkeeping requirements under section 204 of the FDA Food Safety Modernization Act (other than the requirements under subsection (f) of such section) have not been complied with regarding such article, [then such article shall be refused admission] *or (5) such article is an article of concern (as defined in subsection (u)), or (6) such article is a drug that is being imported or offered for import in violation of section 301(cc), or (5) in the case of a drug, such drug is subject to an order under section 568 to cease distribution of or recall the drug, then such article shall be refused admission*, except as provided in subsection (b) of this section. With respect to an article of food, if importation of such food is subject to, but not compliant with, the requirement under subsection (q) that such food be accompanied by a certification or other assurance that the food meets applicable requirements of this Act, then such article shall be refused admission. If such article is subject to a requirement under section 760 or 761 and if the Secretary has credible evidence or information indicating that the responsible person (as defined in such section 760 or 761) has not complied with a requirement of such section 760 or 761 with respect to any such article, or has not allowed access to records described in such section 760 or 761, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations, [except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug refused admission under this section, if such drug is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930 (19 U.S.C. 1498(a)(1)) and was not brought into compliance as described under subsection (b)..] *except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug refused admission under this section, if such drug is declared to be valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930 or such higher amount as the Commissioner of Food and Drugs may set based on a finding by the Commissioner that the higher amount is in the interest of public health), or if such drug is entering the United States by mail, and was not brought into compliance as described under subsection (b); and the Secretary of Health and Human Services may destroy, without the opportunity for export, any article refused admission under clause (6) of the*

*third sentence of this subsection.* The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of ⟦a drug⟧ *an article* under the sixth sentence of this subsection. The regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy ⟦the drug⟧ *the article*. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of ⟦a drug⟧ *an article*, the Secretary of Health and Human Services shall store and, as applicable, dispose of ⟦the drug⟧ *the article* after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c). Such process may be combined with the notice and opportunity to appear before the Secretary and introduce testimony, as described in the first sentence of this subsection, as long as appropriate notice is provided to the owner or consignee. ⟦Clause (2) of the third sentence of this paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act.⟧ *Clauses (2), (5), and (6) of the third sentence of this subsection shall not be construed to prohibit the admission of narcotic or nonnarcotic drugs or other substances, the importation of which is permitted under the Controlled Substances Import and Export Act.*

(b) Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health and Human Services that (1) an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with the Act or rendered other than a food, drug, device, or cosmetic, or (2) with respect to an article described in subsection (a) relating to the requirements of sections 760 or 761,, the responsible person (as defined in section 760 or 761) can take action that would assure that the responsible person is in compliance with section 760 or 761, as the case may be, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary may, in accordance with regulations, authorize the applicant, or, with respect to clause (2), the responsible person, to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Health and Human Services designated by the Secretary, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

(c) All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any article refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

(d)(1)(A) Except as provided in paragraph (2) and section 804, no drug subject to section 503(b) or composed wholly or partly of insulin which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.

(B) Except as authorized by the Secretary in the case of a drug that appears on the drug shortage list under section 506E or in the case of importation pursuant to section 804, no drug that is subject to section 503(b)(1) may be imported into the United States for commercial use if such drug is manufactured outside the United States, unless the manufacturer has authorized the drug to be marketed in the United States and has caused the drug to be labeled to be marketed in the United States.

(2) The Secretary may authorize the importation of a drug the importation of which is prohibited by paragraph (1) if the drug is required for emergency medical care.

(3)(A) Subject to subparagraph (B), no component of a drug, no component part or accessory of a device, or other article of device requiring further processing, which is ready or suitable for

use for health-related purposes, and no article of a food additive, color additive, or dietary supplement, including a product in bulk form, shall be excluded from importation into the United States under subsection (a) if each of the following conditions is met:

(i) The importer of such article of a drug or device or importer of such article of a food additive, color additive, or dietary supplement submits to the Secretary, at the time of initial importation, a statement in accordance with the following:

(I) Such statement provides that such article is intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 802, or with section 351(h) of the Public Health Service Act.

(II) The statement identifies the manufacturer of such article and each processor, packer, distributor, or other entity that had possession of the article in the chain of possession of the article from the manufacturer to such importer of the article.

(III) The statement is accompanied by such certificates of analysis as are necessary to identify such article, unless the article is a device or is an article described in paragraph (4).

(ii) At the time of initial importation and before the delivery of such article to the importer or the initial owner or consignee, such owner or consignee executes a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury.

(iii) Such article is used and exported by the initial owner or consignee in accordance with the intent described under clause (i)(I), except for any portions of the article that are destroyed.

(iv) The initial owner or consignee maintains records on the use or destruction of such article or portions thereof, as the case may be, and submits to the Secretary any such records requested by the Secretary.

(v) Upon request of the Secretary, the initial owner or consignee submits a report that provides an accounting of the exportation or destruction of such article or portions thereof, and the manner in which such owner or consignee complied with the requirements of this subparagraph.

(B) Notwithstanding subparagraph (A), the Secretary may refuse admission to an article that otherwise would be imported into the United States under such subparagraph if the Secretary determines that there is credible evidence or information indicating that such article is not intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 802, or with section 351(h) of the Public Health Service Act.

(C) This section may not be construed as affecting the responsibility of the Secretary to ensure that articles imported into the United States under authority of subparagraph (A) meet each of the conditions established in such subparagraph for importation.

(4) The importation into the United States of blood, blood components, source plasma, or source leukocytes or of a component, accessory, or part thereof is not permitted pursuant to paragraph (3) unless the importation complies with section 351(a) of the Public Health Service Act or the Secretary permits the importation under appropriate circumstances and conditions, as determined by the Secretary. The importation of tissue or a component or part of tissue is not permitted pursuant to paragraph (3) unless the importation complies with section 361 of the Public Health Service Act.

(e)(1) A food, drug, device, tobacco product or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act, and a tobacco product intended for export shall not be deemed to be in violation of section 906(e), 907, 911, or 920(a), if it—

(A) accords to the specifications of the foreign purchaser,

(B) is not in conflict with the laws of the country to which it is intended for export,

(C) is labeled on the outside of the shipping package that it is intended for export, and

(D) is not sold or offered for sale in domestic commerce.

(2) Paragraph (1) does not apply to any device—

(A) which does not comply with an applicable requirement of section 514 or 515,

(B) which under section 520(g) is exempt from either such section, or

(C) which is a banned device under section 516,

unless, in addition to the requirements of paragraph (1), either (i) the Secretary has determined that the exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export or (ii) the device is eligible for export under section 802.

(3) A new animal drug that requires approval under section 512 shall not be exported pursuant to paragraph (1) if such drug has been banned in the United States.

(4)(A) Any person who exports a food, drug, animal drug, or device may request that the Secretary—

(i) certify in writing that the exported food, drug, animal drug, or device meets the requirements of paragraph (1) or section 802; or

(ii) certify in writing that the food, drug, animal drug, or device being exported meets the applicable requirements of this Act upon a showing that the food, drug or device meets the applicable requirements of this Act.

The Secretary shall issue such a certification within 20 days of the receipt of a request for such certification.

(B) If the Secretary issues a written export certification within the 20 days prescribed by subparagraph (A), a fee for such certification may be charged but shall not exceed $175 for each certification. Fees collected for a fiscal year pursuant to this subparagraph shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriations Acts until expended without fiscal year limitation. Such fees shall be collected in each fiscal year in an amount equal to the amount specified in appropriations Acts for such fiscal year and shall only be collected and available for the costs of the Food and Drug Administration.

(C) For purposes of this paragraph, a certification by the Secretary shall be made on such basis, and in such form (including a publicly available listing) as the Secretary determines appropriate.

(D) With regard to fees pursuant to subparagraph (B) in connection with written export certifications for food:

(i) Such fees shall be collected and available solely for the costs of the Food and Drug Administration associated with issuing such certifications.

(ii) Such fees may not be retained in an amount that exceeds such costs for the respective fiscal year.

(E)(i)(I) If the Secretary denies a request for certification under subparagraph (A)(ii) with respect to a device manufactured in an establishment (foreign or domestic) registered under section 510, the Secretary shall provide in writing to the person seeking such certification the basis for such denial, and specifically identify the finding upon which such denial is based.

(II) If the denial of a request as described in subclause (I) is based on grounds other than an injunction proceeding pursuant to section 302, seizure action pursuant to section 304, or a recall designated Class I or Class II pursuant to part 7, title 21, Code of Federal Regulations, and is based on the facility being out of compliance with part 820 of title 21, Code of Federal Regulations, the Secretary shall provide a substantive summary of the specific grounds for noncompliance identified by the Secretary.

(III) With respect to a device manufactured in an establishment that has received a report under section 704(b), the Secretary shall not deny a request for certification as described in subclause (I) with respect to a device based solely on the issuance of that report if the owner, operator, or agent in charge of such establishment has agreed to a plan of correction in response to such report.

(ii)(I) The Secretary shall provide a process for a person who is denied a certification as described in clause (i)(I) to request a review that conforms to the standards of section 517A(b).

(II) Notwithstanding any previous review conducted pursuant to subclause (I), a person who has been denied a certification as described in clause (i)(I) may at any time request a review in order to present new information relating to actions taken by such person to address the reasons identified by the Secretary for the denial of certification, including evidence that corrective actions are being or have been implemented to address grounds for noncompliance identified by the Secretary.

(III) Not later than 1 year after the date of enactment of the FDA Reauthorization Act of 2017, the Secretary shall issue guidance providing for a process to carry out this subparagraph. Not later than 1 year after the close of the comment period for such guidance, the Secretary shall issue final guidance.

(iii)(I) Subject to subclause (II), this subparagraph applies to requests for certification on behalf of any device establishment registered under section 510, whether the establishment is located inside or outside of the United States, and regardless of whether such devices are to be exported from the United States.

(II) If an establishment described in subclause (I) is not located within the United States and does not demonstrate that the devices manufactured, prepared, propagated, compounded, or processed at such establishment are to be exported from the United States, this subparagraph shall apply only if—

(aa) the establishment has been inspected by the Secretary within 3 years of the date of the request; or

(bb) the establishment participates in an audit program in which the United States participates or the United States recognizes, an audit under such program has been conducted, and the findings of such audit are provided to the Secretary within 3 years of the date of the request.

(f)(1) If a drug (other than insulin, an antibiotic drug, an animal drug, or a drug exported under section 802) being exported in accordance with subsection (e) is being exported to a country that has different or additional labeling requirements or conditions for use and such country requires the drug to be labeled in accordance with those requirements or uses, such drug may be labeled in accordance with such requirements and conditions for use in the country to which such drug is being exported if it also is labeled in accordance with the requirements of this Act.

(2) If, pursuant to paragraph (1), the labeling of an exported drug includes conditions for use that have not been approved under this Act, the labeling must state that such conditions for use have not been approved under this Act. A drug exported under section 802 is exempt from this section.

(g)(1) With respect to a prescription drug being imported or offered for import into the United States, the Secretary, in the case of an individual who is not in the business of such importations, may not send a warning notice to the individual unless the following conditions are met:

(A) The notice specifies, as applicable to the importation of the drug, that the Secretary has made a determination that—

(i) importation is in violation of section 801(a) because the drug is or appears to be adulterated, misbranded, or in violation of section 505;

(ii) importation is in violation of section 801(a) because the drug is or appears to be forbidden or restricted in sale in the country in which it was produced or from which it was exported;

(iii) importation is or appears to be in violation of section 801(d)(1); or

(iv) importation otherwise is or appears to be in violation of Federal law.

(B) The notice does not specify any provision described in subparagraph (A) that is not applicable to the importation of the drug.

(C) The notice states the reasons underlying such determination by the Secretary, including a brief application to the principal facts involved of the provision of law described in subparagraph (A) that is the basis of the determination by the Secretary.

(2) For purposes of this section, the term "warning notice", with respect to the importation of a drug, means a communication from the Secretary (written or otherwise) notifying a person, or clearly suggesting to the person, that importing the drug for personal use is, or appears to be, a violation of this Act.

(h)(1) The Secretary shall give high priority to increasing the number of inspections under this section for the purpose of enabling the Secretary to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food.

(2) The Secretary shall give high priority to making necessary improvements to the information management systems of the Food and Drug Administration that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of the Secretary to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is in compliance with this Act.

(3) The Secretary shall improve linkages with other regulatory agencies of the Federal Government that share responsibility for food safety, and shall with respect to such safety improve linkages with the States and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))).

(i)(1) For use in inspections of food under this section, the Secretary shall provide for research on the development of tests and sampling methodologies—

(A) whose purpose is to test food in order to rapidly detect the adulteration of the food, with the greatest priority given to detect the intentional adulteration of food; and

(B) whose results offer significant improvements over the available technology in terms of accuracy, timing, or costs.

(2) In providing for research under paragraph (1), the Secretary shall give priority to conducting research on the development of tests that are suitable for inspections of food at ports of entry into the United States.

