DECEMBER 6, 2019

RULES COMMITTEE PRINT 116–41

TEXT OF H.R. 3, ELIJAH E. CUMMINGS LOWER DRUG COSTS NOW ACT

[Showing the text of H.R. 3, as ordered reported by the Committee on Energy and Commerce, the Committee on Ways and Means, and the Committee on Education and Labor, with modifications.]

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Elijah E. Cummings Lower Drug Costs Now Act''.

(b) TABLE OF CONTENTS.—The table of contents is as follows:

TITLE I—LOWERING PRICES THROUGH FAIR DRUG PRICE NEGOTIATION

SEC. 101. PROVIDING FOR LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS.

(a) PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part:

"PART E—FAIR PRICE NEGOTIATION PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS

"SEC. 1191. ESTABLISHMENT OF PROGRAM.

"(a) IN GENERAL.—The Secretary shall establish a Fair Price Negotiation Program (in this part referred to

as the 'program'). Under the program, with respect to each price applicability period, the Secretary shall—

''(1) publish a list of selected drugs in accordance with section 1192;

''(2) enter into agreements with manufacturers of selected drugs with respect to such period, in accordance with section 1193;

''(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1194; and

''(4) carry out the administrative duties described in section 1196.

''(b) DEFINITIONS RELATING TO TIMING.—For purposes of this part:

''(1) INITIAL PRICE APPLICABILITY YEAR.—The term 'initial price applicability year' means a plan year (beginning with plan year 2023) or, if agreed to in an agreement under section 1193 by the Secretary and manufacturer involved, a period of more than one plan year (beginning on or after January 1, 2023).

''(2) PRICE APPLICABILITY PERIOD.—The term 'price applicability period' means, with respect to a drug, the period beginning with the initial price applicability year with respect to which such drug is a

selected drug and ending with the last plan year during which the drug is a selected drug.

''(3) SELECTED DRUG PUBLICATION DATE.—The term 'selected drug publication date' means, with respect to each initial price applicability year, April 15 of the plan year that begins 2 years prior to such year.

''(4) VOLUNTARY NEGOTIATION PERIOD.—The term 'voluntary negotiation period' means, with respect to an initial price applicability year with respect to a selected drug, the period—

''(A) beginning on the sooner of—

''(i) the date on which the manufacturer of the drug and the Secretary enter into an agreement under section 1193 with respect to such drug; or

''(ii) June 15 following the selected drug publication date with respect to such selected drug; and

''(B) ending on March 31 of the year that begins one year prior to the initial price applicability year.

''(c) OTHER DEFINITIONS.—For purposes of this part:

''(1) FAIR PRICE ELIGIBLE INDIVIDUAL.—The term 'fair price eligible individual' means, with respect to a selected drug—

''(A) in the case such drug is furnished or dispensed to the individual at a pharmacy or by a mail order service—

''(i) an individual who is enrolled under a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title if coverage is provided under such plan for such selected drug; and

''(ii) an individual who is enrolled under a group health plan or health insurance coverage offered in the group or individual market (as such terms are defined in section 2791 of the Public Health Service Act) with respect to which there is in effect an agreement with the Secretary under section 1197 with respect to such selected drug as so furnished or dispensed; and

''(B) in the case such drug is furnished or administered to the individual by a hospital,

physician, or other provider of services or supplier—

''(i) an individual who is entitled to benefits under part A of title XVIII or enrolled under part B of such title if such selected drug is covered under the respective part; and

''(ii) an individual who is enrolled under a group health plan or health insurance coverage offered in the group or individual market (as such terms are defined in section 2791 of the Public Health Service Act) with respect to which there is in effect an agreement with the Secretary under section 1197 with respect to such selected drug as so furnished or administered.

''(2) MAXIMUM FAIR PRICE.—The term 'maximum fair price' means, with respect to a plan year during a price applicability period and with respect to a selected drug (as defined in section 1192(c)) with respect to such period, the price published pursuant to section 1195 in the Federal Register for such drug and year.

''(3) AVERAGE INTERNATIONAL MARKET PRICE DEFINED.—

''(A) IN GENERAL.—The terms 'average international market price' and 'AIM price' mean, with respect to a drug, the average price (which shall be the net average price, if practicable, and volume-weighted, if practicable) for a unit (as defined in paragraph (4)) of the drug for sales of such drug (calculated across different dosage forms and strengths of the drug and not based on the specific formulation or package size or package type), as computed (as of the date of publication of such drug as a selected drug under section 1192(a)) in all countries described in clause (ii) of subparagraph (B) that are applicable countries (as described in clause (i) of such subparagraph) with respect to such drug.

''(B) APPLICABLE COUNTRIES.—

''(i) IN GENERAL.—For purposes of subparagraph (A), a country described in clause (ii) is an applicable country described in this clause with respect to a drug if there is available an average price

for any unit for the drug for sales of such drug in such country.

''(ii) COUNTRIES DESCRIBED.—For purposes of this paragraph, the following are countries described in this clause:

''(I) Australia.

''(II) Canada.

''(III) France.

''(IV) Germany.

''(V) Japan.

''(VI) The United Kingdom.

''(4) UNIT.—The term 'unit' means, with respect to a drug, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug that is dispensed.

''SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS AS SELECTED DRUGS.

''(a) IN GENERAL.—Not later than the selected drug publication date with respect to an initial price applicability year, the Secretary shall select and publish in the Federal Register a list of—

''(1)(A) with respect to an initial price applicability year during the period beginning with 2023 and ending with 2027, at least 25 negotiation-eligible drugs described in subparagraphs (A) and (B),

but not subparagraph (C), of subsection (d)(1) (or, with respect to an initial price applicability year during such period beginning after 2023, the maximum number (if such number is less than 25) of such negotiation-eligible drugs for the year) with respect to such year;

''(B) with respect to an initial price applicability year during the period beginning with 2028 and ending with 2032, at least 30 negotiation-eligible drugs described in subparagraphs (A) and (B), but not subparagraph (C), of subsection (d)(1) (or, with respect to an initial price applicability year during such period, the maximum number (if such number is less than 30) of such negotiation-eligible drugs for the year) with respect to such year; and

''(C) with respect to an initial price applicability year beginning after 2032, at least 35 negotiation-eligible drugs described in subparagraphs (A) and (B), but not subparagraph (C), of subsection (d)(1) (or, with respect to an initial price applicability year during such period, the maximum number (if such number is less than 35) of such negotiation-eligible drugs for the year) with respect to such year;

''(2) all negotiation-eligible drugs described in subparagraph (C) of such subsection with respect to such year; and

''(3) all new-entrant negotiation-eligible drugs (as defined in subsection (g)(1)) with respect to such year.

Each drug published on the list pursuant to the previous sentence shall be subject to the negotiation process under section 1194 for the voluntary negotiation period with respect to such initial price applicability year (and the renegotiation process under such section as applicable for any subsequent year during the applicable price applicability period). In applying this subsection, any negotiation-eligible drug that is selected under this subsection for an initial price applicability year shall not count toward the required minimum amount of drugs to be selected under paragraph (1) for any subsequent year, including such a drug so selected that is subject to renegotiation under section 1194.

''(b) SELECTION OF DRUGS.—In carrying out subsection (a)(1) the Secretary shall select for inclusion on the published list described in subsection (a) with respect to a price applicability period, the negotiation-eligible drugs that the Secretary projects will result in the greatest savings to the Federal Government or fair price eligible

individuals during the price applicability period. In making this projection of savings for drugs for which there is an AIM price for a price applicability period, the savings shall be projected across different dosage forms and strengths of the drugs and not based on the specific formulation or package size or package type of the drugs, taking into consideration both the volume of drugs for which payment is made, to the extent such data is available, and the amount by which the net price for the drugs exceeds the AIM price for the drugs.

''(c) SELECTED DRUG.—For purposes of this part, each drug included on the list published under subsection (a) with respect to an initial price applicability year shall be referred to as a 'selected drug' with respect to such year and each subsequent plan year beginning before the first plan year beginning after the date on which the Secretary determines two or more drug products—

''(1) are approved or licensed (as applicable)—

''(A) under section 505(j) of the Federal Food, Drug, and Cosmetic Act using such drug as the listed drug; or

''(B) under section 351(k) of the Public Health Service Act using such drug as the reference product; and

''(2) continue to be marketed.

''(d) NEGOTIATION-ELIGIBLE DRUG.—

''(1) IN GENERAL.—For purposes of this part, the term 'negotiation-eligible drug' means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in subsection (e), that meets any of the following criteria:

''(A) COVERED PART D DRUGS.—The drug is among the 125 covered part D drugs (as defined in section 1860D–2(e)) for which there was an estimated greatest net spending under parts C and D of title XVIII, as determined by the Secretary, during the most recent plan year prior to such drug publication date for which data are available.

''(B) OTHER DRUGS.—The drug is among the 125 drugs for which there was an estimated greatest net spending in the United States (including the 50 States, the District of Columbia, and the territories of the United States), as determined by the Secretary, during the most recent plan year prior to such drug publication date for which data are available.

''(C) INSULIN.—The drug is a qualifying single source drug described in subsection (e)(3).

''(2) CLARIFICATION.—In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1), the Secretary shall, to the extent practicable, use data that is aggregated across dosage forms and strengths of the drug and not based on the specific formulation or package size or package type of the drug.

''(3) PUBLICATION.—Not later than the selected drug publication date with respect to an initial price applicability year, the Secretary shall publish in the Federal Register a list of negotiation-eligible drugs with respect to such selected drug publication date.

''(e) QUALIFYING SINGLE SOURCE DRUG.—For purposes of this part, the term 'qualifying single source drug' means any of the following:

''(1) DRUG PRODUCTS.—A drug that—

''(A) is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and continues to be marketed pursuant to such approval; and

''(B) is not the listed drug for any drug that is approved and continues to be marketed under section 505(j) of such Act.

''(2) BIOLOGICAL PRODUCTS.—A biological product that—

''(A) is licensed under section 351(a) of the Public Health Service Act, including any product that has been deemed to be licensed under section 351 of such Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009, and continues to be marketed under section 351 of such Act; and

''(B) is not the reference product for any biological product that is licensed and continues to be marketed under section 351(k) of such Act.

''(3) INSULIN PRODUCT.—Notwithstanding paragraphs (1) and (2), any insulin product that is approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under subsection (a) or (k) of section 351 of the Public Health Service Act and continues to be marketed under such section 505 or 351, including any insulin product that has been deemed to be li-

censed under section 351(a) of the Public Health Service Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and continues to be marketed pursuant to such licensure.

For purposes of applying paragraphs (1) and (2), a drug or biological product that is marketed by the same sponsor or manufacturer (or an affiliate thereof or a cross-licensed producer or distributor) as the listed drug or reference product described in such respective paragraph shall not be taken into consideration.

''(f) INFORMATION ON INTERNATIONAL DRUG PRICES.—For purposes of determining which negotiation-eligible drugs to select under subsection (a) and, in the case of such drugs that are selected drugs, to determine the maximum fair price for such a drug and whether such maximum fair price should be renegotiated under section 1194, the Secretary shall use data relating to the AIM price with respect to such drug as available or provided to the Secretary and shall on an ongoing basis request from manufacturers of selected drugs information on the AIM price of such a drug.

''(g) NEW-ENTRANT NEGOTIATION-ELIGIBLE DRUGS.—

''(1) IN GENERAL.—For purposes of this part, the term 'new-entrant negotiation-eligible drug' means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug—

''(A) that is first approved or licensed, as described in paragraph (1), (2), or (3) of subsection (e), as applicable, during the year preceding such selected drug publication date; and

''(B) that the Secretary determines under paragraph (2) is likely to be included as a negotiation-eligible drug with respect to the subsequent selected drug publication date.

''(2) DETERMINATION.—In the case of a qualifying single source drug that meets the criteria described in subparagraph (A) of paragraph (1), with respect to an initial price applicability year, if the wholesale acquisition cost at which such drug is first marketed in the United States is equal to or greater than the median household income (as determined according to the most recent data collected by the United States Census Bureau), the Secretary shall determine before the selected drug publication date with respect to the initial price applicability year, if the drug is likely to be included as a negotiation-eli-

gible drug with respect to the subsequent selected drug publication date, based on the projected spending under title XVIII or in the United States on such drug. For purposes of this paragraph the term 'United States' includes the 50 States, the District of Columbia, and the territories of the United States.

"SEC. 1193. MANUFACTURER AGREEMENTS.

''(a) IN GENERAL.—For purposes of section 1191(a)(2), the Secretary shall enter into agreements with manufacturers of selected drugs with respect to a price applicability period, by not later than June 15 following the selected drug publication date with respect to such selected drug, under which—

''(1) during the voluntary negotiation period for the initial price applicability year for the selected drug, the Secretary and manufacturer, in accordance with section 1194, negotiate to determine (and, by not later than the last date of such period and in accordance with subsection (c), agree to) a maximum fair price for such selected drug of the manufacturer in order to provide access to such price—

''(A) to fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1191(c)(1) and are

furnished or dispensed such drug during, subject to subparagraph (2), the price applicability period; and

''(B) to hospitals, physicians, and other providers of services and suppliers with respect to fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during, subject to subparagraph (2), the price applicability period;

''(2) the Secretary and the manufacturer shall, in accordance with a process and during a period specified by the Secretary pursuant to rulemaking, renegotiate (and, by not later than the last date of such period and in accordance with subsection (c), agree to) the maximum fair price for such drug if the Secretary determines that there is a material change in any of the factors described in section 1194(d) relating to the drug, including changes in the AIM price for such drug, in order to provide access to such maximum fair price (as so renegotiated)—

''(A) to fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1191(c)(1) and are

furnished or dispensed such drug during any year during the price applicability period (beginning after such renegotiation) with respect to such selected drug; and

''(B) to hospitals, physicians, and other providers of services and suppliers with respect to fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during any year described in subparagraph (A);

''(3) the maximum fair price (including as renegotiated pursuant to paragraph (2)), with respect to such a selected drug, shall be provided to fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1191(c)(1), at the pharmacy or by a mail order service at the point-of-sale of such drug;

''(4) the manufacturer, subject to subsection (d), submits to the Secretary, in a form and manner specified by the Secretary—

''(A) for the voluntary negotiation period for the price applicability period (and, if applicable, before any period of renegotiation specified pursuant to paragraph (2)) with respect to

such drug all information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part, including information described in section 1192(f) and section 1194(d)(1); and

''(B) on an ongoing basis, information on changes in prices for such drug that would affect the AIM price for such drug or otherwise provide a basis for renegotiation of the maximum fair price for such drug pursuant to paragraph (2);

''(5) the manufacturer agrees that in the case the selected drug of a manufacturer is a drug described in subsection (c), the manufacturer will, in accordance with such subsection, make any payment required under such subsection with respect to such drug; and

''(6) the manufacturer complies with requirements imposed by the Secretary for purposes of administering the program, including with respect to the duties described in section 1196.

''(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO LONGER A SELECTED DRUG.—An agreement entered into under this section shall be effective, with respect to a drug,

until such drug is no longer considered a selected drug under section 1192(c).

''(c) SPECIAL RULE FOR CERTAIN SELECTED DRUGS WITHOUT AIM PRICE.—

''(1) IN GENERAL.—In the case of a selected drug for which there is no AIM price available with respect to the initial price applicability year for such drug and for which an AIM price becomes available beginning with respect to a subsequent plan year during the price applicability period for such drug, if the Secretary determines that the amount described in paragraph (2)(A) for a unit of such drug is greater than the amount described in paragraph (2)(B) for a unit of such drug, then by not later than one year after the date of such determination, the manufacturer of such selected drug shall pay to the Treasury an amount equal to the product of—

''(A) the difference between such amount described in paragraph (2)(A) for a unit of such drug and such amount described in paragraph (2)(B) for a unit of such drug; and

''(B) the number of units of such drug sold in the United States, including the 50 States, the District of Columbia, and the territories of

the United States, during the period described in paragraph (2)(B).

''(2) AMOUNTS DESCRIBED.—

''(A) WEIGHTED AVERAGE PRICE BEFORE AIM PRICE AVAILABLE.—For purposes of paragraph (1), the amount described in this subparagraph for a selected drug described in such paragraph, is the amount equal to the weighted average manufacturer price (as defined in section 1927(k)(1)) for such dosage strength and form for the drug during the period beginning with the first plan year for which the drug is included on the list of negotiation-eligible drugs published under section 1192(d) and ending with the last plan year during the price applicability period for such drug with respect to which there is no AIM price available for such drug.

''(B) AMOUNT MULTIPLIER AFTER AIM PRICE AVAILABLE.—For purposes of paragraph (1), the amount described in this subparagraph for a selected drug described in such paragraph, is the amount equal to 200 percent of the AIM price for such drug with respect to the first plan year during the price applicability period

for such drug with respect to which there is an AIM price available for such drug.

''(d) CONFIDENTIALITY OF INFORMATION.—Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) may be used only by the Secretary or disclosed to and used by the Comptroller General of the United States or the Medicare Payment Advisory Commission for purposes of carrying out this part.

''(e) REGULATIONS.—

''(1) IN GENERAL.—The Secretary shall, pursuant to rulemaking, specify, in accordance with paragraph (2), the information that must be submitted under subsection (a)(4).

''(2) INFORMATION SPECIFIED.—Information described in paragraph (1), with respect to a selected drug, shall include information on sales of the drug (by the manufacturer of the drug or by another entity under license or other agreement with the manufacturer, with respect to the sales of such drug, regardless of the name under which the drug is sold) in any foreign country that is part of the AIM price. The Secretary shall verify, to the extent practicable,

such sales from appropriate officials of the government of the foreign country involved.

''(f) COMPLIANCE WITH REQUIREMENTS FOR ADMINISTRATION OF PROGRAM.—Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under section 1196(c)(1), as applicable, for purposes of administering the program.

''SEC. 1194. NEGOTIATION AND RENEGOTIATION PROCESS.

''(a) IN GENERAL.—For purposes of this part, under an agreement under section 1193 between the Secretary and a manufacturer of a selected drug, with respect to the period for which such agreement is in effect and in accordance with subsections (b) and (c), the Secretary and the manufacturer—

''(1) shall during the voluntary negotiation period with respect to the initial price applicability year for such drug, in accordance with this section, negotiate a maximum fair price for such drug for the purpose described in section 1193(a)(1); and

''(2) as applicable pursuant to section 1193(a)(2) and in accordance with the process specified pursuant to such section, renegotiate such maximum fair price for such drug for the purpose described in such section.

''(b) NEGOTIATING METHODOLOGY AND OBJECTIVE.—

''(1) IN GENERAL.—The Secretary shall develop and use a consistent methodology for negotiations under subsection (a) that, in accordance with paragraph (2) and subject to paragraph (3), achieves the lowest maximum fair price for each selected drug while appropriately rewarding innovation.

''(2) PRIORITIZING FACTORS.—In considering the factors described in subsection (d) in negotiating (and, as applicable, renegotiating) the maximum fair price for a selected drug, the Secretary shall, to the extent practicable, consider all of the available factors listed but shall prioritize the following factors:

''(A) RESEARCH AND DEVELOPMENT COSTS.—The factor described in paragraph (1)(A) of subsection (d).

''(B) MARKET DATA.—The factor described in paragraph (1)(B) of such subsection.

''(C) UNIT COSTS OF PRODUCTION AND DISTRIBUTION.—The factor described in paragraph (1)(C) of such subsection.

''(D) COMPARISON TO EXISTING THERAPEUTIC ALTERNATIVES.—The factor described in paragraph (2)(A) of such subsection.

''(3) REQUIREMENT.—

''(A) IN GENERAL.—In negotiating the maximum fair price of a selected drug, with respect to an initial price applicability year for the selected drug, and, as applicable, in renegotiating the maximum fair price for such drug, with respect to a subsequent year during the price applicability period for such drug, in the case that the manufacturer of the selected drug offers under the negotiation or renegotiation, as applicable, a price for such drug that is not more than the target price described in subparagraph (B) for such drug for the respective year, the Secretary shall agree under such negotiation or renegotiation, respectively, to such offered price as the maximum fair price.

''(B) TARGET PRICE.—

''(i) IN GENERAL.—Subject to clause (ii), the target price described in this subparagraph for a selected drug with respect to a year, is the average price (which shall be the net average price, if practicable, and volume-weighted, if practicable) for a unit of such drug for sales of such drug, as computed (across different dosage forms

and strengths of the drug and not based on the specific formulation or package size or package type of the drug) in the applicable country described in section 1191(c)(3)(B) with respect to such drug that, with respect to such year, has the lowest average price for such drug as compared to the average prices (as so computed) of such drug with respect to such year in the other applicable countries described in such section with respect to such drug.

''(ii) SELECTED DRUGS WITHOUT AIM PRICE.—In applying this paragraph in the case of negotiating the maximum fair price of a selected drug for which there is no AIM price available with respect to the initial price applicability year for such drug, or, as applicable, renegotiating the maximum fair price for such drug with respect to a subsequent year during the price applicability period for such drug before the first plan year for which there is an AIM price available for such drug, the target price described in this subparagraph for

such drug and respective year is the amount that is 80 percent of the average manufacturer price (as defined in section 1927(k)(1)) for such drug and year.

''(4) ANNUAL REPORT.—After the completion of each voluntary negotiation period, the Secretary shall submit to Congress a report on the maximum fair prices negotiated (or, as applicable, renegotiated) for such period. Such report shall include information on how such prices so negotiated (or renegotiated) meet the requirements of this part, including the requirements of this subsection.

''(c) LIMITATION.—

''(1) IN GENERAL.—Subject to paragraph (2), the maximum fair price negotiated (including as renegotiated) under this section for a selected drug, with respect to each plan year during a price applicability period for such drug, shall not exceed 120 percent of the AIM price applicable to such drug with respect to such year.

''(2) SELECTED DRUGS WITHOUT AIM PRICE.—In the case of a selected drug for which there is no AIM price available with respect to the initial price applicability year for such drug, for each plan year during the price applicability period before the first

plan year for which there is an AIM price available for such drug, the maximum fair price negotiated (including as renegotiated) under this section for the selected drug shall not exceed the amount equal to 85 percent of the average manufacturer price for the drug with respect to such year.

''(d) CONSIDERATIONS.—For purposes of negotiating and, as applicable, renegotiating (including for purposes of determining whether to renegotiate) the maximum fair price of a selected drug under this part with the manufacturer of the drug, the Secretary, consistent with subsection (b)(2), shall take into consideration the factors described in paragraphs (1), (2), (3), and (5), and may take into consideration the factor described in paragraph (4):

''(1) MANUFACTURER-SPECIFIC INFORMATION.—The following information, including as submitted by the manufacturer:

''(A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.

''(B) Market data for the drug, including the distribution of sales across different programs and purchasers and projected future revenues for the drug.

''(C) Unit costs of production and distribution of the drug.

''(D) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.

''(E) Data on patents and on existing and pending exclusivity for the drug.

''(F) National sales data for the drug.

''(G) Information on clinical trials for the drug in the United States or in applicable countries described in section 1191(c)(3)(B).

''(2) INFORMATION ON ALTERNATIVE PRODUCTS.—The following information:

''(A) The extent to which the drug represents a therapeutic advance as compared to existing therapeutic alternatives and, to the extent such information is available, the costs of such existing therapeutic alternatives.

''(B) Information on approval by the Food and Drug Administration of alternative drug products.

''(C) Information on comparative effectiveness analysis for such products, taking into consideration the effects of such products on specific populations, such as individuals with

disabilities, the elderly, terminally ill, children, and other patient populations.

In considering information described in subparagraph (C), the Secretary shall not use evidence or findings from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Nothing in the previous sentence shall affect the application or consideration of an AIM price for a selected drug.

''(3) FOREIGN SALES INFORMATION.—To the extent available on a timely basis, including as provided by a manufacturer of the selected drug or otherwise, information on sales of the selected drug in each of the countries described in section 1191(c)(3)(B).

''(4) VA DRUG PRICING INFORMATION.—Information disclosed to the Secretary pursuant to subsection (f).

''(5) ADDITIONAL INFORMATION.—Information submitted to the Secretary, in accordance with a process specified by the Secretary, by other parties

that are affected by the establishment of a maximum fair price for the selected drug.

''(e) REQUEST FOR INFORMATION.—For purposes of negotiating and, as applicable, renegotiating (including for purposes of determining whether to renegotiate) the maximum fair price of a selected drug under this part with the manufacturer of the drug, with respect to a price applicability period, and other relevant data for purposes of this section—

''(1) the Secretary shall, not later than the selected drug publication date with respect to the initial price applicability year of such period, request drug pricing information from the manufacturer of such selected drug, including information described in subsection (d)(1); and

''(2) by not later than October 1 following the selected drug publication date, the manufacturer of such selected drug shall submit to the Secretary such requested information in such form and manner as the Secretary may require.

The Secretary shall request, from the manufacturer or others, such additional information as may be needed to carry out the negotiation and renegotiation process under this section.

''(f) DISCLOSURE OF INFORMATION.—For purposes of this part, the Secretary of Veterans Affairs may disclose to the Secretary of Health and Human Services the price of any negotiation-eligible drug that is purchased pursuant to section 8126 of title 38, United States Code.

"SEC. 1195. PUBLICATION OF MAXIMUM FAIR PRICES.

''(a) IN GENERAL.—With respect to an initial price applicability year and selected drug with respect to such year, not later than April 1 of the plan year prior to such initial price applicability year, the Secretary shall publish in the Federal Register the maximum fair price for such drug negotiated under this part with the manufacturer of such drug.

''(b) UPDATES.—

''(1) SUBSEQUENT YEAR MAXIMUM FAIR PRICES.—For a selected drug, for each plan year subsequent to the initial price applicability year for such drug with respect to which an agreement for such drug is in effect under section 1193, the Secretary shall publish in the Federal Register—

''(A) subject to subparagraph (B), the amount equal to the maximum fair price published for such drug for the previous year, increased by the annual percentage increase in the consumer price index for all urban con-

sumers (all items; U.S. city average) as of September of such previous year; or

''(B) in the case the maximum fair price for such drug was renegotiated, for the first year for which such price as so renegotiated applies, such renegotiated maximum fair price.

''(2) PRICES NEGOTIATED AFTER DEADLINE.—In the case of a selected drug with respect to an initial price applicability year for which the maximum fair price is determined under this part after the date of publication under this section, the Secretary shall publish such maximum fair price in the Federal Register by not later than 30 days after the date such maximum price is so determined.

''SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PROVISIONS.

''(a) ADMINISTRATIVE DUTIES.—

''(1) IN GENERAL.—For purposes of section 1191, the administrative duties described in this section are the following:

''(A) The establishment of procedures (including through agreements with manufacturers under this part, contracts with prescription drug plans under part D of title XVIII and MA–PD plans under part C of such title, and

agreements under section 1197 with group health plans and health insurance issuers of health insurance coverage offered in the individual or group market) under which the maximum fair price for a selected drug is provided to fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1191(c)(1), at pharmacies or by mail order service at the point-of-sale of the drug for the applicable price period for such drug and providing that such maximum fair price is used for determining cost-sharing under such plans or coverage for the selected drug.

