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116TH CONGRESS
1st Session

HOUSE OF REPRESENTATIVES

REPT. 116–324
Part 2

ELIJAH E. CUMMINGS LOWER DRUG COSTS NOW ACT

R E P O R T

OF THE

COMMITTEE ON WAYS AND MEANS HOUSE OF REPRESENTATIVES

ON

H.R. 3

together with

DISSENTING VIEWS

DECEMBER 6, 2019.—Ordered to be printed

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CONTENTS

	Page
I. SUMMARY AND BACKGROUND	36
A. Purpose and Summary	36
B. Background and Need for Legislation	36
C. Legislative History	39
II. EXPLANATION OF THE BILL	40
The Lower Drug Costs Now Act of 2019	40
III. VOTES OF THE COMMITTEE	55
IV. BUDGET EFFECTS OF THE BILL	66
A. Committee Estimate of Budgetary Effects	66
B. Statement Regarding New Budget Authority and Tax Expenditures Budget Authority	66
C. Cost Estimate Prepared by the Congressional Budget Office	66
V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE	66
A. Committee Oversight Findings and Recommendations	66
B. Statement of General Performance Goals and Objectives	67
C. Information Relating to Unfunded Mandates	67
D. Congressional Earmarks, Limited Tax Benefits, and Limited Tariff Benefits	67
E. Duplication of Federal Programs	67
F. Hearings	67
VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED	68
VII. DISSENTING VIEWS	383

116TH CONGRESS *1st Session* } HOUSE OF REPRESENTATIVES { REPT. 116–324 Part 2

ELIJAH E. CUMMINGS LOWER DRUG COSTS NOW ACT

DECEMBER 6, 2019.—Ordered to be printed

Mr. NEAL, from the Committee on Ways and Means, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 3]

The Committee on Ways and Means, to whom was referred the bill (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, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

Strike all after the enacting clause and insert the following:

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:

Sec. 1. Short title; table of contents.

TITLE I—LOWERING PRICES THROUGH FAIR DRUG PRICE NEGOTIATION

Sec. 101. Providing for lower prices for certain high-priced single source drugs.
Sec. 102. Selected drug manufacturer excise tax imposed during noncompliance periods.

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

Sec. 201. Medicare part B rebate by manufacturers.
Sec. 202. Medicare part D rebate by manufacturers.

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

Sec. 301. Medicare part D benefit redesign.
Sec. 302. Allowing certain enrollees of prescription drugs plans and MA–PD plans under Medicare program to spread out cost-sharing under certain circumstances.
Sec. 303. Establishment of pharmacy quality measures under Medicare part D.

TITLE IV—PRESCRIPTION DRUG POLICIES FOR LOW-INCOME INDIVIDUALS

Sec. 401. Adjustments to Medicare part D cost-sharing reductions for low-income individuals.

Sec. 402. Dissemination to Medicare part D subsidy eligible individuals of information comparing premiums of certain prescription drug plans.
Sec. 403. Providing for intelligent assignment of certain subsidy eligible individuals auto-enrolled under Medicare prescription drug plans and MA–PD plans.
Sec. 404. Expanding eligibility for low-income subsidies under part D of the Medicare program.
Sec. 405. Automatic eligibility of certain low-income territorial residents for premium and cost-sharing subsidies under the Medicare program; Sunset of enhanced allotment program.
Sec. 406. Automatic qualification of certain Medicaid beneficiaries for premium and cost-sharing subsidies under part D of the Medicare program.
Sec. 407. Eliminating the resource requirement with respect to subsidy eligible individuals under part D of the Medicare program.
Sec. 408. Providing for certain rules regarding the treatment of eligible retirement plans in determining the eligibility of individuals for premium and cost-sharing subsidies under part D of the Medicare program.

TITLE V—DRUG PRICE TRANSPARENCY

Sec. 501. Drug price transparency.

TITLE I—LOWERING PRICES THROUGH FAIR DRUG PRICE NEGOTIATION

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

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

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

"SEC. 1191. ESTABLISHMENT OF PROGRAM.

"(a) IN GENERAL.—The Secretary shall establish a Fair Price Negotiation Program (in this part referred to as the 'program'). Under the program, with respect to each price applicability period, the Secretary shall—

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

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

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

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

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

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

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

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

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

"(A) beginning on the sooner of—

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

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

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

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

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

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

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

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

"(B) in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier—

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

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

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

"(3) AVERAGE INTERNATIONAL MARKET PRICE DEFINED.—

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

"(B) APPLICABLE COUNTRIES.—

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

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

"(I) Australia.
"(II) Canada.
"(III) France.
"(IV) Germany.
"(V) Japan.
"(VI) The United Kingdom.

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

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

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

"(1)(A) with respect to an initial price applicability year during the period beginning with 2023 and ending with 2027, at least 25 negotiation-eligible drugs described in subparagraphs (A) and (B), but not subparagraph (C), of subsection (d)(1) (or, with respect to an initial price applicability year during such period beginning after 2023, the maximum number (if such number is less than 25) of such negotiation-eligible drugs for the year) with respect to such year;

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

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

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

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

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

"(b) SELECTION OF DRUGS.—In carrying out subsection (a)(1) the Secretary shall select for inclusion on the published list described in subsection (a) with respect to a price applicability period, the negotiation-eligible drugs that the Secretary projects will result in the greatest savings to the Federal Government or fair price eligible individuals during the price applicability period. In making this projection of savings for drugs for which there is an AIM price for a price applicability period, the savings shall be projected across different dosage forms and strengths of the drugs and not based on the specific formulation or package size or package type of the drugs, taking into consideration both the volume of drugs for which payment is made, to the extent such data is available, and the amount by which the net price for the drugs exceeds the AIM price for the drugs.

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

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

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

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

"(2) continue to be marketed.

"(d) NEGOTIATION-ELIGIBLE DRUG.—

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

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

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

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

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

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

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

"(1) DRUG PRODUCTS.—A drug that—

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

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

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

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

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

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

"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 dis-

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

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

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

"(A) to fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1191(c)(1) and are furnished or dispensed such drug during any year during the price applicability period (beginning after such renegotiation) with respect to such selected drug; and

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

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

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

"(A) for the voluntary negotiation period for the price applicability period (and, if applicable, before any period of renegotiation specified pursuant to paragraph (2)) with respect to such drug all information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part, including information described in section 1192(f) and section 1194(d)(1); and

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

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

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

"(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO LONGER A SELECTED DRUG.—An agreement entered into under this section shall be effective, with respect to a drug, until such drug is no longer considered a selected drug under section 1192(c).

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

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

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

"(B) the number of units of such drug sold in the United States, including the 50 States, the District of Columbia, and the territories of the United States, during the period described in paragraph (2)(B).

"(2) AMOUNTS DESCRIBED.—

"(A) WEIGHTED AVERAGE PRICE BEFORE AIM PRICE AVAILABLE.—For purposes of paragraph (1), the amount described in this subparagraph for a se-

lected drug described in such paragraph, is the amount equal to the weighted average manufacturer price (as defined in section 1927(k)(1)) for such dosage strength and form for the drug during the period beginning with the first plan year for which the drug is included on the list of negotiation-eligible drugs published under section 1192(d) and ending with the last plan year during the price applicability period for such drug with respect to which there is no AIM price available for such drug.

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

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

"(e) REGULATIONS.—

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

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

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

"SEC. 1194. NEGOTIATION AND RENEGOTIATION PROCESS.

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

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

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

"(b) NEGOTIATING METHODOLOGY AND OBJECTIVE.—

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

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

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

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

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

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

"(3) REQUIREMENT.—

"(A) IN GENERAL.—In negotiating the maximum fair price of a selected drug, with respect to an initial price applicability year for the selected drug, and, as applicable, in renegotiating the maximum fair price for such drug, with respect to a subsequent year during the price applicability period for such drug, in the case that the manufacturer of the selected drug offers

under the negotiation or renegotiation, as applicable, a price for such drug that is not more than the target price described in subparagraph (B) for such drug for the respective year, the Secretary shall agree under such negotiation or renegotiation, respectively, to such offered price as the maximum fair price.

"(B) TARGET PRICE.—

"(i) IN GENERAL.—Subject to clause (ii), the target price described in this subparagraph for a selected drug with respect to a year, is the average price (which shall be the net average price, if practicable, and volume-weighted, if practicable) for a unit of such drug for sales of such drug, as computed (across different dosage forms and strengths of the drug and not based on the specific formulation or package size or package type of the drug) in the applicable country described in section 1191(c)(3)(B) with respect to such drug that, with respect to such year, has the lowest average price for such drug as compared to the average prices (as so computed) of such drug with respect to such year in the other applicable countries described in such section with respect to such drug.