(3) In providing for research under paragraph (1), the Secretary shall as appropriate coordinate with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Administrator of the Environmental Protection Agency, and the Secretary of Agriculture.

(4) The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the progress made in research under paragraph (1), including progress regarding paragraph (2).

(j)(1) If an officer or qualified employee of the Food and Drug Administration has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and such officer or qualified employee is unable to inspect, examine, or investigate such article upon the article being offered for import at a port of entry into the United States, the officer or qualified employee shall request the Secretary of Treasury to hold the food at the port of entry for a reasonable period of time, not to exceed 24 hours, for the purpose of enabling the Secretary to inspect, examine, or investigate the article as appropriate.

(2) The Secretary shall request the Secretary of Treasury to remove an article held pursuant to paragraph (1) to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held.

(3) An officer or qualified employee of the Food and Drug Administration may make a request under paragraph (1) only if the Secretary or an official designated by the Secretary approves the request. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

(4) With respect to an article of food for which a request under paragraph (1) is made, the Secretary, promptly after the request is made, shall notify the State in which the port of entry involved is located that the request has been made, and as applicable, that such article is being held under this subsection.

(k)(1) If an article of food is being imported or offered for import into the United States, and the importer, owner, or consignee of the article is a person who has been debarred under section 306(b)(3), such article shall be held at the port of entry for the article, and may not be delivered to such person. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(2) An article of food held under paragraph (1) may be delivered to a person who is not a debarred person under section 306(b)(3) if such person affirmatively establishes, at the expense of the person, that the article complies with the requirements of this Act, as determined by the Secretary.

(l)(1) If an article of food is being imported or offered for import into the United States, and such article is from a foreign facility for which a registration has not been submitted to the Secretary under section 415 (or for which a registration has been suspended under such section), such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is so registered. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry

into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(m)(1) In the case of an article of food that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; if known within the specified period of time that notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; any country to which the article has been refused entry; and the anticipated port of entry for the article. An article of food imported or offered for import without submission of such notice in accordance with the requirements under this paragraph shall be refused admission into the United States. Nothing in this section may be construed as a limitation on the port of entry for an article of food.

(2)(A) Regulations under paragraph (1) shall require that a notice under such paragraph be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days. In determining the specified period of time required under this subparagraph, the Secretary may consider, but is not limited to consideration of, the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration. Nothing in the preceding sentence may be construed as a limitation on the obligation of the Secretary to receive, review, and appropriately respond to any notice under paragraph (1).

(B)(i) If an article of food is being imported or offered for import into the United States and a notice under paragraph (1) is not provided in advance in accordance with the requirements under paragraph (1), such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such notice is submitted to the Secretary, and the Secretary examines the notice and determines that the notice is in accordance with the requirements under paragraph (1). Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(ii) In carrying out clause (i) with respect to an article of food, the Secretary shall determine whether there is in the possession of the Secretary any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

(3)(A) This subsection may not be construed as limiting the authority of the Secretary to obtain information under any other provision of this Act.

(B) This subsection may not be construed as authorizing the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

(n)(1) If a food has been refused admission under subsection (a), other than such a food that is required to be destroyed, the Secretary may require the owner or consignee of the food to affix to the container of the food a label that clearly and conspicuously bears the statement: "UNITED STATES: REFUSED ENTRY".

(2) All expenses in connection with affixing a label under paragraph (1) shall be paid by the owner or consignee of the food involved, and in default of such payment, shall constitute a lien against future importations made by such owner or consignee.

(3) A requirement under paragraph (1) remains in effect until the Secretary determines that the food involved has been brought into compliance with this Act.

(o) If an article that is a device is being imported or offered for import into the United States, and the importer, owner, or consignee of such article does not, at the time of offering the article for import, submit to the Secretary a statement that identifies the registration under section 510(i) of each establishment that with respect to such article is required under such section to register with the Secretary, the article may be refused admission. If the article is refused admission for

failure to submit such a statement, the article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such a statement is submitted to the Secretary. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(p)(1) Not later than 36 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report regarding—

(A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this Act;

(B) the public health implications of such exports, including any evidence of a negative public health impact; and

(C) recommendations or assessments of policy alternatives available to Congress and the executive branch to reduce any negative public health impact caused by such exports.

(2) The Secretary is authorized to establish appropriate information disclosure requirements to carry out this subsection.

(q) CERTIFICATIONS CONCERNING IMPORTED FOODS.—

(1) IN GENERAL.—The Secretary may require, as a condition of granting admission to an article of food imported or offered for import into the United States, that an entity described in paragraph (3) provide a certification, or such other assurances as the Secretary determines appropriate, that the article of food complies with applicable requirements of this Act. Such certification or assurances may be provided in the form of shipment-specific certificates, a listing of certified facilities that manufacture, process, pack, or hold such food, or in such other form as the Secretary may specify.

(2) FACTORS TO BE CONSIDERED IN REQUIRING CERTIFICATION.—The Secretary shall base the determination that an article of food is required to have a certification described in paragraph (1) on the risk of the food, including—

(A) known safety risks associated with the food;

(B) known food safety risks associated with the country, territory, or region of origin of the food;

(C) a finding by the Secretary, supported by scientific, risk-based evidence, that—

(i) the food safety programs, systems, and standards in the country, territory, or region of origin of the food are inadequate to ensure that the article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act; and

(ii) the certification would assist the Secretary in determining whether to refuse or admit the article of food under subsection (a); and

(D) information submitted to the Secretary in accordance with the process established in paragraph (7).

(3) CERTIFYING ENTITIES.—For purposes of paragraph (1), entities that shall provide the certification or assurances described in such paragraph are—

(A) an agency or a representative of the government of the country from which the article of food at issue originated, as designated by the Secretary; or

(B) such other persons or entities accredited pursuant to section 808 to provide such certification or assurance.

(4) RENEWAL AND REFUSAL OF CERTIFICATIONS.—The Secretary may—

(A) require that any certification or other assurance provided by an entity specified in paragraph (2) be renewed by such entity at such times as the Secretary determines appropriate; and

(B) refuse to accept any certification or assurance if the Secretary determines that such certification or assurance is not valid or reliable.

(5) ELECTRONIC SUBMISSION.—The Secretary shall provide for the electronic submission of certifications under this subsection.

(6) FALSE STATEMENTS.—Any statement or representation made by an entity described in paragraph (2) to the Secretary shall be subject to section 1001 of title 18, United States Code.

(7) ASSESSMENT OF FOOD SAFETY PROGRAMS, SYSTEMS, AND STANDARDS.—If the Secretary determines that the food safety programs, systems, and standards in a foreign region, country, or territory are inadequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act, the Secretary shall, to the extent practicable, identify such inadequacies and establish a process by which the foreign region, country, or territory may inform the Secretary of improvements made to such food safety program, system, or standard and demonstrate that those controls are adequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act.

(r)(1) The Secretary may require, pursuant to the regulations promulgated under paragraph (4)(A), as a condition of granting admission to a drug imported or offered for import into the United States, that the importer electronically submit information demonstrating that the drug complies with applicable requirements of this Act.

(2) The information described under paragraph (1) may include—

(A) information demonstrating the regulatory status of the drug, such as the new drug application, abbreviated new drug application, or investigational new drug or drug master file number;

(B) facility information, such as proof of registration and the unique facility identifier;

(C) indication of compliance with current good manufacturing practice, testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations; and

(D) any other information deemed necessary and appropriate by the Secretary to assess compliance of the article being offered for import.

(3) Information requirements referred to in paragraph (2)(C) may, at the discretion of the Secretary, be satisfied—

(A) through representation by a foreign government, if an inspection is conducted by a foreign government using standards and practices as determined appropriate by the Secretary;

(B) through representation by a foreign government or an agency of a foreign government recognized under section 809; or

(C) other appropriate documentation or evidence as described by the Secretary.

(4)(A) Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this subsection. Such requirements shall be appropriate for the type of import, such as whether the drug is for import into the United States for use in preclinical research or in a clinical investigation under an investigational new drug exemption under 505(i).

(B) In promulgating the regulations under subparagraph (A), the Secretary—

(i) may, as appropriate, take into account differences among importers and types of imports, and, based on the level of risk posed by the imported drug, provide for expedited clearance for those importers that volunteer to participate in partnership programs for highly compliant companies and pass a review of internal controls, including sourcing of foreign manufacturing inputs, and plant inspections; and

(ii) shall—

(I) issue a notice of proposed rulemaking that includes the proposed regulation;

(II) provide a period of not less than 60 days for comments on the proposed regulation; and

(III) publish the final regulation not less than 30 days before the effective date of the regulation.

(C) Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this subsection only as described in subparagraph (B).

(s) REGISTRATION OF COMMERCIAL IMPORTERS.—

(1) REGISTRATION.—The Secretary shall require a commercial importer of drugs—

(A) to be registered with the Secretary in a form and manner specified by the Secretary; and

(B) subject to paragraph (4), to submit, at the time of registration, a unique identifier for the principal place of business for which the importer is required to register under this subsection.

(2) REGULATIONS.—

(A) IN GENERAL.—The Secretary, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, shall promulgate regulations to establish good importer practices that specify the measures an importer shall take to ensure imported drugs are in compliance with the requirements of this Act and the Public Health Service Act.

(B) PROCEDURE.—In promulgating a regulation under subparagraph (A), the Secretary shall—

(i) issue a notice of proposed rulemaking that includes the proposed regulation;

(ii) provide a period of not less than 60 days for comments on the proposed regulation; and

(iii) publish the final regulation not less than 30 days before the regulation's effective date.

(C) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing this subsection, the Secretary shall only promulgate regulations as described in subparagraph (B).

(D) EFFECTIVE DATE.—In establishing the effective date of the regulations under subparagraph (A), the Secretary shall, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, as determined appropriate by the Secretary of Health and Human Services, provide a reasonable period of time for an importer of a drug to comply with good importer practices, taking into account differences among importers and types of imports, including based on the level of risk posed by the imported product.

(3) DISCONTINUANCE OF REGISTRATION.—The Secretary shall discontinue the registration of any commercial importer of drugs that fails to comply with the regulations promulgated under this subsection.

(4) UNIQUE FACILITY IDENTIFIER.—The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1). The requirement to include a unique facility identifier in a registration under paragraph (1) shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.

(5) EXEMPTIONS.—The Secretary, by notice in the Federal Register, may establish exemptions from the requirements of this subsection.

*(t) SINGLE SOURCE PATTERN OF SHIPMENTS OF ADULTERATED OR MISBRANDED DRUGS.—If the Secretary identifies a pattern of adulterated or misbranded drugs being offered for import from the same manufacturer, distributor, or importer, the Secretary may by order choose to treat all drugs being offered for import from such manufacturer, distributor, or importer as adulterated or misbranded unless otherwise demonstrated.*

*(t) ARTICLES TREATED AS DRUGS FOR PURPOSES OF THIS SECTION.—*

*(1) LABELED ARTICLES.—An article shall not be treated as a drug pursuant to this subsection if—*

*(A) an electronic import entry for such article is submitted using an authorized electronic data interchange system; and*

*(B) such article is designated in such system as a drug, device, dietary supplement, or other product that is regulated under this Act.*

*(2) ARTICLES COVERED.—Subject to paragraph (1), for purposes of this section, an article described in this paragraph may be treated by the Secretary as a drug if it—*

*(A) is or contains an ingredient that is an active ingredient that is contained within—*

*(i) a drug that has been approved under section 505 of this Act; or*

*(ii) a biological product that has been approved under section 351 of the Public Health Service Act;*

*(B) is or contains an ingredient that is an active ingredient in a drug or biological product if—*

*(i) an investigational use exemption has been authorized for such drug or biological product under section 505(i) of this Act or section 351(a) of the Public Health Service Act;*

*(ii) substantial clinical investigation has been instituted for such drug or biological product; and*

*(iii) the existence of such clinical investigation has been made public; or*

*(C) is or contains a substance that has a chemical structure that is substantially similar to the chemical structure of an active ingredient in a drug or biological product described in subparagraph (A) or (B).*

*(3) EFFECT.—Except to the extent that an article may be treated as a drug pursuant to paragraph (2), this subsection shall not be construed as bearing on or being relevant to the question of whether any article is a drug as defined in section 201(g).*

*(u) ARTICLE OF CONCERN DEFINED.—For purposes of subsection (a), the term "article of concern" means an article that is or contains a drug or other substance—*

*(1) for which, during the 24-month period prior to the article being imported or offered for import, the Secretary of Health and Human Services—*

*(A) has requested that, based on a determination that the drug or other substance appears to meet the requirements for temporary or permanent scheduling pursuant to section 201 of the Controlled Substances Act, the Attorney General initiate the process to control the drug or other substance in accordance with such Act; or*