''(B) The establishment of procedures (including through agreements with manufacturers under this part and contracts with hospitals, physicians, and other providers of services and suppliers and agreements under section 1197 with group health plans and health insurance issuers of health insurance coverage offered in the individual or group market) under which, in the case of a selected drug furnished or administered by such a hospital, physician, or other provider of services or supplier to fair price eligible individuals (who with respect to such drug

are described in subparagraph (B) of section 1191(c)(1)), the maximum fair price for the selected drug is provided to such hospitals, physicians, and other providers of services and suppliers (as applicable) with respect to such individuals and providing that such maximum fair price is used for determining cost-sharing under the respective part, plan, or coverage for the selected drug.

''(C) The establishment of procedures (including through agreements and contracts described in subparagraphs (A) and (B)) to ensure that, not later than 90 days after the dispensing of a selected drug to a fair price eligible individual by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

''(i) the lesser of—

''(I) the wholesale acquisition cost of the drug;

''(II) the national average drug acquisition cost of the drug; and

''(III) any other similar determination of pharmacy acquisition

costs of the drug, as determined by the Secretary; and

''(ii) the maximum fair price for the drug.

''(D) The establishment of procedures to ensure that the maximum fair price for a selected drug is applied before—

''(i) any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of fair price eligible individuals as the Secretary may specify; and

''(ii) any other discounts.

''(E) The establishment of procedures to enter into appropriate agreements and protocols for the ongoing computation of AIM prices for selected drugs, including, to the extent possible, to compute the AIM price for selected drugs and including by providing that the manufacturer of such a selected drug should provide information for such computation not later than 3 months after the first date of the voluntary negotiation period for such selected drug.

''(F) The establishment of procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of the drug.

''(G) The establishment of procedures to negotiate and apply the maximum fair price in a manner that does not include any dispensing or similar fee.

''(H) The establishment of procedures to carry out the provisions of this part, as applicable, with respect to—

''(i) fair price eligible individuals who are enrolled under a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title;

''(ii) fair price eligible individuals who are enrolled under a group health plan or health insurance coverage offered by a health insurance issuer in the individual or group market with respect to which there is an agreement in effect under section 1197; and

''(iii) fair price eligible individuals who are entitled to benefits under part A of title XVIII or enrolled under part B of such title.

''(I) The establishment of a negotiation process and renegotiation process in accordance with section 1194, including a process for acquiring information described in subsection (d) of such section and determining amounts described in subsection (b) of such section.

''(J) The provision of a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, fair price eligible individuals, and the third party with a contract under subsection (c)(1).

''(2) MONITORING COMPLIANCE.—

''(A) IN GENERAL.—The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under section 1193, including by establishing a mechanism through which violations of such terms may be reported.

''(B) NOTIFICATION.—If a third party with a contract under subsection (c)(1) determines that the manufacturer is not in compliance with such agreement, the third party shall

notify the Secretary of such noncompliance for appropriate enforcement under section 4192 of the Internal Revenue Code of 1986 or section 1198, as applicable.

''(b) COLLECTION OF DATA.—

''(1) FROM PRESCRIPTION DRUG PLANS AND MA–PD PLANS.—The Secretary may collect appropriate data from prescription drug plans under part D of title XVIII and MA–PD plans under part C of such title in a timeframe that allows for maximum fair prices to be provided under this part for selected drugs.

''(2) FROM HEALTH PLANS.—The Secretary may collect appropriate data from group health plans or health insurance issuers offering group or individual health insurance coverage in a timeframe that allows for maximum fair prices to be provided under this part for selected drugs.

''(3) COORDINATION OF DATA COLLECTION.—To the extent feasible, as determined by the Secretary, the Secretary shall ensure that data collected pursuant to this subsection is coordinated with, and not duplicative of, other Federal data collection efforts.

''(c) CONTRACT WITH THIRD PARTIES.—

''(1) IN GENERAL.—The Secretary may enter into a contract with 1 or more third parties to administer the requirements established by the Secretary in order to carry out this part. At a minimum, the contract with a third party under the preceding sentence shall require that the third party—

''(A) receive and transmit information between the Secretary, manufacturers, and other individuals or entities the Secretary determines appropriate;

''(B) receive, distribute, or facilitate the distribution of funds of manufacturers to appropriate individuals or entities in order to meet the obligations of manufacturers under agreements under this part;

''(C) provide adequate and timely information to manufacturers, consistent with the agreement with the manufacturer under this part, as necessary for the manufacturer to fulfill its obligations under this part; and

''(D) permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the third party to determine discounts for applicable drugs of the manufacturer under the program.

''(2) PERFORMANCE REQUIREMENTS.—The Secretary shall establish performance requirements for a third party with a contract under paragraph (1) and safeguards to protect the independence and integrity of the activities carried out by the third party under the program under this part.

"SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER HEALTH PLANS.

''(a) AGREEMENT TO PARTICIPATE UNDER PROGRAM.—

''(1) IN GENERAL.—Subject to paragraph (2), under the program under this part the Secretary shall be treated as having in effect an agreement with a group health plan or health insurance issuer offering group or individual health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act), with respect to a price applicability period and a selected drug with respect to such period—

''(A) with respect to such selected drug furnished or dispensed at a pharmacy or by mail order service if coverage is provided under such plan or coverage during such period for such selected drug as so furnished or dispensed; and

"(B) with respect to such selected drug furnished or administered by a hospital, physician, or other provider of services or supplier if coverage is provided under such plan or coverage during such period for such selected drug as so furnished or administered.

"(2) OPTING OUT OF AGREEMENT.—The Secretary shall not be treated as having in effect an agreement under the program under this part with a group health plan or health insurance issuer offering group or individual health insurance coverage with respect to a price applicability period and a selected drug with respect to such period if such a plan or issuer affirmatively elects, through a process specified by the Secretary, not to participate under the program with respect to such period and drug.

"(b) PUBLICATION OF ELECTION.—With respect to each price applicability period and each selected drug with respect to such period, the Secretary and the Secretary of Labor and the Secretary of the Treasury, as applicable, shall make public a list of each group health plan and each health insurance issuer offering group or individual health insurance coverage, with respect to which coverage is provided under such plan or coverage for such drug, that has

elected under subsection (a) not to participate under the program with respect to such period and drug.

"SEC. 1198. CIVIL MONETARY PENALTY.

''(a) VIOLATIONS RELATING TO OFFERING OF MAXIMUM FAIR PRICE.—Any manufacturer of a selected drug that has entered into an agreement under section 1193, with respect to a plan year during the price applicability period for such drug, that does not provide access to a price that is not more than the maximum fair price (or a lesser price) for such drug for such year—

''(1) to a fair price eligible individual who with respect to such drug is described in subparagraph (A) of section 1191(c)(1) and who is furnished or dispensed such drug during such year; or

''(2) to a hospital, physician, or other provider of services or supplier with respect to fair price eligible individuals who with respect to such drug is described in subparagraph (B) of such section and is furnished or administered such drug by such hospital, physician, or provider or supplier during such year;

shall be subject to a civil monetary penalty equal to ten times the amount equal to the difference between the price for such drug made available for such year by such manufacturer with respect to such individual or hospital, physi-

cian, provider, or supplier and the maximum fair price for such drug for such year.

''(b) VIOLATIONS OF CERTAIN TERMS OF AGREEMENT.—Any manufacturer of a selected drug that has entered into an agreement under section 1193, with respect to a plan year during the price applicability period for such drug, that is in violation of a requirement imposed pursuant to section 1193(a)(6) shall be subject to a civil monetary penalty of not more than $1,000,000 for each such violation.

''(c) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this section in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''SEC. 1199. MISCELLANEOUS PROVISIONS.

''(a) PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to data collected under this part.

''(b) NATIONAL ACADEMY OF MEDICINE STUDY.—Not later than December 31, 2025, the National Academy of Medicine shall conduct a study, and submit to Congress a report, on recommendations for improvements to the program under this part, including the determination of the limits applied under section 1194(c).

''(c) MEDPAC STUDY.—Not later than December 31, 2025, the Medicare Payment Advisory Commission shall conduct a study, and submit to Congress a report, on the program under this part with respect to the Medicare program under title XVIII, including with respect to the effect of the program on individuals entitled to benefits or enrolled under such title.

''(d) LIMITATION ON JUDICIAL REVIEW.—The following shall not be subject to judicial review:

''(1) The selection of drugs for publication under section 1192(a).

''(2) The determination of whether a drug is a negotiation-eligible drug under section 1192(d).

''(3) The determination of the maximum fair price of a selected drug under section 1194.

''(4) The determination of units of a drug for purposes of section 1191(c)(3).

''(e) COORDINATION.—In carrying out this part with respect to group health plans or health insurance coverage offered in the group market that are subject to oversight by the Secretary of Labor or the Secretary of the Treasury, the Secretary of Health and Human Services shall coordinate with such respective Secretary.

''(f) DATA SHARING.—The Secretary shall share with the Secretary of the Treasury such information as is nec-

essary to determine the tax imposed by section 4192 of the Internal Revenue Code of 1986.

''(g) GAO STUDY.—Not later than December 31, 2025, the Comptroller General of the United States shall conduct a study of, and submit to Congress a report on, the implementation of the Fair Price Negotiation Program under this part.''.

(b) APPLICATION OF MAXIMUM FAIR PRICES AND CONFORMING AMENDMENTS.—

(1) UNDER MEDICARE.—

(A) APPLICATION TO PAYMENTS UNDER PART B.—Section 1847A(b)(1)(B) of the Social Security Act (42 U.S.C. 1395w–3a(b)(1)(B)) is amended by inserting ''or in the case of such a drug or biological that is a selected drug (as defined in section 1192(c)), with respect to a price applicability period (as defined in section 1191(b)(2)), 106 percent of the maximum fair price (as defined in section 1191(c)(2) applicable for such drug and a plan year during such period'' after ''paragraph (4)''.

(B) EXCEPTION TO PART D NON-INTERFERENCE.—Section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)) is

amended by inserting ", except as provided under part E of title XI" after "the Secretary".

(C) APPLICATION AS NEGOTIATED PRICE UNDER PART D.—Section 1860D–2(d)(1) of the Social Security Act (42 U.S.C. 1395w–102(d)(1)) is amended—

(i) in subparagraph (B), by inserting ", subject to subparagraph (D)," after "negotiated prices"; and

(ii) by adding at the end the following new subparagraph:

"(D) APPLICATION OF MAXIMUM FAIR PRICE FOR SELECTED DRUGS.—In applying this section, in the case of a covered part D drug that is a selected drug (as defined in section 1192(c)), with respect to a price applicability period (as defined in section 1191(b)(2)), the negotiated prices used for payment (as described in this subsection) shall be the maximum fair price (as defined in section 1191(c)(2)) for such drug and for each plan year during such period.".

(D) INFORMATION FROM PRESCRIPTION DRUG PLANS AND MA–PD PLANS REQUIRED.—

(i) PRESCRIPTION DRUG PLANS.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended by adding at the end the following new paragraph:

"(8) PROVISION OF INFORMATION RELATED TO MAXIMUM FAIR PRICES.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall require the sponsor to provide information to the Secretary as requested by the Secretary in accordance with section 1196(b).".

(ii) MA–PD PLANS.—Section 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–27(f)(3)) is amended by adding at the end the following new subparagraph:

"(E) PROVISION OF INFORMATION RELATED TO MAXIMUM FAIR PRICES.—Section 1860D–12(b)(8).".

(2) UNDER GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE.—

(A) PHSA.—Part A of title XXVII of the Public Health Service Act is amended by insert-

ing after section 2729 the following new section:

"SEC. 2729A. FAIR PRICE NEGOTIATION PROGRAM AND APPLICATION OF MAXIMUM FAIR PRICES.

"(a) IN GENERAL.—In the case of a group health plan or health insurance issuer offering group or individual health insurance coverage that is treated under section 1197 of the Social Security Act as having in effect an agreement with the Secretary under the Fair Price Negotiation Program under part E of title XI of such Act, with respect to a price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 1192(c) of such Act) with respect to such period with respect to which coverage is provided under such plan or coverage—

"(1) the provisions of such part shall apply—

"(A) if coverage of such selected drug is provided under such plan or coverage if the drug is furnished or dispensed at a pharmacy or by a mail order service, to the plans or coverage offered by such plan or issuer, and to the individuals enrolled under such plans or coverage, during such period, with respect to such selected drug, in the same manner as such provisions apply to prescription drug plans and

MA–PD plans, and to individuals enrolled under such prescription drug plans and MA–PD plans during such period; and

''(B) if coverage of such selected drug is provided under such plan or coverage if the drug is furnished or administered by a hospital, physician, or other provider of services or supplier, to the plans or coverage offered by such plan or issuers, to the individuals enrolled under such plans or coverage, and to hospitals, physicians, and other providers of services and suppliers during such period, with respect to such drug in the same manner as such provisions apply to the Secretary, to individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, and to hospitals, physicians, and other providers and suppliers participating under title XVIII during such period;

''(2) the plan or issuer shall apply any cost-sharing responsibilities under such plan or coverage, with respect to such selected drug, by substituting an amount not more than the maximum fair price negotiated under such part E of title XI for such drug in lieu of the drug price upon which the cost-

sharing would have otherwise applied, and such cost-sharing responsibilities with respect to such selected drug may not exceed such maximum fair price; and

''(3) the Secretary shall apply the provisions of such part E to such plan, issuer, and coverage, such individuals so enrolled in such plans and coverage, and such hospitals, physicians, and other providers and suppliers participating in such plans and coverage.

''(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall publicly disclose in a manner and in accordance with a process specified by the Secretary any election made under section 1197 of the Social Security Act by the plan or issuer to not participate in the Fair Drug Price Negotiation Program under part E of title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under such plan or coverage before the beginning of the plan year for which such election was made.''.

(B) ERISA.—

(i) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee

Retirement Income Security Act of 1974 (29 U.S.C. 1181 et. seq.) is amended by adding at the end the following new section:

"SEC. 716. FAIR PRICE NEGOTIATION PROGRAM AND APPLICATION OF MAXIMUM FAIR PRICES.

''(a) IN GENERAL.—In the case of a group health plan or health insurance issuer offering group health insurance coverage that is treated under section 1197 of the Social Security Act as having in effect an agreement with the Secretary under the Fair Price Negotiation Program under part E of title XI of such Act, with respect to a price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 1192(c) of such Act) with respect to such period with respect to which coverage is provided under such plan or coverage—

''(1) the provisions of such part shall apply, as applicable—

''(A) if coverage of such selected drug is provided under such plan or coverage if the drug is furnished or dispensed at a pharmacy or by a mail order service, to the plans or coverage offered by such plan or issuer, and to the individuals enrolled under such plans or cov-

erage, during such period, with respect to such selected drug, in the same manner as such provisions apply to prescription drug plans and MA–PD plans, and to individuals enrolled under such prescription drug plans and MA–PD plans during such period; and

''(B) if coverage of such selected drug is provided under such plan or coverage if the drug is furnished or administered by a hospital, physician, or other provider of services or supplier, to the plans or coverage offered by such plan or issuers, to the individuals enrolled under such plans or coverage, and to hospitals, physicians, and other providers of services and suppliers during such period, with respect to such drug in the same manner as such provisions apply to the Secretary, to individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, and to hospitals, physicians, and other providers and suppliers participating under title XVIII during such period;

''(2) the plan or issuer shall apply any cost-sharing responsibilities under such plan or coverage, with respect to such selected drug, by substituting

an amount not more than the maximum fair price negotiated under such part E of title XI for such drug in lieu of the drug price upon which the cost-sharing would have otherwise applied, and such cost-sharing responsibilities with respect to such selected drug may not exceed such maximum fair price; and

''(3) the Secretary shall apply the provisions of such part E to such plan, issuer, and coverage, and such individuals so enrolled in such plans.

''(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group health plan or a health insurance issuer offering group health insurance coverage shall publicly disclose in a manner and in accordance with a process specified by the Secretary any election made under section 1197 of the Social Security Act by the plan or issuer to not participate in the Fair Drug Price Negotiation Program under part E of title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under such plan or coverage before the beginning of the plan year for which such election was made.''.

(ii) APPLICATION TO RETIREE AND CERTAIN SMALL GROUP HEALTH PLANS.—Section 732(a) of the Employee Retirement Income Security Act of 1974 (29

U.S.C. 1191a(a)) is amended by striking ''section 711'' and inserting ''sections 711 and 716''.

(iii) CLERICAL AMENDMENT.—The table of sections for subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following:

''Sec. 716. Fair Price Negotiation Program and application of maximum fair prices.''.

(C) IRC.—

(i) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

''SEC. 9816. FAIR PRICE NEGOTIATION PROGRAM AND APPLICATION OF MAXIMUM FAIR PRICES.

''(a) IN GENERAL.—In the case of a group health plan that is treated under section 1197 of the Social Security Act as having in effect an agreement with the Secretary under the Fair Price Negotiation Program under part E of title XI of such Act, with respect to a price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 1192(c)

of such Act) with respect to such period with respect to which coverage is provided under such plan—

''(1) the provisions of such part shall apply, as applicable—

''(A) if coverage of such selected drug is provided under such plan if the drug is furnished or dispensed at a pharmacy or by a mail order service, to the plan, and to the individuals enrolled under such plan during such period, with respect to such selected drug, in the same manner as such provisions apply to prescription drug plans and MA–PD plans, and to individuals enrolled under such prescription drug plans and MA–PD plans during such period; and

''(B) if coverage of such selected drug is provided under such plan if the drug is furnished or administered by a hospital, physician, or other provider of services or supplier, to the plan, to the individuals enrolled under such plan, and to hospitals, physicians, and other providers of services and suppliers during such period, with respect to such drug in the same manner as such provisions apply to the Secretary, to individuals entitled to benefits under

part A of title XVIII or enrolled under part B of such title, and to hospitals, physicians, and other providers and suppliers participating under title XVIII during such period;

''(2) the plan shall apply any cost-sharing responsibilities under such plan, with respect to such selected drug, by substituting an amount not more than the maximum fair price negotiated under such part E of title XI for such drug in lieu of the drug price upon which the cost-sharing would have otherwise applied, and such cost-sharing responsibilities with respect to such selected drug may not exceed such maximum fair price; and

''(3) the Secretary shall apply the provisions of such part E to such plan and such individuals so enrolled in such plan.

''(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group health plan shall publicly disclose in a manner and in accordance with a process specified by the Secretary any election made under section 1197 of the Social Security Act by the plan to not participate in the Fair Drug Price Negotiation Program under part E of title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under

such plan before the beginning of the plan year for which such election was made.''.

(ii) APPLICATION TO RETIREE AND CERTAIN SMALL GROUP HEALTH PLANS.—Section 9831(a)(2) of the Internal Revenue Code of 1986 is amended by inserting ''other than with respect to section 9816,'' before ''any group health plan''.

(iii) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of such Code is amended by adding at the end the following new item:

''Sec. 9816. Fair Price Negotiation Program and application of maximum fair prices.''.

(3) FAIR PRICE NEGOTIATION PROGRAM PRICES INCLUDED IN BEST PRICE AND AMP.—Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(A) in subsection (c)(1)(C)(ii)—

(i) in subclause (III), by striking at the end ''; and'';

(ii) in subclause (IV), by striking at the end the period and inserting ''; and''; and

(iii) by adding at the end the following new subclause:

''(V) in the case of a rebate period and a covered outpatient drug that is a selected drug (as defined in section 1192(c)) during such rebate period, shall be inclusive of the price for such drug made available from the manufacturer during the rebate period by reason of application of part E of title XI to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States.''; and

(B) in subsection (k)(1)(B), by adding at the end the following new clause:

''(iii) CLARIFICATION.—Notwithstanding clause (i), in the case of a rebate period and a covered outpatient drug that is a selected drug (as defined in section 1192(c)) during such rebate period, any reduction in price paid during the rebate period to the manufacturer for the drug by a wholesaler or retail community pharmacy described in subparagraph (A) by reason of application of part E of title XI shall be

included in the average manufacturer price for the covered outpatient drug.''.

SEC. 102. SELECTED DRUG MANUFACTURER EXCISE TAX IMPOSED DURING NONCOMPLIANCE PERIODS.

(a) IN GENERAL.—Subchapter E of chapter 32 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

''SEC. 4192. SELECTED DRUGS DURING NONCOMPLIANCE PERIODS.

''(a) IN GENERAL.—There is hereby imposed on the sale by the manufacturer, producer, or importer of any selected drug during a day described in subsection (b) a tax in an amount such that the applicable percentage is equal to the ratio of—

''(1) such tax, divided by

''(2) the sum of such tax and the price for which so sold.

''(b) NONCOMPLIANCE PERIODS.—A day is described in this subsection with respect to a selected drug if it is a day during one of the following periods:

''(1) The period beginning on the June 16th immediately following the selected drug publication date and ending on the first date during which the manufacturer of the drug has in place an agreement

described in subsection (a) of section 1193 of the Social Security Act with respect to such drug.

''(2) The period beginning on the April 1st immediately following the June 16th described in paragraph (1) and ending on the first date during which the manufacturer of the drug has agreed to a maximum fair price under such agreement.

''(3) In the case of a selected drug with respect to which the Secretary of Health and Human Services has specified a renegotiation period under such agreement, the period beginning on the first date after the last date of such renegotiation period and ending on the first date during which the manufacturer of the drug has agreed to a renegotiated maximum fair price under such agreement.

''(4) With respect to information that is required to be submitted to the Secretary of Health and Human Services under such agreement, the period beginning on the date on which such Secretary certifies that such information is overdue and ending on the date that such information is so submitted.

''(5) In the case of a selected drug with respect to which a payment is due under subsection (c) of such section 1193, the period beginning on the date on which the Secretary of Health and Human Serv-

ices certifies that such payment is overdue and ending on the date that such payment is made in full.

''(c) APPLICABLE PERCENTAGE.—For purposes of this section, the term 'applicable percentage' means—

''(1) in the case of sales of a selected drug during the first 90 days described in subsection (b) with respect to such drug, 65 percent,

''(2) in the case of sales of such drug during the 91st day through the 180th day described in subsection (b) with respect to such drug, 75 percent,

''(3) in the case of sales of such drug during the 181st day through the 270th day described in subsection (b) with respect to such drug, 85 percent, and

''(4) in the case of sales of such drug during any subsequent day, 95 percent.

''(d) SELECTED DRUG.—For purposes of this section—

''(1) IN GENERAL.—The term 'selected drug' means any selected drug (within the meaning of section 1192 of the Social Security Act) which is manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing.

''(2) UNITED STATES.—The term 'United States' has the meaning given such term by section 4612(a)(4).

''(3) COORDINATION WITH RULES FOR POSSESSIONS OF THE UNITED STATES.—Rules similar to the rules of paragraphs (2) and (4) of section 4132(c) shall apply for purposes of this section.

''(e) OTHER DEFINITIONS.—For purposes of this section, the terms 'selected drug publication date' and 'maximum fair price' have the meaning given such terms in section 1191 of the Social Security Act.

''(f) ANTI-ABUSE RULE.—In the case of a sale which was timed for the purpose of avoiding the tax imposed by this section, the Secretary may treat such sale as occurring during a day described in subsection (b).''.

(b) NO DEDUCTION FOR EXCISE TAX PAYMENTS.—Section 275 of the Internal Revenue Code of 1986 is amended by adding ''or by section 4192'' before the period at the end of subsection (a)(6).

(c) CONFORMING AMENDMENTS.—

(1) Section 4221(a) of the Internal Revenue Code of 1986 is amended by inserting ''or 4192'' after ''section 4191''.

(2) Section 6416(b)(2) of such Code is amended by inserting ''or 4192'' after ''section 4191''.

(d) CLERICAL AMENDMENTS.—

(1) The heading of subchapter E of chapter 32 of the Internal Revenue Code of 1986 is amended by striking "**Medical Devices**" and inserting "**Other Medical Products**".

(2) The table of subchapters for chapter 32 of such Code is amended by striking the item relating to subchapter E and inserting the following new item:

"SUBCHAPTER E. OTHER MEDICAL PRODUCTS".

(3) The table of sections for subchapter E of chapter 32 of such Code is amended by adding at the end the following new item:

"Sec. 4192. Selected drugs during noncompliance periods.".

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to sales after the date of the enactment of this Act.

SEC. 103. FAIR DRUG PRICE NEGOTIATION IMPLEMENTATION FUND.

(a) IN GENERAL.—There is hereby established a Fair Drug Price Negotiation Implementation Fund (referred to in this section as the "Fund"). The Secretary of Health and Human Services may obligate and expend amounts in the Fund to carry out this title and titles II and III (and the amendments made by such titles).

(b) FUNDING.—There is authorized to be appropriated, and there is hereby appropriated, out of any monies in the Treasury not otherwise appropriated, to the Fund $3,000,000,000, to remain available until expended, of which—

(1) $600,000,000 shall become available on the date of the enactment of this Act;

(2) $600,000,000 shall become available on October 1, 2020;

(3) $600,000,000 shall become available on October 1, 2021;

(4) $600,000,000 shall become available on October 1, 2022; and

(5) $600,000,000 shall become available on October 1, 2023.

(c) SUPPLEMENT NOT SUPPLANT.—Any amounts appropriated pursuant to this section shall be in addition to any other amounts otherwise appropriated pursuant to any other provision of law.

TITLE II—MEDICARE PARTS B AND D PRESCRIPTION DRUG INFLATION REBATES

SEC. 201. MEDICARE PART B REBATE BY MANUFACTURERS.

(a) IN GENERAL.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

''(x) REBATE BY MANUFACTURERS FOR SINGLE SOURCE DRUGS WITH PRICES INCREASING FASTER THAN INFLATION.—

''(1) REQUIREMENTS.—

''(A) SECRETARIAL PROVISION OF INFORMATION.—Not later than 6 months after the end of each calendar quarter beginning on or after July 1, 2021, the Secretary shall, for each part B rebatable drug, report to each manufacturer of such part B rebatable drug the following for such calendar quarter:

''(i) Information on the total number of units of the billing and payment code described in subparagraph (A)(i) of paragraph (3) with respect to such drug and calendar quarter.

''(ii) Information on the amount (if any) of the excess average sales price in-

crease described in subparagraph (A)(ii) of such paragraph for such drug and calendar quarter.

''(iii) The rebate amount specified under such paragraph for such part B rebatable drug and calendar quarter.

''(B) MANUFACTURER REQUIREMENT.—For each calendar quarter beginning on or after July 1, 2021, the manufacturer of a part B rebatable drug shall, for such drug, not later than 30 days after the date of receipt from the Secretary of the information described in subparagraph (A) for such calendar quarter, provide to the Secretary a rebate that is equal to the amount specified in paragraph (3) for such drug for such calendar quarter.

''(2) PART B REBATABLE DRUG DEFINED.—

''(A) IN GENERAL.—In this subsection, the term 'part B rebatable drug' means a single source drug or biological (as defined in subparagraph (D) of section 1847A(c)(6)), including a biosimilar biological product (as defined in subparagraph (H) of such section), paid for under this part, except such term shall not include such a drug or biological—

''(i) if the average total allowed charges for a year per individual that uses such a drug or biological, as determined by the Secretary, are less than, subject to subparagraph (B), $100; or

''(ii) that is a vaccine described in subparagraph (A) or (B) of section 1861(s)(10).