"(ii) SELECTED DRUGS WITHOUT AIM PRICE.—In applying this paragraph in the case of negotiating the maximum fair price of a selected drug for which there is no AIM price available with respect to the initial price applicability year for such drug, or, as applicable, renegotiating the maximum fair price for such drug with respect to a subsequent year during the price applicability period for such drug before the first plan year for which there is an AIM price available for such drug, the target price described in this subparagraph for such drug and respective year is the amount that is 80 percent of the average manufacturer price (as defined in section 1927(k)(1)) for such drug and year.

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

"(c) LIMITATION.—

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

"(2) SELECTED DRUGS WITHOUT AIM PRICE.—In the case of a selected drug for which there is no AIM price available with respect to the initial price applicability year for such drug, for each plan year during the price applicability period before the first plan year for which there is an AIM price available for such drug, the maximum fair price negotiated (including as renegotiated) under this section for the selected drug shall not exceed the amount equal to 85 percent of the average manufacturer price for the drug with respect to such year.

"(d) CONSIDERATIONS.—For purposes of negotiating and, as applicable, renegotiating (including for purposes of determining whether to renegotiate) the maximum fair price of a selected drug under this part with the manufacturer of the drug, the Secretary shall, consistent with subsection (b)(2), take into consideration the following factors:

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

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

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

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

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

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

"(F) National sales data for the drug.

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

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

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

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

"(C) Information on comparative effectiveness analysis for such products, taking into consideration the effects of such products on specific populations, such as individuals with disabilities, the elderly, terminally ill, children, and other patient populations.

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

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

"(4) ADDITIONAL INFORMATION.—Information submitted to the Secretary, in accordance with a process specified by the Secretary, by other parties that are affected by the establishment of a maximum fair price for the selected drug.

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

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

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

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

"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 in-

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

"(B) The establishment of procedures (including through agreements with manufacturers under this part and contracts with hospitals, physicians, and other providers of services and suppliers and agreements under section 1197 with group health plans and health insurance issuers of health insurance coverage offered in the individual or group market) under which, in the case of a selected drug furnished or administered by such a hospital, physician, or other provider of services or supplier to fair price eligible individuals (who with respect to such drug are described in subparagraph (B) of section 1191(c)(1)), the maximum fair price for the selected drug is provided to such hospitals, physicians, and other providers of services and suppliers (as applicable) with respect to such individuals and providing that such maximum fair price is used for determining cost-sharing under the respective part, plan, or coverage for the selected drug.

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

"(i) the lesser of—

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

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

"(III) any other similar determination of pharmacy acquisition costs of the drug, as determined by the Secretary; and

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

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

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

"(ii) any other discounts.

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

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

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

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

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

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

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

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

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

"(2) MONITORING COMPLIANCE.—

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

"(B) NOTIFICATION.—If a third party with a contract under subsection (c)(1) determines that the manufacturer is not in compliance with such agreement, the third party shall notify the Secretary of such noncompliance for appropriate enforcement under section 4192 of the Internal Revenue Code of 1986 or section 1198, as applicable.

"(b) COLLECTION OF DATA.—

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

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

"(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 health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act), with respect to a price applicability period and a selected drug with respect to such period—

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

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

"(2) OPTING OUT OF AGREEMENT.—The Secretary shall not be treated as having in effect an agreement under the program under this part with a group health plan or health insurance issuer offering 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 issuer of 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, 2025, the National Academy of Medicine shall conduct a study, and submit to Congress a report, on recommendations for improvements to the program under this part, including the determination of the limits applied under section 1194(c).

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

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

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

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

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

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

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

"(f) DATA SHARING.—The Secretary shall share with the Secretary of the Treasury such information as is necessary to determine the tax imposed by section 4192 of the Internal Revenue Code of 1986.".

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

(1) UNDER MEDICARE.—

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

(B) EXCEPTION TO PART D NON-INTERFERENCE.—Section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)) is amended by inserting ", except as provided under part E of title XI" after "the Secretary".

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

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

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

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

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

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

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

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

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

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

(A) PHSA.—Part A of title XXVII of the Public Health Service Act is amended by inserting after section 2729 the following new section:

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

"(a) IN GENERAL.—In the case of a group health plan or health insurance issuer offering 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 Drug 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 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;

"(2) the plan or issuer shall apply any cost-sharing responsibilities under such plan or coverage, with respect to such selected drug, by substituting the maximum fair price negotiated under such part for such drug in lieu of the contracted rate under such plan or coverage for such selected drug; and

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

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

(B) ERISA.—

(i) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1181 et. seq.) is amended by adding at the end the following new section:

"SEC. 716. FAIR PRICE DRUG 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 Drug 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 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;

"(2) the plan or issuer shall apply any cost-sharing responsibilities under such plan or coverage, with respect to such selected drug, by substituting the maximum fair price negotiated under such part for such drug in lieu of the contracted rate under such plan or coverage for such selected drug; and

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

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

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

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

(C) IRC.—

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

"SEC. 9816. FAIR PRICE DRUG 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 Drug Negotiation Program under part E of title XI of such Act, with respect to a price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 1192(c) of such Act) with respect to such period with respect to which coverage is provided under such plan—

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

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

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

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

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

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

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

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

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

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.

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

SEC. 201. MEDICARE PART B REBATE BY MANUFACTURERS.

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

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

"(1) REQUIREMENTS.—

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

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

"(ii) Information on the amount (if any) of the excess average sales price 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, 2021, the manufacturer of a part B rebatable drug shall, for such drug, not later than 30 days after the date of receipt from the Secretary of the information described in subparagraph (A) for such calendar quarter, provide to the Secretary a rebate that is equal to the amount specified in paragraph (3) for such drug for such calendar quarter.

"(2) PART B REBATABLE DRUG DEFINED.—

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

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

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

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

"(i) for 2022, shall be the dollar amount specified under such subparagraph for 2021, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12 month period ending with June of the previous year; and

"(ii) for a subsequent year, shall be the dollar amount specified in this clause (or clause (i)) for the previous year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12 month period ending with June of the previous year.

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

"(3) REBATE AMOUNT.—

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

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

"(ii) the amount (if any) by which—

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

"(II) the inflation-adjusted payment amount determined under subparagraph (C) for such part B rebatable drug during the calendar quarter.

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

"(i) units packaged into the payment for a procedure or service under section 1833(t) or under section 1833(i) (instead of separately payable under such respective section);

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

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

"(C) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this subparagraph for a part B rebatable drug for a calendar quarter is—

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

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

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

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

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

"(G) COUNTING UNITS.—

"(i) CUT-OFF PERIOD TO COUNT UNITS.—For purposes of subparagraph (A)(i), subject to clause (ii), to count the total number of billing units for a part B rebatable drug for a quarter, the Secretary may use a cut-

off period in order to exclude from such total number of billing units for such quarter claims for services furnished during such quarter that were not processed at an appropriate time prior to the end of the cut-off period.

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

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

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

"(B) TIMELINE FOR PROVISION OF REBATES FOR SUBSEQUENTLY APPROVED DRUGS.—In the case of a part B rebatable drug first approved or licensed by the Food and Drug Administration after July 1, 2015, paragraph (1)(B) shall be applied as if the reference to 'July 1, 2021' under such paragraph were a reference to the later of the 6th full calendar quarter after the day on which the drug was first marketed or July 1, 2021.

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

"(D) SELECTED DRUGS.—In the case of a part B rebatable drug that is a selected drug (as defined in section 1192(c)) for a price applicability period (as defined in section 1191(b)(2)) and is determined (pursuant to such section 1192(c)) to no longer be a selected drug, for each applicable year beginning after the price applicability period with respect to such drug, clause (i) of paragraph (3)(C) shall be applied as if the term 'payment amount benchmark quarter' were defined under paragraph (3)(D) as the calendar quarter beginning January 1 of the last year beginning during such price applicability period with respect to such selected drug and clause (ii) of paragraph (3)(C) shall be applied as if the term 'benchmark period CPI–U' were defined under paragraph (3)(E) as if the reference to 'July 2015' under such paragraph were a reference to the July of the year preceding such last year.

"(5) APPLICATION TO BENEFICIARY COINSURANCE.—In the case of a part B rebatable drug, if the payment amount for a quarter exceeds the inflation adjusted payment for such quarter—

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

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

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

"(7) CIVIL MONEY PENALTY.—If a manufacturer of a part B rebatable drug has failed to comply with the requirements under paragraph (1)(B) for such drug for a calendar quarter, the manufacturer shall be subject to, in accordance with a process established by the Secretary pursuant to regulations, a civil money penalty in an amount equal to at least 125 percent of the amount specified in paragraph (3) for such drug for such calendar quarter. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(8) STUDY AND REPORT.—

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

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

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

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

"(B) REPORT.—Not later than 3 years after the date of the enactment of this subsection, the Secretary shall submit to Congress a report on the study conducted under subparagraph (A).

