I

117TH CONGRESS
1ST SESSION

H. R. 3

To establish a fair price negotiation program, protect the Medicare program from excessive price increases, and establish an out-of-pocket maximum for Medicare part D enrollees, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 22, 2021

Mr. PALLONE (for himself, Mr. NEAL, and Mr. SCOTT of Virginia) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Education and Labor, Oversight and Reform, and Veterans' Affairs, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To establish a fair price negotiation program, protect the Medicare program from excessive price increases, and establish an out-of-pocket maximum for Medicare part D enrollees, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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 2024) 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, 2024).

''(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 insur-

ance 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, subject to subsection (h), the Secretary shall select and publish in the Federal Register a list of—

''(1)(A) with respect to an initial price applicability year during 2024, 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 2024, the maximum number (if such number is less than 25) of such negotiation-eligible drugs for the year) with respect to such year; and

''(B) with respect to an initial price applicability year during 2025 or a subsequent year, at least 50 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 max-

imum number (if such number is less than 50) 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 re-

cent 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 licensed 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-eligible 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.

''(h) CONFLICT OF INTEREST.—

''(1) IN GENERAL.—In the case the Inspector General of the Department of Health and Human Services determines the Secretary has a conflict, with respect to a matter described in paragraph (2), the individual described in paragraph (3) shall carry out the duties of the Secretary under this part, with respect to a negotiation-eligible drug, that would otherwise be such a conflict.

''(2) MATTER DESCRIBED.—A matter described in this paragraph is—

''(A) a financial interest (as described in section 2635.402 of title 5, Code of Federal Regulations, as in effect on the date of the enactment of this section, (except for an interest described in subsection (b)(2)(iv) of such sec-

tion)) on the date of the selected drug publication date, with respect the price applicability year (as applicable);

"(B) a personal or business relationship (as described in section 2635.502 of such title) on the date of the selected drug publication date, with respect the price applicability year;

"(C) employment by a manufacturer of a negotiation-eligible drug during the preceding 10-year period beginning on the date of the selected drug publication date, with respect to each price applicability year; and

"(D) any other matter the General Counsel determines appropriate.

"(3) INDIVIDUAL DESCRIBED.—An individual described in this paragraph is—

"(A) the highest-ranking officer or employee of the Department of Health and Human Services (as determined by the organizational chart of the Department) that does not have a conflict under this subsection; and

"(B) is nominated by the President and confirmed by the Senate with respect to the position.

"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 subpara-

graph (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 sub-

paragraph (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 de-

scribed 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 ap-

plication 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 ini-

tial 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 consumers (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 de-

scribed 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 provi-

sion 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 offer-

ing 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, physician, 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, 2027, 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, 2027, 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 necessary to determine the tax imposed by section 4192 of the Internal Revenue Code of 1986.

''(g) GAO STUDY.—Not later than December 31, 2027, 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 D of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–111 et seq.) is amended by adding at the end the following new section:

''SEC. 2799A–11. 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 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 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. 726. 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 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, and such individuals so enrolled in such plans.

''(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR PRICE NEGOTIATION PROGRAM.—A group health plan or a health insurance issuer offering group health in-

surance 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 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 726''.

(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. 726. 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. 9826. 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 individ-

uals 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 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 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 9826,'' before ''any group health plan''.

(iii) CLERICAL AMENDMENT.—The table of sections for subchapter B of chap-

ter 100 of such Code is amended by adding at the end the following new item:

''Sec. 9826. 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 organi-

zation, 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.''.

(4) FEHBP.—Section 8902 of title 5, United States Code, is amended by adding at the end the following:

''(p) A contract may not be made or a plan approved under this chapter with any carrier that has affirmatively elected, pursuant to section 1197 of the Social Security Act, not to participate in the Fair Price Negotiation Program established under section 1191 of such Act for any

selected drug (as that term is defined in section 1192(c) of such Act).''.