''(B) INCREASE.—The dollar amount applied under subparagraph (A)(i)—

''(i) for 2022, shall be the dollar amount specified under such subparagraph for 2021, increased 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 previous year; and

''(ii) for a subsequent year, shall be the dollar amount specified in this clause (or clause (i)) for the previous year, increased 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 previous year.

Any dollar amount specified under this subparagraph that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''(3) REBATE AMOUNT.—

''(A) IN GENERAL.—For purposes of paragraph (1), the amount specified in this paragraph for a part B rebatable drug assigned to a billing and payment code for a calendar quarter is, subject to paragraph (4), the amount equal to the product of—

''(i) subject to subparagraphs (B) and (G), the total number of units of the billing and payment code for such part B rebatable drug furnished under this part during the calendar quarter; and

''(ii) the amount (if any) by which—

''(I) the payment amount under subparagraph (B) or (C) of section 1847A(b)(1), as applicable, for such part B rebatable drug during the calendar quarter; exceeds

''(II) the inflation-adjusted payment amount determined under subparagraph (C) for such part B

rebatable drug during the calendar quarter.

''(B) EXCLUDED UNITS.—For purposes of subparagraph (A)(i), the total number of units of the billing and payment code for each part B rebatable drug furnished during a calendar quarter shall not include—

''(i) units packaged into the payment for a procedure or service under section 1833(t) or under section 1833(i) (instead of separately payable under such respective section);

''(ii) units included under the single payment system for renal dialysis services under section 1881(b)(14); or

''(iii) units of a part B rebatable drug of a manufacturer furnished to an individual, if such manufacturer, with respect to the furnishing of such units of such drug, provides for discounts under section 340B of the Public Health Service Act or for rebates under section 1927.

''(C) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this

subparagraph for a part B rebatable drug for a calendar quarter is—

"(i) the payment amount for the billing and payment code for such drug in the payment amount benchmark quarter (as defined in subparagraph (D)); increased by

"(ii) the percentage by which the rebate period CPI–U (as defined in subparagraph (F)) for the calendar quarter exceeds the benchmark period CPI–U (as defined in subparagraph (E)).

"(D) PAYMENT AMOUNT BENCHMARK QUARTER.—The term 'payment amount benchmark quarter' means the calendar quarter beginning January 1, 2016.

"(E) BENCHMARK PERIOD CPI–U.—The term 'benchmark period CPI–U' means the consumer price index for all urban consumers (United States city average) for July 2015.

"(F) REBATE PERIOD CPI–U.—The term 'rebate period CPI–U' means, with respect to a calendar quarter described in subparagraph (C), the greater of the benchmark period CPI–U and the consumer price index for all urban consumers (United States city average) for the

first month of the calendar quarter that is two calendar quarters prior to such described calendar quarter.

"(G) COUNTING UNITS.—

"(i) CUT-OFF PERIOD TO COUNT UNITS.—For purposes of subparagraph (A)(i), subject to clause (ii), to count the total number of billing units for a part B rebatable drug for a quarter, the Secretary may use a cut-off period in order to exclude from such total number of billing units for such quarter claims for services furnished during such quarter that were not processed at an appropriate time prior to the end of the cut-off period.

"(ii) COUNTING UNITS FOR CLAIMS PROCESSED AFTER CUT-OFF PERIOD.—If the Secretary uses a cut-off period pursuant to clause (i), in the case of units of a part B rebatable drug furnished during a quarter but pursuant to application of such cut-off period excluded for purposes of subparagraph (A)(i) from the total number of billing units for the drug for such quarter, the Secretary shall count such units of

such drug so furnished in the total number of billing units for such drug for a subsequent quarter, as the Secretary determines appropriate.

''(4) SPECIAL TREATMENT OF CERTAIN DRUGS AND EXEMPTION.—

''(A) SUBSEQUENTLY APPROVED DRUGS.—Subject to subparagraph (B), in the case of a part B rebatable drug first approved or licensed by the Food and Drug Administration after July 1, 2015, clause (i) of paragraph (3)(C) shall be applied as if the term 'payment amount benchmark quarter' were defined under paragraph (3)(D) as the third full calendar quarter after the day on which the drug was first marketed and clause (ii) of paragraph (3)(C) shall be applied as if the term 'benchmark period CPI–U' were defined under paragraph (3)(E) as if the reference to 'July 2015' under such paragraph were a reference to 'the first month of the first full calendar quarter after the day on which the drug was first marketed'.

''(B) TIMELINE FOR PROVISION OF REBATES FOR SUBSEQUENTLY APPROVED DRUGS.—In the case of a part B rebatable drug

first approved or licensed by the Food and Drug Administration after July 1, 2015, paragraph (1)(B) shall be applied as if the reference to 'July 1, 2021' under such paragraph were a reference to the later of the 6th full calendar quarter after the day on which the drug was first marketed or July 1, 2021.

''(C) EXEMPTION FOR SHORTAGES.—The Secretary may reduce or waive the rebate amount under paragraph (1)(B) with respect to a part B rebatable drug that is described as currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act or in the case of other exigent circumstances, as determined by the Secretary.

''(D) SELECTED DRUGS.—In the case of a part B rebatable drug that is a selected drug (as defined in section 1192(c)) for a price applicability period (as defined in section 1191(b)(2))—

''(i) for calendar quarters during such period for which a maximum fair price (as defined in section 1191(c)(2)) for such drug has been determined and is applied

under part E of title XI, the rebate amount under paragraph (1)(B) shall be waived; and

''(ii) in the case such drug is determined (pursuant to such section 1192(c)) to no longer be a selected drug, for each applicable year beginning after the price applicability period with respect to such drug, clause (i) of paragraph (3)(C) shall be applied as if the term 'payment amount benchmark quarter' were defined under paragraph (3)(D) as the calendar quarter beginning January 1 of the last year beginning during such price applicability period with respect to such selected drug and clause (ii) of paragraph (3)(C) shall be applied as if the term 'benchmark period CPI–U' were defined under paragraph (3)(E) as if the reference to 'July 2015' under such paragraph were a reference to the July of the year preceding such last year.

''(5) APPLICATION TO BENEFICIARY COINSURANCE.—In the case of a part B rebatable drug, if

the payment amount for a quarter exceeds the inflation adjusted payment for such quarter—

''(A) in computing the amount of any coinsurance applicable under this title to an individual with respect to such drug, the computation of such coinsurance shall be based on the inflation-adjusted payment amount determined under paragraph (3)(C) for such part B rebatable drug; and

''(B) the amount of such coinsurance is equal to 20 percent of such inflation-adjusted payment amount so determined.

''(6) REBATE DEPOSITS.—Amounts paid as rebates under paragraph (1)(B) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

''(7) CIVIL MONEY PENALTY.—If a manufacturer of a part B rebatable drug has failed to comply with the requirements under paragraph (1)(B) for such drug for a calendar quarter, the manufacturer shall be subject to, in accordance with a process established by the Secretary pursuant to regulations, a civil money penalty in an amount equal to at least 125 percent of the amount specified in paragraph (3) for such drug for such calendar quarter.

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 paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(8) STUDY AND REPORT.—

''(A) STUDY.—The Secretary shall conduct a study of the feasibility of and operational issues involved with the following:

''(i) Including multiple source drugs (as defined in section 1847A(c)(6)(C)) in the rebate system under this subsection.

''(ii) Including drugs and biologicals paid for under MA plans under part C in the rebate system under this subsection.

''(iii) Including drugs excluded under paragraph (2)(A) and units of the billing and payment code of the drugs excluded under paragraph (3)(B) in the rebate system under this subsection.

''(B) REPORT.—Not later than 3 years after the date of the enactment of this subsection, the Secretary shall submit to Congress

a report on the study conducted under subparagraph (A).

''(9) APPLICATION TO MULTIPLE SOURCE DRUGS.—The Secretary may, based on the report submitted under paragraph (8) and pursuant to rulemaking, apply the provisions of this subsection to multiple source drugs (as defined in section 1847A(c)(6)(C)), including, for purposes of determining the rebate amount under paragraph (3), by calculating manufacturer-specific average sales prices for the benchmark period and the rebate period.''.

(b) AMOUNTS PAYABLE; COST-SHARING.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (S), by striking ''with respect to'' and inserting ''subject to subparagraph (DD), with respect to'';

(ii) by striking ''and (CC)'' and inserting ''(CC)''; and

(iii) by inserting before the semicolon at the end the following: '', and (DD) with respect to a part B rebatable drug (as de-

fined in paragraph (2) of section 1834(x)) for which the payment amount for a calendar quarter under paragraph (3)(A)(ii)(I) of such section for such quarter exceeds the inflation-adjusted payment under paragraph (3)(A)(ii)(II) of such section for such quarter, the amounts paid shall be the difference between (i) the payment amount under paragraph (3)(A)(ii)(I) of such section for such drug, and (ii) 20 percent of the inflation-adjusted payment amount under paragraph (3)(A)(ii)(II) of such section for such drug'';

(B) by adding at the end of the flush left matter following paragraph (9), the following: ''For purposes of applying paragraph (1)(DD), subsections (i)(9) and (t)(8)(F), and section 1834(x)(5), the Secretary shall make such estimates and use such data as the Secretary determines appropriate, and notwithstanding any other provision of law, may do so by program instruction or otherwise.'';

(2) in subsection (i), by adding at the end the following new paragraph:

''(9) In the case of a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) for which payment under this subsection is not packaged into a payment for a covered OPD service (as defined in subsection (t)(1)(B)) (or group of services) furnished on or after July 1, 2021, under the system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1834(x)(5), paragraph (1)(DD) of subsection (a), and the flush left matter following paragraph (9) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1834(x)(5) and subsection (a) apply under such section and subsection.''; and

(3) in subsection (t)(8), by adding at the end the following new subparagraph:

''(F) PART B REBATABLE DRUGS.—In the case of a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) for which payment under this part is not packaged into a payment for a service furnished on or after July 1, 2021, under the system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section

1834(x)(5), paragraph (1)(DD) of subsection (a), and the flush left matter following paragraph (9) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1834(x)(5) and subsection (a) apply under such section and subsection.''.

(c) CONFORMING AMENDMENTS.—

(1) TO PART B ASP CALCULATION.—Section 1847A(c)(3) of the Social Security Act (42 U.S.C. 1395w–3a(c)(3)) is amended by inserting ''or section 1834(x)'' after ''section 1927''.

(2) EXCLUDING PARTS B DRUG INFLATION REBATE FROM BEST PRICE.—Section 1927(c)(1)(C)(ii)(I) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is amended by inserting ''or section 1834(x)'' after ''this section''.

SEC. 202. MEDICARE PART D REBATE BY MANUFACTURERS.

(a) IN GENERAL.—Part D of title XVIII of the Social Security Act is amended by inserting after section 1860D–14A (42 U.S.C. 1395w–114a) the following new section:

''SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN DRUGS WITH PRICES INCREASING FASTER THAN INFLATION.

''(a) IN GENERAL.—

''(1) IN GENERAL.—Subject to the provisions of this section, in order for coverage to be available under this part for a part D rebatable drug (as defined in subsection (h)(1)) of a manufacturer (as defined in section 1927(k)(5)) dispensed during an applicable year, the manufacturer must have entered into and have in effect an agreement described in subsection (b).

''(2) AUTHORIZING COVERAGE FOR DRUGS NOT COVERED UNDER AGREEMENTS.—Paragraph (1) shall not apply to the dispensing of a covered part D drug if—

''(A) the Secretary has made a determination that the availability of the drug is essential to the health of beneficiaries under this part; or

''(B) the Secretary determines that in the period beginning on January 1, 2022, and ending on December 31, 2022, there were extenuating circumstances.

''(3) APPLICABLE YEAR.—For purposes of this section the term 'applicable year' means a year beginning with 2022.

''(b) AGREEMENTS.—

''(1) TERMS OF AGREEMENT.—An agreement described in this subsection, with respect to a manu-

facturer of a part D rebatable drug, is an agreement under which the following shall apply:

"(A) SECRETARIAL PROVISION OF INFORMATION.—Not later than 9 months after the end of each applicable year with respect to which the agreement is in effect, the Secretary, for each part D rebatable drug of the manufacturer, shall report to the manufacturer the following for such year:

"(i) Information on the total number of units (as defined in subsection (h)(2)) for each dosage form and strength with respect to such part D rebatable drug and year.

"(ii) Information on the amount (if any) of the excess average manufacturer price increase described in subsection (c)(1)(B) for each dosage form and strength with respect to such drug and year.

"(iii) The rebate amount specified under subsection (c) for each dosage form and strength with respect to such drug and year.

''(B) MANUFACTURER REQUIREMENTS.—For each applicable year with respect to which the agreement is in effect, the manufacturer of the part D rebatable drug, for each dosage form and strength with respect to such drug, not later than 30 days after the date of receipt from the Secretary of the information described in subparagraph (A) for such year, shall provide to the Secretary a rebate that is equal to the amount specified in subsection (c) for such dosage form and strength with respect to such drug for such year.

''(2) LENGTH OF AGREEMENT.—

''(A) IN GENERAL.—An agreement under this section, with respect to a part D rebatable drug, shall be effective for an initial period of not less than one year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

''(B) TERMINATION.—

''(i) BY SECRETARY.—The Secretary may provide for termination of an agreement under this section for violation of the requirements of the agreement or other

good cause shown. Such termination shall not be effective earlier than 30 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 an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

''(I) if the termination occurs before January 30 of the plan year, as of the day after the end of the plan year; and

''(II) if the termination occurs on or after January 30 of the plan year, as of the day after the end of the succeeding plan year.

''(C) EFFECTIVENESS OF TERMINATION.—Any termination under this paragraph shall not affect rebates due under the agreement under

this section before the effective date of its termination.

''(D) DELAY BEFORE REENTRY.—In the case of any agreement under this section with a manufacturer that is terminated in a plan year, the Secretary may not enter into another such agreement with the manufacturer (or a successor manufacturer) before the subsequent plan year, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

''(c) REBATE AMOUNT.—

''(1) IN GENERAL.—For purposes of this section, the amount specified in this subsection for a dosage form and strength with respect to a part D rebatable drug and applicable year is, subject to subparagraphs (B) and (C) of paragraph (5), the amount equal to the product of—

''(A) the total number of units of such dosage form and strength with respect to such part D rebatable drug and year; and

''(B) the amount (if any) by which—

''(i) the annual manufacturer price (as determined in paragraph (2)) paid for such dosage form and strength with re-

spect to such part D rebatable drug for the year; exceeds

''(ii) the inflation-adjusted payment amount determined under paragraph (3) for such dosage form and strength with respect to such part D rebatable drug for the year.

''(2) DETERMINATION OF ANNUAL MANUFACTURER PRICE.—The annual manufacturer price determined under this paragraph for a dosage form and strength, with respect to a part D rebatable drug and an applicable year, is the sum of the products of—

''(A) the average manufacturer price (as defined in subsection (h)(6)) of such dosage form and strength, as calculated for a unit of such drug, with respect to each of the calendar quarters of such year; and

''(B) the ratio of—

''(i) the total number of units of such dosage form and strength dispensed during each such calendar quarter of such year; to

''(ii) the total number of units of such dosage form and strength dispensed during such year.

''(3) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this paragraph for a dosage form and strength with respect to a part D rebatable drug for an applicable year, subject to subparagraphs (A) and (D) of paragraph (5), is—

''(A) the benchmark year manufacturer price determined under paragraph (4) for such dosage form and strength with respect to such drug and an applicable year; increased by

''(B) the percentage by which the applicable year CPI–U (as defined in subsection (h)(5)) for the applicable year exceeds the benchmark period CPI–U (as defined in subsection (h)(4)).

''(4) DETERMINATION OF BENCHMARK YEAR MANUFACTURER PRICE.—The benchmark year manufacturer price determined under this paragraph for a dosage form and strength, with respect to a part D rebatable drug and an applicable year, is the sum of the products of—

''(A) the average manufacturer price (as defined in subsection (h)(6)) of such dosage form and strength, as calculated for a unit of such drug, with respect to each calendar quar-

ter of the payment amount benchmark year (as defined in subsection (h)(3)); and

''(B) the ratio of—

''(i) the total number of units of such dosage form and strength dispensed during such calendar quarter of the payment amount benchmark year; to

''(ii) the total number of units of such dosage form and strength dispensed during the payment amount benchmark year.

''(5) SPECIAL TREATMENT OF CERTAIN DRUGS AND EXEMPTION.—

''(A) SUBSEQUENTLY APPROVED DRUGS.—In the case of a part D rebatable drug first approved or licensed by the Food and Drug Administration after January 1, 2016, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term 'payment amount benchmark year' were defined under subsection (h)(3) as the first calendar year beginning after the day on which the drug was first marketed by any manufacturer and subparagraph (B) of paragraph (3) shall be applied as if the term 'benchmark period CPI–U' were defined under subsection (h)(4) as if the reference to 'January

2016' under such subsection were a reference to 'January of the first year beginning after the date on which the drug was first marketed by any manufacturer'.

''(B) EXEMPTION FOR SHORTAGES.—The Secretary may reduce or waive the rebate under paragraph (1) with respect to a part D rebatable drug that is described as currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act or in the case of other exigent circumstances, as determined by the Secretary.

''(C) TREATMENT OF NEW FORMULATIONS.—

''(i) IN GENERAL.—In the case of a part D rebatable drug that is a line extension of a part D rebatable drug that is an oral solid dosage form, the Secretary shall establish a formula for determining the amount specified in this subsection with respect to such part D rebatable drug and an applicable year with consideration of the original part D rebatable drug.

''(ii) LINE EXTENSION DEFINED.—In this subparagraph, the term 'line exten-

sion' means, with respect to a part D rebatable drug, a new formulation of the drug (as determined by the Secretary), 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) SELECTED DRUGS.—In the case of a part D rebatable drug that is a selected drug (as defined in section 1192(c)) for a price applicability period (as defined in section 1191(b)(2))—

''(i) for plan years during such period for which a maximum fair price (as defined in section 1191(c)(2)) for such drug has been determined and is applied under part E of title XI, the rebate under subsection (b)(1)(B) shall be waived; and

''(ii) in the case such drug is determined (pursuant to such section 1192(c)) to no longer be a selected drug, for each applicable year beginning after the price applicability period with respect to such

drug, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term 'payment amount benchmark year' were defined under subsection (h)(3) as the last year beginning during such price applicability period with respect to such selected drug and subparagraph (B) of paragraph (3) shall be applied as if the term 'benchmark period CPI–U' were defined under subsection (h)(4) as if the reference to 'January 2016' under such subsection were a reference to January of the last year beginning during such price applicability period with respect to such drug.

''(d) REBATE DEPOSITS.—Amounts paid as rebates under subsection (c) shall be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

''(e) INFORMATION.—For purposes of carrying out this section, the Secretary shall use information submitted by manufacturers under section 1927(b)(3).

''(f) CIVIL MONEY PENALTY.—In the case of a manufacturer of a part D rebatable drug with an agreement in effect under this section who has failed to comply with

the terms of the agreement under subsection (b)(1)(B) with respect to such drug for an applicable year, the Secretary may impose a civil money penalty on such manufacturer in an amount equal to 125 percent of the amount specified in subsection (c) for such drug for such year. 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 subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(g) JUDICIAL REVIEW.—There shall be no judicial review of the following:

''(1) The determination of units under this section.

''(2) The determination of whether a drug is a part D rebatable drug under this section.

''(3) The calculation of the rebate amount under this section.

''(h) DEFINITIONS.—In this section:

''(1) PART D REBATABLE DRUG DEFINED.—

''(A) IN GENERAL.—The term 'part D rebatable drug' means a drug or biological that would (without application of this section) be a covered part D drug, except such term shall,

with respect to an applicable year, not include such a drug or biological if the average annual total cost under this part for such year per individual who uses such a drug or biological, as determined by the Secretary, is less than, subject to subparagraph (B), $100, as determined by the Secretary using the most recent data available or, if data is not available, as estimated by the Secretary.

''(B) INCREASE.—The dollar amount applied under subparagraph (A)—

''(i) for 2023, shall be the dollar amount specified under such subparagraph for 2022, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period beginning with January of 2022; and

''(ii) for a subsequent year, shall be the dollar amount specified in this subparagraph for the previous year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-

month period beginning with January of the previous year.

Any dollar amount specified under this subparagraph that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''(2) UNIT DEFINED.—The term 'unit' means, with respect to a part D rebatable drug, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the part D rebatable drug that is dispensed to individuals under this part.

''(3) PAYMENT AMOUNT BENCHMARK YEAR.—The term 'payment amount benchmark year' means the year beginning January 1, 2016.

''(4) BENCHMARK PERIOD CPI–U.—The term 'benchmark period CPI–U' means the consumer price index for all urban consumers (United States city average) for January 2016.

''(5) APPLICABLE YEAR CPI–U.—The term 'applicable year CPI–U' means, with respect to an applicable year, the consumer price index for all urban consumers (United States city average) for January of such year.

''(6) AVERAGE MANUFACTURER PRICE.—The term 'average manufacturer price' has the meaning,

with respect to a part D rebatable drug of a manufacturer, given such term in section 1927(k)(1), with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927.''.

(b) CONFORMING AMENDMENTS.—

(1) TO PART B ASP CALCULATION.—Section 1847A(c)(3) of the Social Security Act (42 U.S.C. 1395w–3a(c)(3)), as amended by section 201(c)(1), is further amended by striking ''section 1927 or section 1834(x)'' and inserting ''section 1927, section 1834(x), or section 1860D–14B''.

(2) EXCLUDING PART D DRUG INFLATION REBATE FROM BEST PRICE.—Section 1927(c)(1)(C)(ii)(I) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)), as amended by section 201(c)(2), is further amended by striking ''or section 1834(x)'' and inserting '', section 1834(x), or section 1860D–14B''.

SEC. 203. PROVISION REGARDING INFLATION REBATES FOR GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.

Not later than December 31, 2021, the Secretary of Labor, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, shall submit to Congress a report on—

(1) potential models for an agreement process with manufacturers of prescription drugs under which such manufacturers provide for inflation rebates with respect to such drugs that are furnished or dispensed to participants and beneficiaries of group health plans and health insurance coverage offered in the group market in a manner similar to how manufacturers provide for rebates under section 1834(x) of the Social Security Act, as added by section 201, and section 1860D–14B of such Act, as added by section 202, with respect to prescription drugs that are furnished or dispensed under part B of title XVIII of such Act and part D of such title, respectively;

(2) potential models for enforcement mechanisms with respect to such an agreement process that ensure that such inflation rebates are proportionally distributed, with respect to costs, to group health plans and health insurance issuers offering health insurance coverage in the group market, to participants and beneficiaries of such plans and coverage, or to both; and

(3) for each potential model under paragraphs (1) and (2) any additional statutory authority needed to implement such model.

SEC. 204. ANNUAL REPORT ON DRUG COSTS IN GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.

(a) INITIAL REPORT.—Not later than December 31, 2021, the Secretary of Labor shall, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, submit to Congress a report, with respect to a period (as determined by the Secretary of Labor), on—

(1) whether the prices of prescription drugs that are furnished or dispensed to participants and beneficiaries of group health plans and health insurance coverage offered in the group market during such period have increased at a percentage that exceeds the percentage by which the consumer price index for all urban consumers (United States city average) increased for such period; and

(2) whether there are mechanisms by which manufacturers of prescription drugs have attempted to recover rebate payments required of such manufacturers under section 1834(x) of the Social Security Act, as added by section 201, and section 1860D–14B of such Act, as added by section 202, with respect to prescription drugs that are furnished or dispensed under part B of title XVIII of such Act and part D of such title, respectively, through in-

creased prices charged with respect to drugs that are furnished or dispensed to participants and beneficiaries of group health plans and health insurance coverage offered in the group market during such period.

(b) ANNUAL REPORT.—Not later than December 31 of each year following 2021, the Secretary of Labor shall, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, submit to Congress a report updating the information and analysis included in the report required under subsection (a), reflecting, in part, new price and cost information and data for the 12-month period after the period on which the prior year's report was based.

SEC. 205. COLLECTION OF DATA.

(a) MANUFACTURERS OF PRESCRIPTION DRUGS.—Manufacturers of prescription drugs shall submit to the Secretary of Health and Human Services, Secretary of Labor, and the Secretary of the Treasury appropriate data as necessary for the Secretaries to obtain information needed to provide the reports under sections 203 and 204.

(b) GROUP HEALTH PLANS AND HEALTH INSURANCE ISSUERS OFFERING HEALTH INSURANCE COVERAGE IN THE GROUP MARKET.—Group health plans and health insurance issuers offering health insurance cov-

erage in the group market shall submit to the Secretary of Health and Human Services, Secretary of Labor, and the Secretary of the Treasury appropriate data as necessary for the Secretaries to obtain information needed to provide the reports under sections 203 and 204.

TITLE III—PART D IMPROVEMENTS AND MAXIMUM OUT-OF-POCKET CAP FOR MEDICARE BENEFICIARIES

SEC. 301. MEDICARE PART D BENEFIT REDESIGN.

(a) BENEFIT STRUCTURE REDESIGN.—Section 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–102(b)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (A), in the matter preceding clause (i), by inserting ''for a year preceding 2022 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2022 and each subsequent year'' after ''paragraph (3)'';

(B) in subparagraph (C)—

(i) in clause (i), in the matter preceding subclause (I), by inserting ''for a

year preceding 2022,'' after ''paragraph (4),''; and

(ii) in clause (ii)(III), by striking ''and each subsequent year'' and inserting ''and 2021''; and

(C) in subparagraph (D)—

(i) in clause (i)—

(I) in the matter preceding subclause (I), by inserting ''for a year preceding 2022,'' after ''paragraph (4),''; and

(II) in subclause (I)(bb), by striking ''a year after 2018'' and inserting ''each of years 2018 through 2021''; and

(ii) in clause (ii)(V), by striking ''2019 and each subsequent year'' and inserting ''each of years 2019 through 2021'';

(2) in paragraph (3)(A)—

(A) in the matter preceding clause (i), by inserting ''for a year preceding 2022,'' after ''and (4),''; and

(B) in clause (ii), by striking ''for a subsequent year'' and inserting ''for each of years 2007 through 2021''; and

(3) in paragraph (4)—

(A) in subparagraph (A)—

(i) in clause (i)—

(I) by redesignating subclauses (I) and (II) as items (aa) and (bb), respectively, and moving the margin of each such redesignated item 2 ems to the right;

(II) in the matter preceding item (aa), as redesignated by subclause (I), by striking ''is equal to the greater of—'' and inserting ''is equal to—

''(I) for a year preceding 2022, the greater of—'';

(III) by striking the period at the end of item (bb), as redesignated by subclause (I), and inserting ''; and''; and

(IV) by adding at the end the following:

''(II) for 2022 and each succeeding year, $0.''; and

(ii) in clause (ii), by striking ''clause (i)(I)'' and inserting ''clause (i)(I)(aa)'';

(B) in subparagraph (B)—

(i) in clause (i)—

(I) in subclause (V), by striking ''or'' at the end;

(II) in subclause (VI)—

(aa) by striking ''for a subsequent year'' and inserting ''for 2021''; and

(bb) by striking the period at the end and inserting a semicolon; and

(III) by adding at the end the following new subclauses:

''(VII) for 2022, is equal to $2,000; or

''(VIII) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.''; and

(ii) in clause (ii), by striking ''clause (i)(II)'' and inserting ''clause (i)'';

(C) in subparagraph (C)(i), by striking ''and for amounts'' and inserting ''and, for a year preceding 2022, for amounts''; and

(D) in subparagraph (E), by striking ''In applying'' and inserting ''For each of years 2011 through 2021, in applying''.