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

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

(1) in subsection (a)—

(A) in paragraph (1)—

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

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

(iii) by inserting before the semicolon at the end the following: ", and (DD) with respect to a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) for which the payment amount for a calendar quarter under paragraph (3)(A)(ii)(I) of such section for such quarter exceeds the inflation-adjusted payment under paragraph (3)(A)(ii)(II) of such section for such quarter, the amounts paid shall be the difference between (i) the payment amount under paragraph (3)(A)(ii)(I) of such section for such drug, and (ii) 20 percent of the inflation-adjusted payment amount under paragraph (3)(A)(ii)(II) of such section for such drug";

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

"For purposes of applying paragraph (1)(DD), subsections (i)(9) and (t)(3)(H), and section 1834(x)(5), the Secretary shall make such estimates and use such data as the Secretary determines appropriate, and notwithstanding any other provision of law, may do so by program instruction or otherwise.";

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

"(9) In the case of a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) furnished on or after July 1, 2021, under the system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1834(x)(5), paragraph (1)(DD) of subsection (a), and the flush left matter following paragraph (9) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1834(x)(5) and subsection (a) apply under such section and subsection."; and

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

"(H) PART B REBATABLE DRUGS.—In the case of a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) furnished on or after July 1, 2021, under the system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1834(x)(5), paragraph (1)(DD) of subsection (a), and the flush left matter following paragraph (9) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1834(x)(5) and subsection (a) apply under such section and subsection.".

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

SEC. 202. MEDICARE PART D REBATE BY MANUFACTURERS.

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

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

"(a) IN GENERAL.—

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

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

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

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

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

"(b) AGREEMENTS.—

"(1) TERMS OF AGREEMENT.—An agreement described in this subsection, with respect to a 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 calendar quarter of the payment amount benchmark year (as defined in subsection (h)(3)); and

"(B) the ratio of—

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

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

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

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

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

"(C) TREATMENT OF NEW FORMULATIONS.—

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

"(ii) LINE EXTENSION DEFINED.—In this subparagraph, the term 'line 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)) and is determined (pursuant to such section 1192(c)) to no longer be a selected drug, for each applicable year beginning after the price applicability period with respect to such drug, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term 'payment amount benchmark year' were defined under subsection (h)(3) as the last year beginning during such price applicability period with respect to such selected drug and subparagraph (B) of paragraph (3) shall be applied as if the term 'benchmark period CPI–U' were defined under subsection (h)(4) as if the reference to 'January 2016' under such subsection were a reference to January of the last year beginning during such price applicability period with respect to such drug.

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

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

"(f) CIVIL MONEY PENALTY.—In the case of a manufacturer of a part D rebatable drug with an agreement in effect under this section who has failed to comply with the terms of the agreement under subsection (b)(1)(B) with respect to such drug for an applicable year, the Secretary may impose a civil money penalty on such manufacturer in an amount equal to 125 percent of the amount specified in subsection (c) for such drug for such year. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

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

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

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

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

"(h) DEFINITIONS.—In this section:

"(1) PART D REBATABLE DRUG DEFINED.—

"(A) IN GENERAL.—The term 'part D rebatable drug' means a drug or biological that would (without application of this section) be a covered part D drug, except such term shall, with respect to an applicable year, not include such a drug or biological if the average annual total cost under this part for such year per individual who uses such a drug or biological, as determined by the Secretary, is less than, subject to subparagraph (B), $100, as determined by the Secretary using the most recent data available or, if data is not available, as estimated by the Secretary.

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

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

"(ii) for a subsequent year, shall be the dollar amount specified in this subparagraph for the previous year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period beginning with January of the previous year.

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

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

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

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

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

"(6) AVERAGE MANUFACTURER PRICE.—The term 'average manufacturer price' has the meaning, with respect to a part D rebatable drug of a manufacturer, given such term in section 1927(k)(1), with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927.".

(b) CONFORMING AMENDMENT 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), is further amended by striking "section 1927 or section 1834(x)" and inserting "section 1927, section 1834(x), or section 1860D–14B".

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

SEC. 301. MEDICARE PART D BENEFIT REDESIGN.

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

(1) in paragraph (2)—

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

(B) in subparagraph (C)—

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

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

(C) in subparagraph (D)—

(i) in clause (i)—

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

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

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

(2) in paragraph (3)(A)—

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

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

(3) in paragraph (4)—

(A) in subparagraph (A)—

(i) in clause (i)—

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

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

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

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

(IV) by adding at the end the following:

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

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

(B) in subparagraph (B)—

(i) in clause (i)—

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

(II) in subclause (VI)—

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

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

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

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

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

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

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

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

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

(c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

"(a) ESTABLISHMENT.—The Secretary shall establish a manufacturer discount program (in this section referred to as the 'program'). Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of the duties described in subsection (c). The Secretary shall establish a model agreement for use under the program by not later than January 1, 2021, in consultation with manufacturers, and allow for comment on such model agreement.

"(b) TERMS OF AGREEMENT.—

"(1) IN GENERAL.—

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

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

"(C) TIMING OF AGREEMENT.—

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

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

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

"(3) COMPLIANCE WITH REQUIREMENTS FOR ADMINISTRATION OF PROGRAM.—Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under subsection (d)(3), as applicable, for purposes of administering the program, including any determination under subparagraph (A) of subsection (c)(1) or procedures established under such subsection (c)(1).

"(4) LENGTH OF AGREEMENT.—

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

"(B) TERMINATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

"(D) the establishment of procedures to ensure that the discounted price for an 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 for covered part D drugs in the year that are equal to or exceed the annual deductible specified in section 1860D–2(b)(1) for such year.

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

"(A) means a covered part D drug—

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

"(ii)(I) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on

the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

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

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

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

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

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

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

"(4) DISCOUNTED PRICE.—

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

"(i) who has not incurred costs 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 in the year that are equal to or exceed such threshold for the year, 70 percent of the negotiated price of such drug.

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

"(C) SPECIAL CASE FOR CERTAIN CLAIMS.—

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

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

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

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

"(5) MANUFACTURER.—The term 'manufacturer' means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

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

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

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

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

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

"(h) SUNSET OF PROGRAM.—

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

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

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

(A) in subsection (b)(2)(C)(iii)—

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

"(I) the reinsurance"; and

(ii) by adding at the end the following:

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

(B) in subsection (c)(1)(C)—

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

"(i) the reinsurance";

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

(iii) by adding at the end the following:

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

(d) CONFORMING AMENDMENTS.—

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

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

(B) in subsection (c)(1)(C)—

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

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

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

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

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

(A) in paragraph (1)—

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

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

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

(B) in paragraph (2)—

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) in subsection (a)—

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

"(1) participate in—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"(E) ENROLLEE OPTION REGARDING SPREADING COST-SHARING.—The Secretary shall establish by regulation a process under which, with respect to plan year 2022 and subsequent plan years, a prescription drug plan or an MA–PD plan shall, in the case of a part D eligible individual enrolled with such plan for such plan year who is not a subsidy eligible individual (as defined in section 1860D–14(a)(3)) and with respect to whom the plan projects that the dispensing of the first fill of a covered part D drug to such individual will result in the individual incurring costs that are equal to or above the annual out-of-pocket threshold specified in paragraph (4)(B) for such plan year, provide such individual with the option to make the coinsurance payment required under subparagraph (A) (for the portion of such costs that are not above such annual out-of-pocket threshold) in the form of periodic installments over the remainder of such plan year.".

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

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

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

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

"(8) APPLICATION OF PHARMACY QUALITY MEASURES.—

"(A) IN GENERAL.—A PDP sponsor that implements incentive payments to a pharmacy or price concessions paid by a pharmacy based on quality measures shall use measures established or approved by the Secretary under subparagraph (B) with respect to payment for covered part D drugs dispensed by such pharmacy.

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

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

TITLE IV—PRESCRIPTION DRUG POLICIES FOR LOW-INCOME INDIVIDUALS

SEC. 401. ADJUSTMENTS TO MEDICARE PART D COST-SHARING REDUCTIONS FOR LOW-INCOME INDIVIDUALS.