*(B) has, following the publication by the Attorney General of a notice in the Federal Register of the intention to issue an order temporarily scheduling such drug or substance in schedule I of section 202 of the Controlled Substances Act pursuant to section 201(h) of such Act, made a determination that such article presents an imminent hazard to public safety; and*

*(2) with respect to which the Attorney General has not—*

*(A) scheduled the drug or other substance under such Act; or*

*(B) notified the Secretary of Health and Human Services that the Attorney General has made a determination not to schedule the drug or other substance under such Act.*

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## CHAPTER X—MISCELLANEOUS

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***SEC. 1015. FUND TO STRENGTHEN EFFORTS OF FDA TO COMBAT THE OPIOID AND SUBSTANCE USE EPIDEMIC.***

*(a) IN GENERAL.—The Commissioner of Food and Drugs shall use any funds appropriated pursuant to the authorization of appropriations under subsection (c) to carry out the programs and activities described in subsection (d) to strengthen and facilitate the Food and Drug Administration's efforts to address the opioid and substance use epidemic. Such funds shall be in addition to any funds which are otherwise available to carry out such programs and activities.*

*(b) FDA OPIOID AND SUBSTANCE USE EPIDEMIC RESPONSE FUND.—*

*(1) ESTABLISHMENT OF FUND.—There is established in the Treasury a fund, to be known as the FDA Opioid and Substance Use Epidemic Response Fund (referred to in this subsection as the "Fund"), for purposes of funding the programs and activities described in subsection (d).*

*(2) TRANSFER.—For the period of fiscal years 2019 through 2023, $110,000,000 shall be transferred to the Fund from the general fund of the Treasury.*

*(3) AMOUNTS DEPOSITED.—Any amounts transferred under paragraph (2) shall remain unavailable in the Fund until such amounts are appropriated pursuant to subsection (c).*

*(c) APPROPRIATIONS.—*

*(1) AUTHORIZATION OF APPROPRIATIONS.—For the period of fiscal years 2019 through 2023, there is authorized to be appropriated from the Fund to the Food and Drug Administration, for the purpose of carrying out the programs and activities described in subsection (d), an amount not to exceed the total amount transferred to the Fund under subsection (b)(2). Notwithstanding subsection (g), such funds shall remain available until expended.*

*(2) OFFSETTING FUTURE APPROPRIATIONS.—For any of fiscal years 2019 through 2023, for any discretionary appropriation out of the Fund to the Food and Drug Administration pursuant to the authorization of appropriations under paragraph (1) for the purpose of carrying out the programs and activities described in subsection (d), the total amount of such appropriations for the applicable fiscal year (not to exceed the total amount remaining in the Fund) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Fund shall be reduced by the same amount.*

*(d) FOOD AND DRUG ADMINISTRATION.—The entirety of the funds made available pursuant to subsection (c)(1) shall be for the Commissioner of Food and Drugs, pursuant to applicable authorities in the Public Health Service Act (42 U.S.C. 201 et seq.) or this Act and other applicable Federal law, to support widespread innovation in non-opioid and non-addictive medical products for pain treatment, access to opioid addiction treatments, appropriate use of approved opioids, and efforts to reduce illicit importation of opioids. Such support may include the following programs and activities:*

*(1) Obligating contract funds beginning in fiscal year 2019 for an educational campaign that will—*

*(A) educate patients and their families to differentiate opioid medications;*

*(B) raise awareness about preferred storage and disposal methods; and*

*(C) inform patients, families, and communities about medication-assisted treatment options.*

*(2) Building the Food and Drug Administration's presence in international mail facilities, including through—*

*(A) improvements in equipment and information technology enhancements to identify unapproved, counterfeit, or other unlawful pharmaceuticals for destruction;*

*(B) increased and improved surveillance;*

*(C) renovations at international mail facility locations; and*

*(D) the purchase of laboratory equipment.*

*(3) Enhancing the identification and targeting of entities offering products and products being offered by such entities for import into the United States through review and analysis of Internet websites, import data, and other sources of intelligence for purposes of making the best use of the Food and Drug Administration's inspection and analytical resources.*

*(4) Increasing the number of staff of the Food and Drug Administration to increase the number of packages being examined, ensuring the safety of the staff undertaking such examinations, and ensuring that packages identified as illegal, counterfeit, misbranded, or adulterated are removed from commerce through available authorities, including administrative destruction.*

*(5) Enhancing the Food and Drug Administration's criminal investigations resources (including full-time equivalent employees and equipment), imports surveillance, and international work.*

*(6) Obtaining for the Food and Drug Administration equipment and full-time equivalent employees needed to efficiently screen and analyze products offered for import, including by building data libraries of new substances and analogues to facilitate identification and evaluation of pharmaceutical-based agents and by purchasing screening technologies for use at international mail facilities.*

*(7) Operating the Food and Drug Administration's forensic laboratory facility to ensure adequate laboratory space and functionality for additional work and full-time equivalent employees.*

*(e) ACCOUNTABILITY AND OVERSIGHT.—*

*(1) WORK PLAN.—*

*(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Commissioner of Food and Drugs shall submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a work plan including the proposed allocation of funds appropriated pursuant to the authorization of appropriations under subsection (c) for each of fiscal years 2019 through 2023 and the contents described in subparagraph (B).*

*(B) CONTENTS.—The work plan submitted under subparagraph (A) shall include—*

*(i) the amount of money to be obligated or expended out of the Fund in each fiscal year for each program and activity described in subsection (d); and*

*(ii) a description and justification of each such program and activity.*

*(2) REPORTS.—*

*(A) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2020 through 2024, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—*

*(i) the amount of money obligated or expended out of the Fund in the prior fiscal year for each program and activity described in subsection (d);*

*(ii) a description of all programs and activities using funds provided pursuant to the authorization of appropriations under subsection (c); and*

*(iii) how the programs and activities are advancing public health.*

*(B) ADDITIONAL REPORTS.—At the request of the Committee on Health, Education, Labor and Pensions of the Senate or the Committee on Energy and Commerce of the House of Representatives, the Commissioner shall provide an update in the form of testimony and any additional reports to the respective congressional committee regarding the allocation of funding under this section or the description of the programs and activities undertaken with such funding.*

*(f) LIMITATIONS.—Notwithstanding any transfer authority authorized by this section or any appropriations Act, any funds made available pursuant to the authorization of appropriations under subsection (c) may not be used for any purpose other than the programs and activities described in subsection (d) to strengthen and facilitate the Food and Drug Administration's efforts to address the opioid and substance use epidemic.*

*(g) SUNSET.—This section shall expire on September 30, 2022, except that—*

*(1) this subsection does not apply to reporting under subsection (e)(2); and*

*(2) this section shall remain in effect until such time, and to such extent, as may be necessary for the funds transferred by subsection (b)(2) to be fully expended.*

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## CONSOLIDATED OMNIBUS BUDGET RECONCILIATION ACT OF 1985

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**SEC. 13031. FEES FOR CERTAIN CUSTOMS SERVICES.**

(a) SCHEDULE OF FEES.—In addition to any other fee authorized by law, the Secretary of the Treasury shall charge and collect the following fees (subject to adjustment under subsection (l)) for the provision of customs services in connection with the following:

(1) For the arrival of a commercial vessel of 100 net tons or more, $397.

(2) For the arrival of a commercial truck, $5.

(3) For the arrival of each railroad car carrying passengers or commercial freight, $7.50.

(4) For all arrivals made during a calendar year by a private vessel or private aircraft, $25.

(5)(A) Subject to subparagraph (B), for the arrival of each passenger aboard a commercial vessel or commercial aircraft from a place outside the United States (other than a place referred to in subsection (b)(1)(A)(i) of this section), $5.

(B) For the arrival of each passenger aboard a commercial vessel from a place referred to in subsection (b)(1)(A)(i) of this section, $1.75.

(6) For each item of dutiable mail for which a document is prepared by a customs officer *(other than an item subject to a fee under subsection (b)(9)(D))*, $5.

(7) For each customs broker permit held by an individual, partnership, association, or corporate customs broker, $125 per year.

(8) For the arrival of a barge or other bulk carrier from Canada or Mexico, $100.

(9)(A) For the processing of merchandise that is formally entered or released during any fiscal year, a fee in an amount equal to 0.21 percent ad valorem, unless adjusted under subparagraph (B).

(B)(i) The Secretary of the Treasury may adjust the ad valorem rate specified in subparagraph (A) to an ad valorem rate (but not to a rate of more than 0.21 percent nor less than 0.15 percent) and the amounts specified in subsection (b)(8)(A)(i) (but not to more than $485 nor less than $21) to rates and amounts which would, if charged, offset the salaries and expenses that will likely be incurred by the Customs Service in the processing of such entries and releases during the fiscal year in which such costs are incurred.

(ii) In determining the amount of any adjustment under clause (i), the Secretary of the Treasury shall take into account whether there is a surplus or deficit in the fund established under subsection (f) with respect to the provision of customs services for the processing of formal entries and releases of merchandise.

(iii) An adjustment may not be made under clause (i) with respect to the fee charged during any fiscal year unless the Secretary of the Treasury—

(I) not later than 45 days after the date of the enactment of the Act providing full-year appropriations for the Customs Service for that fiscal year, publishes in the Federal Register a notice of intent to adjust the fee under this paragraph and the amount of such adjustment;

(II) provides a period of not less than 30 days following publication of the notice described in subclause (I) for public comment and consultation with the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives regarding the proposed adjustment and the methodology used to determine such adjustment;

(III) upon the expiration of the period provided under subclause (II), notifies such committees in writing regarding the final determination to adjust the fee, the amount of such adjustment, and the methodology used to determine such adjustment; and

(IV) upon the expiration of the 15-day period following the written notification described in subclause (III), submits for publication in the Federal Register notice of the final determination regarding the adjustment of the fee.

(iv) The 15-day period referred to in clause (iii)(IV) shall be computed by excluding—

(I) the days on which either House is not in session because of an adjournment of more than 3 days to a day certain or an adjournment of the Congress sine die; and

(II) any Saturday and Sunday, not excluded under subclause (I), when either House is not in session.

(v) An adjustment made under this subparagraph shall become effective with respect to formal entries and releases made on or after the 15th calendar day after the date of publication of the notice described in clause (iii)(IV) and shall remain in effect until adjusted under this subparagraph.

(C) Any fee charged under this paragraph, whether or not adjusted under subparagraph (B), is subject to the limitations in subsection (b)(8)(A).

(10) For the processing of merchandise that is informally entered or released, other than at—

(A) a centralized hub facility,

(B) an express consignment carrier facility, or

(C) a small airport or other facility to which section 236 of the Trade and Tariff Act of 1984 applies, if more than 25,000 informal entries were cleared through such airport or facility during the fiscal year preceding such entry or release *(other than Inbound EMS items described in subsection (b)(9)(D))*,

a fee of—

(i) $2 if the entry or release is automated and not prepared by customs personnel;

(ii) $6 if the entry or release is manual and not prepared by customs personnel; or

(iii) $9 if the entry or release, whether automated or manual, is prepared by customs personnel.

For provisions relating to the informal entry or release of merchandise at facilities referred to in subparagraphs (A), (B), and (C), *or of Inbound EMS items described in subsection (b)(9)(D),* see subsection (b)(9).

(b) LIMITATIONS ON FEES.—(1)(A) Except as provided in subsection (a)(5)(B) of this section, no fee may be charged under subsection (a) of this section for customs services provided in connection with—

(i) the arrival of any passenger whose journey—

(I) originated in a territory or possession of the United States; or

(II) originated in the United States and was limited to territories and possessions of the United States;

(ii) the arrival of any railroad car the journey of which originates and terminates in the same country, but only if no passengers board or disembark from the train and no cargo is loaded or unloaded from such car while the car is within any country other than the country in which such car originates and terminates;

(iii) the arrival of a ferry, except for a ferry whose operations begin on or after August 1, 1999, and that operates south of 27 degrees latitude and east of 89 degrees longitude; or

(iv) the arrival of any passenger on board a commercial vessel traveling only between ports which are within the customs territory of the United States.

(B) The exemption provided for in subparagraph (A) shall not apply in the case of the arrival of any passenger on board a commercial vessel whose journey originates and terminates at the same place in the United States if there are no intervening stops.

(C) The exemption provided for in subparagraph (A)(i) shall not apply to fiscal years 1994, 1995, 1996, and 1997.

(2) No fee may be charged under subsection (a)(2) for the arrival of a commercial truck during any calendar year after a total of $100 in fees (subject to adjustment under subsection (l)) has been paid to the Secretary of the Treasury for the provision of customs services for all arrivals of such commercial truck during such calendar year.

(3) No fee may be charged under subsection (a)(3) for the arrival of a railroad car whether passenger or freight during any calendar year after a total of $100 in fees (subject to adjustment under subsection (l)) has been paid to the Secretary of the Treasury for the provision of customs services for all arrivals of such passenger or freight rail car during such calendar year.