(b) DECREASING REINSURANCE PAYMENT AMOUNT.—Section 1860D–15(b)(1) of the Social Security Act (42 U.S.C. 1395w–115(b)(1)) is amended by inserting after ''80 percent'' the following: ''(or, with respect to a coverage year after 2021, 20 percent)''.

(c) MANUFACTURER DISCOUNT PROGRAM.—

(1) IN GENERAL.—Part D of title XVIII of the Social Security Act (42 U.S.C. 1395w–101 et seq.), as amended by section 202, is further amended by inserting after section 1860D–14B the following new section:

''SEC. 1860D–14C. MANUFACTURER DISCOUNT PROGRAM.

''(a) ESTABLISHMENT.—The Secretary shall establish a manufacturer discount program (in this section referred to as the 'program'). Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of the duties described in subsection (c). The Secretary shall establish a model agreement for use under the pro-

gram by not later than January 1, 2021, in consultation with manufacturers, and allow for comment on such model agreement.

''(b) TERMS OF AGREEMENT.—

''(1) IN GENERAL.—

''(A) AGREEMENT.—An agreement under this section shall require the manufacturer to provide applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer that are dispensed on or after January 1, 2022.

''(B) PROVISION OF DISCOUNTED PRICES AT THE POINT-OF-SALE.—The discounted prices described in subparagraph (A) shall be provided to the applicable beneficiary at the pharmacy or by the mail order service at the point-of-sale of an applicable drug.

''(C) TIMING OF AGREEMENT.—

''(i) SPECIAL RULE FOR 2022.—In order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2022, and ending on December 31, 2022, the manufacturer shall enter into such agreement not later than 30 days

after the date of the establishment of a model agreement under subsection (a).

''(ii) 2023 AND SUBSEQUENT YEARS.—In order for an agreement with a manufacturer to be in effect under this section with respect to plan year 2023 or a subsequent plan year, the manufacturer shall enter into such agreement (or such agreement shall be renewed under paragraph (4)(A)) not later than January 30 of the preceding year.

''(2) PROVISION OF APPROPRIATE DATA.—Each manufacturer with an agreement in effect under this section shall collect and have available appropriate data, as determined by the Secretary, to ensure that it can demonstrate to the Secretary compliance with the requirements under the program.

''(3) COMPLIANCE WITH REQUIREMENTS FOR ADMINISTRATION OF PROGRAM.—Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under subsection (d)(3), as applicable, for purposes of administering the program, including any determination

under subparagraph (A) of subsection (c)(1) or procedures established under such subsection (c)(1).

''(4) LENGTH OF AGREEMENT.—

''(A) IN GENERAL.—An agreement under this section shall be effective for an initial period of not less than 12 months and shall be automatically renewed for a period of not less than 1 year unless terminated under subparagraph (B).

''(B) TERMINATION.—

''(i) BY THE SECRETARY.—The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

''(ii) BY A MANUFACTURER.—A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

''(I) if the termination occurs before January 30 of a plan year, as of the day after the end of the plan year; and

''(II) if the termination occurs on or after January 30 of a plan year, as of the day after the end of the succeeding plan year.

''(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect discounts for applicable drugs of the manufacturer that are due under the agreement before the effective date of its termination.

''(iv) NOTICE TO THIRD PARTY.—The Secretary shall provide notice of such termination to a third party with a contract under subsection (d)(3) within not less than 30 days before the effective date of such termination.

''(c) DUTIES DESCRIBED.—The duties described in this subsection are the following:

''(1) ADMINISTRATION OF PROGRAM.—Administering the program, including—

''(A) the determination of the amount of the discounted price of an applicable drug of a manufacturer;

''(B) the establishment of procedures under which discounted prices are provided to applicable beneficiaries at pharmacies or by mail order service at the point-of-sale of an applicable drug;

''(C) the establishment of procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

''(i) the negotiated price of the applicable drug; and

''(ii) the discounted price of the applicable drug;

''(D) the establishment of procedures to ensure that the discounted price for an applica-

ble drug under this section is applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries as the Secretary may specify; and

''(E) providing a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the third party with a contract under subsection (d)(3).

''(2) MONITORING COMPLIANCE.—

''(A) IN GENERAL.—The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under this section.

''(B) NOTIFICATION.—If a third party with a contract under subsection (d)(3) determines that the manufacturer is not in compliance with such agreement, the third party shall notify the Secretary of such noncompliance for appropriate enforcement under subsection (e).

''(3) COLLECTION OF DATA FROM PRESCRIPTION DRUG PLANS AND MA–PD PLANS.—The Secretary may collect appropriate data from prescrip-

tion drug plans and MA–PD plans in a timeframe that allows for discounted prices to be provided for applicable drugs under this section.

''(d) ADMINISTRATION.—

''(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall provide for the implementation of this section, including the performance of the duties described in subsection (c).

''(2) LIMITATION.—In providing for the implementation of this section, the Secretary shall not receive or distribute any funds of a manufacturer under the program.

''(3) CONTRACT WITH THIRD PARTIES.—The Secretary shall enter into a contract with 1 or more third parties to administer the requirements established by the Secretary in order to carry out this section. At a minimum, the contract with a third party under the preceding sentence shall require that the third party—

''(A) receive and transmit information between the Secretary, manufacturers, and other individuals or entities the Secretary determines appropriate;

''(B) receive, distribute, or facilitate the distribution of funds of manufacturers to ap-

propriate individuals or entities in order to meet the obligations of manufacturers under agreements under this section;

''(C) provide adequate and timely information to manufacturers, consistent with the agreement with the manufacturer under this section, as necessary for the manufacturer to fulfill its obligations under this section; and

''(D) permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the third party to determine discounts for applicable drugs of the manufacturer under the program.

''(4) PERFORMANCE REQUIREMENTS.—The Secretary shall establish performance requirements for a third party with a contract under paragraph (3) and safeguards to protect the independence and integrity of the activities carried out by the third party under the program under this section.

''(5) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement the program under this section by program instruction or otherwise.

''(6) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the program under this section.

''(e) ENFORCEMENT.—

''(1) AUDITS.—Each manufacturer with an agreement in effect under this section shall be subject to periodic audit by the Secretary.

''(2) CIVIL MONEY PENALTY.—

''(A) IN GENERAL.—The Secretary may impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with such agreement for each such failure in an amount the Secretary determines is equal to the sum of—

''(i) the amount that the manufacturer would have paid with respect to such discounts under the agreement, which will then be used to pay the discounts which the manufacturer had failed to provide; and

''(ii) 25 percent of such amount.

''(B) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under

this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(f) CLARIFICATION REGARDING AVAILABILITY OF OTHER COVERED PART D DRUGS.—Nothing in this section shall prevent an applicable beneficiary from purchasing a covered part D drug that is not an applicable drug (including a generic drug or a drug that is not on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in).

''(g) DEFINITIONS.—In this section:

''(1) APPLICABLE BENEFICIARY.—The term 'applicable beneficiary' means an individual who, on the date of dispensing a covered part D drug—

''(A) is enrolled in a prescription drug plan or an MA–PD plan;

''(B) is not enrolled in a qualified retiree prescription drug plan; and

''(C) has incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual deductible with respect to such individual for such year, as specified in section 1860D–2(b)(1), section 1860D–

14(a)(1)(B), or section 1860D–14(a)(2)(B), as applicable.

''(2) APPLICABLE DRUG.—The term 'applicable drug', with respect to an applicable beneficiary—

''(A) means a covered part D drug—

''(i) approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act; and

''(ii)(I) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

''(II) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

"(III) is provided through an exception or appeal; and

"(B) does not include a selected drug (as defined in section 1192(c)) during a price applicability period (as defined in section 1191(b)(2)) with respect to such drug.

"(3) APPLICABLE NUMBER OF CALENDAR DAYS.—The term 'applicable number of calendar days' means—

"(A) with respect to claims for reimbursement submitted electronically, 14 days; and

"(B) with respect to claims for reimbursement submitted otherwise, 30 days.

"(4) DISCOUNTED PRICE.—

"(A) IN GENERAL.—The term 'discounted price' means, with respect to an applicable drug of a manufacturer furnished during a year to an applicable beneficiary—

"(i) who has not incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i)

for the year, 90 percent of the negotiated price of such drug; and

''(ii) who has incurred such costs, as so determined, in the year that are equal to or exceed such threshold for the year, 70 percent of the negotiated price of such drug.

''(B) CLARIFICATION.—Nothing in this section shall be construed as affecting the responsibility of an applicable beneficiary for payment of a dispensing fee for an applicable drug.

''(C) SPECIAL CASE FOR CERTAIN CLAIMS.—

''(i) CLAIMS SPANNING DEDUCTIBLE.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall at or above the annual deductible specified in section 1860D–2(b)(1) for the year, the manufacturer of the applicable drug shall provide the discounted price under this section on only the portion of the negotiated price of the applicable drug

that falls at or above such annual deductible.

''(ii) CLAIMS SPANNING OUT-OF-POCKET THRESHOLD.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall entirely below or entirely above the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year, the manufacturer of the applicable drug shall provide the discounted price—

''(I) in accordance with subparagraph (A)(i) on the portion of the negotiated price of the applicable drug that falls below such threshold; and

''(II) in accordance with subparagraph (A)(ii) on the portion of such price of such drug that falls at or above such threshold.

''(5) MANUFACTURER.—The term 'manufacturer' means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug prod-

ucts, 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. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

''(6) NEGOTIATED PRICE.—The term 'negotiated price' has the meaning given such term in section 423.100 of title 42, Code of Federal Regulations (or any successor regulation), except that, with respect to an applicable drug, such negotiated price shall not include any dispensing fee for the applicable drug.

''(7) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—The term 'qualified retiree prescription drug plan' has the meaning given such term in section 1860D–22(a)(2).''.

(2) SUNSET OF MEDICARE COVERAGE GAP DISCOUNT PROGRAM.—Section 1860D–14A of the Social Security Act (42 U.S.C. 1395–114a) is amended—

(A) in subsection (a), in the first sentence, by striking ''The Secretary'' and inserting ''Subject to subsection (h), the Secretary''; and

(B) by adding at the end the following new subsection:

''(h) SUNSET OF PROGRAM.—

''(1) IN GENERAL.—The program shall not apply with respect to applicable drugs dispensed on or after January 1, 2022, and, subject to paragraph (2), agreements under this section shall be terminated as of such date.

''(2) CONTINUED APPLICATION FOR APPLICABLE DRUGS DISPENSED PRIOR TO SUNSET.—The provisions of this section (including all responsibilities and duties) shall continue to apply after January 1, 2022, with respect to applicable drugs dispensed prior to such date.''.

(3) INCLUSION OF ACTUARIAL VALUE OF MANUFACTURER DISCOUNTS IN BIDS.—Section 1860D–11 of the Social Security Act (42 U.S.C. 1395w–111) is amended—

(A) in subsection (b)(2)(C)(iii)—

(i) by striking ''assumptions regarding the reinsurance'' and inserting ''assumptions regarding—

''(I) the reinsurance''; and

(ii) by adding at the end the following:

''(II) for 2022 and each subsequent year, the manufacturer discounts provided under section 1860D–14C subtracted from the actuarial value to produce such bid; and''; and

(B) in subsection (c)(1)(C)—

(i) by striking ''an actuarial valuation of the reinsurance'' and inserting ''an actuarial valuation of—

''(i) the reinsurance'';

(ii) in clause (i), as inserted by clause (i) of this subparagraph, by adding ''and'' at the end; and

(iii) by adding at the end the following:

''(ii) for 2022 and each subsequent year, the manufacturer discounts provided under section 1860D–14C;''.

(d) CONFORMING AMENDMENTS.—

(1) Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102) is amended—

(A) in subsection (a)(2)(A)(i)(I), by striking '', or an increase in the initial'' and inserting ''or, for a year preceding 2022, an increase in the initial'';

(B) in subsection (c)(1)(C)—

(i) in the subparagraph heading, by striking ''AT INITIAL COVERAGE LIMIT''; and

(ii) by inserting ''for a year preceding 2022 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2022 and each subsequent year'' after ''subsection (b)(3) for the year'' each place it appears; and

(C) in subsection (d)(1)(A), by striking ''or an initial'' and inserting ''or, for a year preceding 2022, an initial''.

(2) Section 1860D–4(a)(4)(B)(i) of the Social Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is amended by striking ''the initial'' and inserting ''for a year preceding 2022, the initial''.

(3) Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)) is amended—

(A) in paragraph (1)—

(i) in subparagraph (C), by striking ''The continuation'' and inserting ''For a year preceding 2022, the continuation'';

(ii) in subparagraph (D)(iii), by striking ''1860D–2(b)(4)(A)(i)(I)'' and inserting ''1860D–2(b)(4)(A)(i)(I)(aa)''; and

(iii) in subparagraph (E), by striking ''The elimination'' and inserting ''For a year preceding 2022, the elimination''; and

(B) in paragraph (2)—

(i) in subparagraph (C), by striking ''The continuation'' and inserting ''For a year preceding 2022, the continuation''; and

(ii) in subparagraph (E), by striking ''1860D–2(b)(4)(A)(i)(I)'' and inserting ''1860D–2(b)(4)(A)(i)(I)(aa)''.

(4) Section 1860D–21(d)(7) of the Social Security Act (42 U.S.C. 1395w–131(d)(7)) is amended by striking ''section 1860D–2(b)(4)(B)(i)'' and inserting ''section 1860D–2(b)(4)(C)(i)''.

(5) Section 1860D–22(a)(2)(A) of the Social Security Act (42 U.S.C. 1395w–132(a)(2)(A)) is amended—

(A) by striking ''the value of any discount'' and inserting the following: ''the value of—

''(i) for years prior to 2022, any discount'';

(B) in clause (i), as inserted by subparagraph (A) of this paragraph, by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following new clause:

''(ii) for 2022 and each subsequent year, any discount provided pursuant to section 1860D–14C.''.

(6) Section 1860D–41(a)(6) of the Social Security Act (42 U.S.C. 1395w–151(a)(6)) is amended—

(A) by inserting ''for a year before 2022'' after ''1860D–2(b)(3)''; and

(B) by inserting ''for such year'' before the period.

(7) Section 1860D–43 of the Social Security Act (42 U.S.C. 1395w–153) is amended—

(A) in subsection (a)—

(i) by striking paragraph (1) and inserting the following:

''(1) participate in—

''(A) for 2011 through 2021, the Medicare coverage gap discount program under section 1860D–14A; and

''(B) for 2022 and each subsequent year, the manufacturer discount program under section 1860D–14C;'';

(ii) by striking paragraph (2) and inserting the following:

''(2) have entered into and have in effect—

''(A) for 2011 through 2021, an agreement described in subsection (b) of section 1860D–14A with the Secretary; and

''(B) for 2022 and each subsequent year, an agreement described in subsection (b) of section 1860D–14C with the Secretary; and''; and

(iii) by striking paragraph (3) and inserting the following:

''(3) have entered into and have in effect, under terms and conditions specified by the Secretary—

''(A) for 2011 through 2021, a contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of section 1860D–14A; and

''(B) for 2022 and each subsequent year, a contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of section 1860D–14C.''; and

(B) by striking subsection (b) and inserting the following:

''(b) EFFECTIVE DATE.—Paragraphs (1)(A), (2)(A), and (3)(A) of subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011, and before January 1, 2022, and paragraphs (1)(B), (2)(B), and (3)(B) of such subsection shall apply to covered part D drugs dispensed under this part on or after January 1, 2022.''.

(8) Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(A) in subsection (c)(1)(C)(i)(VI), by inserting before the period at the end the following: ''or under the manufacturer discount program under section 1860D–14C''; and

(B) in subsection (k)(1)(B)(i)(V), by inserting before the period at the end the following: ''or under section 1860D–14C''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan year 2022 and subsequent plan years.

SEC. 302. ALLOWING CERTAIN ENROLLEES OF PRESCRIPTION DRUGS PLANS AND MA–PD PLANS UNDER MEDICARE PROGRAM TO SPREAD OUT COST-SHARING UNDER CERTAIN CIRCUMSTANCES.

Section 1860D–2(b)(2) of the Social Security Act (42 U.S.C. 1395w–102(b)(2)), as amended by section 301, is further amended—

(1) in subparagraph (A), by striking ''Subject to subparagraphs (C) and (D)'' and inserting ''Subject to subparagraphs (C), (D), and (E)''; and

(2) by adding at the end the following new subparagraph:

''(E) ENROLLEE OPTION REGARDING SPREADING COST-SHARING.—The Secretary shall establish by regulation a process under which, with respect to plan year 2022 and subsequent plan years, a prescription drug plan or an MA–PD plan shall, in the case of a part D eligible individual enrolled with such plan for such plan year who is not a subsidy eligible individual (as defined in section 1860D–14(a)(3)) and with respect to whom the plan projects that the dispensing of the first fill of a covered part D drug to such individual will result in the individual incurring costs that are equal to or above

the annual out-of-pocket threshold specified in paragraph (4)(B) for such plan year, provide such individual with the option to make the coinsurance payment required under subparagraph (A) (for the portion of such costs that are not above such annual out-of-pocket threshold) in the form of periodic installments over the remainder of such plan year.''.

SEC. 303. ESTABLISHMENT OF PHARMACY QUALITY MEASURES UNDER MEDICARE PART D.

Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) is amended—

(1) by redesignating the paragraph (6), as added by section 50354 of division E of the Bipartisan Budget Act of 2018 (Public Law 115–123), as paragraph (7); and

(2) by adding at the end the following new paragraph:

''(8) APPLICATION OF PHARMACY QUALITY MEASURES.—

''(A) IN GENERAL.—A PDP sponsor that implements incentive payments to a pharmacy or price concessions paid by a pharmacy based on quality measures shall use measures established or approved by the Secretary under sub-

paragraph (B) with respect to payment for covered part D drugs dispensed by such pharmacy.

''(B) STANDARD PHARMACY QUALITY MEASURES.—The Secretary shall establish or approve standard quality measures from a consensus and evidence-based organization for payments described in subparagraph (A). Such measures shall focus on patient health outcomes and be based on proven criteria measuring pharmacy performance.

''(C) EFFECTIVE DATE.—The requirement under subparagraph (A) shall take effect for plan years beginning on or after January 1, 2021, or such earlier date specified by the Secretary if the Secretary determines there are sufficient measures established or approved under subparagraph (B) to meet the requirement under subparagraph (A).''.

TITLE IV—DRUG PRICE TRANSPARENCY

SEC. 401. DRUG PRICE TRANSPARENCY.

Part A of title XI of the Social Security Act is amended by adding at the end the following new sections:

''SEC. 1150C. REPORTING ON DRUG PRICES.

''(a) DEFINITIONS.—In this section:

''(1) MANUFACTURER.—The term 'manufacturer' means the person—

''(A) that holds the application for a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act; or

''(B) who is responsible for setting the wholesale acquisition cost for the drug.

''(2) QUALIFYING DRUG.—The term 'qualifying drug' means any drug that is approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under subsection (a) or (k) of section 351 of the Public Health Service Act—

''(A) that has a wholesale acquisition cost of $100 or more, adjusted for inflation occurring after the date of enactment of this section, for a month's supply or a typical course of treatment that lasts less than a month, and is—

''(i) subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act; and

''(ii) not a preventative vaccine; and

''(B) for which, during the previous calendar year, at least 1 dollar of the total amount of sales were for individuals enrolled under the Medicare program under title XVIII or under a State Medicaid plan under title XIX or under a waiver of such plan.

''(3) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given that term in section 1847A(c)(6)(B).

''(b) REPORT.—

''(1) REPORT REQUIRED.—The manufacturer of a qualifying drug shall submit a report to the Secretary if, with respect to the qualifying drug—

''(A) there is an increase in the price of the qualifying drug that results in an increase in the wholesale acquisition cost of that drug that is equal to—

''(i) 10 percent or more within a 12-month period beginning on or after January 1, 2019; or

''(ii) 25 percent or more within a 36-month period beginning on or after January 1, 2019;

''(B) the estimated price of the qualifying drug or spending per individual or per user of

such drug (as estimated by the Secretary) for the applicable year (or per course of treatment in such applicable year as determined by the Secretary) is at least $26,000 beginning on or after January 1, 2021; or

''(C) there was an increase in the price of the qualifying drug that resulted in an increase in the wholesale acquisition cost of that drug that is equal to—

''(i) 10 percent or more within a 12-month period that begins and ends during the 5-year period preceding January 1, 2021; or

''(ii) 25 percent or more within a 36-month period that begins and ends during the 5-year period preceding January 1, 2021.

''(2) REPORT DEADLINE.—Each report described in paragraph (1) shall be submitted to the Secretary—

''(A) in the case of a report with respect to an increase in the price of a qualifying drug that occurs during the period beginning on January 1, 2019, and ending on the day that is 60 days after the date of the enactment of this sec-

tion, not later than 90 days after such date of enactment;

''(B) in the case of a report with respect to an increase in the price of a qualifying drug that occurs after the period described in subparagraph (A), not later than 30 days prior to the planned effective date of such price increase for such qualifying drug;

''(C) in the case of a report with respect to a qualifying drug that meets the criteria under paragraph (1)(B), not later than 30 days after such drug meets such criteria; and

''(D) in the case of a report with respect to an increase in the price of a qualifying drug that occurs during a 12-month or 36-month period described in paragraph (1)(C), not later than April 1, 2021.

''(c) CONTENTS.—A report under subsection (b), consistent with the standard for disclosures described in section 213.3(d) of title 12, Code of Federal Regulations (as in effect on the date of enactment of this section), shall, at a minimum, include—

''(1) with respect to the qualifying drug—

''(A) the percentage by which the manufacturer will raise the wholesale acquisition cost of

the drug within the 12-month period or 36-month period as described in subsection (b)(1)(A)(i), (b)(1)(A)(ii), (b)(1)(C)(i), or (b)(1)(C)(ii), as applicable, and the effective date of such price increase or the cost associated with a qualifying drug if such drug meets the criteria under subsection (b)(1)(B) and the effective date at which such drug meets such criteria;

''(B) an explanation for, and description of, each price increase for such drug that will occur during the 12-month period or the 36-month period described in subsection (b)(1)(A)(i), (b)(1)(A)(ii), (b)(1)(C)(i), or (b)(1)(C)(ii), as applicable;

''(C) an explanation for, and description of, the cost associated with a qualifying drug if such drug meets the criteria under subsection (b)(1)(B), as applicable;

''(D) if known and different from the manufacturer of the qualifying drug, the identity of—

''(i) the sponsor or sponsors of any investigational new drug applications under section 505(i) of the Federal Food, Drug,

and Cosmetic Act for clinical investigations with respect to such drug, for which the full reports are submitted as part of the application—

''(I) for approval of the drug under section 505 of such Act; or

''(II) for licensure of the drug under section 351 of the Pubic Health Service Act; and

''(ii) the sponsor of an application for the drug approved under such section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act;

''(E) a description of the history of the manufacturer's price increases for the drug since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351 of the Public Health Service Act, or since the manufacturer acquired such approved application or license, if applicable;

''(F) the current wholesale acquisition cost of the drug;

"(G) the total expenditures of the manufacturer on—

"(i) materials and manufacturing for such drug;

"(ii) acquiring patents and licensing for such drug; and

"(iii) purchasing or acquiring such drug from another manufacturer, if applicable;

"(H) the percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds;

"(I) the total expenditures of the manufacturer on research and development for such drug that is necessary to demonstrate that it meets applicable statutory standards for approval under section 505 of the Federal Food, Drug, and Cosmetic Act or licensure under section 351 of the Public Health Service Act, as applicable;

"(J) the total expenditures of the manufacturer on pursuing new or expanded indications or dosage changes for such drug under section 505 of the Federal Food, Drug, and Cosmetic

Act or section 351 of the Public Health Service Act;

''(K) the total expenditures of the manufacturer on carrying out postmarket requirements related to such drug, including under section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act;

''(L) the total revenue and the net profit generated from the qualifying drug for each calendar year since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351 of the Public Health Service Act, or since the manufacturer acquired such approved application or license; and

''(M) the total costs associated with marketing and advertising for the qualifying drug;

''(2) with respect to the manufacturer—

''(A) the total revenue and the net profit of the manufacturer for each of the 12-month period described in subsection (b)(1)(A)(i) or (b)(1)(C)(i) or the 36-month period described in subsection (b)(1)(A)(ii) or (b)(1)(C)(ii), as applicable;

''(B) all stock-based performance metrics used by the manufacturer to determine executive compensation for each of the 12-month periods described in subsection (b)(1)(A)(i) or (b)(1)(C)(i) or the 36-month periods described in subsection (b)(1)(A)(ii) or (b)(1)(C)(ii), as applicable; and

''(C) any additional information the manufacturer chooses to provide related to drug pricing decisions, such as total expenditures on—

''(i) drug research and development; or

''(ii) clinical trials, including on drugs that failed to receive approval by the Food and Drug Administration; and

''(3) such other related information as the Secretary considers appropriate and as specified by the Secretary.

''(d) INFORMATION PROVIDED.—The manufacturer of a qualifying drug that is required to submit a report under subsection (b), shall ensure that such report and any explanation for, and description of, each price increase described in subsection (c)(1) shall be truthful, not misleading, and accurate.

''(e) CIVIL MONETARY PENALTY.—Any manufacturer of a qualifying drug that fails to submit a report for the drug as required by this section, following notification by the Secretary to the manufacturer that the manufacturer is not in compliance with this section, shall be subject to a civil monetary penalty of $75,000 for each day on which the violation continues.

''(f) FALSE INFORMATION.—Any manufacturer that submits a report for a drug as required by this section that knowingly provides false information in such report is subject to a civil monetary penalty in an amount not to exceed $100,000 for each item of false information.

''(g) PUBLIC POSTING.—

''(1) IN GENERAL.—Subject to paragraph (4), the Secretary shall post each report submitted under subsection (b) on the public website of the Department of Health and Human Services the day the price increase of a qualifying drug is scheduled to go into effect.

''(2) FORMAT.—In developing the format in which reports will be publicly posted under paragraph (1), the Secretary shall consult with stakeholders, including beneficiary groups, and shall seek feedback from consumer advocates and readability experts on the format and presentation of the con-

tent of such reports to ensure that such reports are—

"(A) user-friendly to the public; and

"(B) written in plain language that consumers can readily understand.

"(3) LIST.—In addition to the reports submitted under subsection (b), the Secretary shall also post a list of each qualifying drug with respect to which the manufacturer was required to submit such a report in the preceding year and whether such manufacturer was required to submit such report based on a qualifying price increase or whether such drug meets the criteria under subsection (b)(1)(B).

"(4) PROTECTED INFORMATION.—In carrying out this section, the Secretary shall enforce applicable law concerning the protection of confidential commercial information and trade secrets.

"SEC. 1150D. ANNUAL REPORT TO CONGRESS.