(5) OPTION OF SECRETARY OF VETERANS AFFAIRS TO PURCHASE COVERED DRUGS AT MAXIMUM FAIR PRICES.—Section 8126 of title 38, United States Code, is amended—

(A) in subsection (a)(2), by inserting '', subject to subsection (j),'' after ''may not exceed'';

(B) in subsection (d), in the matter preceding paragraph (1), by inserting '', subject to subsection (j)'' after ''for the procurement of the drug''; and

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

''(j)(1) In the case of a covered drug that is a selected drug, for any year during the price applicability period for such drug, if the Secretary determines that the maximum fair price of such drug for such year is less than the price for such drug otherwise in effect pursuant to this section (including after application of any reduction under subsection (a)(2) and any discount under subsection (c)), at the option of the Secretary, in lieu of the maximum price (determined after application of the reduction under subsection (a)(2) and any discount under subsection (c), as

applicable) that would be permitted to be charged during such year for such drug pursuant to this section without application of this subsection, the maximum price permitted to be charged during such year for such drug pursuant to this section shall be such maximum fair price for such drug and year.

''(2) For purposes of this subsection:

''(A) The term 'maximum fair price' means, with respect to a selected drug and year during the price applicability period for such drug, the maximum fair price (as defined in section 1191(c)(2) of the Social Security Act) for such drug and year.

''(B) The term 'negotiation eligible drug' has the meaning given such term in section 1192(d)(1) of the Social Security Act.

''(C) The term 'price applicability period' has, with respect to a selected drug, the meaning given such term in section 1191(b)(2) of such Act.

''(D) The term 'selected drug' means, with respect to a year, a drug that is a selected drug under section 1192(c) of such Act for such year.''.

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 Services 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 PRICE NEGOTIATION IMPLEMENTATION FUND.

(a) IN GENERAL.—There is hereby established a Fair 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, 2022;

(3) $600,000,000 shall become available on October 1, 2023;

(4) $600,000,000 shall become available on October 1, 2024; and

(5) $600,000,000 shall become available on October 1, 2025.

(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—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:

''(z) 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, 2023, 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 increase 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, 2023, 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 2024, shall be the dollar amount specified under such subparagraph for 2023, 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 ex-

ceeds 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, 2023' 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, 2023.

"(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 deter-

mining 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 (DD)'' and inserting ''(EE)''; and

(iii) by inserting before the semicolon at the end the following: '', and (EE) with respect to a part B rebatable drug (as defined in paragraph (2) of section 1834(z)) 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 pay-

ment 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''; and

(B) by adding at the end of the flush left matter following paragraph (9), the following:

''For purposes of applying paragraph (1)(EE), subsections (i)(9) and (t)(8)(F), and section 1834(z)(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(z)) 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, 2023, 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(z)(5), paragraph (1)(EE) 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(z)(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(z)) for which payment under this part is not packaged into a payment for a service furnished on or after July 1, 2023, 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(z)(5), paragraph (1)(EE) 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(z)(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(z)'' 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(z)'' after ''this section''.

(3) COORDINATION WITH MEDICAID REBATE INFORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)(i)) is amended by striking ''or to carry out section 1847B'' and inserting ''to carry out section 1847B or section 1834(z)''.

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, 2023, and ending on December 31, 2023, there were extenuating circumstances.

''(3) APPLICABLE YEAR.—For purposes of this section the term 'applicable year' means a year beginning with 2023.

''(b) AGREEMENTS.—

''(1) TERMS OF AGREEMENT.—An agreement described in this subsection, with respect to a manufacturer 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 respect 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 of the calendar quarters 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 each such calendar quarter of such payment amount benchmark year; to

''(ii) the total number of units of such dosage form and strength dispensed during such 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 extension' 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 Sec-

retary 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 2024, shall be the dollar amount specified under such subparagraph for 2023, 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 2023; 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(z)'' and inserting ''section 1927, section 1834(z), 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(z)'' and inserting '', section 1834(z), or section 1860D–14B''.

(3) COORDINATION WITH MEDICAID REBATE INFORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)(i)), as amended by section 201(c)(3), is further amended by striking ''or section 1834(z)'' and inserting '', section 1834(z), or section 1860D–14B''.