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

(1) in paragraph (1)—

(A) in subparagraph (D)—

(i) in clause (ii)—

(I) by striking "that does not exceed $1 for" and all that follows through the period at the end and inserting "that does not exceed—

"(I) for plan years before plan year 2021—

"(aa) for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i)), $1 or, if less, the copayment amount applicable to an individual under clause (iii); and

"(bb) for any other drug, $3 or, if less, the copayment amount applicable to an individual under clause (iii); and"; and

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

"(II) for plan year 2021—

"(aa) for a generic drug, $0; and

"(bb) for any other drug, the dollar amount applied under this clause (after application of paragraph (4)(A)) for plan year 2020 for a drug described in subclause (I)(bb); and

"(III) for a subsequent year, the dollar amount applied under this clause for the previous year for the drug, increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year."; and

(ii) in clause (iii)—

(I) by striking "does not exceed the copayment amount specified under" and inserting "does not exceed—

"(I) for plan years beginning before plan year 2021, the copayment amount specified under";

(II) by striking the period at the end and inserting "; and"; and

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

"(II) for plan year 2021 and each subsequent plan year, the copayment amount applied under clause (ii) for the drug and year involved."; and

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

"(F) ROUNDING.—Any amount established under clause (ii) of subparagraph (D), including as applied under clause (iii) of such subparagraph or paragraph (2)(D), that is based on an increase of $3, that is not a multiple of 5 cents or 10 cents, respectively, shall be rounded to the nearest multiple of 5 cents or 10 cents, respectively.";

(2) in paragraph (2)—

(A) in subparagraph (D)—

(i) by striking "of coinsurance of" and inserting "of—

"(i) for plan years before plan year 2021, coinsurance of";

(ii) by striking the period at the end and inserting "; and"; and

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

"(ii) for plan year 2021 and each subsequent plan year, a copayment amount that does not exceed the copayment amount applied under paragraph (1)(D)(ii) for the drug and year involved."; and

(B) in subparagraph (E)—

(i) by striking "subsection (c), the substitution for" and inserting "subsection (c)—

"(i) for plan years before plan year 2021, the substitution for";

(ii) by striking the period at the end and inserting "; and"; and

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

"(ii) for plan year 2021, the elimination of any cost-sharing imposed under section 1860D–2(b)(4)(A)."; and

(3) in paragraph (4)(A)(ii), by inserting "(before 2021)" after "subsequent year".

SEC. 402. DISSEMINATION TO MEDICARE PART D SUBSIDY ELIGIBLE INDIVIDUALS OF INFORMATION COMPARING PREMIUMS OF CERTAIN PRESCRIPTION DRUG PLANS.

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

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

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

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

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

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

SEC. 403. PROVIDING FOR INTELLIGENT ASSIGNMENT OF CERTAIN SUBSIDY ELIGIBLE INDIVIDUALS AUTO-ENROLLED UNDER MEDICARE PRESCRIPTION DRUG PLANS AND MA–PD PLANS.

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

(1) in subparagraph (C)—

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

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

(2) in subparagraph (D)—

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

of a prescription drug plan as measured by quality ratings established by the Secretary"; and

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

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

SEC. 404. EXPANDING ELIGIBILITY FOR LOW-INCOME SUBSIDIES UNDER PART D OF THE MEDICARE PROGRAM.

Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)), as amended by sections 301(d) and 401, is further amended—

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

(2) in paragraph (1)—

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

(B) in the matter preceding subparagraph (A), by inserting "(or, with respect to a plan year beginning on or after January 1, 2022, 150 percent)" after "135 percent";

(3) in paragraph (2)—

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

(B) in subparagraph (A)—

(i) by inserting "(or, with respect to a plan year beginning on or after January 1, 2022, 150 percent)" after "135 percent"; and

(ii) by inserting "(or, with respect to a plan year beginning on or after January 1, 2022, 200 percent)" after "150 percent"; and

(4) in paragraph (3)(A)(ii), by inserting "(or, with respect to a plan year beginning on or after January 1, 2022, 200 percent)" after "150 percent".

SEC. 405. AUTOMATIC ELIGIBILITY OF CERTAIN LOW-INCOME TERRITORIAL RESIDENTS FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER THE MEDICARE PROGRAM; SUNSET OF ENHANCED ALLOTMENT PROGRAM.

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

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

(A) in subparagraph (B)(v)—

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

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

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

"(III) with respect to plan years beginning on or after January 1, 2021, shall provide that any part D eligible individual who is enrolled for medical assistance under the State Medicaid plan of a territory (as defined in section 1935(f)) under title XIX (or a waiver of such a plan) shall be treated as a subsidy eligible individual described in paragraph (1).."; and

(B) in subparagraph (F), by adding at the end the following new sentence: "The previous sentence shall not apply with respect to eligibility determinations for premium and cost-sharing subsidies under this section made on or after January 1, 2021.".

(2) CONFORMING AMENDMENT.—Section 1860D–31(j)(2)(D) of the Social Security Act (42 U.S.C. 1395w–141(j)(2)(D)) is amended by adding at the end the following new sentence: "The previous sentence shall not apply with respect to amounts made available to a State under this paragraph on or after January 1, 2021.".

(b) SUNSET OF ENHANCED ALLOTMENT PROGRAM.—

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

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

(B) in paragraph (3)—

(i) in subparagraph (A), in the matter preceding clause (i), by inserting after "a year" the following: "(before 2021)"; and

(ii) in subparagraph (B)(iii), by striking "a subsequent year" and inserting "each of fiscal years 2008 through 2020".

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

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

SEC. 406. AUTOMATIC QUALIFICATION OF CERTAIN MEDICAID BENEFICIARIES FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER PART D OF THE MEDICARE PROGRAM.

Clause (v) of section 1860D–14(a)(3)(B) of the Social Security Act (42 U.S.C. 1395w–114(a)(3)(B)), as amended by section 405, is further amended—

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

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

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

"(IV) with respect to plan years beginning on or after January 1, 2022, shall, notwithstanding the preceding clauses of this subparagraph, provide that any part D eligible individual not described in subclause (I), (II), or (III) who is enrolled, as of the day before the date on which such individual attains the age of 65, for medical assistance under a State plan under title XIX (or a waiver of such plan) pursuant to clause (i)(VIII) or (ii)(XX) of section 1902(a)(10)(A), and who has income below 200 percent of the poverty line applicable to a family of the size involved, shall be treated as a subsidy eligible individual described in paragraph (1) for a limited period of time, as specified by the Secretary.".

SEC. 407. ELIMINATING THE RESOURCE REQUIREMENT WITH RESPECT TO SUBSIDY ELIGIBLE INDIVIDUALS UNDER PART D OF THE MEDICARE PROGRAM.

Section 1860D–14(a)(3)(A)(iii) of the Social Security Act (42 U.S.C. 1395w–114(a)(3)(A)(iii)) is amended by inserting "in the case of a plan year beginning before January 1, 2022," before "meets".

SEC. 408. PROVIDING FOR CERTAIN RULES REGARDING THE TREATMENT OF ELIGIBLE RETIREMENT PLANS IN DETERMINING THE ELIGIBILITY OF INDIVIDUALS FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER PART D OF THE MEDICARE PROGRAM.

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

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

"(II) for plan years beginning on or after January 1, 2022, any distribution or withdrawal from an eligible retirement plan (as defined in subparagraph (B) of section 402(c)(8) of the Internal Revenue Code of 1986, but excluding any defined benefit plan described in clause (iv) or (v) of such subparagraph and any qualified trust (as defined in subparagraph (A) of such section) which is part of such a defined benefit plan) shall be counted as income; and".

TITLE V—DRUG PRICE TRANSPARENCY

SEC. 501. DRUG PRICE TRANSPARENCY.

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

"SEC. 1150C. REPORTING ON DRUG PRICES.

"(a) DEFINITIONS.—In this section:

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

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

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

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

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

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

"(ii) not a preventative vaccine; and

"(B) for which, during the previous calendar year, at least 1 dollar of the total amount of sales were for individuals enrolled under the Medicare pro-

gram under title XVIII or under a State Medicaid plan under title XIX or under a waiver of such plan.

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

"(b) REPORT.—

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

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

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

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

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

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

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

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

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

"(A) in the case of a report with respect to an increase in the price of a qualifying drug that occurs during the period beginning on January 1, 2019, and ending on the day that is 60 days after the date of the enactment of this section, not later than 90 days after such date of enactment;

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

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

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

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

"(1) with respect to the qualifying drug—

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

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

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

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

"(i) the sponsor or sponsors of any investigational new drug applications under section 505(i) of the Federal Food, Drug, and Cosmetic Act for clinical investigations with respect to such drug, for which the full reports are submitted as part of the application—

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

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

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

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

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

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

"(i) materials and manufacturing for such drug;

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

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

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

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

"(J) the total expenditures of the manufacturer on pursuing new or expanded indications or dosage changes for such drug under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act;

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

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

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

"(2) with respect to the manufacturer—

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

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

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

"(i) drug research and development; or

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

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

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

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

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

"(g) PUBLIC POSTING.—

"(1) IN GENERAL.—Subject to paragraph (4), the Secretary shall post each report submitted under subsection (b) on the public website of the Department of

Health and Human Services the day the price increase of a qualifying drug is scheduled to go into effect.

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

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

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

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

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

"SEC. 1150D. ANNUAL REPORT TO CONGRESS.