(4)(A) No fee may be charged under subsection (a)(5) with respect to the arrival of any passenger—

(i) who is in transit to a destination outside the customs territory of the United States, and

(ii) for whom customs inspectional services are not provided.

(B) In the case of a commercial vessel making a single voyage involving 2 or more United States ports with respect to which the passengers would otherwise be charged a fee pursuant to subsection (a)(5), such fee shall be charged only 1 time for each passenger.

(5) No fee may be charged under subsection (a)(1) for the arrival of—

(A) a vessel during a calendar year after a total of $5,955 in fees (subject to adjustment under subsection (l)) charged under paragraph (1) or (8) of subsection (a) has been paid to the Secretary of the Treasury for the provision of customs services for all arrivals of such vessel during such calendar year,

(B) any vessel which, at the time of the arrival, is being used solely as a tugboat, or

(C) any barge or other bulk carrier from Canada or Mexico.

(6) No fee may be charged under subsection (a)(8) for the arrival of a barge or other bulk carrier during a calendar year after a total of $1,500 in fees (subject to adjustment under subsection (l)) charged under paragraph (1) or (8) of subsection (a) has been paid to the Secretary of the Treasury for the provision of customs services for all arrivals of such barge or other bulk carrier during such calendar year.

(7) No fee may be charged under paragraph (2), (3), or (4) of subsection (a) for the arrival of any—

(A) commercial truck,

(B) railroad car, or

(C) private vessel,

that is being transported, at the time of the arrival, by any vessel that is not a ferry.

(8)(A)(i) Subject to clause (ii), the fee charged under subsection (a)(9) for the formal entry or release of merchandise may not exceed $485 or be less than $25, unless adjusted pursuant to subsection (a)(9)(B) or (l).

(ii) A surcharge of $3 (subject to adjustment under subsection (l)) shall be added to the fee determined after application of clause (i) for any manual entry or release of merchandise.

(B) No fee may be charged under subsection (a) (9) or (10) for the processing of any article that is—

(i) provided for under any item in chapter 98 of the Harmonized Tariff Schedule of the United States, except subheading 9802.00.60 or 9802.00.80,

(ii) a product of an insular possession of the United States, or

(iii) a product of any country listed in subdivision (c)(ii)(B) or (c)(v) of general note 3 to such Schedule.

(C) For purposes of applying subsection (a) (9) or (10)—

(i) expenses incurred by the Secretary of the Treasury in the processing of merchandise do not include costs incurred in—

(I) air passenger processing,

(II) export control, or

(III) international affairs, and

(ii) any reference to a manual formal or informal entry or release includes any entry or release filed by a broker or importer that requires the inputting of cargo selectivity data into the Automated Commercial System by customs personnel, except when—

(I) the broker or importer is certified as an ABI cargo release filer under the Automated Commercial System at any port within the United States, or

(II) the entry or release is filed at ports prior to the full implementation of the cargo selectivity data system by the Customs Service at such ports.

(D) The fee charged under subsection (a)(9) or (10) with respect to the processing of merchandise shall—

(i) be paid by the importer of record of the merchandise;

(ii) except as otherwise provided in this paragraph, be based on the value of the merchandise as determined under section 402 of the Tariff Act of 1930;

(iii) in the case of merchandise classified under subheading 9802.00.60 of the Harmonized Tariff Schedule of the United States, be applied to the value of the foreign repairs or alterations to the merchandise;

(iv) in the case of merchandise classified under heading 9802.00.80 of such Schedule, be applied to the full value of the merchandise, less the cost or value of the component United States products;

(v) in the case of agricultural products of the United States that are processed and packed in a foreign trade zone, be applied only to the value of material used to make the container for such merchandise, if such merchandise is subject to entry and the container is of a kind normally used for packing such merchandise; and

(vi) in the case of merchandise entered from a foreign trade zone (other than merchandise to which clause (v) applies), be applied only to the value of the privileged or nonprivileged foreign status merchandise under section 3 of the Act of June 18, 1934 (commonly known as the Foreign Trade Zones Act, 19 U.S.C. 81c).

With respect to merchandise that is classified under subheading 9802.00.60 or heading 9802.00.80 of such Schedule and is duty-free, the Secretary may collect the fee charged on the processing of the merchandise under subsection (a) (9) or (10) on the basis of aggregate data derived from financial and manufacturing reports used by the importer in the normal course of business, rather than on the basis of entry-by-entry accounting.

(E) For purposes of subsection (a) (9) and (10), merchandise is entered or released, as the case may be, if the merchandise is—

(i) permitted or released under section 448(b) of the Tariff Act of 1930,

(ii) entered or released from customs custody under section 484(a)(1)(A) of the Tariff Act of 1930, or

(iii) withdrawn from warehouse for consumption.

(9)(A) With respect to the processing of letters, documents, records, shipments, merchandise, or any other item that is valued at an amount that is $2,000 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498 of the Tariff Act of 1930 and subject to adjustment under subsection (l)), except such items entered for transportation and exportation or immediate exportation at a centralized hub facility, an express consignment carrier facility, or a small airport or other facility, the following reimbursements and payments are required:

(i) In the case of a small airport or other facility—

(I) the reimbursement which such facility is required to make during the fiscal year under section 9701 of title 31, United States Code or section 236 of the Trade and Tariff Act of 1984; and

(II) an annual payment by the facility to the Secretary of the Treasury, which is in lieu of the payment of fees under subsection (a)(10) for such fiscal year, in an amount equal to the reimbursement under subclause (I).

(ii) Notwithstanding subsection (e)(6) and subject to the provisions of subparagraph (B), in the case of an express consignment carrier facility or centralized hub facility—

(I) $.66 per individual airway bill or bill of lading (subject to adjustment under subsection (l)); and

(II) if the merchandise is formally entered, the fee provided for in subsection (a)(9), if applicable.

(B)(i) Beginning in fiscal year 2004, the Secretary of the Treasury may adjust (not more than once per fiscal year) the amount described in subparagraph (A)(ii) to an amount that is not less

than $.35 and not more than $1.00 per individual airway bill or bill of lading (subject to adjustment under subsection (l)). The Secretary shall provide notice in the Federal Register of a proposed adjustment under the preceding sentence and the reasons therefor and shall allow for public comment on the proposed adjustment.

(ii) Notwithstanding section 451 of the Tariff Act of 1930, the payment required by subparagraph (A)(ii) (I) or (II) shall be the only payment required for reimbursement of the Customs Service in connection with the processing of an individual airway bill or bill of lading in accordance with such subparagraph and for providing services at express consignment carrier facilities or centralized hub facilities, except that the Customs Service may require such facilities to cover expenses of the Customs Service for adequate office space, equipment, furnishings, supplies, and security.

(iii)(I) The payment required by subparagraph (A)(ii) and clause (ii) of this subparagraph shall be paid on a quarterly basis by the carrier using the facility to the Customs Service in accordance with regulations prescribed by the Secretary of the Treasury.

(II) 50 percent of the amount of payments received under subparagraph (A)(ii) and clause (ii) of this subparagraph shall, in accordance with section 524 of the Tariff Act of 1930, be deposited in the Customs User Fee Account and shall be used to directly reimburse each appropriation for the amount paid out of that appropriation for the costs incurred in providing services to express consignment carrier facilities or centralized hub facilities. Amounts deposited in accordance with the preceding sentence shall be available until expended for the provision of customs services to express consignment carrier facilities or centralized hub facilities.

(III) Notwithstanding section 524 of the Tariff Act of 1930, the remaining 50 percent of the amount of payments received under subparagraph (A)(ii) and clause (ii) of this subparagraph shall be paid to the Secretary of the Treasury, which is in lieu of the payment of fees under subsection (a)(10) of this section.

(C) For purposes of this paragraph:

(i) The terms "centralized hub facility" and "express consignment carrier facility" have the respective meanings that are applied to such terms in part 128 of chapter I of title 19, Code of Federal Regulations. Nothing in this paragraph shall be construed as prohibiting the Secretary of the Treasury from processing merchandise that is informally entered or released at any centralized hub facility or express consignment carrier facility during the normal operating hours of the Customs Service, subject to reimbursement and payment under subparagraph (A).

(ii) The term "small airport or other facility" means any airport or facility to which section 236 of the Trade and Tariff Act of 1984 applies, if more than 25,000 informal entries were cleared through such airport or facility during the preceding fiscal year.

*(D)(i) With respect to the processing of items that are sent to the United States through the international postal network by "Inbound Express Mail service" or "Inbound EMS" (as that service is described in the mail classification schedule referred to in section 3631 of title 39, United States Code), the following payments are required:*

*(I) $1 per Inbound EMS item.*

*(II) If an Inbound EMS item is formally entered, the fee provided for under subsection (a)(9), if applicable.*

*(ii) Notwithstanding section 451 of the Tariff Act of 1930 (19 U.S.C. 1451), the payments required by clause (i), as allocated pursuant to clause (iii)(I), shall be the only payments required for reimbursement of U.S. Customs and Border Protection for customs services provided in connection with the processing of an Inbound EMS item.*

*(iii)(I) The payments required by clause (i)(I) shall be allocated as follows:*

*(aa) 50 percent of the amount of the payments shall be paid on a quarterly basis by the United States Postal Service to the Commissioner of U.S. Customs and Border Protection in accordance with regulations prescribed by the Secretary of the Treasury to reimburse U.S. Customs and Border Protection for customs services provided in connection with the processing of Inbound EMS items.*

*(bb) 50 percent of the amount of the payments shall be retained by the Postal Service to reimburse the Postal Service for services provided in connection with the customs processing of Inbound EMS items.*

*(II) Payments received by U.S. Customs and Border Protection under subclause (I)(aa) shall, in accordance with section 524 of the Tariff Act of 1930 (19 U.S.C. 1524), be deposited in the Customs User Fee Account and used to directly reimburse each appropriation for the*

*amount paid out of that appropriation for the costs incurred in providing services to international mail facilities. Amounts deposited in accordance with the preceding sentence shall be available until expended for the provision of such services.*

*(III) Payments retained by the Postal Service under subclause (I)(bb) shall be used to directly reimburse the Postal Service for the costs incurred in providing services in connection with the customs processing of Inbound EMS items.*

*(iv) Beginning in fiscal year 2021, the Secretary, in consultation with the Postmaster General, may adjust, not more frequently than once each fiscal year, the amount described in clause (i)(I) to an amount commensurate with the costs of services provided in connection with the customs processing of Inbound EMS items, consistent with the obligations of the United States under international agreements.*

(10)(A) The fee charged under subsection (a) (9) or (10) with respect to goods of Canadian origin (as determined under section 202 of the United States-Canada Free-Trade Agreement Implementation Act of 1988) when the United States-Canada Free-Trade Agreement is in force shall be in accordance with article 403 of that Agreement.

(B) For goods qualifying under the rules of origin set out in section 202 of the North American Free Trade Agreement Implementation Act, the fee under subsection (a) (9) or (10)—

(i) may not be charged with respect to goods that qualify to be marked as goods of Canada pursuant to Annex 311 of the North American Free Trade Agreement, for such time as Canada is a NAFTA country, as defined in section 2(4) of such Implementation Act; and

(ii) may not be increased after December 31, 1993, and may not be charged after June 29, 1999, with respect to goods that qualify to be marked as goods of Mexico pursuant to such Annex 311, for such time as Mexico is a NAFTA country.

Any service for which an exemption from such fee is provided by reason of this paragraph may not be funded with money contained in the Customs User Fee Account.

(11) No fee may be charged under subsection (a) (9) or (10) with respect to products of Israel if an exemption with respect to the fee is implemented under section 112 of the Customs and Trade Act of 1990.

(12) No fee may be charged under subsection (a) (9) or (10) with respect to goods that qualify as originating goods under section 202 of the United States-Chile Free Trade Agreement Implementation Act. Any service for which an exemption from such fee is provided by reason of this paragraph may not be funded with money contained in the Customs User Fee Account.

(13) No fee may be charged under subsection (a) (9) or (10) with respect to goods that qualify as originating goods under section 202 of the United States-Singapore Free Trade Agreement Implementation Act. Any service for which an exemption from such fee is provided by reason of this paragraph may not be funded with money contained in the Customs User Fee Account.

(14) No fee may be charged under subsection (a) (9) or (10) with respect to goods that qualify as originating goods under section 203 of the United States-Australia Free Trade Agreement Implementation Act. Any service for which an exemption from such fee is provided by reason of this paragraph may not be funded with money contained in the Customs User Fee Account.

(15) No fee may be charged under subsection (a) (9) or (10) with respect to goods that qualify as originating goods under section 203 of the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act. Any service for which an exemption from such fee is provided by reason of this paragraph may not be funded with money contained in the Customs User Fee Account.

(16) No fee may be charged under subsection (a) (9) or (10) with respect to goods that qualify as originating goods under section 202 of the United States-Bahrain Free Trade Agreement Implementation Act. Any service for which an exemption from such fee is provided by reason of this paragraph may not be funded with money contained in the Customs User Fee Account.