"(a) IN GENERAL.—Subject to subsection (b), the Secretary shall submit to the Committees on Energy and Commerce and Ways and Means of the House of Representatives and the Committees on Health, Education, Labor, and Pensions and Finance of the Senate, and post on the public website of the Department of Health and Human Services in a way that is user-friendly to the pub-

lic and written in plain language that consumers can readily understand, an annual report—

''(1) summarizing the information reported pursuant to section 1150C;

''(2) including copies of the reports and supporting detailed economic analyses submitted pursuant to such section;

''(3) detailing the costs and expenditures incurred by the Department of Health and Human Services in carrying out section 1150C; and

''(4) explaining how the Department of Health and Human Services is improving consumer and provider information about drug value and drug price transparency.

''(b) PROTECTED INFORMATION.—In carrying out this section, the Secretary shall enforce applicable law concerning the protection of confidential commercial information and trade secrets.''.

TITLE V—PROGRAM IMPROVEMENTS FOR MEDICARE LOW-INCOME BENEFICIARIES

SEC. 501. DISSEMINATION TO MEDICARE PART D SUBSIDY ELIGIBLE INDIVIDUALS OF INFORMATION COMPARING PREMIUMS OF CERTAIN PRESCRIPTION DRUG PLANS.

Section 1860D–1(c)(3) of the Social Security Act (42 U.S.C. 1395w–101(c)(3)) is amended by adding at the end the following new subparagraph:

"(C) INFORMATION ON PREMIUMS FOR SUBSIDY ELIGIBLE INDIVIDUALS.—

"(i) IN GENERAL.—For plan year 2022 and each subsequent plan year, the Secretary shall disseminate to each subsidy eligible individual (as defined in section 1860D–14(a)(3)) information under this paragraph comparing premiums that would apply to such individual for prescription drug coverage under LIS benchmark plans, including, in the case of an individual enrolled in a prescription drug plan under this part, information that compares the premium that would apply if such individual were to remain enrolled in such plan

to premiums that would apply if the individual were to enroll in other LIS benchmark plans.

''(ii) LIS BENCHMARK PLAN.—For purposes of clause (i), the term 'LIS benchmark plan' means, with respect to an individual, a prescription drug plan under this part that is offered in the region in which the individual resides and—

''(I) that provides for a premium that is not more than the low-income benchmark premium amount (as defined in section 1860D–14(b)(2)) for such region; or

''(II) with respect to which the premium would be waived as de minimis pursuant to section 1860D–14(a)(5) for such individual.''.

SEC. 502. PROVIDING FOR INTELLIGENT ASSIGNMENT OF CERTAIN SUBSIDY ELIGIBLE INDIVIDUALS AUTO-ENROLLED UNDER MEDICARE PRESCRIPTION DRUG PLANS AND MA–PD PLANS.

(a) IN GENERAL.—Section 1860D–1(b)(1) of the Social Security Act (42 U.S.C. 1395w–101(b)(1)) is amended—

(1) in subparagraph (C)—

(A) by inserting after ''PDP region'' the following: ''or through use of an intelligent assignment process that is designed to maximize the access of such individual to necessary prescription drugs while minimizing costs to such individual and to the program under this part to the greatest extent possible. In the case the Secretary enrolls such individuals through use of an intelligent assignment process, such process shall take into account the extent to which prescription drugs necessary for the individual are covered in the case of a PDP sponsor of a prescription drug plan that uses a formulary, the use of prior authorization or other restrictions on access to coverage of such prescription drugs by such a sponsor, and the overall quality of a prescription drug plan as measured by quality ratings established by the Secretary''; and

(B) by striking ''Nothing in the previous sentence'' and inserting ''Nothing in this subparagraph''; and

(2) in subparagraph (D)—

(A) by inserting after ''PDP region'' the following: ''or through use of an intelligent assignment process that is designed to maximize the access of such individual to necessary prescription drugs while minimizing costs to such individual and to the program under this part to the greatest extent possible. In the case the Secretary enrolls such individuals through use of an intelligent assignment process, such process shall take into account the extent to which prescription drugs necessary for the individual are covered in the case of a PDP sponsor of a prescription drug plan that uses a formulary, the use of prior authorization or other restrictions on access to coverage of such prescription drugs by such a sponsor, and the overall quality of a prescription drug plan as measured by quality ratings established by the Secretary''; and

(B) by striking ''Nothing in the previous sentence'' and inserting ''Nothing in this subparagraph''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply with respect to plan years beginning with plan year 2022.

SEC. 503. EXPANDING ELIGIBILITY FOR LOW-INCOME SUBSIDIES UNDER PART D OF THE MEDICARE PROGRAM.

Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)), as amended by section 301(d), is further amended—

(1) in the subsection heading, by striking ''INDIVIDUALS'' and all that follows through ''LINE'' and inserting ''CERTAIN INDIVIDUALS'';

(2) in paragraph (1)—

(A) by striking the paragraph heading and inserting ''INDIVIDUALS WITH CERTAIN LOW INCOMES''; and

(B) in the matter preceding subparagraph (A), by inserting ''(or, with respect to a plan year beginning on or after January 1, 2024, 150 percent)'' after ''135 percent''; and

(3) in paragraph (2)—

(A) by striking the paragraph heading and inserting ''OTHER LOW-INCOME INDIVIDUALS''; and

(B) in the matter preceding subparagraph (A), by striking ''In the case of a subsidy'' and inserting ''With respect to a plan year beginning before January 1, 2024, in the case of a subsidy''.

SEC. 504. AUTOMATIC ELIGIBILITY OF CERTAIN LOW-INCOME TERRITORIAL RESIDENTS FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER THE MEDICARE PROGRAM; SUNSET OF ENHANCED ALLOTMENT PROGRAM.

(a) AUTOMATIC ELIGIBILITY OF CERTAIN LOW-INCOME TERRITORIAL RESIDENTS FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER THE MEDICARE PROGRAM.—

(1) IN GENERAL.—Section 1860D–14(a)(3) of the Social Security Act (42 U.S.C. 1395w–114(a)(3)) is amended—

(A) in subparagraph (B)(v)—

(i) in subclause (I), by striking ''and'' at the end;

(ii) in subclause (II), by striking the period and inserting ''; and''; and

(iii) by inserting after subclause (II) the following new subclause:

''(III) with respect to plan years beginning on or after January 1, 2024, shall provide that any part D eligible individual who is enrolled for medical assistance under the State Medicaid plan of a territory (as defined in section 1935(f)) under title

XIX (or a waiver of such a plan) shall be treated as a subsidy eligible individual described in paragraph (1).''; and

(B) in subparagraph (F), by adding at the end the following new sentence: ''The previous sentence shall not apply with respect to eligibility determinations for premium and cost-sharing subsidies under this section made on or after January 1, 2024.''.

(2) CONFORMING AMENDMENT.—Section 1860D–31(j)(2)(D) of the Social Security Act (42 U.S.C. 1395w–141(j)(2)(D)) is amended by adding at the end the following new sentence: ''The previous sentence shall not apply with respect to amounts made available to a State under this paragraph on or after January 1, 2024.''.

(b) SUNSET OF ENHANCED ALLOTMENT PROGRAM.—

(1) IN GENERAL.—Section 1935(e) of the Social Security Act (42 U.S.C. 1396u–5(e)) is amended—

(A) in paragraph (1)(A), by inserting after ''such State'' the following: ''before January 1, 2021''; and

(B) in paragraph (3)—

(i) in subparagraph (A), in the matter preceding clause (i), by inserting after ''a year'' the following: ''(before 2024)''; and

(ii) in subparagraph (B)(iii), by striking ''a subsequent year'' and inserting ''each of fiscal years 2008 through 2023''.

(2) TERRITORY DEFINED.—Section 1935 of the Social Security Act (42 U.S.C. 1396u–5) is amended by adding at the end the following new subsection:

''(f) TERRITORY DEFINED.—In this section, the term 'territory' means Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.''.

SEC. 505. AUTOMATIC QUALIFICATION OF CERTAIN MEDICAID BENEFICIARIES FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER PART D OF THE MEDICARE PROGRAM.

Clause (v) of section 1860D–14(a)(3)(B) of the Social Security Act (42 U.S.C. 1395w–114(a)(3)(B)), as amended by section 504, is further amended—

(1) in subclause (II), by striking ''and'' at the end;

(2) in subclause (III), by striking the period and inserting ''; and''; and

(3) by inserting after subclause (III) the following new subclause:

"(IV) with respect to plan years beginning on or after January 1, 2024, shall, notwithstanding the preceding clauses of this subparagraph, provide that any part D eligible individual not described in subclause (I), (II), or (III) who is enrolled, as of the day before the date on which such individual attains the age of 65, for medical assistance under a State plan under title XIX (or a waiver of such plan) pursuant to clause (i)(VIII) or (ii)(XX) of section 1902(a)(10)(A), and who has income below 200 percent of the poverty line applicable to a family of the size involved, shall be treated as a subsidy eligible individual described in paragraph (1) for a limited period of time, as specified by the Secretary.".

SEC. 506. PROVIDING FOR CERTAIN RULES REGARDING THE TREATMENT OF ELIGIBLE RETIREMENT PLANS IN DETERMINING THE ELIGIBILITY OF INDIVIDUALS FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER PART D OF THE MEDICARE PROGRAM.

Section 1860D–14(a)(3)(C)(i) of the Social Security Act (42 U.S.C. 1395w–114(a)(3)(C)(i)) is amended, by striking ''except that support and maintenance furnished in kind shall not be counted as income; and'' and inserting ''except that—

''(I) support and maintenance furnished in kind shall not be counted as income; and

''(II) for plan years beginning on or after January 1, 2024, any distribution or withdrawal from an eligible retirement plan (as defined in subparagraph (B) of section 402(c)(8) of the Internal Revenue Code of 1986, but excluding any defined benefit plan described in clause (iv) or (v) of such subparagraph and any qualified trust (as defined in subparagraph (A) of such section) which is part of such a

defined benefit plan) shall be counted as income; and''.

SEC. 507. REDUCING COST-SHARING AND OTHER PROGRAM IMPROVEMENTS FOR LOW-INCOME BENEFICIARIES.

(a) INCREASE IN INCOME ELIGIBILITY TO 150 PERCENT OF FPL FOR QUALIFIED MEDICARE BENEFICIARIES.—

(1) IN GENERAL.—Section 1905(p)(2)(A) of the Social Security Act (42 U.S.C. 1396d(p)(2)(A)) is amended by striking ''shall be at least the percent provided under subparagraph (B) (but not more than 100 percent) of the official poverty line'' and all that follows through the period at the end and inserting the following: ''shall be—

''(i) before January 1, 2024, 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; and

''(ii) on or after January 1, 2024, equal to 150 percent of the official poverty line (as so defined and revised) applicable to a family of the size involved.''.

(2) NOT COUNTING IN-KIND SUPPORT AND MAINTENANCE AS INCOME.—Section 1905(p)(2)(D) of the Social Security Act (42 U.S.C. 1396d(p)(2)(D)) is amended by adding at the end the following new clause:

''(iii) In determining income under this subsection, support and maintenance furnished in kind shall not be counted as income.''.

(3) CONFORMING AMENDMENTS.—

(A) Section 1902(a)(10)(E) of the Social Security Act (42 U.S.C. 1396a(a)(10)(E)) is amended—

(i) in clause (iii), by striking ''for making medical'' and inserting ''before January 1, 2024, for making medical''; and

(ii) in clause (iv), by striking ''subject to sections'' and inserting ''before January 1, 2024, subject to sections''.

(B) Section 1933 of the Social Security Act (42 U.S.C. 1396u–3) is amended—

(i) in subsection (a), by striking ''A State plan'' and inserting ''Subject to subsection (h), a State plan''; and

(ii) by adding at the end the following new subsection:

''(h) SUNSET.—The provisions of this section shall have no force or effect after December 31, 2023.''.

(b) 100 PERCENT FMAP.—Section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended by adding at the end the following new subsection:

''(gg) INCREASED FMAP FOR EXPANDED MEDICARE COST-SHARING POPULATIONS.—

''(1) IN GENERAL.—Notwithstanding subsection (b), with respect to expenditures described in paragraph (2) the Federal medical assistance percentage shall be equal to 100 percent.

''(2) EXPENDITURES DESCRIBED.—The expenditures described in this paragraph are expenditures made on or after January 1, 2024, for medical assistance for medicare cost-sharing provided to any individual under clause (i) or (ii) of section 1902(a)(10)(E) who would not have been eligible for medicare cost-sharing under any such clause under

the income or resource eligibility standards in effect on October 1, 2018.''.

TITLE VI—PROVIDING FOR DENTAL, VISION, AND HEARING COVERAGE UNDER THE MEDICARE PROGRAM

SEC. 601. DENTAL AND ORAL HEALTH CARE.

(a) COVERAGE.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended—

(1) in subparagraph (GG), by striking ''and'' after the semicolon at the end;

(2) in subparagraph (HH), by striking the period at the end and adding ''; and''; and

(3) by adding at the end the following new subparagraph:

''(II) dental and oral health services (as defined in subsection (kkk));''.

(b) DENTAL AND ORAL HEALTH SERVICES DEFINED.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''(kkk) DENTAL AND ORAL HEALTH SERVICES.—

''(1) IN GENERAL.—The term 'dental and oral health services' means items and services (other than such items and services for which payment may

be made under part A as inpatient hospital services) that are furnished during 2025 or a subsequent year, for which coverage was not provided under part B as of the date of the enactment of this subsection, and that are—

''(A) the preventive and screening services described in paragraph (2) furnished by a doctor of dental surgery or of dental medicine (as described in subsection (r)(2)) or an oral health professional (as defined in paragraph (4)); or

''(B) the basic treatments specified for such year by the Secretary pursuant to paragraph (3)(A) and the major treatments specified for such year by the Secretary pursuant to paragraph (3)(B) furnished by such a doctor or such a professional.

''(2) PREVENTIVE AND SCREENING SERVICES.—The preventive and screening services described in this paragraph are the following:

''(A) Oral exams.

''(B) Dental cleanings.

''(C) Dental x-rays performed in the office of a doctor or professional described in paragraph (1)(A).

''(D) Fluoride treatments.

''(3) BASIC AND MAJOR TREATMENTS.—For 2025 and each subsequent year, the Secretary shall specify—

''(A) basic treatments (which may include basic tooth restorations, basic periodontic services, tooth extractions, and oral disease management services); and

''(B) major treatments (which may include major tooth restorations, major periodontic services, bridges, crowns, and root canals);

that shall be included as dental and oral health services for such year.

''(4) ORAL HEALTH PROFESSIONAL.—The term 'oral health professional' means, with respect to dental and oral health services, a health professional who is licensed to furnish such services, acting within the scope of such license, by the State in which such services are furnished.''.

(c) PAYMENT; COINSURANCE; AND LIMITATIONS.—

(1) IN GENERAL.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended—

(A) in subparagraph (N), by inserting ''and dental and oral health services (as defined

in section 1861(kkk))'' after ''section 1861(hhh)(1))'';

(B) by striking ''and'' before ''(CC)''; and

(C) by inserting before the semicolon at the end the following: '', and (DD) with respect to dental and oral health services (as defined in section 1861(kkk)), the amount paid shall be the payment amount specified under section 1834(x)''.

(2) PAYMENT AND LIMITS SPECIFIED.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

''(x) PAYMENT AND LIMITS FOR DENTAL AND ORAL HEALTH SERVICES.—

''(1) IN GENERAL.—The payment amount under this part for dental and oral health services (as defined in section 1861(kkk)) shall be, subject to paragraph (3), the applicable percent (specified in paragraph (2)) of the lesser of the actual charge for the services or the amount determined under the payment basis determined under section 1848. In determining such amounts determined under such payment basis, the Secretary shall consider payment rates paid to dentists for comparable services under

State plans under title XIX, under the TRICARE program under chapter 55 of title 10 of the United States Code, and by other health care payers, such as Medicare Advantage plans under part C.

''(2) APPLICABLE PERCENT.—For purposes of paragraph (1), the applicable percent specified in this paragraph is, with respect to dental and oral health services (as defined in section 1861(kkk)) furnished in a year—

''(A) that are preventive and screening services described in paragraph (2) or basic treatments specified for such year pursuant to paragraph (3)(A) of such section, 80 percent; and

''(B) that are major treatments specified for such year pursuant to paragraph (3)(B) of such section—

''(i) in the case such services are furnished during 2025, 10 percent;

''(ii) in the case such services are furnished during 2026 or a subsequent year before 2029, the applicable percent specified under this subparagraph for the previous year, increased by 10 percentage points; and

''(iii) in the case such services are furnished during 2029 or a subsequent year, 50 percent.

''(3) LIMITATIONS.—With respect to dental and oral health services that are—

''(A) preventive and screening oral exams, payment may be made under this part for not more than two such exams during a 12-month period;

''(B) dental cleanings, payment may be made under this part for not more than two such cleanings during a 12-month period; and

''(C) not described in subparagraph (A) or (B), payment may be made under this part only at such frequencies and under such circumstances determined appropriate by the Secretary.''.

(d) PAYMENT UNDER PHYSICIAN FEE SCHEDULE.—

(1) IN GENERAL.—Section 1848(j)(3) of the Social Security Act (42 U.S.C. 1395w–4(j)(3)) is amended by inserting ''(2)(II),'' before ''(3)''.

(2) EXCLUSION FROM MIPS.—Section 1848(q)(1)(C)(ii) of the Social Security Act (42 U.S.C. 1395w–4(q)(1)(C)(ii)) is amended—

(A) in subclause (II), by striking ''or'' at the end;

(B) in subclause (III), by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following new subclause:

''(IV) with respect to 2025 and each subsequent year, is a doctor of dental surgery or of dental medicine (as described in section 1861(r)(2)) or is an oral health professional (as defined in section 1861(kkk)(4)).''.

(3) INCLUSION OF ORAL HEALTH PROFESSIONALS AS CERTAIN PRACTITIONERS.—Section 1842(b)(18)(C) of the Social Security Act (42 U.S.C. 1395u(b)(18)(C)) is amended by adding at the end the following new clause:

''(vii) With respect to 2025 and each subsequent year, an oral health professional (as defined in section 1861(kkk)(4)).''.

(e) DENTURES.—

(1) IN GENERAL.—Section 1861(s)(8) of the Social Security Act (42 U.S.C. 1395x(s)(8)) is amended—

(A) by striking ''(other than dental)''; and

(B) by inserting ''and excluding dental, except for a full or partial set of dentures furnished on or after January 1, 2025'' after ''colostomy care''.

(2) SPECIAL PAYMENT RULES.—

(A) LIMITATIONS.—Section 1834(h) of the Social Security Act (42 U.S.C. 1395m(h)) is amended by adding at the end the following new paragraph:

''(6) SPECIAL PAYMENT RULE FOR DENTURES.—Payment may be made under this part with respect to an individual for dentures—

''(A) not more than once during any 5-year period (except in the case that a doctor or professional described in section 1861(kkk)(1)(A) determines such dentures do not fit the individual); and

''(B) only to the extent that such dentures are furnished pursuant to a written order of such a doctor or professional.''.

(B) APPLICATION OF COMPETITIVE ACQUISITION.—

(i) IN GENERAL.—Section 1834(h)(1)(H) of the Social Security Act (42 U.S.C. 1395m(h)(1)(H)) is amended—

(I) in the subparagraph heading, by inserting ", DENTURES" after "ORTHOTICS";

(II) by inserting ", of dentures described in paragraph (2)(D) of such section," after "2011,"; and

(III) in clause (i), by inserting ", such dentures" after "orthotics".

(ii) CONFORMING AMENDMENT.—Section 1847(a)(2) of the Social Security Act (42 U.S.C. 1395w–3(a)(2)) is amended by adding at the end the following new subparagraph:

"(D) DENTURES.—Dentures described in section 1861(s)(8) for which payment would otherwise be made under section 1834(h).".

(iii) EXEMPTION OF CERTAIN ITEMS FROM COMPETITIVE ACQUISITION.—Section 1847(a)(7) of the Social Security Act (42 U.S.C. 1395w–3(a)(7)) is amended by adding at the end the following new subparagraph:

"(C) CERTAIN DENTURES.—Those items and services described in paragraph (2)(D) if furnished by a physician or other practitioner

(as defined by the Secretary) to the physician's or practitioner's own patients as part of the physician's or practitioner's professional service.''.

(f) EXCLUSION MODIFICATIONS.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (O), by striking ''and'' at the end;

(B) in subparagraph (P), by striking the semicolon at the end and inserting '', and''; and

(C) by adding at the end the following new subparagraph:

''(Q) in the case of dental and oral health services (as defined in section 1861(kkk)) that are preventive and screening services described in paragraph (2) of such section, which are furnished more frequently than provided under section 1834(x)(3) and under circumstances other than circumstances determined appropriate under such section;''; and

(2) in paragraph (12), by inserting before the semicolon at the end the following: ''and except that payment may be made under part B for dental and

oral health services that are covered under section 1861(s)(2)(II)''.

(g) CERTAIN NON-APPLICATION.—

(1) IN GENERAL.—Paragraphs (1) and (4) of section 1839(a) of the Social Security Act (42 U.S.C. 1395r(a)) are amended by adding at the end of each such paragraphs the following: ''In applying this paragraph there shall not be taken into account benefits and administrative costs attributable to the amendments made by section 601 (other than subsection (g)) of the Elijah E. Cummings Lower Drug Costs Now Act and the Government contribution under section 1844(a)(4)''.

(2) PAYMENT.—Section 1844(a) of such Act (42 U.S.C. 1395w(a)) is amended—

(A) in paragraph (3), by striking the period at the end and inserting ''; plus''; and

(B) by adding at the end the following new paragraph:

''(4) a Government contribution equal to the amount that is estimated to be payable for benefits and related administrative costs incurred that are attributable to the amendments made by section 601 (other than subsection (g)) of the Elijah E. Cummings Lower Drug Costs Now Act.''.

(h) IMPLEMENTATION FUNDING.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the ''Secretary'') shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) to the Centers for Medicare & Medicaid Services Program Management Account of—

(A) $20,000,000 for each of fiscal years 2020 through 2025 for purposes of implementing the amendments made by this section; and

(B) such sums as determined appropriate by the Secretary for each subsequent fiscal year for purposes of administering the provisions of such amendments.

(2) AVAILABILITY AND ADDITIONAL USE OF FUNDS.—Funds transferred pursuant to paragraph (1) shall remain available until expended and may be used, in addition to the purpose specified in paragraph (1)(A), to implement the amendments made by sections 602 and 603.

SEC. 602. PROVIDING COVERAGE FOR HEARING CARE UNDER THE MEDICARE PROGRAM.

(a) PROVISION OF AURAL REHABILITATION AND TREATMENT SERVICES BY QUALIFIED AUDIOLOGISTS.—Section 1861(ll)(3) of the Social Security Act (42 U.S.C. 1395x(ll)(3)) is amended by inserting ''(and, beginning January 1, 2024, such aural rehabilitation and treatment services)'' after ''assessment services''.

(b) COVERAGE OF HEARING AIDS.—

(1) INCLUSION OF HEARING AIDS AS PROSTHETIC DEVICES.—Section 1861(s)(8) of the Social Security Act (42 U.S.C. 1395x(s)(8)) is amended by inserting '', and including hearing aids furnished on or after January 1, 2024, to individuals diagnosed with profound or severe hearing loss'' before the semicolon at the end.

(2) PAYMENT LIMITATIONS FOR HEARING AIDS.—Section 1834(h) of the Social Security Act (42 U.S.C. 1395m(h)), as amended by section 601(e)(2)(A), is further amended by adding at the end the following new paragraph:

''(7) LIMITATIONS FOR HEARING AIDS.—Payment may be made under this part with respect to an individual, with respect to hearing aids furnished on or after January 1, 2024—

''(A) not more than once during a 5-year period;

''(B) only for types of such hearing aids that are not over-the-counter hearing aids (as defined in section 520(q)(1) of the Federal Food, Drug, and Cosmetic Act) and that are determined appropriate by the Secretary; and

''(C) only if furnished pursuant to a written order of a physician or qualified audiologist (as defined in section 1861(ll)(4)(B)).''.

(3) APPLICATION OF COMPETITIVE ACQUISITION.—

(A) IN GENERAL.—Section 1834(h)(1)(H) of the Social Security Act (42 U.S.C. 1395m(h)(1)(H)), as amended by section 601(e)(2)(B)(i), is further amended—

(i) in the header, by inserting '', HEARING AIDS'' after ''DENTURES'';

(ii) by inserting '', of hearing aids described in paragraph (2)(E) of such section,'' after ''paragraph (2)(D) of such section''; and

(iii) in clause (i), by inserting '', such hearing aids'' after ''such dentures''.

(B) CONFORMING AMENDMENT.—

(i) IN GENERAL.—Section 1847(a)(2) of the Social Security Act (42 U.S.C. 1395w–3(a)(2)), as amended by section 601(e)(2)(B)(ii), is further amended by adding at the end the following new subparagraph:

''(E) HEARING AIDS.—Hearing aids described in section 1861(s)(8) for which payment would otherwise be made under section 1834(h).''.

(ii) EXEMPTION OF CERTAIN ITEMS FROM COMPETITIVE ACQUISITION.—Section 1847(a)(7) of the Social Security Act (42 U.S.C. 1395w–3(a)(7)), as amended by section 601(e)(2)(B)(iii), is further amended by adding at the end the following new subparagraph:

''(D) CERTAIN HEARING AIDS.—Those items and services described in paragraph (2)(E) if furnished by a physician or other practitioner (as defined by the Secretary) to the physician's or practitioner's own patients as part of the physician's or practitioner's professional service.''.

(4) INCLUSION OF AUDIOLOGISTS AS CERTAIN PRACTITIONERS TO RECEIVE PAYMENT ON AN ASSIGNMENT-RELATED BASIS.—Section 1842(b)(18)(C) of the Social Security Act (42 U.S.C. 1395u(b)(18)(C)), as amended by section 601(d)(4), is further amended by adding at the end the following new clause:

"(viii) With respect to 2024 and each subsequent year, a qualified audiologist (as defined in section 1861(ll)(4)(B))."

(c) EXCLUSION MODIFICATION.—Section 1862(a)(7) of the Social Security Act (42 U.S.C. 1395y(a)(7)) is amended by inserting "(except such hearing aids or examinations therefor as described in and otherwise allowed under section 1861(s)(8))" after "hearing aids or examinations therefor".

(d) CERTAIN NON-APPLICATION.—

(1) IN GENERAL.—The last sentence of section 1839(a)(1) of the Social Security Act (42 U.S.C. 1395r(a)(1)), as added by section 601(g)(1), is amended by striking "section 601 (other than subsection (g))" and inserting "sections 601 (other than subsection (g)), 602 (other than subsection (d))".

(2) PAYMENT.—Paragraph (4) of section 1844(a) of such Act (42 U.S.C. 1395w(a)), as added

by section 601(g)(2), is amended by striking ''section 601 (other than subsection (g))'' and inserting ''sections 601 (other than subsection (g)), 602 (other than subsection (d))''.