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

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

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

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

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

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

I. SUMMARY AND BACKGROUND

A. PURPOSE AND SUMMARY

The bill, H.R. 3, the Lower Drug Costs Now Act of 2019, as amended and ordered reported by the Committee on Ways and Means on October 22, 2019, amends Part D of title XVIII of the Social Security Act. H.R. 3 also amends the following: chapters 32 and 100, and sections 4221(a) and 9831(a)(2) of the Internal Revenue Code of 1986; title XI of the Social Security Act; title XXVII of the Public Health Service Act; and title I of the Employee Retirement Income Security Act of 1974.

B. BACKGROUND AND NEED FOR LEGISLATION

With six in ten Americans reporting they currently take at least one prescription medication (and one in four reporting they take four or more), high drug prices have far-reaching effects.[1] According to a 2018 Kaiser Family Foundation poll, 79 percent of Americans believe the costs of prescription drugs are unreasonable, and 26 percent are worried they may not be able to afford the prescription drugs they need.[2]

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[1] Public Opinion on Prescription Drugs and Their Prices. *Henry J. Kaiser Family Foundation*, (2019). Available at: https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/

[2] *Id*.

The U.S., on average, spends nearly four times more than other similar countries on drugs. A recent report released by the Ways and Means Committee found that on average, U.S. drug prices are nearly four times higher than prices for the same drugs in other countries. In some cases, Americans pay 67 times more than consumers in other countries pay for the same drug.[3]

In 2016, the U.S. spent $457 billion on combined retail (dispensed at the pharmacy) and non-retail (dispensed in physician offices) drugs.[4 5] During the same year, Medicare spent nearly $130 billion on prescription drugs, of which $99.5 billion was spent on Part D pharmacy drugs and another $29.1 billion was spent on Part B physician-administered drugs.[6] In total, 30 percent of Medicare spending went to prescription drug costs.[7]

The rise in spending for specialty drugs has in large part driven the increase in overall drug costs under Part D and Medicaid. In 2015, the average total cost of treating a patient with specialty medications was more than $52,000, with patients responsible for a bill in excess of $10,000.[8] A 2019 Congressional Budget Office (CBO) report found that specialty drugs accounted for 13 percent of Part D spending in 2010 and rose to 31 percent by 2015.[9] In Medicaid, 25 percent of spending in 2010 was on specialty drugs rising to 35 percent by 2015.[10]

While overall drug spending has grown significantly, a relatively small number of drugs are responsible for a disproportionately large share of Medicare costs. According to the Centers for Medicare & Medicare Services (CMS) Medicare Part D data, the 250 top-spending drugs (8.7 percent of Part D drugs) account for 77.9 percent of total Part D spending.[11]

Additionally, the Congressional Budget Office notes that brand-name specialty drugs accounted for about 30 percent of net spending on prescription drugs under Medicare Part D and Medicaid, but they accounted for only about 1 percent of all prescriptions dispensed in each program. Yet, the net prices paid for these drugs are very high, due to the fact that rebates in Medicare Part D are significantly lower than in Medicaid. In fact, net of rebates and discounts, the average price per standardized prescription was nearly

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[3] A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices. *U.S. House of Representatives: The Committee on Ways and Means*, (2019). Available at: *https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20Inter national%20Prescription%20Drug*_2Prices_2.pdf

[4] Observation on Trends in Prescription Drug Spending. *Department of Health and Human Services,* (2019). Available at: https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf

[5] "Retail Prescription Drugs Filled at Pharmacies per Capita," *Henry J. Kaiser Family Foundation,* (2018). Available at: https://www.kff.org/health-costs/state-indicator/retail-rx-drugs-per-capita/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

[6] "10 Essential Facts About Medicare and Prescription Drug Spending," *Henry J. Kaiser Family Foundation*, (2019). Available at: *https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug- spending/*

[7] *Id.*

[8] Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2015. *AARP Public Policy Institute*, (2017). Available at: https://www.aarp.org/content/dam/aarp/ppi/2017/11/full-report-trendsin-retail-prices-of-specialty-prescription-drugs-widely-used-by-older-americans.pdf

[9] Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid. *Congressional Budget Office*, (2019). Available at: https://www.cbo.gov/system/files/2019–03/54964–Specialty_Drugs.pdf

[10] *Id.*

[11] "10 Essential Facts About Medicare and Prescription Drug Spending," *Henry J. Kaiser Family Foundation*, (2019). Available at: https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/

twice as high in Medicare Part D as in Medicaid for specialty drugs and three times as high for top-selling non-specialty drugs. Because many of these drugs have little or no competition, there are no market forces to apply downward pressure to provide lowered prices to the millions who have coverage for such medicines under Medicare.[12]

In response to the rising cost of drugs, many have called for Medicare to negotiate prices of prescription drugs on behalf of beneficiaries. Current law requires "noninterference," which explicitly prohibits the Secretary from negotiating with drug manufacturers.[13] Instead, Part D plans negotiate directly with drug companies to obtain discounts (rebates) for their enrollees, retaining the most leverage when multiple drugs or therapies exist on the market for the same condition. Negotiation is a tool that will mitigate the potential for even higher launch prices because manufacturers will attempt to avoid participating in such a process. And as their leverage in such negotiations, Medicare Part D plans can offer manufacturers preferred formulary placement (e.g., a tier that has better patient cost-sharing or fewer utilization management tools) to incentivize higher utilization of the drug.

External Reference Pricing (ERP) is the practice of using the price of a pharmaceutical product (generally an ex-factory or list price) in one or several countries to create a benchmark or reference price for the purposes of setting or negotiating prices in a given country.[14] [15] With the exceptions of Denmark, Sweden, and the U.K., almost every European country—and most other developed nations—has established some form of an ERP, creating a "basket" of rates in comparable countries and using the average of all prices in the basket as a benchmark.[16]

Empirical evidence shows ERPs are effective in moderating drug prices within a market, resulting in price reductions of about 15 percent over 10 years. Further as outlined in the Ways and Means Committee report, purchasing the same drugs using an index of average drug prices across the comparator countries could reduce Part D spending by $48.8 billion annually.[17] [18]

Drug manufacturers admit that they continue to make profits in countries where drug prices are significantly lower.[19] Yet, when presented proposals to relax the noninterference clause, critics argue such a policy would limit patient access to drugs and inhibit

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[12] Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid. *Congressional Budget Office*, (2019). Available at: https://www.cbo.gov/system/files/2019-03/54964-Specialty_Drugs.pdf

[13] Section 1860D–11(i) of the Social Security Act.

[14] Dimitra Panteli et al. Pharmaceutical Regulation in 15 European Countries. *Health Systems in Transition*, (2016). Available at: http://www.euro.who.int/data/assets/pdf_file/0019/322444/HiT-pharmaceutical-regulation-15-European-countries.pdf?ua=1

[15] WHO Guideline on Country Pharmaceutical Pricing Policies. *World Health Organization*, (2013). Available at: https://www.ncbi.nlm.nih.gov/books/NBK258618/

[16] A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices. U.S. House of Representatives: The Committee on Ways and Means, (2019). Available at: https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20Inter national%20Prescription%20Drug%20Prices_0.pdf

[17] Dimitra Panteli et al. Pharmaceutical Regulation in 15 European Countries. *Health Systems in Transition*, (2016). Available at: http://www.euro.who.int/data/assets/pdf_file/0019/322444/HiT-pharmaceutical-regulation-15-European-countries.pdf?ua=1

[18] A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices. *U.S. House of Representatives: The Committee on Ways and Means,* (2019). Available at: https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20Inter national%20Prescription%20Drug%20Prices_0.pdf

[19] https://www.npr.org/sections/health-shots/2019/02/26/698136259/pharmaceutical-company-ceos-face-grilling-in-senate-over-high-drug-prices

innovation among manufacturers. Many drug manufacturers cite research and development costs as the reason for high prices. Yet as reported by the Washington Post, nine out of 10 large pharmaceutical companies spend more on sales, marketing, and other overhead than on innovation or research and development.[20] And according to PhRMA's most recent numbers, the industry spent nearly $30 billion on marketing and promotion in 2016 and the industry will spend over $300 billion over the next 10 years.[21] While research is crucial to the continued development of new, life-saving drugs and therapies, innovation is of no use if Americans cannot afford its benefits.

While Medicare provides important financial and health security for more than 60 million Americans, the program still has gaps in coverage that pose significant financial hardship for more than half of all Medicare beneficiaries who have incomes of less than $2,200 a month.[22] In addition, many working-age adults who become disabled and can no longer work are on Social Security Disability, which pays on average less than $1400 a month.[23] Addressing coverage gaps and working to address out-of-pocket costs would go a long way toward improving overall health by helping beneficiaries to avoid depression and social isolation, and prevent health care costs due to accidents, falls, cognitive impairments, an increase in chronic conditions, and oral cancer.