(17) No fee may be charged under subsection (a) (9) or (10) with respect to goods that qualify as originating goods under section 202 of the United States-Oman Free Trade Agreement Implementation Act. Any service for which an exemption from such fee is provided by reason of this paragraph may not be funded with money contained in the Customs User Fee Account.

(18) No fee may be charged under subsection (a) (9) or (10) with respect to goods that qualify as originating goods under section 203 of the United States-Peru Trade Promotion Agreement Implementation Act. Any service for which an exemption from such fee is provided by reason of this paragraph may not be funded with money contained in the Customs User Fee Account.

(19) No fee may be charged under subsection (a) (9) or (10) with respect to goods that qualify as originating goods under section 202 of the United States–Korea Free Trade Agreement Imple-

mentation Act. Any service for which an exemption from such fee is provided by reason of this paragraph may not be funded with money contained in the Customs User Fee Account.

(20) No fee may be charged under subsection (a) (9) or (10) with respect to goods that qualify as originating goods under section 203 of the United States–Colombia Trade Promotion Agreement Implementation Act. Any service for which an exemption from such fee is provided by reason of this paragraph may not be funded with money contained in the Customs User Fee Account.

(21) No fee may be charged under subsection (a)(9) or (10) with respect to goods that qualify as originating goods under section 203 of the United States–Panama Trade Promotion Agreement Implementation Act. Any service for which an exemption from such fee is provided by reason of this paragraph may not be funded with money contained in the Customs User Fee Account.

(c) DEFINITIONS.—For purposes of this section—

(1) The term "ferry" means any vessel which is being used—

(A) to provide transportation only between places that are no more than 300 miles apart, and

(B) to transport only—

(i) passengers, or

(ii) vehicles, or railroad cars, which are being used, or have been used, in transporting passengers or goods.

(2) The term "arrival" means arrival at a port of entry in the customs territory of the United States.

(3) The term "customs territory of the United States" has the meaning given to such term by general note 2 of the Harmonized Tariff Schedule of the United States.

(4) The term "customs broker permit" means a permit issued under section 641(c) of the Tariff Act of 1930 (19 U.S.C. 1641(c)).

(5) The term "barge or other bulk carrier" means any vessel which—

(A) is not self-propelled, or

(B) transports fungible goods that are not packaged in any form.

(d) COLLECTION.—(1) Each person that issues a document or ticket to an individual for transportation by a commercial vessel or commercial aircraft into the customs territory of the United States shall—

(A) collect from that individual the fee charged under subsection (a)(5) at the time the document or ticket is issued; and

(B) separately identify on that document or ticket the fee charged under subsection (a)(5) as a Federal inspection fee.

(2) If—

(A) a document or ticket for transportation of a passenger into the customs territory of the United States is issued in a foreign country; and

(B) the fee charged under subsection (a)(5) is not collected at the time such document or ticket is issued;

the person providing transportation to such passenger shall collect such fee at the time such passenger departs from the customs territory of the United States and shall provide such passenger a receipt for the payment of such fee.

(3) The person who collects fees under paragraph (1) or (2) shall remit those fees to the Secretary of the Treasury at any time before the date that is 31 days after the close of the calendar quarter in which the fees are collected.

(4)(A) Notice of the date on which payment of the fee imposed by subsection (a)(7) is due shall be published by the Secretary of the Treasury in the Federal Register by no later than the date that is 60 days before such due date.

(B) A customs broker permit may be revoked or suspended for nonpayment of the fee imposed by subsection (a)(7) only if notice of the date on which payment of such fee is due was published in the Federal Register at least 60 days before such due date.

(C) The customs broker's license issued under section 641(b) of the Tariff Act of 1930 (19 U.S.C. 1641(b)) may not be revoked or suspended merely by reason of nonpayment of the fee imposed under subsection (a)(7).

(e) PROVISION OF CUSTOMS SERVICES.—

(1)(A) Notwithstanding section 451 of the Tariff Act of 1930 (19 U.S.C. 1451) or any other provision of law (other than subparagraph (B) and paragraph (2)), the customs services required to be provided to passengers upon arrival in the United States shall be adequately provided in con-

nection with scheduled airline flights at customs serviced airports when needed and at no cost (other than the fees imposed under subsection (a)) to airlines and airline passengers.

(B)(i) An appropriate officer of U.S. Customs and Border Protection may assign a sufficient number of employees of U.S. Customs and Border Protection (if available) to perform services described in clause (ii) for a charter air carrier (as defined in section 40102 of title 49, United States Code) for a charter flight arriving after normal operating hours at an airport that is an established port of entry serviced by U.S. Customs and Border Protection, notwithstanding that overtime funds for those services are not available, if the charter air carrier—

(I) not later than 4 hours before the flight arrives, specifically requests that such services be provided; and

(II) pays any overtime fees incurred in connection with such services.

(ii) Services described in this clause are customs services for passengers and their baggage or any other similar service that could lawfully be performed during regular hours of operation.

(2)(A) This subsection shall not apply with respect to any airport to which section 236 of the Trade and Tariff Act of 1984 (19 U.S.C. 58b) applies.

(B) Subparagraph (C) of paragraph (6) shall not apply with respect to any foreign trade zone or subzone that is located at, or in the vicinity of, an airport to which section 236 of the Trade and Tariff Act of 1984 applies.

(3) Notwithstanding section 451 of the Tariff Act of 1930 (19 U.S.C. 1451) or any other provision of law—

(A) the customs services required to be provided to passengers upon arrival in the United States shall be adequately provided in connection with scheduled airline flights when needed at places located outside the customs territory of the United States at which a customs officer is stationed for the purpose of providing such customs services, and

(B) other than the fees imposed under subsection (a), the airlines and airline passengers shall not be required to reimburse the Secretary of the Treasury for the costs of providing overtime customs inspectional services at such places.

(4) Notwithstanding any other provision of law, all customs services (including, but not limited to, normal and overtime clearance and preclearance services) shall be adequately provided, when requested, for—

(A) the clearance of any commercial vessel, vehicle, or aircraft or its passengers, crew, stores, material, or cargo arriving, departing, or transiting the United States;

(B) the preclearance at any customs facility outside the United States of any commercial vessel, vehicle or aircraft or its passengers, crew, stores, material, or cargo; and

(C) the inspection or release of commercial cargo or other commercial shipments being entered into, or withdrawn from, the customs territory of the United States.

(5) For purposes of this subsection, customs services shall be treated as being "adequately provided" if such of those services that are necessary to meet the needs of parties subject to customs inspection are provided in a timely manner taking into account factors such as—

(A) the unavoidability of weather, mechanical, and other delays;

(B) the necessity for prompt and efficient passenger and baggage clearance;

(C) the perishability of cargo;

(D) the desirability or unavoidability of late night and early morning arrivals from various time zones;

(E) the availability (in accordance with regulations prescribed under subsection (g)(2)) of customs personnel and resources; and

(F) the need for specific enforcement checks.

(6) Notwithstanding any other provision of law except paragraph (2), during any period when fees are authorized under subsection (a), no charges, other than such fees, may be collected—

(A) for any—

(i) cargo inspection, clearance, or other customs activity, expense, or service performed (regardless whether performed outside of normal business hours on an overtime basis), or

(ii) customs personnel provided,

in connection with the arrival or departure of any commercial vessel, vehicle, or aircraft, or its passengers, crew, stores, material, or cargo, in the United States;

(B) for any preclearance or other customs activity, expense, or service performed, and any customs personnel provided, outside the United States in connection with the departure of any commercial vessel, vehicle, or aircraft, or its passengers, crew, stores, material, or cargo, for the United States; or

(C) in connection with—

(i) the activation or operation (including Customs Service supervision) of any foreign trade zone or subzone established under the Act of June 18, 1934 (commonly known as the Foreign Trade Zones Act, 19 U.S.C. 81a et seq.), or

(ii) the designation or operation (including Customs Service supervision) of any bonded warehouse under section 555 of the Tariff Act of 1930 (19 U.S.C. 1555).

(f) DISPOSITION OF FEES.—(1) There is established in the general fund of the Treasury a separate account which shall be known as the "Customs User Fee Account". Notwithstanding section 524 of the Tariff Act of 1930 (19 U.S.C. 1524), there shall be deposited as offsetting receipts into the Customs User Fee Account all fees collected under subsection (a) except—

(A) the portion of such fees that is required under paragraph (3) for the direct reimbursement of appropriations, and

(B) amounts deposited into the Customs Commercial and Homeland Security Automation Account under paragraph (4).

(2) Except as otherwise provided in this subsection, all funds in the Customs User Fee Account shall be available, to the extent provided for in appropriations Acts, to pay the costs (other than costs for which direct reimbursement under paragraph (3) is required) incurred by the United States Customs Service in conducting customs revenue functions as defined in section 415 of the Homeland Security Act of 2002 (other than functions performed by the Office of International Affairs referred to in section 415(8) of that Act), and for automation (including the Automation Commercial Environment computer system), and for no other purpose. To the extent that funds in the Customs User Fee Account are insufficient to pay the costs of such customs revenue functions, customs duties in an amount equal to the amount of such insufficiency shall be available, to the extent provided for in appropriations Acts, to pay the costs of such customs revenue functions in the amount of such insufficiency, and shall be available for no other purpose. The provisions of the first and second sentences of this paragraph specifying the purposes for which amounts in the Customs User Fee Account may be made available shall not be superseded except by a provision of law which specifically modifies or supersedes such provisions. So long as there is a surplus of funds in the Customs User Fee Account, the Secretary of the Treasury may not reduce personnel staffing levels for providing commercial clearance and preclearance services.

(3)(A) The Secretary of the Treasury, in accordance with section 524 of the Tariff Act of 1930 and subject to subparagraph (B), shall directly reimburse, from the fees collected under subsection (a) (other than the fees under subsection (a) (9) and (10) and the excess fees determined by the Secretary under paragraph (4)), each appropriation for the amount paid out of that appropriation for the costs incurred by the Secretary—

(i) in—

(I) paying overtime compensation under section 5(a) of the Act of February 13, 1911,

(II) paying premium pay under section 5(b) of the Act of February 13, 1911, but the amount for which reimbursement may be made under this subclause may not, for any fiscal year, exceed the difference between the total cost of all the premium pay for such year calculated under section 5(b) and the cost of the night and holiday premium pay that the Customs Service would have incurred for the same inspectional work on the day before the effective date of section 13813 of the Omnibus Budget Reconciliation Act of 1993,

(III) paying agency contributions to the Civil Service Retirement and Disability Fund to match deductions from the overtime compensation paid under subclause (I),

(IV) providing all preclearance services for which the recipients of such services are not required to reimburse the Secretary of the Treasury, and

(V) paying foreign language proficiency awards under section 13812(b) of the Omnibus Budget Reconciliation Act of 1993,

(ii) to the extent funds remain available after making reimbursements under clause (i), in providing salaries for full-time and part-time inspectional personnel and equipment that enhance customs services for those persons or entities that are required to pay fees under paragraphs (1) through (8) of subsection (a) (distributed on a basis proportionate to the fees collected under paragraphs (1) through (8) of subsection (a), and

(iii) to the extent funds remain available after making reimbursements under clause (ii), in providing salaries for up to 50 full-time equivalent inspectional positions to provide preclearance services.

The transfer of funds required under subparagraph (C)(iii) has priority over reimbursements under this subparagraph to carry out subclauses (II), (III), (IV), and (V) of clause (i). Funds described

in clause (ii) shall only be available to reimburse costs in excess of the highest amount appropriated for such costs during the period beginning with fiscal year 1990 and ending with the current fiscal year.

(B) Reimbursement of appropriations under this paragraph—

(i) shall be subject to apportionment or similar administrative practices;

(ii) shall be made at least quarterly; and

(iii) to the extent necessary, may be made on the basis of estimates made by the Secretary of the Treasury and adjustments shall be made in subsequent reimbursements to the extent that the estimates were in excess of, or less than, the amounts required to be reimbursed.

(C)(i) For fiscal year 1991 and subsequent fiscal years, the amount required to reimburse costs described in subparagraph (A)(i) shall be projected from actual requirements, and only the excess of collections over such projected costs for such fiscal year shall be used as provided in subparagraph (A)(ii).

(ii) The excess of collections over inspectional overtime and preclearance costs (under subparagraph (A)(i)) reimbursed for fiscal years 1989 and 1990 shall be available in fiscal year 1991 and subsequent fiscal years for the purposes described in subparagraph (A)(ii), except that $30,000,000 of such excess shall remain without fiscal year limitation in a contingency fund and, in any fiscal year in which receipts are insufficient to cover the costs described in subparagraph (A) (i) and (ii), shall be used for—

(I) the costs of providing the services described in subparagraph (A)(i), and

(II) after the costs described in subclause (I) are paid, the costs of providing the personnel and equipment described in subparagraph (A)(ii) at the preceding fiscal year level.