(e) REPORT; REGULATIONS.—

(1) REPORT.—Not later than the date that is 3 years after the date of the enactment of this Act, the Inspector General of the Department of Health and Human Services shall conduct a study to assess (and submit to the Secretary of Health and Human Services a report on) any program integrity or over-utilization risks with respect to allowing qualified audiologists (as defined in paragraph (4)(B) of 1861(ll) of the Social Security Act (42 U.S.C. 1395x(ll))) to furnish audiology services (as defined in paragraph (3) of such section) to individuals entitled to benefits under part A of title XVIII of such Act (42 U.S.C. 1395c et seq.) and enrolled for benefits under part B of such title (42 U.S.C.1395j et seq.) without such individuals being referred by a physician (as defined in section 1861(r) of such Act (42 U.S.C. 1395x(r))) or practitioner (as described in section 602.32 of title 42, Code of Federal Regulations) to such qualified audiologists. In conducting such study, the Inspector General may take into ac-

count experiences with audiologists furnishing audiology services to enrollees in other Federal programs, including in a health benefit plan under chapter 89 of title 5, United States Code or in health care benefits under the TRICARE program under chapter 55 of title 10 of the United States Code or under chapter 17 of title 38 of such Code.

(2) REGULATIONS.—The Secretary of Health and Human Services may promulgate regulations to allow qualified audiologists (as so defined) to furnish audiology services (as so defined) without a referral from a physician or practitioner, consistent with the findings submitted to the Secretary pursuant to paragraph (1)(B).

(f) IMPLEMENTATION FUNDING.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the ''Secretary'') shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) to the Centers for Medicare & Medicaid Services Program Management Account of—

(A) $20,000,000 for each of fiscal years 2020 through 2024 for purposes of imple-

menting the amendments made by this section; and

(B) such sums as determined appropriate by the Secretary for each subsequent fiscal year for purposes of administering the provisions of such amendments.

(2) AVAILABILITY AND ADDITIONAL USE OF FUNDS.—Funds transferred pursuant to paragraph (1) shall remain available until expended and may be used, in addition to the purpose specified in paragraph (1)(A), to implement the amendments made by sections 601 and 603.

SEC. 603. PROVIDING COVERAGE FOR VISION CARE UNDER THE MEDICARE PROGRAM.

(a) COVERAGE.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)), as amended by section 601(a), is further amended—

(1) in subparagraph (HH), by striking ''and'' after the semicolon at the end;

(2) in subparagraph (II), by striking the period at the end and adding ''; and''; and

(3) by adding at the end the following new subparagraph:

''(JJ) vision services (as defined in subsection (lll));''.

(b) VISION SERVICES DEFINED.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as amended by section 601(b), is further amended by adding at the end the following new subsection:

''(lll) VISION SERVICES.—The term 'vision services' means—

''(1) routine eye examinations to determine the refractive state of the eyes, including procedures performed during the course of such examination; and

''(2) contact lens fitting services;

furnished on or after January 1, 2024, by or under the direct supervision of an optometrist or ophthalmologist who is legally authorized to furnish such examinations, procedures, or fitting services (as applicable) under State law (or the State regulatory mechanism provided by State law) of the State in which the examinations, procedures, or fitting services are furnished.''.

(c) PAYMENT LIMITATIONS.—Section 1834 of the Social Security Act (42 U.S.C. 1395m), as amended by section 601(c)(2), is further amended by adding at the end the following new subsection:

''(y) LIMITATION FOR VISION SERVICES.—With respect to vision services (as defined in section 1861(lll)) and an individual, payment may be made under this part for only 1 routine eye examination described in paragraph

(1) of such section and 1 contact lens fitting service described in paragraph (2) of such section during a 2-year period.''.

(d) PAYMENT UNDER PHYSICIAN FEE SCHEDULE.—Section 1848(j)(3) of the Social Security Act (42 U.S.C. 1395w–4(j)(3)), as amended by section 601(d)(1), is further amended by inserting ''(2)(JJ),'' before ''(3)''.

(e) COVERAGE OF CONVENTIONAL EYEGLASSES AND CONTACT LENSES.—Section 1861(s)(8) of the Social Security Act (42 U.S.C. 1395x(s)(8)), as amended by section 602(b)(1), is further amended by striking '', and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens'' and inserting '', including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens, if furnished before January 1, 2024, including conventional eyeglasses or contact lenses, whether or not furnished subsequent to such a surgery, if furnished on or after January 1, 2024''.

(f) SPECIAL PAYMENT RULES FOR EYEGLASSES AND CONTACT LENSES.—

(1) LIMITATIONS.—Section 1834(h) of the Social Security Act (42 U.S.C. 1395m(h)), as amended by section 601(e)(2)(A) and section 602(b)(2), is

further amended by adding at the end the following new paragraph:

''(8) PAYMENT LIMITATIONS FOR EYEGLASSES AND CONTACT LENSES.—

''(A) IN GENERAL.—With respect to eyeglasses and contact lenses furnished to an individual on or after January 1, 2024, subject to subparagraph (B), payment may be made under this part only—

''(i) during a 2-year period, for either 1 pair of eyeglasses (including lenses and frames) or not more than a 2-year supply of contact lenses that is provided in not more than 180-day increments;

''(ii) with respect to amounts attributable to the lenses and frames of such a pair of eyeglasses or amounts attributable to such a 2-year supply of contact lenses, in an amount not greater than—

''(I) for a pair of eyeglasses furnished in, or a 2-year supply of contact lenses beginning in, 2024—

''(aa) $85 for the lenses of such pair of eyeglasses and $85

for the frames of such pair of eyeglasses; or

''(bb) $85 for such 2-year supply of contact lenses; and

''(II) for the lenses and frames of a pair of eyeglasses furnished in, or a 2-year supply of contact lenses beginning in, a subsequent year, the dollar amounts specified under this subparagraph for the previous year, increased by the percentage change 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 types of eyeglass lenses, and for types of contact lenses, as determined appropriate by the Secretary;

''(iv) if furnished pursuant to a written order of a physician described in section 1861(lll); and

''(v) if during the 2-year period described in clause (i), the individual did not already receive (as described in subparagraph (B)) one pair of conventional eye-

glasses or contact lenses subsequent to a cataract surgery with insertion of an intraocular lens furnished during such period.

''(B) EXCEPTION.—With respect to a 2-year period described in subparagraph (A)(i), in the case of an individual who receives cataract surgery with insertion of an intraocular lens, notwithstanding subparagraph (A), payment may be made under this part for one pair of conventional eyeglasses or contact lenses furnished subsequent to such cataract surgery during such period.''.

(2) APPLICATION OF COMPETITIVE ACQUISITION.—

(A) IN GENERAL.—Section 1834(h)(1)(H) of the Social Security Act (42 U.S.C. 1395m(h)(1)(H)), as amended by section 601(e)(2)(B)(i) and section 602(b)(3)(A), is further amended—

(i) in the header by inserting '', EYEGLASSES, AND CONTACT LENSES'' after ''HEARING AIDS'';

(ii) by inserting ''and of eyeglasses and contact lenses described in paragraph

(2)(F) of such section,'' after ''paragraph (2)(E) of such section,''; and

(iii) in clause (i), by inserting '', or such eyeglasses and contact lenses'' after ''such hearing aids''.

(B) CONFORMING AMENDMENT.—

(i) IN GENERAL.—Section 1847(a)(2) of the Social Security Act (42 U.S.C. 1395w–3(a)(2)), as amended by section 601(e)(2)(B)(ii) and section 602(b)(3)(B)(i), is further amended by adding at the end the following new subparagraph:

''(F) EYEGLASSES AND CONTACT LENSES.—Eyeglasses and contact lenses described in section 1861(s)(8) for which payment would otherwise be made under section 1834(h).''.

(ii) EXEMPTION OF CERTAIN ITEMS FROM COMPETITIVE ACQUISITION.—Section 1847(a)(7) of the Social Security Act (42 U.S.C. 1395w–3(a)(7)), as amended by section 601(e)(2)(B)(iii) and section 602(b)(3)(B)(ii), is further amended by

adding at the end the following new subparagraph:

''(E) CERTAIN EYEGLASSES AND CONTACT LENSES.—Those items and services described in paragraph (2)(F) if furnished by a physician or other practitioner (as defined by the Secretary) to the physician's or practitioner's own patients as part of the physician's or practitioner's professional service.''.

(g) EXCLUSION MODIFICATIONS.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)), as amended by section 601(f), is further amended—

(1) in paragraph (1)—

(A) in subparagraph (P), by striking ''and'' at the end;

(B) in subparagraph (Q), by striking the semicolon at the end and inserting '', and''; and

(C) by adding at the end the following new subparagraph:

''(R) in the case of vision services (as defined in section 1861(lll)) that are routine eye examinations and contact lens fitting services (as described in paragraph (1) or (2), respectively, of such section), which are furnished more frequently than once during a 2-year period;''; and

(2) in paragraph (7)—

(A) by inserting ''(other than such an examination that is a vision service that is covered under section 1861(s)(2)(JJ))'' after ''eye examinations''; and

(B) by inserting ''(other than such a procedure that is a vision service that is covered under section 1861(s)(2)(JJ))'' after ''refractive state of the eyes''.

(h) CERTAIN NON-APPLICATION.—

(1) IN GENERAL.—The last sentence of section 1839(a)(1) of the Social Security Act (42 U.S.C. 1395r(a)(1)), as added by section 601(g)(1) and amended by section 602(d)(1), is further amended by inserting '', and 603 (other than subsection (h))'' after ''602 (other than subsection (d))''.

(2) PAYMENT.—Paragraph (4) of section 1844(a) of such Act (42 U.S.C. 1395w(a)), as added by section 601(g)(2) and amended by section 602(d)(2), is further amended by inserting '', and 603 (other than subsection (h))'' after ''602 (other than subsection (d))''.

(i) IMPLEMENTATION FUNDING.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as

the ''Secretary'') shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) to the Centers for Medicare & Medicaid Services Program Management Account of—

(A) $20,000,000 for each of fiscal years 2020 through 2024 for purposes of implementing the amendments made by this section; and

(B) such sums as determined appropriate by the Secretary for each subsequent fiscal year for purposes of administering the provisions of such amendments.

(2) AVAILABILITY AND ADDITIONAL USE OF FUNDS.—Funds transferred pursuant to paragraph (1) shall remain available until expended and may be used, in addition to the purpose specified in paragraph (1)(A), to implement the amendments made by sections 601 and 602.

TITLE VII—NIH, FDA, AND OPIOIDS FUNDING

Subtitle A—Biomedical Innovation Expansion

SEC. 701. NIH INNOVATION INITIATIVES.

(a) NIH INNOVATION ACCOUNT.—

(1) IN GENERAL.—Section 1001(b) of the 21st Century Cures Act (Public Law 114–255) is amended by adding at the end the following:

''(5) SUPPLEMENTAL FUNDING AND ADDITIONAL ACTIVITIES.—

''(A) IN GENERAL.—In addition to the funds made available under paragraph (2), there are authorized to be appropriated, and are hereby appropriated, to the Account, out of any monies in the Treasury not otherwise appropriated, to be available until expended without further appropriation, the following:

''(i) For fiscal year 2021, $255,400,000.

''(ii) For fiscal year 2022, $260,400,000.

''(iii) For fiscal year 2023, $163,400,000.

"(iv) For fiscal year 2024, $547,000,000.

"(v) For fiscal year 2025, $848,000,000.

"(vi) For fiscal year 2026, $842,400,000.

"(vii) For fiscal year 2027, $1,089,600,000.

"(viii) For fiscal year 2028, $1,115,600,000.

"(ix) For fiscal year 2029, $1,170,600,000.

"(x) For fiscal year 2030, $1,207,600,000.

"(B) SUPPLEMENTAL FUNDING FOR CERTAIN PROJECTS.—Of the total amounts made available under subparagraph (A) for each of fiscal years 2021 through 2030, a total amount not to exceed the following shall be made available for the following categories of NIH Innovation Projects:

"(i) For projects described in paragraph (4)(A), an amount not to exceed a total of $2,070,600,000 as follows:

''(I) For each of fiscal years 2021 and 2022, $50,000,000.

''(II) For fiscal year 2024, $100,000,000.

''(III) For each of fiscal years 2025 and 2026, $300,000,000.

''(IV) For each of fiscal years 2027 through 2029, $317,000,000.

''(V) For fiscal year 2030, $319,600,000.

''(ii) For projects described in paragraph (4)(B), an amount not to exceed a total of $2,041,900,000 as follows:

''(I) For each of fiscal years 2021 and 2022, $50,000,000.

''(II) For fiscal year 2024, $128,000,000.

''(III) For fiscal year 2025, $209,000,000.

''(IV) For fiscal year 2026, $100,000,000.

''(V) For fiscal year 2027, $325,000,000.

''(VI) For fiscal year 2028, $350,000,000.

"(VII) For fiscal year 2029, $400,000,000.

"(VIII) For fiscal year 2030, $429,900,000.

"(iii) For projects described in paragraph (4)(C), an amount not to exceed a total of $1,558,400,000 as follows:

"(I) For each of fiscal years 2024 and 2025, $151,200,000.

"(II) For each of fiscal years 2026 through 2030, $251,200,000.

"(iv) For projects described in paragraph (4)(D), an amount not to exceed $15,400,000 for each of fiscal years 2021 through 2030.

"(C) ADDITIONAL NIH INNOVATION PROJECTS.—In addition to funding NIH Innovation Projects pursuant to subparagraph (B), of the total amounts made available under subparagraph (A), a total amount not to exceed the following shall be made available for the following categories of NIH Innovation Projects:

"(i) To support research related to combating antimicrobial resistance and antibiotic resistant bacteria, including re-

search into new treatments, diagnostics, and vaccines, research, in consultation with the Centers for Disease Control and Prevention, into stewardship, and the development of strategies, in coordination with the Biomedical Advanced Research and Development Authority under section 319L of the Public Health Service Act, to support commercialization of new antibiotics, not to exceed a total of 1,144,500,000, as follows:

''(I) For each of fiscal years 2021 through 2024, $100,000,000.

''(II) For each of fiscal years 2025 and 2026, $120,000,000.

''(III) For each of fiscal years 2027 through 2029, $125,000,000.

''(IV) For fiscal year 2030, $129,500,000.

''(ii) To support research and research activities related to rare diseases or conditions, including studies or analyses that help to better understand the natural history of a rare disease or condition and translational studies related to rare dis-

eases or conditions, not to exceed a total of $530,600,000, as follows:

"(I) For fiscal year 2021, $40,000,000.

"(II) For fiscal year 2022, $45,000,000.

"(III) For fiscal year 2023, $48,000,000.

"(IV) For each of fiscal years 2024 and 2025, $52,400,000.

"(V) For fiscal year 2026, $55,800,000.

"(VI) For fiscal year 2027, $56,000,000.

"(VII) For fiscal year 2028, $57,000,000.

"(VIII) For each of fiscal years 2029 and 2030, $62,000,000.".

(2) CONFORMING AMENDMENTS.—Section 1001 of the 21st Century Cures Act (Public Law 114–255) is amended—

(A) in subsection (a), by striking "subsection (b)(4)" and inserting "subsections (b)(4) and (b)(5)";

(B) in subsection (b)(1), by striking ''paragraph (4)'' and inserting ''paragraphs (4) and (5)''; and

(C) in subsection (c)(2)(A)(ii), by inserting ''or pursuant to subsection (b)(5)'' after ''subsection (b)(3)''; and

(D) in subsection (d), by inserting ''or pursuant to subsection (b)(5)'' after ''subsection (b)(3)''.

(b) WORKPLAN.—Section 1001(c)(1) of the 21st Century Cures Act (Public Law 114–255) is amended by adding at the end the following:

''(D) UPDATES.—The Director of NIH shall , after seeking recommendations in accordance with the process described in subparagraph (C), update the work plan submitted under this subsection for each of fiscal years 2021 through 2030 to reflect the amendments made to this section by the Elijah E. Cummings Lower Drug Costs Now Act.''.

(c) ANNUAL REPORTS.—Section 1001(c)(2)(A) of the 21st Century Cures Act (Public Law 114–255) is amended by striking ''2027'' and inserting ''2030''.

(d) SUNSET.—Section 1001(e) of the 21st Century Cures Act (Public Law 114–255) is amended by striking

''September 30, 2026'' and inserting ''September 30, 2030''.

SEC. 702. NIH CLINICAL TRIAL.

Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

''SEC. 404O. CLINICAL TRIAL ACCELERATION PILOT INITIATIVE.

''(a) ESTABLISHMENT OF PILOT PROGRAM.—The Secretary, acting through the Director of the National Institutes of Health, shall, not later than 2 years after the date of enactment of this Act, establish and implement a pilot program to award multi-year contracts to eligible entities to support phase II clinical trials and phase III clinical trials—

''(1) to promote innovation in treatments and technologies supporting the advanced research and development and production of high need cures; and

''(2) to provide support for the development of medical products and therapies.

''(b) ELIGIBLE ENTITIES.—To be eligible to receive assistance under the pilot program established under subsection (a), an entity shall—

''(1) be seeking to market a medical product or therapy that is the subject of clinical trial or trials to be supported using such assistance;

''(2) be a public or private entity, which may include a private or public research institution, a contract research organization, an institution of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001)), a medical center, a biotechnology company, or an academic research institution; and

''(3) comply with requirements of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product.

''(c) DUTIES.—The Secretary, acting through the Director of National Institutes of Health, shall—

''(1) in establishing the pilot program under subsection (a), consult with—

''(A) the Director of the National Center for Advancing Translational Sciences and the other national research institutes in considering their requests for new or expanded clinical trial support efforts; and

''(B) the Commissioner of Food and Drugs and any other head of a Federal agency as the Secretary determines to be appropriate to ensure coordination and efficiently advance clinical trial activities;

''(2) in implementing the pilot program under subsection (a), consider consulting with patients and patient advocates; and

''(3) in awarding contracts under the pilot program under subsection (a), consider—

''(A) the expected health impacts of the clinical trial or trials to be supported under the contract; and

''(B) the the degree to which the medical product or therapy that is the subject of such clinical trial or trials is a high need cure.

''(d) EXCLUSION.—A contract may not be awarded under the pilot program under subsection (a) if the drug that is the subject of the clinical trial or trials to be supported under the contract is a drug designated under section 526 of the Federal Food, Drug, and Cosmetic Act as a drug for a rare disease or condition.

''(e) NIH CLINICAL TRIAL ACCELERATOR ACCOUNT.—

''(1) ESTABLISHMENT.—There is established in the Treasury an account, to be known as the 'NIH Clinical Trial Accelerator Account' (referred to in this section as the 'Account'), for purposes of carrying out this section.

''(2) TRANSFER OF DIRECT SPENDING SAVINGS.—There shall be transferred to the Account from the general fund of the Treasury, $500,000,000 for each of fiscal years 2021 through 2025, to be available until expended without further appropriation.

''(3) WORK PLAN.—Not later than 180 days after the date of enactment of this Act, the Secretary shall 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 work plan that includes the proposed implementation of this section and the proposed allocation of funds in the Account.

''(f) REPORTS TO CONGRESS.—Not later than October 1 of each fiscal year, the Secretary shall 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 implementation of this section;

''(2) any available results on phase II clinical trials and phase III clinical trials supported under this section during such fiscal year; and

''(3) the extent to which Federal funds are obligated to support such clinical trials, including the specific amount of such support and awards pursuant to an allocation from the Account under subsection (e).

''(g) DEFINITIONS.—In this section:

''(1) PHASE II CLINICAL TRIAL.—The term 'phase II clinical trial' means a phase II clinical investigation, as described in section 312.21 of title 21, Code of Federal Regulations (or any successor regulations).

''(2) PHASE III CLINICAL TRIALS.—The term 'phase III clinical trial' means a phase III clinical investigation, as described in section 312.21 of title 21, Code of Federal Regulations (or any successor regulations).

''(3) HIGH NEED CURE.—The term 'high need cure' has the meaning given such term in section 480(a)(3).''.

Subtitle B—Investing in Safety and Innovation

SEC. 711. FOOD AND DRUG ADMINISTRATION.

(a) FDA INNOVATION ACCOUNT.—

(1) IN GENERAL.—Section 1002(b) of the 21st Century Cures Act (Public Law 114–255) is amended—

(A) in paragraph (1), by striking ''paragraph (4)'' and inserting ''paragraphs (4) and (5)''; and

(B) by adding at the end the following new paragraph:

''(5) SUPPLEMENTAL FUNDING AND ADDITIONAL ACTIVITIES.—

''(A) IN GENERAL.—In addition to the funds made available under paragraph (2), there are authorized to be appropriated, and are hereby appropriated, to the Account, out of any monies in the Treasury not otherwise appropriated, to be available until expended without further appropriation, the following:

''(i) For fiscal year 2020, $417,500,000.

''(ii) For each of fiscal years 2021 and 2022, $157,500,000.

"(iii) For each of fiscal years 2023 through 2025, $152,500,000.

"(iv) For each of fiscal years 2026 through 2029, $202,500,000.

"(B) SUPPLEMENTAL FUNDING FOR CERTAIN ACTIVITIES.—Of the total amounts made available under subparagraph (A) for each of fiscal years 2026 through 2029, a total amount not to exceed $50,000,000 for each such fiscal year, shall be made available for the activities under subtitles A through F (including the amendments made by such subtitles) of title III of this Act and section 1014 of the Federal Food, Drug, and Cosmetic Act, as added by section 3073 of this Act.

"(C) ADDITIONAL FDA ACTIVITIES.—In addition to funding activities pursuant to subparagraph (B), of the total amounts made available under subparagraph (A), a total amount not to exceed the following shall be made available for the following categories of activities:

"(i) For modernization of the technical infrastructure of the Food and Drug Administration, including enhancements

such as interoperability across the agency, and additional capabilities to develop an advanced information technology infrastructure to support the agency's regulatory mission:

"(I) For fiscal year 2020, $180,000,000.

"(II) For each of fiscal years 2021 through 2029, $60,000.

"(ii) For support for continuous manufacturing of drugs and biological products, including complex biological products such as regenerative medicine therapies, through grants to institutions of higher education and nonprofit organizations and other appropriate mechanisms, for each of fiscal years 2020 through 2029, $20,000,000.

"(iii) For support for the Commissioner of Food and Drugs to engage experts, such as through the formation and operation of public-private partnerships or other appropriate collaborative efforts, to advance the development and delivery of

individualized human gene therapy products:

''(I) For fiscal year 2020, $50,000,000.

''(II) For each of fiscal years 2021 through 2029, $10,000,000.

''(iv) For support for inspections, enforcement, and quality surveillance activities across the Food and Drug Administration, including foreign and domestic inspections across products, for each of fiscal years 2020 through 2029, $20,000,000.

''(v) For support for activities of the Food and Drug Administration related to customs and border protection to provide improvements to technologies, inspection capacity, and sites of import (including international mail facilities) in which the Food and Drug Administration operates, for each of fiscal years 2020 through 2029, $10,000,000.

''(vi) To further advance the development of a coordinated postmarket surveillance system for all medical products, including drugs, biological products, and de-

vices, linked to electronic health records in furtherance of the Food and Drug Administration's postmarket surveillance capabilities:

"(I) For fiscal year 2020, $112,500,000.

"(II) For each of fiscal years 2021 through 2029, $12,500,000.

"(vii) For support for Food and Drug Administration activities to keep pace with the projected product development of regenerative therapies, including cellular and somatic cell gene therapy products:

"(I) For each of fiscal years 2020 through 2022, $10,000,000.

"(II) For each of fiscal years 2023 through 2029, $5,000,000.

"(viii) For carrying out section 714A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d–3a; relating to hiring authority for scientific, technical, and professional personnel), for each of fiscal years 2020 through 2029, $2,500,000.

"(ix) For the Food and Drug Administration to support improvements to the

technological infrastructure for reporting and analysis of adverse events associated with the use of drugs and biological products, for each of fiscal years 2020 through 2029, $12,500,000.''.

(2) CONFORMING AMENDMENTS.—Section 1002 of the 21st Century Cures Act (Public Law 114–255) is amended—

(A) in subsection (a), by inserting before the period at the end the following: ''or pursuant to subparagraph (A) of subsection (b)(5) to carry out the activities described in subparagraphs (B) and (C) of such subsection''; and

(B) in subsection (d)—

(i) by inserting ''or pursuant to subparagraph (A) of subsection (b)(5)'' after ''subsection (b)(3)''; and

(ii) by striking ''subsection (b)(4)'' and inserting ''subsections (b)(4) and (b)(5)''.

(b) ANNUAL REPORT.—Section 1002(c)(2)(A) of the 21st Century Cures Act (Public Law 114–255) is amended, in the matter preceding clause (i), by striking ''2026'' and inserting ''2030''.

(c) SUNSET.—Section 1002(e) of the 21st Century Cures Act (Public Law 114–255) is amended by striking ''September 30, 2025'' and inserting ''September 30, 2030''.

Subtitle C—Opioid Epidemic Response

SEC. 721. OPIOID EPIDEMIC RESPONSE FUND.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall use any funds made available pursuant to subsection (b) to carry out the programs and activities described in subsection (c) to address the opioid and substance use disorder epidemic. Such funds shall be in addition to any funds which are otherwise available to carry out such programs and activities.

(b) OPIOID EPIDEMIC RESPONSE FUND.—

(1) ESTABLISHMENT OF ACCOUNT.—There is established in the Treasury an account, to be known as the Opioid Epidemic Response Fund (referred to in this section as the ''Fund''), for purposes of funding the programs and activities described in subsection (c).

(2) FUNDING.—There is authorized to be appropriated, and there is appropriated, to the Fund, out of any monies in the Treasury not otherwise ap-

propriated $1,980,000,000 for each of fiscal years 2021 through 2025.

(3) AVAILABILITY.—Amounts made available by paragraph (2) shall be made available to the agencies specified in subsection (c) in accordance with such subsection. Amounts made available to an agency pursuant to the preceding sentence for a fiscal year shall remain available until expended.

(c) PROGRAMS AND ACTIVITIES.—Of the total amount in the Fund for each of fiscal years 2021 through 2025, such amount shall be allocated as follows:

(1) SAMHSA.—For the Substance Abuse and Mental Health Services Administration to carry out programs and activities pursuant to section 732, $1,500,000,000 for each of fiscal years 2021 through 2025.

(2) CDC.—For the Centers for Disease Control and Prevention to carry out programs and activities pursuant to section 733, $120,000,000 for each of fiscal years 2021 through 2025.

(3) FDA.—For the Food and Drug Administration to carry out programs and activities pursuant to section 734, $10,000,000 for each of fiscal years 2021 through 2025.

(4) NIH.—For the National Institutes of Health to carry out programs and activities pursuant to section 735, $240,000,000 for each of fiscal years 2021 through 2025.

(5) HRSA.—For the Health Resources and Services Administration to carry out programs and activities pursuant to section 736, $90,000,000 for each of fiscal years 2021 through 2025.

(6) ACF.—For the Administration for Children and Families to carry out programs and activities pursuant to section 737, $20,000,000 for each of fiscal years 2021 through 2025.

(d) ACCOUNTABILITY AND OVERSIGHT.—

(1) WORK PLAN.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce, the Committee on Appropriations, and the Committee on Education and Labor of the House of Representatives, a work plan including the proposed allocation of funds made available pursuant to

subsection (b) for each of fiscal years 2021 through 2025 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 (c); and

(ii) a description and justification of each such program and activity.

(2) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2022 through 2026, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce, the Committee on Appropriations, and the Committee on Education and Labor of the House of Representatives, a report including—

(A) the amount of money obligated or expended out of the Fund in the prior fiscal year for each program and activity described in subsection (c);

(B) a description of all programs and activities using funds made available pursuant to subsection (b); and

(C) how the programs and activities are responding to the opioid and substance use disorder epidemic.