The Medicare Savings Programs (MSPs) and Low-Income Subsidy (LIS) program, often collectively referred to as Extra Help programs, help Medicare beneficiaries with out-of-pocket costs such as premiums, deductibles, and cost sharing. These programs, however, do not reach many beneficiaries with very modest incomes, leaving them exposed to significant financial risk. In addition, many eligible beneficiaries are not enrolled in these programs, with as many as 85 percent of eligible individuals in certain categories not receiving assistance with their Medicare premiums.[24] Eliminating barriers to enrollment and improving availability of these programs will lower out-of-pocket costs and improve access to care.

C. Legislative History

Background

H.R. 3 was introduced on September 19, 2019, and was referred to the Committee on Energy and Commerce, and in addition, the Committee on Ways and Means and the Committee on Education and Labor.

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[20] https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/

[21] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA_Marketing_IssueBrief.pdf?utm_source=STAT+Newsletters&utm_campaign=cb1b1d3d39-RO_COPY_03&utm_medium=email&utm_term=0_8cab1d7961-cb1b1d3d39-150975749

[22] Gretchen Jacobson et al., Income and Assets of Medicare Beneficiaries, 2016–2035. *Henry J. Kaiser Family Foundation*, (2017). Available at: https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare- beneficiaries-2016–2035/

[23] *Id.*

[24] "Medicare Savings Programs: New Estimates Continue to Show Many Eligible Individuals Not Enrolled," *Medicaid and CHIP Payment Advisory Commission (MACPAC)*, (2017). Available at: https://www.macpac.gov/wp-content/uploads/2017/08/Medicare-Savings-Programs-New-Estimates-Continue-to-Show-Many-Eligible-Individuals-Not-Enrolled.pdf

Committee action

The Committee on Ways and Means met on October 22, 2019 to consider H.R.3, and ordered the bill, as amended, favorably reported by a vote of vote, 24–17, with one member voting present.

Committee hearings

On October 17, 2019, the Committee on Ways and Means held a full committee hearing entitled, "Investing in the U.S. Health system by lowering drug prices, reducing out-of-pocket costs, and improving Medicare benefits," to discuss how H.R. 3, the Lower Drug Costs Now Act, will lower prescription drug prices in Medicare and the commercial market, improve affordability of medicine, and reduce costs for patients and taxpayers.

On February 12, 2019, the Committee on Ways and Means held a full committee hearing entitled, "The Cost of Rising Prescription Drug Prices," to discuss the drug pricing crisis.

Members heard testimony from expert witnesses about relevant issues, including: rapidly escalating prices of older medications; high launch prices; misalignment of incentives for responsibly pricing products; and high out-of-pocket costs for patients. Democrats invited four witnesses, including: 1) Odunola Ojaumi (patient); 2) Mark Miller, PhD; 3) Rachel Sachs, JD, MPH; and 4) Alan Reuther, JD. The minority invited Joe Antos, PhD.

On March 7, 2019, the Committee on Ways and Means held a health subcommittee hearing entitled "Promoting Competition to Lower Medicare Drug Prices," to discuss the complicated drug pricing landscape, including how to lower prescription drug prices through competition, pay for value, and lower out-of-pocket costs for patients. Democrats invited four witnesses, including: 1) Robin Feldman, JD; 2) Ameet Sarpatwari, JD, PhD; 3) Amy Kapczynski, MA, M.Phil, JD; and 4) Frederick Isasi, MPH. The minority invited Douglas Holtz-Eakin, PhD.

On June 4, 2019, the Committee on Ways and Means held a full committee Member Day hearing to hear member testimony on a range of issues and proposals regarding prescription drug pricing, dental, vision, and hearing coverage, and Medicare Savings Program, the Low Income Subsidy (LIS) Program, and Medigap improvements. Off-committee Member, Representatives Sharice Davids (D–KS–3), Ben McAdams (D–UT–4), Xochitl Torres Small (D–NM–2), and Elissa Slotkin (D–MI–8) discussed more transparency and the need to ensure better affordability and lower out-of-pocket costs for prescription drugs. On Committee Republican Representatives Devin Nunes (R–CA–2) and David Schweikert (R–AZ–6) discussed the importance of drug affordability, and the former also opposed policies that would establish federal price setting policies.

II. EXPLANATION OF THE BILL

THE LOWER DRUG COSTS NOW ACT OF 2019

Title I: Lowering Prices Through Fair Drug Price Negotiation

PRESENT LAW

Medicare Part A (Hospital Insurance, or HI) covers inpatient hospital services, skilled nursing care, hospice care, and some home

health services.[25] Part A pays providers for drugs as part of a predetermined, per episode payment. Hospitals can also receive add-on payments for certain new innovator drugs under Part A.

Medicare Part B (Supplementary Medical Insurance, or SMI) covers physician services, outpatient services, and some home health and preventive services.[26] Providers who administer prescription drugs under Part B are paid based on a list price defined in statute (Average Sales Price or ASP). Beneficiaries generally pay 20% coinsurance under Part B, including for drugs.

The voluntary Medicare Part D outpatient prescription drug benefit provides coverage to Medicare beneficiaries who enroll in stand-alone private plans (PDP) or Medicare Part C managed care plans (i.e., Medicare Advantage) with a Part D component (MA–PD) (collectively referred to as "Part D plans").[27] The Part D non-interference provision bars the Department of Health and Human Services (HHS) Secretary (Secretary) from negotiating Part D drug prices and from requiring a set formulary or pricing structure.[28]

Part D plan sponsors (insurers), working with pharmacy benefit managers (PBMs), negotiate prescription drug price discounts and rebates with manufacturers and dispensing pharmacies. Sponsors must offer enrollees their negotiated price for covered drugs. Under the HHS definition of negotiated prices, sponsors have latitude to decide whether to pass on rebates and certain other price concessions to enrollees at the pharmacy at the point of sale; however, the vast majority do not. Instead sponsors generally use rebates to buy down or reduce premiums for all plan enrollees.

In the commercial market, which includes group health plans and health insurance offered in the individual and group markets, health plans, in conjunction with PBMs, negotiate discounts and rebates with manufacturers. Currently, there are no federal statutes or regulations related to the prices that health plans pay for prescription drugs.

REASONS FOR CHANGES

To establish a new program at Title XI of the Social Security Act (SSA) that would require the Secretary of Health and Human Services (HHS Secretary) to annually negotiate a maximum price for a group of select, single source prescription drugs dispensed to certain enrollees in Medicare and in commercial health plans (prices will first be available to certain eligible Medicare beneficiaries and enrollees in participating commercial plans in 2023).

EXPLANATION OF PROVISIONS

Section 1 establishes the short title as the *Elijah E. Cummings Lower Drug Costs Now Act of 2019*.

Section 101, "Providing for Lower Prices for Certain High-Priced Single Source Drugs", directs the Secretary to establish a Fair Price Negotiation Program by amending Title XI of the Social Security Act to add a new Part E. The Secretary shall publish a list of selected drugs; enter into agreements with manufacturers of selected drugs; negotiate and renegotiate maximum fair price (MFP)

[25] Section 1812 of the Social Security Act (42 U.S.C. § 1395d).
[26] Section 1832 of the Social Security Act (42 U.S.C. § 1395k).
[27] Section 1860D–2 of the Social Security Act (42 U.S.C. § 1395w–102).
[28] Section 1860D–11(i) of the Social Security Act (42 U.S.C. § 1395w–111(i)).

for each selected drug; and carry out other administrative duties. Prices negotiated under section 101 shall apply beginning in plan year 2023.

Selected Drugs. Every year, the Secretary will identify the 250 brand-name drugs that lack price competition and have the greatest net spending in the U.S. The legislation targets the area of the market failure in which competition between products does not exist and is not successful in lowering prices. By focusing on the most expensive drugs, the Secretary will most effectively utilize the federal government's resources to lower costs. The 25 most expensive drugs in the Medicare Part D program represent 23 percent of total Part D spending.

The Secretary will use data provided by Medicare, Medicaid, and commercial insurance to make the determination about aggregate cost, which is a measure of price and volume of sales. The Secretary is required to select 125 drugs from Medicare and 125 from the commercial market, and in addition to the 250 drugs, identify any new drugs that are eligible for negotiation that would otherwise make the list of high cost drugs, beginning no later than April 15, 2021. The Secretary should adhere to any public notice requirements that are relevant to the annual selection of negotiation eligible drugs, including adhering to standards that require solicitation of public comment.

An eligible drug that lacks price competition is to be defined as a brand-name drug that does not have a generic or biosimilar competitor on the market. Insulin is also included for negotiation. Drugs placed on a selected drug list for a price applicability year would be considered selected drugs for that year and each subsequent plan year until the first plan year beginning after the date the Secretary were to determine that the drug is no longer a qualifying single source drug.