(iii) For each fiscal year, the Secretary of the Treasury shall calculate the difference between—

(I) the estimated cost for overtime compensation that would have been incurred during that fiscal year for inspectional services if section 5 of the Act of February 13, 1911 (19 U.S.C. 261 and 267), as in effect before the enactment of section 13811 of the Omnibus Budget Reconciliation Act of 1993, had governed such costs, and

(II) the actual cost for overtime compensation, premium pay, and agency retirement contributions that is incurred during that fiscal year in regard to inspectional services under section 5 of the Act of February 13, 1911, as amended by section 13811 of the Omnibus Budget Reconciliation Act of 1993, and under section 8331(3) of title 5, United States Code, as amended by section 13812(a)(1) of such Act of 1993, plus the actual cost that is incurred during that fiscal year for foreign language proficiency awards under section 13812(b) of such Act of 1993, and shall transfer from the Customs User Fee Account to the General Fund of the Treasury an amount equal to the difference calculated under this clause, or $18,000,000, whichever amount is less. Transfers shall be made under this clause at least quarterly and on the basis of estimates to the same extent as are reimbursements under subparagraph (B)(iii).

(D) Nothing in this paragraph shall be construed to preclude the use of appropriated funds, from sources other than the fees collected under subsection (a), to pay the costs set forth in clauses (i), (ii), and (iii) of subparagraph (A).

(4)(A) There is created within the general fund of the Treasury a separate account that shall be known as the "Customs Commercial and Homeland Security Automation Account". In each of fiscal years 2003, 2004, and 2005 there shall be deposited into the Account from fees collected under subsection (a)(9)(A), $350,000,000.

(B) There is authorized to be appropriated from the Account in fiscal years 2016 through 2018not less than $153,736,000to complete the development and implementation, establishment, and implementation of the Automated Commercial Environment computer system for the processing of merchandise that is entered or released and for other purposes related to the functions of the Department of Homeland Security. Amounts appropriated pursuant to this subparagraph are authorized to remain available until expended.

(C) In adjusting the fee imposed by subsection (a)(9)(A) for fiscal year 2006, the Secretary of the Treasury shall reduce the amount estimated to be collected in fiscal year 2006 by the amount by which total fees deposited to the Account during fiscal years 2003, 2004, and 2005 exceed total appropriations from that Account.

(5) Of the amounts collected in fiscal year 1999 under paragraphs (9) and (10) of subsection (a), $50,000,000 shall be available to the Customs Service, subject to appropriations Acts, for automated commercial systems. Amounts made available under this paragraph shall remain available until expended.

(g) REGULATIONS AND ENFORCEMENT.—(1) The Secretary of the Treasury may prescribe such rules and regulations as may be necessary to carry out the provisions of this section. Regulations issued by the Secretary of the Treasury under this subsection with respect to the collection of the fees charged under subsection (a)(5) and the remittance of such fees to the Treasury of the United States shall be consistent with the regulations issued by the Secretary of the Treasury for the collection and remittance of the taxes imposed by subchapter C of chapter 33 of the Internal Revenue Code of 1954, but only to the extent the regulations issued with respect to such taxes do not conflict with the provisions of this section.

(2) Except to the extent otherwise provided in regulations, all administrative and enforcement provisions of customs laws and regulations, other than those laws and regulations relating to drawback, shall apply with respect to any fee prescribed under subsection (a) of this section, and with respect to persons liable therefor, as if such fee is a customs duty. For purposes of the preceding sentence, any penalty expressed in terms of a relationship to the amount of the duty shall be treated as not less than the amount which bears a similar relationship to the amount of the fee assessed. For purposes of determining the jurisdiction of any court of the United States or any agency of the United States, any fee prescribed under subsection (a) of this section shall be treated as if such fee is a customs duty.

(h) CONFORMING AMENDMENTS.—(1) Subsection (i) of section 305 of the Rail Passenger Service Act (45 U.S.C. 545(i)) is amended by striking out the last sentence thereof.

(i) EFFECT ON OTHER AUTHORITY.—Except with respect to customs services for which fees are imposed under subsection (a), nothing in this section shall be construed as affecting the authority of the Secretary of the Treasury to charge fees under section 214(b) of the Customs Procedural Reform and Simplification Act of 1978 (19 U.S.C. 58a).

(j) EFFECTIVE DATES.—(1) Except as otherwise provided in this subsection, the provisions of this section, and the amendments and repeals made by this section, shall apply with respect to customs services rendered after the date that is 90 days after the date of enactment of this Act.

(2) Fees may be charged under subsection (a)(5) only with respect to customs services rendered in regard to arriving passengers using transportation for which documents or tickets were issued after the date that is 90 days after such date of enactment.

(3)(A) Fees may not be charged under paragraphs (9) and (10) of subsection (a) after July 21, 2027.

(B)(i) Subject to clause (ii), Fees may not be charged under paragraphs (1) through (8) of subsection (a) after September 30, 2027.

(ii) In fiscal year 2006 and in each succeeding fiscal year for which fees under paragraphs (1) through (8) of subsection (a) are authorized—

(I) the Secretary of the Treasury shall charge fees under each such paragraph in amounts that are reasonably related to the costs of providing customs services in connection with the activity or item for which the fee is charged under such paragraph, except that in no case may the fee charged under any such paragraph exceed by more than 10 percent the amount otherwise prescribed by such paragraph;

(II) the amount of fees collected under such paragraphs may not exceed, in the aggregate, the amounts paid in that fiscal year for the costs described in subsection (f)(3)(A) incurred in providing customs services in connection with the activity or item for which the fees are charged under such paragraphs;

(III) a fee may not be collected under any such paragraph except to the extent such fee will be expended to pay the costs described in subsection (f)(3)(A) incurred in providing customs services in connection with the activity or item for which the fee is charged under such paragraph; and

(IV) any fee collected under any such paragraph shall be available for expenditure only to pay the costs described in subsection (f)(3)(A) incurred in providing customs services in connection with the activity or item for which the fee is charged under such paragraph.

(k) ADVISORY COMMITTEE.—The Commissioner of Customs shall establish an advisory committee whose membership shall consist of representatives from the airline, cruise ship, and other transportation industries who may be subject to fees under subsection (a). The advisory committee shall not be subject to termination under section 14 of the Federal Advisory Committee Act. The advisory committee shall meet on a periodic basis and shall advise the Commissioner on issues related to the performance of the inspectional services of the United States Customs Service. Such advice shall include, but not be limited to, such issues as the time periods during which such services should be performed, the proper number and deployment of inspection officers, the level of

fees, and the appropriateness of any proposed fee. The Commissioner shall give consideration to the views of the advisory committee in the exercise of his or her duties.

(l) ADJUSTMENT OF FEES FOR INFLATION.—

(1) IN GENERAL.—The Secretary of the Treasury shall adjust the fees established under subsection (a), and the limitations on such fees under paragraphs (2), (3), (5), (6), (8), and (9) of subsection (b), on April 1, 2016, and at the beginning of each fiscal year thereafter, to reflect the percentage (if any) of the increase in the average of the Consumer Price Index for the preceding 12-month period compared to the Consumer Price Index for fiscal year 2014.

(2) SPECIAL RULES FOR CALCULATION OF ADJUSTMENT.—In adjusting under paragraph (1) the amount of the fees established under subsection (a), and the limitations on such fees under paragraphs (2), (3), (5), (6), (8), and (9) of subsection (b), the Secretary—

(A) shall round the amount of any increase in the Consumer Price Index to the nearest dollar; and

(B) may ignore any such increase of less than 1 percent.

(3) CONSUMER PRICE INDEX DEFINED.—For purposes of this subsection, the term "Consumer Price Index" means the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics of the Department of Labor.

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**TRADE ACT OF 2002**

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# DIVISION A—TRADE ADJUSTMENT ASSISTANCE

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# TITLE III—CUSTOMS REAUTHORIZATION

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## Subtitle A—United States Customs Service

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### CHAPTER 4—ANTITERRORISM PROVISIONS

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**SEC. 343. MANDATORY [ADVANCED] *ADVANCE* ELECTRONIC INFORMATION FOR CARGO AND OTHER IMPROVED CUSTOMS REPORTING PROCEDURES**

(a) CARGO INFORMATION.—

(1) IN GENERAL.—(A) Subject to paragraphs (2) and (3),the Secretary is authorized to promulgate regulations providingfor the transmission to the Customs Service, through an electronicdata interchange system, of information pertaining tocargo to be brought into the United States or to be sent fromthe United States, prior to the arrival or departure of thecargo.

(B) The Secretary shall endeavor to promulgate an initial set of regulations under subparagraph (A) not later than October 1, 2003.

(2) INFORMATION REQUIRED.—The cargo informationrequired by the regulations promulgated pursuant to paragraph(1) under the parameters set forth in paragraph (3) shall besuch information on cargo as the Secretary determines to bereasonably necessary to ensure cargo safety and security pursuantto those laws enforced and administered by the CustomsService. The Secretary shall provide to appropriate Federaldepartments and agencies cargo information obtained pursuantto paragraph (1).

(3) PARAMETERS.—In developing regulations pursuant to paragraph (1), the Secretary shall adhere to the following parameters:

(A) The Secretary shall solicit comments from and consult with a broad range of parties likely to be affected by the regulations, including importers, exporters, carriers, customs brokers, and freight forwarders, among other interested parties.

(B) In general, the requirement to provide particular information shall be imposed on the party most likely to have direct knowledge of that information. Where requiring information from the party with direct knowledge of that information is not practicable, the regulations shall take into account how, under ordinary commercial practices, information is acquired by the party on which the requirement is imposed, and whether and how such party is able to verify the information. Where information is not reasonably verifiable by the party on which a requirement is imposed, the regulations shall permit that party to transmit information on the basis of what it reasonably believes to be true.

(C) The Secretary shall take into account the existence of competitive relationships among the parties on which requirements to provide particular information are imposed.

(D) Where the regulations impose requirements on carriers of cargo, they shall take into account differences among different modes of transportation, including differences in commercial practices, operational characteristics, and technological capacity to collect and transmit information electronically.

(E) The regulations shall take into account the extent to which the technology necessary for parties to transmit and the Customs Service to receive and analyze data in a timely fashion is available. To the extent that the Secretary determines that the necessary technology will not be widely available to particular modes of transportation or other affected parties until after promulgation of the regulations, the regulations shall provide interim requirements appropriate for the technology that is available at the time of promulgation.

(F) The information collected pursuant to the regulations shall be used exclusively for ensuring cargo safety and security, preventing smuggling, and commercial risk assessment targeting, and shall not be used for any commercial enforcement purposes, including for determining merchandise entry. Notwithstanding the preceding sentence, nothing in this section shall be treated as amending, repealing, or otherwise modifying title IV of the Tariff Act of 1930 or regulations promulgated thereunder.

(G) The regulations shall protect the privacy of business proprietary and any other confidential cargo information provided to the Customs Service pursuant to such regulations, exceptfor the manifest information collected pursuantto section 431 of the Tariff Act of 1930 and requiredto be available for public disclosure pursuant tosection 431(c) of such Act..

(H) In determining the timing for transmittal of any information, the Secretary shall balance likely impact on flow of commerce with impact on cargo safety and security. With respect to requirements that may be imposed on carriers of cargo, the timing for transmittal of information shall take into account differences among different modes of transportation, as described in subparagraph (D).

(I) Where practicable, the regulations shall avoid imposing requirements that are redundant with one another or that are redundant with requirements in other provisions of law.

(J) The Secretary shall determine whether it is appropriate to provide transition periods between promulgation of the regulations and the effective date of the regulations and shall prescribe such transition periods in the regulations, as appropriate. The Secretary may determine that different transition periods are appropriate for different classes of affected parties.