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

(a) IN GENERAL.—Not later than December 31, 2023, 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(z) 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; and

(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.

(b) REGULATIONS.—Not later than December 31, 2024, the Secretary of Labor shall, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, promulgate regulations to implement a model described in subsection (a)(1) and a model described in subsection (a)(2), if the Secretary determines that—

(1) the prices of a sufficient number (as determined by the Secretary) of drugs described in subsection (a)(1) have increased over a period of time (as determined by the Secretary) at a percentage that exceeds the percentage by which the consumer price index for all urban consumers (United States city average) has increased over such period; and

(2) such model described in subsection (a)(1) and such model described in subsection (a)(2) are feasible.

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

(a) INITIAL REPORT.—Not later than December 31, 2023, 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(z) 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 2023, 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, the 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, the 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 2024 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 2024 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 2024,'' after ''paragraph (4),''; and

(ii) in clause (ii)(III), by striking ''and each subsequent year'' and inserting ''through 2023''; and

(C) in subparagraph (D)—

(i) in clause (i)—

(I) in the matter preceding subclause (I), by inserting ''for a year preceding 2024,'' after ''paragraph (4),''; and

(II) in subclause (I)(bb), by striking ''a year after 2018'' and inserting ''each of years 2018 through 2023''; and

(ii) in clause (ii)(V), by striking ''2019 and each subsequent year'' and inserting ''each of years 2019 through 2023'';

(2) in paragraph (3)(A)—

(A) in the matter preceding clause (i), by inserting ''for a year preceding 2024,'' after ''and (4),''; and

(B) in clause (ii), by striking ''for a subsequent year'' and inserting ''for each of years 2007 through 2023''; 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 2024, 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 2024 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 each of years 2021 through 2023''; 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 2024, 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 2024, for amounts''; and

(D) in subparagraph (E), by striking ''In applying'' and inserting ''For each of years 2011 through 2023, 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 2023, 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 program by not later than January 1, 2023, 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, 2024.

"(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 2024.—In order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2024, and ending on December 31,

2024, 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) 2025 AND SUBSEQUENT YEARS.—In order for an agreement with a manufacturer to be in effect under this section with respect to plan year 2025 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 admin-

istering 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 applicable 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 prescription 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 appropriate 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 exceed the annual deductible with respect to such indi-

vidual 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 dispensed 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 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 nego-

tiated price of the applicable drug that falls 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, 2024, 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, 2024, 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 2024 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 2024 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 2024, 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 2024 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2024 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 2024, 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 2024, 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 2024, 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 2024, the elimination''; and

(B) in paragraph (2)—

(i) in subparagraph (C), by striking ''The continuation'' and inserting ''For a year preceding 2024, 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 2024, 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 2024 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 2024'' 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 2023, the Medicare coverage gap discount program under section 1860D–14A; and

''(B) for 2024 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 2023, an agreement described in subsection (b) of section 1860D–14A with the Secretary; and

''(B) for 2024 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 2023, 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 2024 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, 2024, 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, 2024.''.

(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 2024 and subsequent plan years.

SEC. 302. ALLOWING CERTAIN ENROLLEES OF PRESCRIPTION DRUG 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 2024 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 co-insurance 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, 2024, 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. 1150D. 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, 2021; or

''(ii) 25 percent or more within a 36-month period beginning on or after January 1, 2021;

''(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, 2023; 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, 2023; or

''(ii) 25 percent or more within a 36-month period that begins and ends during the 5-year period preceding January 1, 2023.

''(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, 2021, 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, 2023.

"(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 Public 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. 1150E. 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 1150D;

''(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 1150D; 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—NIH, FDA, AND OVERDOSE EPIDEMIC FUNDING

Subtitle A—Biomedical Innovation Expansion

SEC. 501. 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 2022, $255,400,000.

"(ii) For fiscal year 2023, $160,400,000.

"(iii) For fiscal year 2024, $414,600,000.

"(iv) For fiscal year 2025, $547,000,000.