In prioritizing drugs for negotiation each year, the Secretary would take into account the drugs for which the greatest savings to taxpayers, patients, and all payers may be achieved. Recognizing the practical capacity and administrative constraints on HHS, the Secretary will negotiate as many drugs as possible each year, beginning with at least 25 drugs (from calendar year (CY) 2023—CY 2027), and, progressively increasing to 30 drugs (from CY 2028—CY 2032) and 35 drugs by 2032. A drug selected for negotiation would continue to be included in the program until two generic or biosimilar competitors enter the market. CBO believes the first group of selected drugs will yield the greatest savings, even as the overall number increases in 2028 and again in 2032. Additionally, the 25 to 30 to 35 drug thresholds are the bare minimum number of drugs for which prices should be negotiated, and the Secretary has discretion to be more aggressive in pursuing savings for American consumers.

Following the publication of the list of selected drugs by April 15, 2021, the Secretary would need to enter into agreements with manufacturers of selected drugs no later than June 15, 2021. The agreements would specify the process and requirements for negotiating, renegotiating, and administering the MFP for a selected drug during the coming applicability year or period.

Negotiation. The Secretary is required under the legislation to directly negotiate with drug manufacturers to establish a maximum

fair price. The legislation does not broadly repeal the non-interference clause, as simply ending the ban on negotiation would not result in a CBO score that reflects savings for patients or the federal government. In contrast, in a preliminary estimate, this bill saves Medicare alone $345 billion through lower prices, lower premiums, and lower out-of-pocket costs by empowering the Secretary to negotiate while ensuring a structure is in place to achieve savings for patients and the government.[29]

While negotiating the price, the Secretary will consider: research and development costs of the drug as well as cost of production; information on alternative treatments and the value of the drug; and domestic and international sales information. The legislation also establishes an upper limit for the price reached in any negotiation as no more than 1.2 times (or 120 percent) of the volume-weighted average of the price of six countries (Australia, Canada, France, Germany, Japan, and the United Kingdom), known as the Average International Market (AIM) price.

A selected drug's "target price" would depend on whether an available AIM price exists for a negotiation or renegotiation period. The legislation defines "target price" as follows:

> *Available AIM Price:* The average price (net average volume weighted price, if practicable) for any dosage form and strength of a drug unit for sale in an AIM price-applicable country that had the lowest average price compared to the drug's average prices in other AIM price- applicable countries.
>
> *No Available AIM Price*: If no AIM price were to be available for the negotiation or renegotiation period, the target price would be 80 percent of the drug's AMP for such year.

In price negotiations or renegotiations, to the extent practicable, the Secretary would consider information that is manufacturer specific, related to alternative products, foreign sales, and additional information. As part of the negotiation or renegotiation process, H.R. 3 compels the Secretary to accept a manufacturer's offer to sell a selected drug at or below a specified "target price." Specifically, if a manufacturer, in negotiation or renegotiation of an MFP for a selected drug, were to offer a price that was not more than a specified target price, the Secretary would then agree to such price as the MFP.

Maximum Fair Price. The goal is for the Secretary and the manufacturer to negotiate a mutually agreed maximum fair price that is below the AIM price through a voluntary, bi-lateral negotiation process. The maximum fair price would be applied to Medicare, with flexibility for Medicare Advantage and Medicare Part D plans to use additional tools to negotiate even lower prices. A manufacturer would also be required to offer the negotiated price to the commercial market, to group and individual health insurance plans. It is at the discretion of these payers whether to accept the negotiated price. No later than May 1st of a Part D plan year before the initial price applicability year (May 1, 2022, for 2023), the Secretary would publish in the *Federal Register* the MFP for a selected drug that it negotiated with the manufacturer. If the MFP

[29] Letter to Hon. Frank Pallone, Jr., "Effects of Drug Price Negotiation Stemming from Title I of H.R. 3, the Lower Drugs Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare, Congressional Budget Office (October 11, 2019). Available at: https://www.cbo.gov/system/files/2019–10/hr3ltr.pdf

for a selected drug for an initial price applicability year were to be agreed upon after the MFP publication deadline, the Secretary would need to publish the MFP in the Federal Register no later than 30 days after the MFP had been determined.

Once the MFP is established, that drug's maximum fair price will remain in place until there are two or more generic or biosimilar products available. If a manufacturer has agreed to a maximum fair price, and then overcharges Medicare or commercial payers, the manufacturer will be subject to a civil monetary penalty equal to 10 times the difference between the price charged and the maximum fair price for the drug. The Secretary or the manufacturer may request a re-negotiation if new information becomes available after the maximum fair price is agreed to.

Judicial Review. Section 101 excludes the selection of drugs (including qualifying insulin products) for publication as selected drugs and determinations of whether a drug is a negotiation-eligible drug, the MFP, and units of a drug for calculating the AIM price under the MDP Program from being subject to judicial review. This provision is similar to other provision in Medicare statutes where Secretarial determinations are not subject to such review, including sections 1899(g) and 1848(q)(13)(B) of the Social Security Act, and a number of instances in the Medicare Access and CHIP Reauthorization Act (MACRA) (H.R. 2, P.L. 114–10).

Section 102, "Selected Drug Manufacturer Excise Tax Imposed During Noncompliance Periods," establishes an excise tax that will be levied against manufacturers during periods when the manufacturer is noncompliant with the requirements of the fair price negotiation program by adding a new section 4192 to Subchapter E of Chapter 32 of the Internal Revenue Code. The Joint Committee on Taxation estimates that this tax will not yield revenues because drug manufacturers would come to the table to negotiate drug prices rather than pay the tax.[30]

EFFECTIVE DATES

Section 101: Effective beginning on or after January 1, 2021 (negotiations) and January 1, 2023 (fair prices in use).

Section 102: Effective beginning after the date of enactment.

Title II: Medicare Parts B and D Prescription Drug Inflation Rebates

PRESENT LAW

Medicare pays for certain outpatient drugs and biologics under Part B (which covers physician, outpatient, and some home health and preventive services) rather than under the Part D retail prescription drug benefit.[31] Part B-covered drugs include: 1) those administered "incident to physician services" where providers purchase "separately payable" drugs and bill Medicare after administering the products to patients; and 2) those that are not separately payable, but are covered under Part B as part of a procedure or treatment, such as end-stage renal disease dialysis, vaccinations,

[30] "Description of the Revenue Provisions of H.R. 3, the *Lower Drug Costs Now Act Of 2019*," *The Joint Committee on Taxation, Congress of the United States* (October 19, 2019). Available at: https://www.jct.gov/publications.html?func=startdown&id=5224

[31] Section 1833 of the Social Security Act (42 U.S.C. § 1395l).

or new drugs included in outpatient hospital new technology transitional pass-through payments.[32]

With some exceptions, Part B payment for separately payable drugs or biologics is based on a product's average sales price (ASP) plus a 6 percent add-on payment.[33] The ASP is a market price that excludes manufacturer price concessions, government sales, and other adjustments. Each ASP is based on a manufacturer's quarterly sales of a drug to most U.S. purchasers, divided by the total units of the drug sold to those purchasers in the quarter. To encourage the development of lower-priced biosimilar substitutes for biological products, the Part B payment rate for a biosimilar is the ASP of the biosimilar plus an add-on payment equal to 6 percent of the ASP of the more expensive, reference biological. For most Part B services, Medicare beneficiaries are responsible for coinsurance of 20 percent of the cost of the item or service. For Part B drugs, the 20 percent coinsurance is based on a drug's ASP plus the 6 percent add-on payment.[34]

The Secretary sets Part B drug payments by aggregating ASP data for individual drugs into Medicare billing codes. A payment amount for a billing code is the volume-weighted average of the ASPs for all drugs grouped into the code. Generally, there is one drug in a billing code for biological, biosimilar and single source brand name products. In the case of multiple source drugs, brand-name and generic products can be grouped within a billing code.[35]

Manufacturers are not required to pay rebates to Medicare as a condition for having their drugs covered under Part B. By comparison, drug and biological manufacturers that choose to market their products to state Medicaid programs are required to provide rebates on their sales of outpatient drugs and biological products to state Medicaid programs. Medicaid's statutory rebates, which are shared between the federal government and states, include a basic rebate and an inflation rebate.[36]

Computation of the Medicaid basic rebate varies depending on whether a drug is a generic or a brand name product and other characteristics, but is based on either: 1) a percentage of a drug's average manufacturer price (AMP), or 2) the difference between the AMP and the lowest statutorily-defined "best" price at which the drug was sold to most retail pharmacies in the United States during the rebate period. The AMP, defined at section 1927(k)(1) of the Social Security Act, is the average price a manufacturer receives in the United States for sales to wholesalers that supply retail community pharmacies and for sales directly to retail community pharmacies. The AMP does not include manufacturer rebates or discounts to PBMs and health plans, certain manufacturer prompt pay discounts, sales to other government programs, and consumer coupons. Certain other types of sales are exempt for purposes of calculating the AMP.