**[**(K) With respect to requirements imposed on carriers, the Secretary, in consultation with the Postmaster General, shall determine whether it is appropriate to impose the same or similar requirements on shipments by the United States Postal Service. If the Secretary determines that such requirements are appropriate, then they shall be set forth in the regulations.**]**

*(K)(i) The Secretary shall prescribe regulations requiring the United States Postal Service to transmit the information described in paragraphs (1) and (2) to the Commissioner of U.S. Customs and Border Protection for international mail shipments by the Postal Service (including shipments to the Postal Service from foreign postal operators that are transported by private carrier) consistent with the requirements of this subparagraph.*

*(ii) In prescribing regulations under clause (i), the Secretary shall impose requirements for the transmission to the Commissioner of information described in paragraphs (1) and (2) for mail shipments described in clause (i) that are comparable to the requirements for the transmission of such information imposed on similar non-mail shipments of cargo, taking into account the parameters set forth in subparagraphs (A) through (J).*

*(iii) The regulations prescribed under clause (i) shall require the transmission of the information described in paragraphs (1) and (2) with respect to a shipment as soon as practicable in relation to the transportation of the shipment, consistent with subparagraph (H).*

*(iv) Regulations prescribed under clause (i) shall allow for the requirements for the transmission to the Commissioner of information described in paragraphs (1) and (2) for mail shipments described in clause (i) to be implemented in phases, as appropriate, by—*

*(I) setting incremental targets for increasing the percentage of such shipments for which information is required to be transmitted to the Commissioner; and*

*(II) taking into consideration—*

*(aa) the risk posed by such shipments;*

*(bb) the volume of mail shipped to the United States by or through a particular country; and*

*(cc) the capacities of foreign postal operators to provide that information to the Postal Service.*

*(v)(I) Notwithstanding clause (iv), the Postal Service shall, not later than December 31, 2018, arrange for the transmission to the Commissioner of the information described in paragraphs (1) and (2) for not less than 70 percent of the aggregate number of mail shipments, including 100 percent of mail shipments from the People's Republic of China, described in clause (i).*

*(II) If the requirements of subclause (I) are not met, the Comptroller General of the United States shall submit to the appropriate congressional committees, not later than June 30, 2019, a report—*

*(aa) assessing the reasons for the failure to meet those requirements; and*

*(bb) identifying recommendations to improve the collection by the Postal Service of the information described in paragraphs (1) and (2).*

*(vi)(I) Notwithstanding clause (iv), the Postal Service shall, not later than December 31, 2020, arrange for the transmission to the Commissioner of the information described in paragraphs (1) and (2) for 100 percent of the aggregate number of mail shipments described in clause (i).*

*(II) The Commissioner, in consultation with the Postmaster General, may determine to exclude a country from the requirement described in subclause (I) to transmit information for mail shipments described in clause (i) from the country if the Commissioner determines that the country—*

*(aa) does not have the capacity to collect and transmit such information;*

*(bb) represents a low risk for mail shipments that violate relevant United States laws and regulations; and*

*(cc) accounts for low volumes of mail shipments that can be effectively screened for compliance with relevant United States laws and regulations through an alternate means.*

*(III) The Commissioner shall, at a minimum on an annual basis, re-evaluate any determination made under subclause (II) to exclude a country from the requirement described in subclause (I). If, at any time, the Commissioner determines that a country no longer meets the requirements under subclause (II), the Commissioner may not further exclude the country from the requirement described in subclause (I).*

*(IV) The Commissioner shall, on an annual basis, submit to the appropriate congressional committees—*

*(aa) a list of countries with respect to which the Commissioner has made a determination under subclause (II) to exclude the countries from the requirement described in subclause (I); and*

*(bb) information used to support such determination with respect to such countries.*

*(vii)(I) The Postmaster General shall, in consultation with the Commissioner, refuse any shipments received after December 31, 2020, for which the information described in paragraphs (1) and (2) is not transmitted as required under this subparagraph, except as provided in subclause (II).*

*(II) If remedial action is warranted in lieu of refusal of shipments pursuant to subclause (I), the Postmaster General and the Commissioner shall take remedial action with respect to the shipments, including destruction, seizure, controlled delivery or other law enforcement initiatives, or correction of the failure to provide the information described in paragraphs (1) and (2) with respect to the shipments.*

*(viii) Nothing in this subparagraph shall be construed to limit the authority of the Secretary to obtain information relating to international mail shipments from private carriers or other appropriate parties.*

*(ix) In this subparagraph, the term "appropriate congressional committees" means—*

*(I) the Committee on Finance and the Committee on Homeland Security and Governmental Affairs of the Senate; and*

*(II) the Committee on Ways and Means, the Committee on Oversight and Government Reform, and the Committee on Homeland Security of the House of Representatives.*

(L) Not later than 15 days prior to publication of a final rule pursuantto this section, the Secretary shall transmit to the Committees on Finance and Commerce, Science, and Transportation of the Senate and the Committees on Ways and Means and Transportation and Infrastructure of the House of Representatives a report setting forth—

(i) the proposed regulations;

(ii) an explanation of how particular requirements in the proposed regulations meet the needs of cargo safety and security;

(iii) an explanation of how the Secretary expects the proposed regulations to affect the commercial practices of affected parties;

(iv) an explanation of how the proposed regulations address particular comments received from interested parties; and

(v) if the Secretary determines to amend the proposedregulations after they have been transmittedto the Committees pursuant to this subparagraph, theSecretary shall transmit the amended regulations tosuch Committees no later than 5 days prior to thepublication of the final rule.

(4) TRANSMISSION OF DATA.—Pursuant to paragraph (2),not later than 1 year after the date of enactment of this paragraph,the Secretary of Homeland Security, after consultationwith the Secretary of the Treasury, shall establish an electronicdata interchange system through which the United States Customsand Border Protection shall transmit to the Internal RevenueService information pertaining to cargoes of any taxablefuel (as defined in section 4083 of the Internal Revenue Codeof 1986) that the United States Customs and Border Protectionhas obtained electronically under its regulations adopted inaccordance with paragraph (1). For this purpose, not laterthan 1 year after the date of enactment of this paragraph,all filers of required cargo information for such taxable fuels(as so defined) must provide such information to the UnitedStates Customs and Border Protection through such electronicdata interchange system.

*(5) CAPACITY BUILDING.—*

*(A) IN GENERAL.—The Secretary, with the concurrence of the Secretary of State, and in coordination with the Postmaster General and the heads of other Federal agencies, as appropriate, may provide technical assistance, equipment, technology, and training to enhance the capacity of foreign postal operators—*

*(i) to gather and provide the information required by paragraph (3)(K); and*

*(ii) to otherwise gather and provide postal shipment information related to—*

*(I) terrorism;*

*(II) items the importation or introduction of which into the United States is prohibited or restricted, including controlled substances; and*

*(III) such other concerns as the Secretary determines appropriate.*

*(B) PROVISION OF EQUIPMENT AND TECHNOLOGY.—With respect to the provision of equipment and technology under subparagraph (A), the Secretary may lease, loan, provide, or otherwise assist in the deployment of such equipment and technology under such terms and conditions as the Secretary may prescribe, including nonreimbursable loans or the transfer of ownership of equipment and technology.*

(b) DOCUMENTATION OF WATERBORNE CARGO.—Part II of title IV of the Tariff Act of 1930 is amended by inserting after section 431 the following new section:

[Omitted amendatory text]

* * * * * * *".

(c) SECRETARY.—For purposes of this section, the term "Secretary" means the Secretary of the Treasury. If, at the time the regulations required by subsection (a)(1) are promulgated, the Customs Service is no longer located in the Department of the Treasury, then the Secretary of the Treasury shall exercise the authority under subsection (a) jointly with the Secretary of the Department in which the Customs Service is located.

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## TARIFF ACT OF 1930

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# TITLE IV—ADMINISTRATIVE PROVISIONS

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### Part II—Report, Entry, and Unlading of Vessels and Vehicles

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**SEC. 436. PENALTIES FOR VIOLATIONS OF THE ARRIVAL, REPORTING, ENTRY, AND CLEARANCE REQUIREMENTS.**

(a) UNLAWFUL ACTS.—It is unlawful—

(1) to fail to comply with section 431, 433, or 434 of this Act or section 4197 of the Revised Statutes of the United States (46 U.S.C. App. 91);

(2) to present or transmit, electronically or otherwise, any forged, altered, or false document, paper, information, data or manifest to the Customs Service under section 431, 433(d), or 434 of this Act or section 4197 of the Revised Statutes of the United States (46 U.S.C. App. 91) without revealing the facts;

(3) to fail to make entry or to obtain clearance as required by section 434 or 644 of this Act, section 4197 of the Revised Statutes of the United States (46 U.S.C. App. 91), or section 1109 of the Federal Aviation Act of 1958 (49 U.S.C. App. 1509); or

(4) to fail to comply with, or violate, any regulation prescribed under any section referred to in any of paragraphs (1) through (3).

(b) CIVIL PENALTY.—Any master, person in charge of a vehicle, or aircraft pilot who commits any violation listed in subsection (a) is liable for a civil penalty of $5,000 for the first violation, and $10,000 for each subsequent violation, and any conveyance used in connection with any such violation is subject to seizure and forfeiture.

(c) CRIMINAL PENALTY.—In addition to being liable for a civil penalty under subsection (b), any master, person in charge of a vehicle, or aircraft pilot who intentionally commits any violation listed in subsection (a) is, upon conviction, liable for a fine of not more than $2,000 or imprisonment for 1 year, or both; except that if the conveyance has, or is discovered to have had, on board any merchandise (other than sea stores or the equivalent for conveyances other than vessels) the importation of which into the United States is prohibited, such individual is liable for an additional fine of not more than $10,000 or imprisonment for not more than 5 years, or both.

(d) ADDITIONAL CIVIL PENALTY.—If any merchandise (other than sea stores or the equivalent for conveyances other than a vessel) is imported or brought into the United States in or aboard a conveyance which was not properly reported or entered, the master, person in charge of a vehicle, or aircraft pilot shall be liable for a civil penalty equal to the value of the merchandise and the merchandise may be seized and forfeited unless properly entered by the importer or consignee. If the merchandise consists of any controlled substance listed in section 584, the master, individual in charge of a vehicle, or pilot shall be liable to the penalties prescribed in that section.

*(e) CIVIL PENALTIES FOR POSTAL SHIPMENTS.—*

*(1) CIVIL PENALTY.—A civil penalty shall be imposed against the United States Postal Service if the Postal Service accepts a shipment in violation of section 343(a)(3)(K)(vii)(I) of the Trade Act of 2002.*

*(2) MODIFICATION OF CIVIL PENALTY.—*

*(A) IN GENERAL.—U.S. Customs and Border Protection shall reduce or dismiss a civil penalty imposed pursuant to paragraph (1) if U.S. Customs and Border Protection determines that the United States Postal Service—*

*(i) has a low error rate in compliance with section 343(a)(3)(K) of the Trade Act of 2002;*

*(ii) is cooperating with U.S. Customs and Border Protection with respect to the violation of section 343(a)(3)(K)(vii)(I) of the Trade Act of 2002; or*

*(iii) has taken remedial action to prevent future violations of section 343(a)(3)(K)(vii)(I) of the Trade Act of 2002.*

*(B) WRITTEN NOTIFICATION.—U.S. Customs and Border Protection shall issue a written notification to the Postal Service with respect to each exercise of the authority of subparagraph (A) to reduce or dismiss a civil penalty imposed pursuant to paragraph (1).*

*(3) ONGOING LACK OF COMPLIANCE.—If U.S. Customs and Border Protection determines that the United States Postal Service—*

*(A) has repeatedly committed violations of section 343(a)(3)(K)(vii)(I) of the Trade Act of 2002,*

*(B) has failed to cooperate with U.S. Customs and Border Protection with respect to violations of section 343(a)(3)(K)(vii)(I) of the Trade Act of 2002, and*

*(C) has an increasing error rate in compliance with section 343(a)(3)(K) of the Trade Act of 2002,*

*civil penalties may be imposed against the United States Postal Service until corrective action, satisfactory to U.S. Customs and Border Protection, is taken.*

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## TITLE 38, UNITED STATES CODE

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# PART II—GENERAL BENEFITS

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## CHAPTER 17—HOSPITAL, NURSING HOME, DOMICILIARY, AND MEDICAL CARE

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### SUBCHAPTER II—HOSPITAL, NURSING HOME, OR DOMICILIARY CARE AND MEDICAL TREATMENT

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**§ 1720F. Comprehensive program for suicide prevention among veterans**

(a) ESTABLISHMENT.—The Secretary shall develop and carry out a comprehensive program designed to reduce the incidence of suicide among veterans incorporating the components described in this section.

(b) STAFF EDUCATION.—In carrying out the comprehensive program under this section, the Secretary shall provide for mandatory training for appropriate staff and contractors (including all medical personnel) of the Department who interact with veterans. This training shall cover information appropriate to the duties being performed by such staff and contractors. The training shall include information on—

(1) recognizing risk factors for suicide;

(2) proper protocols for responding to crisis situations involving veterans who may be at high risk for suicide; and

(3) best practices for suicide prevention.

(c) HEALTH ASSESSMENTS OF VETERANS.—In carrying out the comprehensive program, the Secretary shall direct that medical staff offer mental health in their overall health assessment when veterans seek medical care at a Department medical facility (including a center established under section 1712A of this title) and make referrals, at the request of the veteran concerned, to appro-

priate counseling and treatment programs for veterans who show signs or symptoms of mental health problems.

(d) DESIGNATION OF SUICIDE PREVENTION COUNSELORS.—In carrying out the comprehensive program, the Secretary shall designate a suicide prevention counselor at each Department medical facility other than centers established under section 1712A of this title. Each counselor shall work with local emergency rooms, police departments, mental health organizations, and veterans service organizations to engage in outreach to veterans and improve the coordination of mental health care to veterans.