"(v) For fiscal year 2026, $948,000,000.

"(vi) For fiscal year 2027, $842,400,000.

"(vii) For fiscal year 2028, $1,089,600,000.

"(viii) For fiscal year 2029, $1,115,600,000.

"(ix) For fiscal year 2030, $1,170,600,000.

"(x) For fiscal year 2031, $956,400,000.

"(B) SUPPLEMENTAL FUNDING FOR CERTAIN PROJECTS.—Of the total amounts made available under subparagraph (A) for each of fiscal years 2022 through 2031, 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 2022 and 2024, $50,000,000.

"(II) For fiscal year 2025, $100,000,000.

"(III) For each of fiscal years 2026 and 2027, $300,000,000.

"(IV) For each of fiscal years 2028 through 2030, $317,000,000.

"(V) For fiscal year 2031, $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 2022 and 2024, $50,000,000.

"(II) For fiscal year 2025, $128,000,000.

"(III) For fiscal year 2026, $209,000,000.

"(IV) For fiscal year 2027, $100,000,000.

"(V) For fiscal year 2028, $325,000,000.

"(VI) For fiscal year 2029, $350,000,000.

"(VII) For fiscal year 2030, $400,000,000.

"(VIII) For fiscal year 2031, $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 2022 through 2031.

"(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 research into new treatments, diagnostics, and vaccines, research, in consultation with the Centers for Disease Control and Prevention, into stewardship, and the develop-

ment 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 2022 through 2025, $100,000,000.

"(II) For each of fiscal years 2026 and 2027, $120,000,000.

"(III) For each of fiscal years 2028 through 2030, $125,000,000.

"(IV) For fiscal year 2031, $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 diseases or conditions, not to exceed a total of $530,600,000, as follows:

"(I) For fiscal year 2022, $40,000,000.

"(II) For fiscal year 2023, $45,000,000.

"(III) For fiscal year 2024, $48,000,000.

"(IV) For each of fiscal years 2025 and 2026, $52,400,000.

"(V) For fiscal year 2027, $55,800,000.

"(VI) For fiscal year 2028, $56,000,000.

"(VII) For fiscal year 2029, $57,000,000.

"(VIII) For each of fiscal years 2030 and 2031, $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)";

(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 2022 through 2031 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 ''2031''.

(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, 2031''.

SEC. 502. 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 and section 351 of this Act, as applicable, 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 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, $400,000,000 for each of fiscal years 2022 through 2026, 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).''.

SEC. 503. INNOVATION NETWORK.

Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by section 502, is further amended by adding at the end the following:

''SEC. 404P. INNOVATION NETWORK.

''(a) FUNDS.—The Director of NIH shall award grants or contracts to eligible entities to develop, expand, and enhance the commercialization of biomedical products.

''(b) ELIGIBLE ENTITY.—In this section, the term 'eligible entity' means an entity receiving funding under—

''(1) the Small Business Innovation Research program of the National Institutes of Health; or

''(2) the Small Business Technology Transfer program of the National Institutes of Health.

''(c) USE OF FUNDS.—An eligible entity shall use the funds received through such grant or contract to support—

''(1) the Commercialization Readiness Pilot program of the National Institutes of Health;

''(2) the Innovation Corps program of the National Institutes of Health;

''(3) the Commercialization Accelerator program of the National Institutes of Health;

''(4) the Commercialization Assistance program of the National Institutes of Health; and

''(5) such other programs and activities as the Director of NIH determines to be appropriate, to support the commercialization stage of research, later stage research and development, technology transfer, and commercialization technical assistance.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section

$100,000,000 for each of fiscal years 2022 through 2026, to be available until expended.''.

Subtitle B—Investing in Safety and Innovation

SEC. 511. 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 2022, $417,500,000.

"(ii) For each of fiscal years 2023 and 2024, $157,500,000.

"(iii) For each of fiscal years 2025 through 2027, $152,500,000.

"(iv) For each of fiscal years 2028 through 2031, $202,500,000.