(e) LIMITATIONS.—Notwithstanding any authority in this subtitle or any appropriations Act, any funds made available pursuant to subsection (b) may not be used for any purpose other than the programs and activities described in subsection (c).

SEC. 722. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.

(a) IN GENERAL.—The entirety of the funds made available pursuant to section 731(c)(1) shall be for the Assistant Secretary for Mental Health and Substance Use to continue to award the State Opioid Response Grants funded by the heading ''Substance Abuse And Mental Health Services Administration—Substance Abuse Treatment'' in title II of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2018 (Public Law 115–141). Subject to subsections (b) and (c), such grants shall be awarded in the same manner and subject to the same conditions as were applicable to such grants for fiscal year 2018.

(b) REQUIREMENT THAT TREATMENT BE EVIDENCE-BASED.—As a condition on receipt of a grant pursuant to subsection (a), a grantee shall agree that—

(1) treatments, practices, or interventions funded through the grant will be evidence-based; and

(2) such treatments, practices, and interventions will include medication-assisted treatment for individuals diagnosed with opioid use disorder, using drugs only if the drugs have been approved or licensed by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(c) RESERVATIONS.—Of the amount made available pursuant to section 731(c)(1) for a fiscal year—

(1) not less than $75,000,000 shall be reserved to make grants under subsection (a) to Indian Tribes or Tribal organizations; and

(2) not less than $50,000,000 shall be reserved to make grants under subsection (a) to political subdivisions of States, such as counties, cities, or towns.

SEC. 723. CENTERS FOR DISEASE CONTROL AND PREVENTION.

(a) ADDRESSING OPIOID USE DISORDER.—The entirety of the funds made available pursuant to section

731(c)(2) shall be for the Director of the Centers for Disease Control and Prevention, pursuant to applicable authorities in the Public Health Service Act (42 U.S.C. 201 et seq.), to continue and expand programs of the Centers for Disease Control and Prevention to address opioid and substance use disorder, including by—

(1) improving the timeliness and quality of data on the opioid use disorder epidemic, including improvement of—

(A) data on fatal and nonfatal overdoses;

(B) syndromic surveillance;

(C) data on long-term sequelae (including neonatal abstinence syndrome); and

(D) cause of death reporting related to substance abuse or opioid overdose;

(2) expanding and strengthening evidence-based prevention and education strategies;

(3) supporting responsible prescribing practices, including through development and dissemination of prescriber guidelines;

(4) improving access to and use of effective prevention, treatment, and recovery support, including through grants and the provision of technical assistance to States and localities;

(5) strengthening partnerships with first responders, including to protect their safety;

(6) considering the needs of vulnerable populations;

(7) addressing infectious diseases linked to the opioid crisis;

(8) strengthening prescription drug monitoring programs; and

(9) providing financial and technical assistance to State and local health department efforts to treat and prevent substance use disorder.

(b) LIMITATION.—Of the funds made available pursuant to section 731(c)(2) for carrying out this section, not more than 20 percent may be used for intramural purposes.

SEC. 724. FOOD AND DRUG ADMINISTRATION.

The entirety of the funds made available pursuant to section 731(c)(3) 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 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and other applicable 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:

(1) Facilitating the development of non-opioid and non-addictive pain treatments.

(2) Advancing guidance documents for sponsors of non-opioid pain products.

(3) Developing evidence to inform the potential for nonprescription overdose therapies.

(4) Examining expanded labeling indications for medication-assisted treatment.

(5) Conducting public education and outreach, including public workshops or public meetings, regarding the benefits of medication-assisted treatment, including all drugs approved by the Food and Drug Administration, and device treatment options approved or cleared by the Food and Drug Administration.

(6) Exploring the expansion and possible mandatory nature of prescriber education regarding pain management and appropriate opioid prescribing through authorities under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1).

(7) Examining options to limit the duration of opioid prescriptions for acute pain, including through packaging options.

(8) Increasing staff and infrastructure capacity to inspect and analyze packages at international mail facilities and pursue criminal investigations.

SEC. 725. NATIONAL INSTITUTES OF HEALTH.

The entirety of the funds made available pursuant to section 731(c)(4) shall be for the Director of the National Institutes of Health, pursuant to applicable authorities in the Public Health Service Act (42 U.S.C. 201 et seq.), to carry out activities related to—

(1) accelerating research for addressing the opioid use disorder epidemic, including developing non-opioid medications and interventions, including non-addictive medications, to manage pain, as well as developing medications and interventions to treat and to prevent substance use disorders;

(2) conducting and supporting research on which treatments (in terms of pain management as well as treating and preventing substance use disorders) are optimal for which patients; and

(3) conducting and supporting research on creating longer-lasting or faster-acting antidotes for

opioid overdose, particularly in response to the prevalence of fentanyl and carfentanyl overdoses.

SEC. 726. HEALTH RESOURCES AND SERVICES ADMINISTRATION.

The entirety of the funds made available pursuant to section 731(c)(5) shall be for the Administrator of the Health Resources and Services Administration, pursuant to applicable authorities in titles III, VII, and VIII of the Public Health Service Act (42 U.S.C. 241 et seq.), to carry out activities that increase the availability and capacity of the behavioral health workforce. Such activities shall include providing loan repayment assistance for substance use disorder treatment providers.

SEC. 727. ADMINISTRATION FOR CHILDREN AND FAMILIES.

Of the funds made available pursuant to section 731(c)(6) for each of fiscal years 2021 through 2025, $20,000,000 for each such fiscal year shall be for the Secretary of Health and Human Services to carry out title I of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101 et seq.).

TITLE VIII—MISCELLANEOUS

SEC. 801. GUARANTEED ISSUE OF CERTAIN MEDIGAP POLICIES.

(a) GUARANTEED ISSUE OF MEDIGAP POLICIES TO ALL MEDIGAP-ELIGIBLE MEDICARE BENEFICIARIES.—

(1) IN GENERAL.—Section 1882(s) of the Social Security Act (42 U.S.C. 1395ss(s)) is amended—

(A) in paragraph (2)(A), by striking ''65 years of age or older and is enrolled for benefits under part B'' and inserting ''entitled to, or enrolled for, benefits under part A and enrolled for benefits under part B'';

(B) in paragraph (2)(D), by striking ''who is 65 years of age or older as of the date of issuance and'';

(C) in paragraph (3)(B)(ii), by striking ''is 65 years of age or older and''; and

(D) in paragraph (3)(B)(vi), by striking ''at age 65''.

(2) ADDITIONAL ENROLLMENT PERIOD FOR CERTAIN INDIVIDUALS.—

(A) ONE-TIME ENROLLMENT PERIOD.—

(i) IN GENERAL.—In the case of a specified individual, the Secretary shall establish a one-time enrollment period described in clause (iii) during which such an individual may enroll in any medicare supplemental policy of the individual's choosing.

(ii) APPLICATION.—The provisions of—

(I) paragraph (2) of section 1882(s) of the Social Security Act (42 U.S.C. 1395ss(s)) shall apply with respect to a specified individual who is described in subclause (I) of subparagraph (B)(iii) as if references in such paragraph (2) to the 6 month period described in subparagraph (A) of such paragraph were references to the one-time enrollment period established under clause (i); and

(II) paragraph (3) of such section shall apply with respect to a specified individual who is described in subclause (II) of subparagraph (B)(iii) as if references in such paragraph (3) to the period specified in subparagraph (E) of such paragraph were references to the one-time enrollment period established under clause (i).

(iii) PERIOD.—The enrollment period established under clause (i) shall be the 6-

month period beginning on January 1, 2024.

(B) SPECIFIED INDIVIDUAL.—For purposes of this paragraph, the term ''specified individual'' means an individual who—

(i) is entitled to hospital insurance benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.) pursuant to section 226(b) or section 226A of such Act (42 U.S.C. 426(b); 426–1);

(ii) is enrolled for benefits under part B of such Act (42 U.S.C. 1395j et seq.); and

(iii)(I) would not, but for the amendments made by subparagraphs (A) and (B) of paragraph (1) and the provisions of this paragraph (if such provisions applied to such individual), be eligible for the guaranteed issue of a medicare supplemental policy under paragraph (2) of section 1882(s) of such Act (42 U.S.C. 1395ss(s)); or

(II) would not, but for the amendments made by subparagraphs (C) and (D) of paragraph (1) and the provisions of this

paragraph (if such provisions applied to such individual), be eligible for the guaranteed issue of a medicare supplemental policy under paragraph (3) of such section.

(C) OUTREACH PLAN.—

(i) IN GENERAL.—The Secretary shall develop an outreach plan to notify specified individuals of the one-time enrollment period established under subparagraph (A).

(ii) CONSULTATION.—In implementing the outreach plan developed under clause (i), the Secretary shall consult with consumer advocates, brokers, insurers, the National Association of Insurance Commissioners, and State Health Insurance Assistance Programs.

(3) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to medicare supplemental policies effective on or after January 1, 2024.

(b) GUARANTEED ISSUE OF MEDIGAP POLICIES FOR MEDICARE ADVANTAGE ENROLLEES.—

(1) IN GENERAL.—Section 1882(s)(3) of the Social Security Act (42 U.S.C. 1395ss(s)(3)), as amended by subsection (a), is further amended—

(A) in subparagraph (B), by adding at the end the following new clause:

''(vii) The individual—

''(I) was enrolled in a Medicare Advantage plan under part C for not less than 12 months;

''(II) subsequently disenrolled from such plan;

''(III) elects to receive benefits under this title through the original Medicare fee-for-service program under parts A and B; and

''(IV) has not previously elected to receive benefits under this title through the original Medicare fee-for-service program pursuant to disenrollment from a Medicare Advantage plan under part C.'';

(B) by striking subparagraph (C)(iii) and inserting the following:

''(iii) Subject to subsection (v)(1), for purposes of an individual described in clause (vi) or (vii) of subparagraph (B), a medicare supplemental policy described in this subparagraph shall include any medicare supplemental policy.''; and

(C) in subparagraph (E)—

(i) in clause (iv), by striking ''and'' at the end;

(ii) in clause (v), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following new clause—

''(vi) in the case of an individual described in subparagraph (B)(vii), the annual, coordinated election period (as defined in section 1851(e)(3)(B)) or a continuous open enrollment period (as defined in section 1851(e)(2)) during which the individual disenrolls from a Medicare Advantage plan under part C.''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to medicare supplemental policies effective on or after January 1, 2024.

SEC. 802. REPORTING REQUIREMENTS FOR PDP SPONSORS REGARDING POINT-OF-SALE REJECTIONS UNDER MEDICARE PART D.

Section 1860D–4(g) of the Social Security Act (42 U.S.C. 1395w–104(g)) is amended by adding at the end the following new paragraph:

''(3) REPORTING REQUIREMENTS REGARDING POINT-OF-SALE REJECTIONS.—

''(A) IN GENERAL.—With respect to a plan year beginning on or after January 1, 2020, a

PDP sponsor offering a prescription drug plan shall submit to the Secretary, in a form and manner specified by the Secretary, information on point-of-sale rejections made during a period of time occurring in such plan year (as specified by the Secretary), including each of the following:

''(i) The reason for each point-of-sale rejection.

''(ii) Identifying information for each drug with respect to which a point-of-sale rejection was made.

''(iii) With respect to applicable types of point-of-sale rejections (as specified by the Secretary), each of the following:

''(I) Whether such a rejection was consistent with the formulary of the plan (as approved by the Secretary).

''(II) Whether a coverage determination or appeal of a coverage determination was requested for the drug with respect to which such a rejection was made.

''(III) The outcome of any such coverage determination or appeal of a coverage determination.

''(IV) The length of time between when such a rejection was made and when the drug with respect to which such rejection was made is dispensed, as applicable.

''(B) PUBLIC AVAILABILITY OF INFORMATION.—The Secretary shall make publicly available on the public website of the Centers for Medicare & Medicaid Services information submitted under subparagraph (A).

''(C) USE OF INFORMATION.—The Secretary may use information submitted under subparagraph (A), as determined appropriate, in developing measures for the 5-star rating system under section 1853(o)(4).

''(D) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph through program instruction or otherwise.

''(E) FUNDING.—The are authorized to be appropriated to the Secretary from the Federal Supplementary Medical Insurance Trust Fund

under section 1841 such sums as may be necessary to implement this paragraph.''.

SEC. 803. PROVIDING ACCESS TO ANNUAL MEDICARE NOTIFICATIONS IN MULTIPLE LANGUAGES.

(a) IN GENERAL.—Section 1804 of the Social Security Act (42 U.S.C. 1395b–2) is amended by adding at the end the following new subsection:

''(e) The notice provided under subsection (a) shall be translated into languages in addition to English and Spanish. In carrying out the previous sentence, the Secretary shall prioritize translation of the notice into languages in which documents provided by the Commissioner of Social Security are translated and language that are the most frequently requested for translation for purposes of applying for old-age insurance benefits under title II.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to notices distributed prior to each Medicare open enrollment period beginning after January 1, 2020.

SEC. 804. TEMPORARY INCREASE IN MEDICARE PART B PAYMENT FOR CERTAIN BIOSIMILAR BIOLOGICAL PRODUCTS.

Section 1847A(b)(8) of the Social Security Act (42 U.S.C. 1395w–3a(b)(8)) is amended—

(1) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and moving the margin of each such redesignated clause 2 ems to the right;

(2) by striking ''PRODUCT.—The amount'' and inserting the following: ''PRODUCT.—

''(A) IN GENERAL.—Subject to subparagraph (B), the amount''; and

(3) by adding at the end the following new subparagraph:

''(B) TEMPORARY PAYMENT INCREASE.—

''(i) IN GENERAL.—In the case of a qualifying biosimilar biological product that is furnished during the applicable 5-year period for such product, the amount specified in this paragraph for such product with respect to such period is the sum determined under subparagraph (A), except that clause (ii) of such subparagraph shall be applied by substituting '8 percent' for '6 percent'.

''(ii) APPLICABLE 5-YEAR PERIOD.—For purposes of clause (i), the applicable 5-year period for a biosimilar biological product is—

''(I) in the case of such a product for which payment was made under this paragraph as of December 31, 2019, the 5-year period beginning on January 1, 2020; and

''(II) in the case of such a product for which payment is first made under this paragraph during a calendar quarter during the period beginning January 1, 2020, and ending December 31, 2024, the 5-year period beginning on the first day of such calendar quarter during which such payment is first made.

''(iii) QUALIFYING BIOSIMILAR BIOLOGICAL PRODUCT DEFINED.—For purposes of this subparagraph, the term 'qualifying biosimilar biological product' means a biosimilar biological product described in paragraph (1)(C) with respect to which—

''(I) in the case of a product described in clause (ii)(I), the average sales price is not more than the aver-

age sales price for the reference biological product; and

''(II) in the case of a product described in clause (ii)(II), the wholesale acquisition cost is not more than the wholesale acquisition cost for the reference biological product.''.

SEC. 805. WAIVING MEDICARE COINSURANCE FOR COLORECTAL CANCER SCREENING TESTS.

Section 1833(a) of the Social Security Act (42 U.S.C. 1395l(a)) is amended—

(1) in the second sentence, by striking ''section 1834(0)'' and inserting ''section 1834(o)'';

(2) by moving such second sentence 2 ems to the left; and

(3) by inserting the following third sentence following such second sentence: ''For services furnished on or after January 1, 2021, paragraph (1)(Y) 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.''.

SEC. 806. MEDICARE COVERAGE OF CERTAIN LYMPHEDEMA COMPRESSION TREATMENT ITEMS.

(a) COVERAGE.—

(1) IN GENERAL.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as amended by section 601 and section 603, is further amended—

(A) in subsection (s)(2)—

(i) in subparagraph (II), by striking ''and'' after the semicolon at the end;

(ii) in subparagraph (JJ), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following new subparagraph:

''(KK) lymphedema compression treatment items (as defined in subsection (mmm));''; and

(B) by adding at the end the following new subsection:

''(mmm) LYMPHEDEMA COMPRESSION TREATMENT ITEMS.—The term 'lymphedema compression treatment items' means compression garments, devices, bandaging systems, components, and supplies, including multilayer compression bandaging systems, standard fit gradient compression garments, and other compression garments,

devices, bandaging systems, components, or supplies (as determined by the Secretary), that are—

''(1) furnished on or after January 1, 2022, to an individual with a diagnosis of lymphedema for the treatment of such condition;

''(2) primarily and customarily used in the medical treatment of lymphedema, as determined by the Secretary; and

''(3) prescribed by a physician (or a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) to the extent authorized under State law).''.

(2) PAYMENT.—

(A) IN GENERAL.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)), as amended by section 601(c)(1), is further amended—

(i) by striking ''and'' before ''(DD)''; and

(ii) by inserting before the semicolon at the end the following: '', and (EE) with respect to lymphedema compression treatment items (as defined in section 1861(mmm)), the amount paid shall be

equal to 80 percent of the lesser of the actual charge or the amount determined under the payment basis determined under section 1834(z)''.

(B) PAYMENT BASIS AND LIMITATIONS.—Section 1834 of the Social Security Act (42 U.S.C. 1395m), as amended by sections 601(c)(2) and 603(c), is further amended by adding at the end the following new subsection:

''(z) PAYMENT FOR LYMPHEDEMA COMPRESSION TREATMENT ITEMS.—

''(1) IN GENERAL.—The Secretary shall determine an appropriate payment basis for lymphedema compression treatment items (as defined in section 1861(mmm)). In making such a determination, the Secretary may take into account payment rates for such items under State plans (or waivers of such plans) under title XIX, the Veterans Health Administration, and group health plans and health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act), and such other information as the Secretary determines appropriate.

''(2) FREQUENCY LIMITATION.—No payment may be made under this part for lymphedema com-

pression treatment items furnished other than at such frequency as the Secretary may establish.

''(3) APPLICATION OF COMPETITIVE ACQUISITION.—In the case of lymphedema compression treatment items that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

''(A) the payment basis under this subsection for such items furnished in such area shall be the payment basis determined under such competitive acquisition program; and

''(B) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise determined under this subsection 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.''.

(3) CONFORMING AMENDMENTS.—

(A) EXCLUSIONS.—Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)), as amended by section 601(f) and section 603(g), is further amended—

(i) in subparagraph (Q), by striking ''and'' at the end;

(ii) in subparagraph (R), by striking the semicolon and inserting '', and''; and

(iii) by adding at the end the following new subparagraph:

''(S) in the case of lymphedema compression treatment items (as defined in section 1861(mmm)), which are furnished more frequently than is established pursuant to section 1834(z)(2);''.

(B) APPLICATION OF COMPETITIVE ACQUISITION.—

(i) IN GENERAL.—Section 1847(a)(2) of the Social Security Act (42 U.S.C. 1395w–3(a)(2)), as amended by sections 601(e)(2)(B)(ii), 602(b)(3)(B)(i), and 603(f)(2)(B), is further amended by adding at the end the following new subparagraph:

''(G) LYMPHEDEMA COMPRESSION TREATMENT ITEMS.—Lymphedema compression treatment items (as defined in section 1861(mmm)) for which payment would otherwise be made under section 1834(z).''.

(b) INCLUSION IN REQUIREMENTS FOR SUPPLIERS OF MEDICAL EQUIPMENT AND SUPPLIES.—Section 1834(j)(5) of the Social Security Act (42 U.S.C. 1395m(j)(5)) is amended—

(1) by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively; and

(2) by inserting after subparagraph (D) the following new subparagraph:

"(E) lymphedema compression treatment items (as defined in section 1861(mmm));".

(c) STUDY AND REPORT ON IMPLEMENTATION.—

(1) STUDY.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall conduct a study on the implementation of Medicare coverage of certain lymphedema compression treatment items under the amendments made by this Act. Such study shall include an evaluation of the following:

(A) Medicare beneficiary utilization of items and services under parts A and B of title XVIII of the Social Security Act as a result of the implementation of such amendments.

(B) Whether the Secretary has determined, pursuant to section 1861(mmm) of the Social Security Act, as added by subsection (a)(1),

that lymphedema compression treatment items other than compression bandaging systems and standard fit gradient compression garments are covered under such section.

(2) REPORT.—Not later than January 1, 2024, the Secretary shall submit to Congress and make available to the public a report on the study conducted under paragraph (1).

SEC. 807. PHYSICIAN FEE UPDATE.

Section 1848(d)(19) of the Social Security Act (42 U.S.C. 1395w–4(d)(19)) is amended to read as follows:

"(19) UPDATE FOR 2020 THROUGH 2025.—The update to the single conversion factor established in paragraph (1)(C)—

"(A) for 2020 and 2021 shall be 0.5 percent; and

"(B) for 2022 and each subsequent year through 2025 shall be 0.0 percent.".

SEC. 808. ADDITIONAL COMMUNITY HEALTH CENTER FUNDING.

Section 10503 of the Patient Protection and Affordable Care Act (42 U.S.C. 254b–2) is amended by striking subsection (c) and inserting the following:

"(c) ADDITIONAL ENHANCED FUNDING; CAPITAL PROJECTS.—There is authorized to be appropriated, and

there is appropriated, out of any monies in the Treasury not otherwise appropriated, to the CHC Fund—

''(1) to be transferred to the Secretary of Health and Human Services to provide additional enhanced funding for the community health center program under section 330 of the Public Health Service Act, $1,000,000,000 for each of fiscal years 2021 through 2025; and

''(2) to be transferred to the Secretary of Health and Human Services for capital projects of the community health center program under section 330 of the Public Health Service Act, $5,000,000,000 for the period of fiscal years 2021 through 2025.''.

SEC. 809. GRANTS TO IMPROVE TRAUMA SUPPORT SERVICES AND MENTAL HEALTH CARE FOR CHILDREN AND YOUTH IN EDUCATIONAL SETTINGS.

(a) GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS AUTHORIZED.—The Secretary, in coordination with the Assistant Secretary for Mental Health and Substance Use, is authorized to award grants to, or enter into contracts or cooperative agreements with, State educational agencies, local educational agencies, Indian Tribes (as defined in section 4 of the Indian Self-Determination

and Education Assistance Act) or their tribal educational agencies, a school operated by the Bureau of Indian Education, a Regional Corporation, or a Native Hawaiian educational organization, for the purpose of increasing student access to evidence-based trauma support services and mental health care by developing innovative initiatives, activities, or programs to link local school systems with local trauma-informed support and mental health systems, including those under the Indian Health Service.

(b) DURATION.—With respect to a grant, contract, or cooperative agreement awarded or entered into under this section, the period during which payments under such grant, contract, or agreement are made to the recipient may not exceed 4 years.

(c) USE OF FUNDS.—An entity that receives a grant, contract, or cooperative agreement under this section shall use amounts made available through such grant, contract, or cooperative agreement for evidence-based activities, which shall include any of the following:

(1) Collaborative efforts between school-based service systems and trauma-informed support and mental health service systems to provide, develop, or improve prevention, screening, referral, and treatment and support services to students, such as pro-

viding trauma screenings to identify students in need of specialized support.

(2) To implement schoolwide positive behavioral interventions and supports, or other trauma-informed models of support.

(3) To provide professional development to teachers, teacher assistants, school leaders, specialized instructional support personnel, and mental health professionals that—

(A) fosters safe and stable learning environments that prevent and mitigate the effects of trauma, including through social and emotional learning;

(B) improves school capacity to identify, refer, and provide services to students in need of trauma support or behavioral health services; or

(C) reflects the best practices for trauma-informed identification, referral, and support developed by the Interagency Task Force on Trauma-Informed Care.

(4) Services at a full-service community school that focuses on trauma-informed supports, which may include a full-time site coordinator, or other activities consistent with section 4625 of the Elemen-

tary and Secondary Education Act of 1965 (20 U.S.C. 7275).

(5) Engaging families and communities in efforts to increase awareness of child and youth trauma, which may include sharing best practices with law enforcement regarding trauma-informed care and working with mental health professionals to provide interventions, as well as longer term coordinated care within the community for children and youth who have experienced trauma and their families.

(6) To provide technical assistance to school systems and mental health agencies.

(7) To evaluate the effectiveness of the program carried out under this section in increasing student access to evidence-based trauma support services and mental health care.

(8) To establish partnerships with or provide subgrants to Head Start agencies (including Early Head Start agencies), public and private preschool programs, child care programs (including home-based providers), or other entities described in subsection (a), to include such entities described in this paragraph in the evidence-based trauma initiatives, activities, support services, and mental health sys-

tems established under this section in order to provide, develop, or improve prevention, screening, referral, and treatment and support services to young children and their families.

(d) APPLICATIONS.—To be eligible to receive a grant, contract, or cooperative agreement under this section, an entity described in subsection (a) shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, which shall include the following:

(1) A description of the innovative initiatives, activities, or programs to be funded under the grant, contract, or cooperative agreement, including how such program will increase access to evidence-based trauma support services and mental health care for students, and, as applicable, the families of such students.

(2) A description of how the program will provide linguistically appropriate and culturally competent services.

(3) A description of how the program will support students and the school in improving the school climate in order to support an environment conducive to learning.

(4) An assurance that—

(A) persons providing services under the grant, contract, or cooperative agreement are adequately trained to provide such services; and

(B) teachers, school leaders, administrators, specialized instructional support personnel, representatives of local Indian Tribes or tribal organizations as appropriate, other school personnel, and parents or guardians of students participating in services under this section will be engaged and involved in the design and implementation of the services.

(5) A description of how the applicant will support and integrate existing school-based services with the program in order to provide mental health services for students, as appropriate.

(6) A description of the entities in the community with which the applicant will partner or to which the applicant will provide subgrants in accordance with subsection (c)(8).

(e) INTERAGENCY AGREEMENTS.—

(1) LOCAL INTERAGENCY AGREEMENTS.—To ensure the provision of the services described in subsection (c), a recipient of a grant, contract, or cooperative agreement under this section, or their designee, shall establish a local interagency agreement

among local educational agencies, agencies responsible for early childhood education programs, Head Start agencies (including Early Head Start agencies), juvenile justice authorities, mental health agencies, child welfare agencies, and other relevant agencies, authorities, or entities in the community that will be involved in the provision of such services.

(2) CONTENTS.—In ensuring the provision of the services described in subsection (e), the local interagency agreement shall specify with respect to each agency, authority, or entity that is a party to such agreement—

(A) the financial responsibility for the services;

(B) the conditions and terms of responsibility for the services, including quality, accountability, and coordination of the services; and

(C) the conditions and terms of reimbursement among such agencies, authorities, or entities, including procedures for dispute resolution.

(f) EVALUATION.—The Secretary shall reserve not more than 3 percent of the funds made available under subsection (l) for each fiscal year to—

(1) conduct a rigorous, independent evaluation of the activities funded under this section; and

(2) disseminate and promote the utilization of evidence-based practices regarding trauma support services and mental health care.

(g) DISTRIBUTION OF AWARDS.—The Secretary shall ensure that grants, contracts, and cooperative agreements awarded or entered into under this section are equitably distributed among the geographical regions of the United States and among tribal, urban, suburban, and rural populations.

(h) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to prohibit an entity involved with a program carried out under this section from reporting a crime that is committed by a student to appropriate authorities; or

(2) to prevent Federal, State, and tribal law enforcement and judicial authorities from exercising their responsibilities with regard to the application of Federal, tribal, and State law to crimes committed by a student.