(e) BEST PRACTICES RESEARCH.—In carrying out the comprehensive program, the Secretary shall provide for research on best practices for suicide prevention among veterans. Research shall be conducted under this subsection in consultation with the heads of the following entities:

(1) The Department of Health and Human Services.

(2) The National Institute of Mental Health.

(3) The Substance Abuse and Mental Health Services Administration.

(4) The Centers for Disease Control and Prevention.

(f) SEXUAL TRAUMA RESEARCH.—In carrying out the comprehensive program, the Secretary shall provide for research on mental health care for veterans who have experienced sexual trauma while in military service. The research design shall include consideration of veterans of a reserve component.

(g) 24-HOUR MENTAL HEALTH CARE.—In carrying out the comprehensive program, the Secretary shall provide for mental health care availability to veterans on a 24-hour basis.

(h) HOTLINE.—In carrying out the comprehensive program, the Secretary may provide for a toll-free hotline for veterans to be staffed by appropriately trained mental health personnel and available at all times.

(i) OUTREACH AND EDUCATION FOR VETERANS AND FAMILIES.—In carrying out the comprehensive program, the Secretary shall provide for outreach to and education for veterans and the families of veterans, with special emphasis on providing information to veterans of Operation Iraqi Freedom and Operation Enduring Freedom and the families of such veterans. Education to promote mental health shall include information designed to—

(1) remove the stigma associated with mental illness;

(2) encourage veterans to seek treatment and assistance for mental illness;

(3) promote skills for coping with mental illness; and

(4) help families of veterans with—

(A) understanding issues arising from the readjustment of veterans to civilian life;

(B) identifying signs and symptoms of mental illness; and

(C) encouraging veterans to seek assistance for mental illness.

(j) PEER SUPPORT COUNSELING PROGRAM.—(1) In carrying out the comprehensive program, the Secretary shall establish and carry out a peer support counseling program, under which veterans shall be permitted to volunteer as peer counselors—

(A) to assist other veterans with issues related to mental health and readjustment; and

(B) to conduct outreach to veterans and the families of veterans.

(2) In carrying out the peer support counseling program under this subsection, the Secretary shall provide adequate training for peer counselors, including training carried out under the national program of training required by section 304(c) of the Caregivers and Veterans Omnibus Health Services Act of 2010 (38 U.S.C. 1712A note).

(3) In addition to other locations the Secretary considers appropriate, the Secretary shall carry out the peer support program under this subsection at each Department medical center.

*(4)(A) As part of the counseling program under this subsection, the Secretary shall emphasize appointing peer support counselors for women veterans. To the degree practicable, the Secretary shall seek to recruit women peer support counselors with expertise in—*

*(i) female gender-specific issues and services;*

*(ii) the provision of information about services and benefits provided under laws administered by the Secretary; or*

*(iii) employment mentoring.*

*(B) To the degree practicable, the Secretary shall emphasize facilitating peer support counseling for women veterans who are eligible for counseling and services under section 1720D of this title, have post-traumatic stress disorder or suffer from another mental health condition, are homeless or at risk of becoming homeless, or are otherwise at increased risk of suicide, as determined by the Secretary.*

*(C) The Secretary shall conduct outreach to inform women veterans about the program and the assistance available under this paragraph.*

*(D) In carrying out this paragraph, the Secretary shall coordinate with such community organizations, State and local governments, institutions of higher education, chambers of commerce, local business organizations, organizations that provide legal assistance, and other organizations as the Secretary considers appropriate.*

*(E) In carrying out this paragraph, the Secretary shall provide adequate training for peer support counselors, including training carried out under the national program of training required by section 304(c) of the Caregivers and Veterans Omnibus Health Services Act of 2010 (38 U.S.C. 1712A note).*

(k) OTHER COMPONENTS.—In carrying out the comprehensive program, the Secretary may provide for other actions to reduce the incidence of suicide among veterans that the Secretary considers appropriate.

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## TITLE 40, UNITED STATES CODE

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# SUBTITLE IV—APPALACHIAN REGIONAL DEVELOPMENT

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## CHAPTER 145—SPECIAL APPALACHIAN PROGRAMS

SUBCHAPTER I—PROGRAMS



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SUBCHAPTER I—PROGRAMS

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### *§ 14510. Drug abuse mitigation initiative*

*(a) IN GENERAL.—The Appalachian Regional Commission may provide technical assistance to, make grants to, enter into contracts with, or otherwise provide amounts to individuals or entities in the Appalachian region for projects and activities to address drug abuse, including opioid abuse, in the region, including projects and activities—*

*(1) to facilitate the sharing of best practices among States, counties, and other experts in the region with respect to reducing such abuse;*

*(2) to initiate or expand programs designed to eliminate or reduce the harm to the workforce and economic growth of the region that results from such abuse;*

*(3) to attract and retain relevant health care services, businesses, and workers; and*

*(4) to develop relevant infrastructure, including broadband infrastructure that supports the use of telemedicine.*

*(b) LIMITATION ON AVAILABLE AMOUNTS.—Of the cost of any activity eligible for a grant under this section—*

*(1) not more than 50 percent may be provided from amounts appropriated to carry out this section; and*

*(2) notwithstanding paragraph (1)—*

*(A) in the case of a project to be carried out in a county for which a distressed county designation is in effect under section 14526, not more than 80 percent may be provided from amounts appropriated to carry out this section; and*

*(B) in the case of a project to be carried out in a county for which an at-risk designation is in effect under section 14526, not more than 70 percent may be provided from amounts appropriated to carry out this section.*

*(c) SOURCES OF ASSISTANCE.—Subject to subsection (b), a grant provided under this section may be provided from amounts made available to carry out this section in combination with amounts made available—*

*(1) under any other Federal program (subject to the availability of subsequent appropriations); or*

*(2) from any other source.*

*(d) FEDERAL SHARE.—Notwithstanding any provision of law limiting the Federal share under any other Federal program, amounts made available to carry out this section may be used to increase that Federal share, as the Appalachian Regional Commission determines to be appropriate.*

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## SECTION 1001 OF THE OMNIBUS CRIME CONTROL AND SAFE STREETS ACT OF 1968

AUTHORIZATION OF APPROPRIATIONS

SEC. 1001. (a)(1) There is authorized to be appropriated $30,000,000 for fiscal year 1992 and $33,000,000 for each of the fiscal years 1994 and 1995 to carry out the functions of the Bureau of Justice Statistics.

(2) There is authorized to be appropriated $30,000,000 for fiscal year 1992 and $33,000,000 for each of the fiscal years 1994 and 1995 to carry out the functions of the National Institute of Justice.

(3) There are authorized to be appropriated such sums as may be necessary for fiscal year 1992 and $28,000,000 for each of the fiscal years 1994 and 1995 to carry out the remaining functions of the Office of Justice Programs and the Bureau of Justice Assistance other than functions under parts D, E, F, G, L, M, N, O, P, Q, or R or EE.

(4) There are authorized to be appropriated for each fiscal year such sums as may be necessary to carry out part L of this title.

(5) There are authorized to be appropriated such sums as may be necessary for fiscal year 1992 and $1,000,000,000 for each of the fiscal years 1994 and 1995 to carry out the programs under parts D and E (other than chapter B of subpart 2) (other than chapter B of subpart 2 of part E) of this title.

(6) There are authorized to be appropriated such sums as may be necessary for fiscal year 1992, $245,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994 and 1995 to carry out chapter B of subpart 2 of part E of this title.

(7) There is authorized to be appropriated to carry out part N $1,000,000 for each of fiscal years 2001 through 2005.

(8) There are authorized to be appropriated such sums as may be necessary for fiscal year 1992, $16,500,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994 and 1995.

(9) There are authorized to be appropriated to carry out part O—

(A) $24,000,000 for fiscal year 1996;

(B) $40,000,000 for fiscal year 1997;

(C) $50,000,000 for fiscal year 1998;

(D) $60,000,000 for fiscal year 1999; and

(E) $66,000,000 for fiscal year 2000.

(10) There are authorized to be appropriated $10,000,000 for each of the fiscal years 1994, 1995, and 1996 to carry out projects under part P.

(11)(A) There are authorized to be appropriated to carry out part Q, to remain available until expended $1,047,119,000 for each of fiscal years 2006 through 2009.

(B) Of funds available under part Q in any fiscal year, up to 3 percent may be used for technical assistance under section 1701(d) or for evaluations or studies carried out or commissioned by the Attorney General in furtherance of the purposes of part Q. Of the remaining funds, 50 percent shall be allocated for grants pursuant to applications submitted by units of local government or law enforcement agencies having jurisdiction over areas with populations exceeding 150,000 or

by public and private entities that serve areas with populations exceeding 150,000, and 50 percent shall be allocated for grants pursuant to applications submitted by units of local government or law enforcement agencies having jurisdiction over areas with populations 150,000 or less or by public and private entities that serve areas with populations 150,000 or less. In view of the extraordinary need for law enforcement assistance in Indian country, an appropriate amount of funds available under part Q shall be made available for grants to Indian tribal governments or tribal law enforcement agencies.

(16) There are authorized to be appropriated to carry out projects under part R—

(A) $20,000,000 for fiscal year 1996;
(B) $25,000,000 for fiscal year 1997;
(C) $30,000,000 for fiscal year 1998;
(D) $35,000,000 for fiscal year 1999; and
(E) $40,000,000 for fiscal year 2000.

(17) There are authorized to be appropriated to carry out the projects under part S—

(A) $27,000,000 for fiscal year 1996;
(B) $36,000,000 for fiscal year 1997;
(C) $63,000,000 for fiscal year 1998;
(D) $72,000,000 for fiscal year 1999; and
(E) $72,000,000 for fiscal year 2000.

(18) There is authorized to be appropriated to carry out part T $222,000,000 for each of fiscal years 2014 through 2018.

(19) There is authorized to be appropriated to carry out part U $73,000,000 for each of fiscal years 2014 through 2018. Funds appropriated under this paragraph shall remain available until expended.

(20) There are authorized to be appropriated to carry out part V, $10,000,000 for each of fiscal years 2001 through 2004.

(21) There are authorized to be appropriated to carry out part W—

(1) $2,500,000 for fiscal year 1996;
(2) $4,000,000 for fiscal year 1997;
(3) $5,000,000 for fiscal year 1998;
(4) $6,000,000 for fiscal year 1999; and
(5) $7,500,000 for fiscal year 2000.

(22) There are authorized to be appropriated to carry out part X—

(1) $1,000,000 for fiscal year 1996;
(2) $3,000,000 for fiscal year 1997;
(3) $5,000,000 for fiscal year 1998;
(4) $13,500,000 for fiscal year 1999; and
(5) $17,500,000 for fiscal year 2000.

(23) There is authorized to be appropriated to carry out part Y, $25,000,000 for each of fiscal years 2016through 2020.

(24) There are authorized to be appropriated to carry out part BB, to remain available until expended—

(A) $35,000,000 for fiscal year 2001;
(B) $85,400,000 for fiscal year 2002;
(C) $134,733,000 for fiscal year 2003;
(D) $128,067,000 for fiscal year 2004;
(E) $56,733,000 for fiscal year 2005;
(F) $42,067,000 for fiscal year 2006;
(G) $20,000,000 for fiscal year 2007;
(H) $20,000,000 for fiscal year 2008;
(I) $20,000,000 for fiscal year 2009; and
(J) $13,500,000 for fiscal year 2017;
(K) $18,500,000 for fiscal year 2018;
(L) $19,000,000 for fiscal year 2019;
(M) $21,000,000 for fiscal year 2020; and
(N) $23,000,000 for fiscal year 2021.

(25)(A) Except as provided in subparagraph (C), there are authorized to be appropriated to carry out part EE—

(i) $50,000,000 for fiscal year 2002;

(ii) $54,000,000 for fiscal year 2003;
(iii) $58,000,000 for fiscal year 2004; and
(iv) $60,000,000 for fiscal year 2005.
(v) $70,000,000 for each of fiscal years 2007 and 2008.
(v) $70,000,000 for fiscal year 2006.

(B) The Attorney General shall reserve not less than 1 percent and not more than 4.5 percent of the sums appropriated for this program in each fiscal year for research and evaluation of this program.

(C) No funds made available to carry out part EE shall be expended if the Attorney General fails to submit the report required to be submitted under section 2401(c) of title II of Division B of the 21st Century Department of Justice Appropriations Authorization Act.

(26) There are authorized to be appropriated to carry out part CC $10,000,000 for each of fiscal years 2009 and 2010.

(27) There are authorized to be appropriated to carry out part LL $103,000,000 for each of fiscal years 2017 **[**through 2021**]** *and 2018, and $330,000,000 for each of fiscal years 2019 through 2023*.

(b) Funds appropriated for any fiscal year may remain available for obligation until expended.

(c) Notwithstanding any other provision of law, no funds appropriated under this section for part E of this title may be transferred or reprogrammed for carrying out any activity which is not authorized under such part.

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