"(B) SUPPLEMENTAL FUNDING FOR CERTAIN ACTIVITIES.—Of the total amounts made available under subparagraph (A) for each of fiscal years 2028 through 2031, 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 (relating to Inter-center Institutes) of the Federal Food, Drug, and Cosmetic 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 2022, $180,000,000.

"(II) For each of fiscal years 2023 through 2031, $60,000,000.

"(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 2022 through 2031, $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 2022, $50,000,000.

"(II) For each of fiscal years 2023 through 2031, $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 2022 through 2031, $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 2022 through 2031, $10,000,000.

"(vi) To further advance the development of a coordinated postmarket surveil-

lance system for all medical products, including drugs, biological products, and devices, linked to electronic health records in furtherance of the Food and Drug Administration's postmarket surveillance capabilities:

"(I) For fiscal year 2022, $112,500,000.

"(II) For each of fiscal years 2023 through 2031, $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 2022 through 2024, $10,000,000.

"(II) For each of fiscal years 2025 through 2031, $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 2022 through 2031, $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 2022 through 2031, $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 amend-

ed, in the matter preceding clause (i), by striking ''2026'' and inserting ''2032''.

(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''.

SEC. 512. STUDY ON HIGH-RISK, HIGH-REWARD DRUGS.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall conduct a study to identify—

(1) diseases or conditions that lack a treatment approved by the Food and Drug Administration and instances in which development of a treatment for such diseases or conditions could fill an unmet medical need for the treatment of a serious or life-threatening disease or condition or a rare disease or condition; and

(2) appropriate incentives that would lead to the development, approval, and marketing of such treatments.

(b) REPORT TO CONGRESS; RECOMMENDATIONS.—Not later than one year after the date of enactment of this Act, the Secretary shall submit to the Congress a report that includes—

(1) findings from the study under subsection (a); and

(2) recommendations regarding legislation necessary to create appropriate incentives identified pursuant to subsection (a)(2).

Subtitle C—Overdose Epidemic Response

SEC. 521. OVERDOSE 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 overdose 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 appropriated $2,000,000,000 for each of fiscal years 2022 through 2026.

(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 2022 through 2026, 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 522, $1,500,000,000 for each of fiscal years 2022 through 2026.

(2) CDC.—For the Centers for Disease Control and Prevention to carry out programs and activities pursuant to section 523, $120,000,000 for each of fiscal years 2022 through 2026.

(3) FDA.—For the Food and Drug Administration to carry out programs and activities pursuant to section 524, $10,000,000 for each of fiscal years 2022 through 2026.

(4) NIH.—For the National Institutes of Health to carry out programs and activities pursuant to section 525, $240,000,000 for each of fiscal years 2022 through 2026.

(5) HRSA.—For the Health Resources and Services Administration to carry out programs and activities pursuant to section 526, $90,000,000 for each of fiscal years 2022 through 2026.

(6) ACF.—For the Administration for Children and Families to carry out programs and activities pursuant to section 527, $40,000,000 for each of fiscal years 2022 through 2026.

(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 2022 through 2026 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 2023 through 2027, 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. 522. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.

(a) IN GENERAL.—The entirety of the funds made available pursuant to section 521(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 521(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. 523. CENTERS FOR DISEASE CONTROL AND PREVENTION.

(a) ADDRESSING OPIOID USE DISORDER.—The entirety of the funds made available pursuant to section

521(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 521(c)(2) for carrying out this section, not more than 20 percent may be used for intramural purposes.

SEC. 524. FOOD AND DRUG ADMINISTRATION.

The entirety of the funds made available pursuant to section 521(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. 525. NATIONAL INSTITUTES OF HEALTH.

The entirety of the funds made available pursuant to section 521(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. 526. HEALTH RESOURCES AND SERVICES ADMINISTRATION.

The entirety of the funds made available pursuant to section 521(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. 527. ADMINISTRATION FOR CHILDREN AND FAMILIES.

Of the funds made available pursuant to section 521(c)(6) for each of fiscal years 2022 through 2026, $40,000,000 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.).

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