(i) SUPPLEMENT, NOT SUPPLANT.—Any services provided through programs carried out under this section shall supplement, and not supplant, existing mental health

services, including any special education and related services provided under the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.).

(j) CONSULTATION WITH INDIAN TRIBES.—In carrying out subsection (a), the Secretary shall, in a timely manner, meaningfully consult with Indian Tribes and their representatives to ensure notice of eligibility.

(k) DEFINITIONS.—In this section:

(1) ELEMENTARY SCHOOL.—The term ''elementary school'' has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(2) EVIDENCE-BASED.—The term ''evidence-based'' has the meaning given such term in section 8101(21)(A)(i) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801(21)(A)(i)).

(3) NATIVE HAWAIIAN EDUCATIONAL ORGANIZATION.—The term ''Native Hawaiian educational organization'' has the meaning given such term in section 6207 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7517).

(4) LOCAL EDUCATIONAL AGENCY.—The term ''local educational agency'' has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(5) REGIONAL CORPORATION.—The term ''Regional Corporation'' has the meaning given the term in section 3 of the Alaska Native Claims Settlement Act (43 U.S.C. 1602).

(6) SCHOOL.—The term ''school'' means a public elementary school or public secondary school.

(7) SCHOOL LEADER.—The term ''school leader'' has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(8) SECONDARY SCHOOL.—The term ''secondary school'' has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(9) SECRETARY.—The term ''Secretary'' means the Secretary of Education.

(10) SPECIALIZED INSTRUCTIONAL SUPPORT PERSONNEL.—The term ''specialized instructional support personnel'' has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(11) STATE EDUCATIONAL AGENCY.—The term ''State educational agency'' has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(l) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, and there is appropriated, out of any money in the Treasury not otherwise appropriated, to carry out this section, $20,000,000 for each of fiscal years 2021 through 2025.

SEC. 810. PATHWAY TO HEALTH CAREERS ACT.

(a) SHORT TITLE.—This section may be cited as the ''Pathways to Health Careers Act''.

(b) EXTENSION THROUGH FISCAL YEAR 2020 OF FUNDING FOR DEMONSTRATION PROJECTS TO ADDRESS HEALTH PROFESSIONS WORKFORCE NEEDS.—

(1) IN GENERAL.—Section 2008(c)(1) of the Social Security Act (42 U.S.C. 1397g(c)(1)) is amended by striking ''2019.'' and inserting ''2020, and to provide technical assistance and cover administrative costs associated with implementing the successor to this section $15,000,000 for fiscal year 2020.''.

(2) AVAILABILITY OF OTHER FUNDS.—Upon the date of the enactment of this section—

(A) amounts expended pursuant to section 1501 of division B of Public Law 116–59, or any other prior law making amounts available for fiscal year 2020 for activities authorized by section 2008 of the Social Security Act, shall be

charged to the appropriation made by subsection (c)(1) of such section 2008 for fiscal year 2020 (not including the amount for technical assistance and administrative costs); and

(B) if such enactment occurs on or before November 21, 2019, the availability of funds appropriated in, and the authority provided under, such section 1501 shall terminate.

(c) CAREER PATHWAYS THROUGH HEALTH PROFESSION OPPORTUNITY GRANTS.—Effective October 1, 2020, section 2008 of the Social Security Act (42 U.S.C. 1397g) is amended to read as follows:

"SEC. 2008. CAREER PATHWAYS THROUGH HEALTH PROFESSION OPPORTUNITY GRANTS.

''(a) APPLICATION REQUIREMENTS.—An eligible entity desiring a grant under this section for a project shall submit to the Secretary an application for the grant, that includes the following:

''(1) A description of how the applicant will use a career pathways approach to train eligible individuals for health professions that pay well or will put eligible individuals on a career path to an occupation that pays well, under the project.

''(2) A description of the adult basic education and literacy activities, work readiness activities,

training activities, and case management and career coaching services that the applicant will use to assist eligible individuals to gain work experience, connection to employers, and job placement, and a description of the plan for recruiting, hiring, and training staff to provide the case management, mentoring, and career coaching services, under the project directly or through local governmental, apprenticeship, educational, or charitable institutions.

''(3) In the case of an application for a grant under this section for a demonstration project described in subsection (c)(2)(B)(i)(I)—

''(A) a demonstration that the State in which the demonstration project is to be conducted has in effect policies or laws that permit certain allied health and behavioral health care credentials to be awarded to people with certain arrest or conviction records (which policies or laws shall include appeals processes, waivers, certificates, and other opportunities to demonstrate rehabilitation to obtain credentials, licensure, and approval to work in the proposed health careers), and a plan described in the application that will use a career pathway to assist participants with such a record in acquiring

credentials, licensing, and employment in the specified careers;

''(B) a discussion of how the project or future strategic hiring decisions will demonstrate the experience and expertise of the project in working with job seekers who have arrest or conviction records or employers with experience working with people with arrest or conviction records;

''(C) an identification of promising innovations or best practices that can be used to provide the training;

''(D) a proof of concept or demonstration that the applicant has done sufficient research on workforce shortage or in-demand jobs for which people with certain types of arrest or conviction records can be hired;

''(E) a plan for recruiting students who are eligible individuals into the project; and

''(F) a plan for providing post-employment support and ongoing training as part of a career pathway under the project.

''(4) In the case of an application for a grant under this section for a demonstration project described in subsection (c)(2)(B)(i)(II)—

''(A) a description of the partnerships, strategic staff hiring decisions, tailored program activities, or other programmatic elements of the project, such as training plans for doulas and other community health workers and training plans for midwives and other allied health professions, that are designed to support a career pathway in pregnancy, birth, or postpartum services; and

''(B) a demonstration that the State in which the demonstration project is to be conducted recognizes doulas or midwives, as the case may be.

''(5) A demonstration that the applicant has experience working with low-income populations, or a description of the plan of the applicant to work with a partner organization that has the experience.

''(6) A plan for providing post-employment support and ongoing training as part of a career pathway under the project.

''(7) A description of the support services that the applicant will provide under the project, including a plan for how child care and transportation support services will be guaranteed and, if the applicant will provide a cash stipend or wage supplement,

how the stipend or supplement would be calculated and distributed.

''(8) A certification by the applicant that the project development included—

''(A) consultation with a local workforce development board established under section 107 of the Workforce Innovation and Opportunity Act;

''(B) consideration of apprenticeship and pre-apprenticeship models registered under the Act of August 16, 1937 (also known as the 'National Apprenticeship Act');

''(C) consideration of career pathway programs in the State in which the project is to be conducted; and

''(D) a review of the State plan under section 102 or 103 of the Workforce Innovation and Opportunity Act.

''(9) A description of the availability and relevance of recent labor market information and other pertinent evidence of in-demand jobs or worker shortages.

''(10) A certification that the applicant will directly provide or contract for the training services described in the application.

''(11) A commitment by the applicant that, if the grant is made to the applicant, the applicant will—

''(A) during the planning period for the project, provide the Secretary with any information needed by the Secretary to establish adequate data reporting and administrative structure for the project;

''(B) hire a person to direct the project not later than the end of the planning period applicable to the project;

''(C) accept all technical assistance offered by the Secretary with respect to the grant;

''(D) participate in such in-person grantee conferences as are regularly scheduled by the Secretary;

''(E) provide all data required by the Secretary under subsection (g); and

''(F) notify the local disabled veterans' outreach program specialists under section 4103A of title 38, United States Code, and the local veterans' employment representatives under section 4104 of such title, of the grantee's outreach plan for advertising training op-

portunities to potential participants in the project.

''(b) PREFERENCES IN CONSIDERING APPLICATIONS.—In considering applications for a grant under this section, the Secretary shall give preference to—

''(1) applications submitted by applicants to whom a grant was made under this section or any predecessor to this section;

''(2) applications submitted by applicants who have business and community partners in each of the following categories:

''(A) State and local government agencies and social service providers, including a State or local entity that administers a State program funded under part A of this title;

''(B) institutions of higher education, apprenticeship programs, and local workforce development boards established under section 107 of the Workforce Innovation and Opportunity Act; and

''(C) health care employers, health care industry or sector partnerships, labor unions, and labor-management partnerships;

''(3) applications that include opportunities for mentoring or peer support, and make career coaching available, as part of the case management plan;

''(4) applications which describe a project that will serve a rural area in which—

''(A) the community in which the individuals to be enrolled in the project reside is located;

''(B) the project will be conducted; or

''(C) an employer partnership that has committed to hiring individuals who successfully complete all activities under the project is located;

''(5) applications that include a commitment to providing project participants with a cash stipend or wage supplement; and

''(6) applications which have an emergency cash fund to assist project participants financially in emergency situations.

''(c) GRANTS.—

''(1) COMPETITIVE GRANTS.—

''(A) GRANT AUTHORITY.—

''(i) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor and the Secretary of Education, may make

a grant in accordance with this paragraph to an eligible entity whose application for the grant is approved by the Secretary, to conduct a project designed to train low-income individuals for allied health professions, health information technology, physicians assistants, nursing assistants, registered nurse, advanced practice nurse, and other professions considered part of a health care career pathway model.

''(ii) GUARANTEE OF GRANTEES IN EACH STATE AND THE DISTRICT OF COLUMBIA.—For each grant cycle, the Secretary shall award a grant under this paragraph to at least 2 eligible entities in each State that is not a territory, to the extent there are a sufficient number of applications submitted by the entities that meet the requirements applicable with respect to such a grant. If, for a grant cycle, there are fewer than 2 such eligible entities in a State, the Secretary shall include that information in the report required by subsection (g)(2) that covers the fiscal year.

"(B) GUARANTEE OF GRANTS FOR INDIAN POPULATIONS.—From the amount reserved under subsection (i)(2)(B) for each fiscal year, the Secretary shall award a grant under this paragraph to at least 10 eligible entities that are an Indian tribe, a tribal organization, or a tribal college or university, to the extent there are a sufficient number of applications submitted by the entities that meet the requirements applicable with respect to such a grant.

"(C) GUARANTEE OF GRANTEES IN THE TERRITORIES.—From the amount reserved under subsection (i)(2)(C) for each fiscal year, the Secretary shall award a grant under this paragraph to at least 2 eligible entities that are located in a territory, to the extent there are a sufficient number of applications submitted by the entities that meet the requirements applicable with respect to such a grant.

"(2) GRANTS FOR DEMONSTRATION PROJECTS.—

"(A) GRANT AUTHORITY.—The Secretary, in consultation with the Secretary of Labor and the Secretary of Education (and, with respect to demonstration projects of the type described

in subparagraph (B)(i)(I), the Attorney General) shall make a grant in accordance with this subsection to an eligible entity whose application for the grant is approved by the Secretary, to conduct a demonstration project that meets the requirements of subparagraph (B).

''(B) REQUIREMENTS.—The requirements of this subparagraph are the following:

''(i) TYPE OF PROJECT.—The demonstration project shall be of 1 of the following types:

''(I) INDIVIDUALS WITH ARREST OR CONVICTION RECORDS DEMONSTRATION.—The demonstration project shall be of a type designed to provide education and training for eligible individuals with arrest or conviction records to enter and follow a career pathway in the health professions through occupations that pay well and are expected to experience a labor shortage or be in high demand.

''(II) PREGNANCY AND CHILDBIRTH CAREER PATHWAY DEMONSTRATION.—The demonstration

project shall be of a type designed to provide education and training for eligible individuals to enter and follow a career pathway in the field of pregnancy, childbirth, or post-partum, in a State that recognizes doulas or midwives and that provides payment for services provided by doulas or midwives, as the case may be, under private or public health insurance plans.

''(ii) DURATION.—The demonstration project shall be conducted for not less than 5 years.

''(C) MINIMUM ALLOCATION OF FUNDS FOR EACH TYPE OF DEMONSTRATION PROJECT.—

''(i) INDIVIDUALS WITH ARREST OR CONVICTION RECORDS DEMONSTRATIONS.—Not less than 25 percent of the amounts made available for grants under this paragraph shall be used to make grants for demonstration projects of the type described in subparagraph (B)(i)(I).

''(ii) PREGNANCY AND CHILDBIRTH CAREER PATHWAY DEMONSTRATIONS.—

Not less than 25 percent of the amounts made available for grants under this paragraph shall be used to make grants for demonstration projects of the type described in subparagraph (B)(i)(II).

''(3) GRANT CYCLE.—The grant cycle under this section shall be not less than 5 years, with a planning period of not more than the 1st 12 months of the grant cycle. During the planning period, the amount of the grant shall be in such lesser amount as the Secretary determines appropriate.

''(d) USE OF GRANT.—

''(1) IN GENERAL.—An entity to which a grant is made under this section shall use the grant in accordance with the approved application for the grant.

''(2) SUPPORT TO BE PROVIDED.—

''(A) REQUIRED SUPPORT.—A project for which a grant is made under this section shall include the following:

''(i) An assessment for adult basic skill competency, and provision of adult basic skills education if necessary for lower-skilled eligible individuals to enroll in the project and go on to enter and com-

plete post-secondary training, through means including the following:

''(I) Establishing a network of partners that offer pre-training activities for project participants who need to improve basic academic skills or English language proficiency before entering a health occupational training career pathway program.

''(II) Offering resources to enable project participants to continue advancing adult basic skill proficiency while enrolled in a career pathway program.

''(III) Embedding adult basic skill maintenance as part of ongoing post-graduation career coaching and mentoring.

''(ii) A guarantee that child care is an available and affordable support service for project participants through means such as the following;

''(I) Referral to, and assistance with, enrollment in a subsidized child care program.

''(II) Direct payment to a child care provider if a slot in a subsidized child care program is not available or reasonably accessible.

''(III) Payment of co-payments or associated fees for child care.

''(iii) Case management plans that include career coaching (with the option to offer appropriate peer support and mentoring opportunities to help develop soft skills and social capital), which may be offered on an ongoing basis before, during, and after initial training as part of a career pathway model.

''(iv) A plan to provide project participants with transportation through means such as the following:

''(I) Referral to, and assistance with enrollment in, a subsidized transportation program.

''(II) If a subsidized transportation program is not reasonably available, direct payments to subsidize transportation costs.

For purposes of this clause, the term 'transportation' includes public transit, or gasoline for a personal vehicle if public transit is not reasonably accessible or available.

''(v) In the case of a demonstration project of the type described in subsection (c)(2)(B)(i)(I), access to legal assistance for project participants for the purpose of addressing arrest or conviction records and associated workforce barriers.

''(B) ALLOWED SUPPORT.—The goods and services provided under a project for which a grant is made under this section may include the following:

''(i) A cash stipend that is at least monthly.

''(ii) A reserve fund for financial assistance to project participants in emergency situations.

''(iii) Tuition, and training materials such as books, software, uniforms, shoes, and hair nets.

''(iv) In-kind resource donations such as interview clothing and conference attendance fees.

''(v) Assistance with accessing and completing high school equivalency or adult basic education courses as necessary to achieve success in the project and make progress toward career goals.

''(vi) Assistance with programs and activities, including legal assistance, deemed necessary to address arrest or conviction records as an employment barrier.

''(vii) Other support services as deemed necessary for family well-being, success in the project, and progress toward career goals.

''(C) TREATMENT OF SUPPORT FOR PURPOSES OF MEANS-TESTED PROGRAMS.—Any goods or services provided to an eligible individual participating in a project for which a grant is made under this section shall not be considered income, and shall not be taken into account for purposes of determining the eligibility of the individual for, or amount of bene-

fits to be provided to the individual, under any means-tested program.

''(3) TRAINING.—The number of hours of training provided to an eligible individual under a project for which a grant is made under this section, for a recognized postsecondary credential, including an industry-recognized credential, which is awarded in recognition of attainment of measurable technical or occupational skills necessary to gain employment or advance within an occupation (including a certificate awarded by a local workforce development board established under section 107 of the Workforce Innovation and Opportunity Act), shall be—

''(A) not less than the number of hours of training required for certification in that level of skill by the State in which the project is conducted; or

''(B) if there is no such requirement, such number of hours of training as the Secretary finds is necessary to achieve that skill level.

''(4) INCOME LIMITATION.—An entity to which a grant is made under this section shall not use the grant to provide support to a person who is not an eligible individual.

''(5) INCLUSION OF TANF RECIPIENTS.—In the case of a project for which a grant is made under this section that is conducted in a State that has a program funded under part A of title IV, at least 10 percent of the eligible individuals to whom support is provided under the project shall meet the income eligibility requirements under that State program, without regard to whether the individuals receive benefits or services directly under that State program.

''(6) PROHIBITION.—An entity to which a grant is made under this section shall not use the grant for purposes of entertainment, except that case management and career coaching services may include celebrations of specific career-based milestones such as completing a semester, graduation, or job placement.

''(e) TECHNICAL ASSISTANCE.—

''(1) IN GENERAL.—The Secretary shall provide technical assistance—

''(A) to assist eligible entities in applying for grants under this section;

''(B) that is tailored to meet the needs of grantees at each stage of the administration of

projects for which grants are made under this section;

''(C) that is tailored to meet the specific needs of Indian tribes, tribal organizations, and tribal colleges and universities;

''(D) that is tailored to meet the specific needs of the territories;

''(E) that is tailored to meet the specific needs of eligible entities in carrying out demonstration projects for which a grant is made under this section; and

''(F) to facilitate the exchange of information among eligible entities regarding best practices and promising practices used in the projects.

''(2) CONTINUATION OF PEER TECHNICAL ASSISTANCE CONFERENCES.—The Secretary shall continue to hold peer technical assistance conferences for entities to which a grant is made under this section or was made under the immediate predecessor of this section.

''(f) EVALUATION OF DEMONSTRATION PROJECTS.—

''(1) IN GENERAL.—The Secretary shall, by grant, contract, or interagency agreement, conduct rigorous and well-designed evaluations of the dem-

onstration projects for which a grant is made under this section.

''(2) REQUIREMENT APPLICABLE TO INDIVIDUALS WITH ARREST OR CONVICTION RECORDS DEMONSTRATION.—In the case of a project of the type described in subsection (c)(2)(B)(i)(I), the evaluation shall include identification of successful activities for creating opportunities for developing and sustaining, particularly with respect to low-income individuals with arrest or conviction records, a health professions workforce that has accessible entry points, that meets high standards for education, training, certification, and professional development, and that provides increased wages and affordable benefits, including health care coverage, that are responsive to the needs of the workforce.

''(3) REQUIREMENT APPLICABLE TO PREGNANCY AND CHILDBIRTH CAREER PATHWAY DEMONSTRATION.—In the case of a project of the type described in subsection (c)(2)(B)(i)(II), the evaluation shall include identification of successful activities for creating opportunities for developing and sustaining, particularly with respect to low-income individuals and other entry-level workers, a career pathway that has accessible entry points, that meets

high standards for education, training, certification, and professional development, and that provides increased wages and affordable benefits, including health care coverage, that are responsive to the needs of the birth, pregnancy, and post-partum workforce.

''(4) RULE OF INTERPRETATION.—Evaluations conducted pursuant to this subsection may include a randomized controlled trial, but this subsection shall not be interpreted to require an evaluation to include such a trial.

''(g) REPORTS.—

''(1) TO THE SECRETARY.—An eligible entity awarded a grant to conduct a project under this section shall submit interim reports to the Secretary on the activities carried out under the project, and, on the conclusion of the project, a final report on the activities. Each such report shall include data on participant outcomes related to earnings, employment in health professions, graduation rate, graduation timeliness, credential attainment, participant demographics, and other data specified by the Secretary.

''(2) TO THE CONGRESS.—During each Congress, the Secretary shall submit to the Committee

on Ways and Means of the House of Representatives and the Committee on Finance of the Senate a report—

"(A) on the demographics of the participants in the projects for which a grant is made under this section;

"(B) on the rate of which project participants completed all activities under the projects;

"(C) on the employment credentials acquired by project participants;

"(D) on the employment of project participants on completion of activities under the projects, and the earnings of project participants at entry into employment;

"(E) on best practices and promising practices used in the projects;

"(F) on the nature of any technical assistance provided to grantees under this section;

"(G) on, with respect to the period since the period covered in the most recent prior report submitted under this paragraph—

"(i) the number of applications submitted under this section, with a separate

statement of the number of applications referred to in subsection (b)(5);

''(ii) the number of applications that were approved, with a separate statement of the number of such applications referred to in subsection (b)(5); and

''(iii) a description of how grants were made in any case described in the last sentence of subsection (c)(1)(A)(ii); and

''(H) that includes an assessment of the effectiveness of the projects with respect to addressing health professions workforce shortages or in-demand jobs.

''(h) DEFINITIONS.—In this section:

''(1) ALLIED HEALTH PROFESSION.—The term 'allied health profession' has the meaning given in section 799B(5) of the Public Health Service Act.

''(2) CAREER PATHWAY.—The term 'career pathway' has the meaning given that term in section 3(7) of the Workforce Innovation and Opportunity Act.

''(3) DOULA.—The term 'doula' means an individual who—

''(A) is certified by an organization that has been established for not less than 5 years

and that requires the completion of continuing education to maintain the certification, to provide non-medical advice, information, emotional support, and physical comfort to an individual during the individual's pregnancy, childbirth, and post-partum period; and

''(B) maintains the certification by completing the required continuing education.

''(4) ELIGIBLE ENTITY.—The term 'eligible entity' means any of the following entities that demonstrates in an application submitted under this section that the entity has the capacity to fully develop and administer the project described in the application:

''(A) A local workforce development board established under section 107 of the Workforce Innovation and Opportunity Act.

''(B) A State or territory, a political subdivision of a State or territory, or an agency of a State, territory, or such a political subdivision, including a State or local entity that administers a State program funded under part A of this title.

''(C) An Indian tribe, a tribal organization, or a tribal college or university.

"(D) An institution of higher education (as defined in the Higher Education Act of 1965).

"(E) A hospital (as defined in section 1861(e)).

"(F) A high-quality skilled nursing facility.

"(G) A Federally qualified health center (as defined in section 1861(aa)(4)).

"(H) A nonprofit organization described in section 501(c)(3) of the Internal Revenue Code of 1986, a labor organization, or an entity with shared labor-management oversight, that has a demonstrated history of providing health profession training to eligible individuals.

"(I) In the case of a demonstration project of the type provided for in subsection (c)(2)(B)(i)(II) of this section, an entity recognized by a State, Indian tribe, or tribal organization as qualified to train doulas or midwives, if midwives or doulas, as the case may be, are permitted to practice in the State involved.

"(J) An opioid treatment program (as defined in section 1861(jjj)(2)), and other high quality comprehensive addiction care providers.

"(5) ELIGIBLE INDIVIDUAL.—The term 'eligible individual' means an individual whose family income

does not exceed 200 percent of the Federal poverty level.

''(6) FEDERAL POVERTY LEVEL.—The term 'Federal poverty level' means the poverty line (as defined in section 673(2) of the Omnibus Budget Reconciliation Act of 1981, including any revision required by such section applicable to a family of the size involved).

''(7) INDIAN TRIBE; TRIBAL ORGANIZATION.—The terms 'Indian tribe' and 'tribal organization' have the meaning given the terms in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b).

''(8) INSTITUTION OF HIGHER EDUCATION.—The term 'institution of higher education' has the meaning given the term in section 101 or 102(a)(1)(B) of the Higher Education Act of 1965.

''(9) TERRITORY.—The term 'territory' means the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.

''(10) TRIBAL COLLEGE OR UNIVERSITY.—The term 'tribal college or university' has the meaning given the term in section 316(b) of the Higher Education Act of 1965.

''(i) FUNDING.—

''(1) IN GENERAL.—Out of any funds in the Treasury of the United States not otherwise appropriated, there are appropriated to the Secretary to carry out this section $425,000,000 for each of fiscal years 2021 through 2025.

''(2) ALLOCATION OF FUNDS.—Of the amount appropriated for a fiscal year under paragraph (1) of this subsection—

''(A) 75 percent shall be available for grants under subsection (c)(1)(A);

''(B) 4 percent shall be reserved for grants under subsection (c)(1)(B);

''(C) 5 percent shall be reserved for grants under subsection (c)(1)(C);

''(D) 6 percent shall be available for demonstration project grants under subsection (c)(2);

''(E) 6 percent, plus all amounts referred to in subparagraphs (A) through (D) of this paragraph that remain unused after all grant awards are made for the fiscal year, shall be available for the provision of technical assistance and associated staffing; and

''(F) 4 percent shall be available for studying the effects of the demonstration and non-demonstration projects for which a grant is made under this section, and for associated staffing, for the purpose of supporting the rigorous evaluation of the demonstration projects, and supporting the continued study of the short-, medium-, and long-term effects of all such projects, including the effectiveness of new or added elements of the non-demonstration projects.

''(j) NONAPPLICABILITY OF PRECEDING SECTIONS OF THIS SUBTITLE.—

''(1) IN GENERAL.—Except as provided in paragraph (2), the preceding sections of this subtitle shall not apply to a grant awarded under this section.

''(2) EXCEPTION FOR CERTAIN LIMITATIONS ON USE OF GRANTS.—Section 2005(a) (other than paragraphs (2), (3), (5), (6), and (8)) shall apply to a grant awarded under this section to the same extent and in the same manner as such section applies to payments to States under this subtitle.''.

SEC. 811. HOME VISITING TO REDUCE MATERNAL MORTALITY AND MORBIDITY ACT.

(a) SHORT TITLE.—This section may be cited as the ''Home Visiting to Reduce Maternal Mortality and Morbidity Act''.

(b) INCREASE IN TRIBAL SET-ASIDE PERCENTAGE.—

(1) IN GENERAL.—Section 511(j)(2)(A) of the Social Security Act (42 U.S.C. 711(j)(2)(A)) is amended by striking ''3'' and inserting ''6''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2020.

(c) INCREASE IN FUNDING.—Section 511(j)(1) of such Act (42 U.S.C. 711(j)(1)) is amended—

(1) by striking ''and'' at the end of subparagraph (G); and

(2) by striking subparagraph (H) and inserting the following:

''(H) $400,000,000 for each of fiscal years 2017 through 2020;

''(I) $600,000,000 for fiscal year 2021; and

''(J) $800,000,000 for fiscal year 2022.''.

(d) USE OF ADDITIONAL FUNDS.—Section 511(c) of such Act (42 U.S.C. 711(c)) is amended by adding at the end the following:

''(6) USE OF CERTAIN FUNDS TO PROVIDE ADDITIONAL RESOURCES TO ADDRESS HIGH RATES OF MATERNAL MORTALITY AND MORBIDITY, SUPPORT UNMET NEEDS IDENTIFIED BY THE NEEDS ASSESSMENT, OR INCREASE ALLOCATIONS TO STATES AND TERRITORIES BASED ON RELATIVE POPULATION OR POVERTY.—The Secretary shall ensure that any amounts exceeding $400,000,000 that are used for grants under this subsection for a fiscal year are used to—

''(A) provide additional funding priority to States, tribes, and territories to address high rates of maternal mortality and morbidity;

''(B) address unmet needs identified by a needs assessment conducted under subsection (b); or

''(C) increase the amounts allocated under this section to States and to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, and American Samoa, based on the proportion of children who have not at-

tained 5 years of age and are living in poverty.''.

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