Manufacturers must pay an additional rebate to Medicaid if they increase a drug's AMP faster than the inflation rate since it was first marketed (with some exceptions), as measured by the change

[32] *Id.*
[33] Section 1847A of the Social Security Act (42 U.S.C. § 1395w–3a).
[34] *Id.*
[35] *Id.*
[36] Section 1927 of the Social Security Act (42 U.S.C. § 1396r–8).

in the CPI–U. The total rebate owed by manufacturers is the sum of the per-drug basic and inflation rebates, up to the drug's rebate period AMP.[37]

To carry out the Medicaid drug rebate program, participating manufacturers must report drug pricing data each calendar quarter. Manufacturers are required to report AMP data and to pay rebates on a quarterly basis for each dosage form and strength of a drug.[38]

REASONS FOR CHANGES

To make modifications to Medicare at Title XVIII of the SSA to impose inflation-based rebates for certain prescription drugs administered in Part B and dispensed in Part D.

EXPLANATION OF PROVISIONS

Section 201, "Medicare Part B Rebate by Manufacturers," amends sections 1833, 1834, and 1847(A) of the Social Security Act and outlines standards for inflation rebates for manufacturers of drugs covered under Part B. To reverse unjustified price hikes, all of the single source drugs and biologicals in Part B would face a new inflation rebate. Drugs with annual total allowed charges less than $100 and vaccines are excluded. If a drug company has raised the price of a drug in Part B above the Consumer Price Index for All Urban Consumers (CPI–U), the above-inflation portion of the price (multiplied by units sold to the program) would be refunded to the Treasury and deposited into the Federal Supplementary Medical Insurance Trust Fund. If manufacturers do not comply with the rebate requirement under Part B, the Secretary may assess a civil money penalty (CMP) equal to at least 125 percent of the rebate amount.

Section 201 also directs the Secretary to study the feasibility of incorporating multiple source drugs, biologicals and drugs paid for under Medicare Advantage (MA), and other drugs excluded from the rebate system. Pending the results of this report, Section 201 grants the Secretary discretion to expand the rebate system to include multiple source drugs under Part B. Section 201 would be effective beginning July 1, 2021.

Section 202, "Medicare Part D Rebate by Manufacturers," amends Part D of title XVIII of the Social Security Act by adding a new section 1860D–14B. Section 202 outlines standards for inflation rebates for manufacturers of drugs covered under Part D. To reverse unjustified price hikes, all of the covered drugs and biologicals in Part D would face a new inflation rebate. Drugs with annual total allowed charges less than $100 are excluded. If a drug company has raised the price of a drug in Part D above the CPI–U, the above-inflation portion of the price (multiplied by units sold to the program) would be refunded to the Treasury and deposited into the Federal Supplementary Medical Insurance Trust Fund. If manufacturers do not comply with the rebate requirement under Part B, the Secretary may assess a CMP equal to at least 125 percent of the rebate amount. Section 202 would be effective beginning in plan year 2022.

[37] 42 C.F.R. § 447.504.
[38] 42 C.F.R. § 447.509.

The inflation rebate penalty is designed to discourage manufacturers from increasing prices in all markets because the drug prices on which the rebate are paid based on the average prices market-wide. The inflation rebate penalty will indirectly apply to the private market and will result in fewer price increases across the board. CBO's estimate of the inflation rebate provision in the Senate Finance bill notes that, "CBO expects that the inflation rebate provision would reduce costs for prescription drug benefits offered by commercial plans." The HHS Office of the Actuary (OACT) notes as a result of this legislation, private health insurance (PHI) enrollees are expected to save $55 billion under the bill. And PHI sponsors will save $28 billion (federal/state) and $46 billion (employer sponsored insurance).

The policies established in Sections 201 and 202 will help to minimize prescription drug price hikes because rather than pay the rebate, manufacturers will choose to minimize increases over time, resulting in savings to Medicare and the private market.

EFFECTIVE DATES

Section 201: Effective beginning on or after July 1, 2021.
Section 202: Effective beginning on or after January 1, 2022.

Title III: Part D Improvements and Maximum Out-of-Pocket Cap for Medicare Beneficiaries

PRESENT LAW

Part D provides a voluntary, outpatient prescription drug benefit for Medicare beneficiaries and is the primary source of drug coverage for dual-eligible individuals enrolled in both Medicare and the state-federal Medicaid program.[39] Part D coverage is provided by private insurers, or plan sponsors, that submit annual bids to offer drug-only plans or Part C Medicare Advantage managed care plans with a Part D benefit. Congress designed Part D as a market- oriented program in which sponsors compete for enrollees based on plan premiums and scope of benefits, including cost-sharing requirements. Private drug plans participating in Part D bear some financial risk, although federal subsidies cover most program costs in an effort to encourage participation and keep benefits affordable. Plans are offered on a calendar year basis and enrollees may change plans each year during an annual enrollment period.

At a minimum, Part D sponsors must offer a "standard coverage" package of benefits as defined in law.[40] Plan sponsors may also offer alternative or enhanced coverage that is at least actuarially equivalent to a standard plan. Medicare provides subsidies to plan sponsors for each enrollee in a Part D plan that, on average, equal 74.5 percent of the value of standard coverage.[41] Part D subsidies include direct subsidies, under which Medicare pays drug plans a risk-adjusted per enrollee payment and reinsurance under which Medicare subsidizes 80 percent of a plan's drug spending above a catastrophic threshold.[42] Medicare covers a greater portion of costs

[39] Section 1395w–101 *et seq.* of the Social Security Act (42 U.S.C. § 1395w–101 *et seq.*).
[40] Section 1395w–102 of the Social Security Act (42 U.S.C. § 1395w–102).
[41] Section 1395w–115 of the Social Security Act (42 U.S.C. § 1395w–115).
[42] *Id.*

for low-income individuals through the low-income subsidy (LIS), which varies by specified income and assets thresholds.

In terms of beneficiary cost-sharing, under the standard Part D benefit in 2019, a beneficiary first pays a deductible ($415). After the deductible has been met, the beneficiary is responsible for 25 percent of the cost of drugs (with the plan covering the remaining 75 percent) up to the initial coverage limit ($3,820).[43]

After the initial coverage limit has been reached, a beneficiary enters the coverage gap ("doughnut hole") and is responsible for co-insurance of 25 percent of the cost of brand-name drugs and 37 percent of the cost of generic drugs until accumulating $5,100 in total out-of-pocket costs. While enrollees are in the coverage gap, plans cover the remaining 63 percent of generic drug costs and 5 percent of brand-name drug costs, with the remaining 70 percent of costs for brand-name drugs, biologics and biosimilars covered through manufacturer discounts. Enrollee out-of-pocket costs in the coverage gap are calculated based on both the required beneficiary coinsurance and the manufacturer discounts. (The manufacturer discounts do not apply to drugs provided to LIS Part D beneficiaries in the coverage gap; rather, Medicare covers the full cost of the drug minus some lower cost-sharing for specified LIS beneficiaries.)

At $5,100 in total out-of-pocket-costs, a beneficiary reaches the out-of-pocket threshold after which cost sharing is the greater of a nominal set co-payment for drugs ($3.40 for generic drugs and $8.50 brand-name drugs in 2019), or 5 percent coinsurance.[44] There is no annual cap on cost-sharing for beneficiaries, with the exception of LIS beneficiaries with the lowest income and assets. During this *catastrophic coverage* period, plans are responsible for 15 percent of costs and Medicare subsidizes 80 percent of costs (the reinsurance subsidy).[45] Total spending (beneficiary and plan costs together) needed for an enrollee to move to the catastrophic threshold is estimated at about $8,139.54 in 2019.

Part D coverage parameters based on dollar amounts are generally updated for each plan year based on the percentage increase in average per-capita spending for covered Part D drugs during the 12-month period ending in July of the previous year. In addition, Part D enrollees also pay monthly premiums, which are based on a rate equal to 25.5 percent of the annual nationwide average of plan bids for standard benefits; however, actual premiums vary widely by the plan selected.

REASONS FOR CHANGES

To make modifications to Medicare at Title XVIII of the SSA to reconfigure the Part D benefit to modify enrollee cost-sharing, including capping annual out-of-pocket spending; reduce Medicare reinsurance subsidies to plan sponsors, and modify an existing manufacturer drug discount program.

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[43] Section 1395w–102 of the Social Security Act (42 U.S.C. § 1395w–102).
[44] *Id.*
[45] Section 1395w–115 of the Social Security Act (42 U.S.C. § 1395w–115).

EXPLANATION OF PROVISIONS

Section 301, "Medicare Part D Benefit Redesign," amends Part D of title XVIII of the Social Security Act by adding a new section 1860D–14C. Section 301 creates a cap on the costs for prescription drugs by setting the annual out-of-pocket limit at $2,000. Beneficiaries who have more than $2,000 in out-of-pocket prescription drug spending will face no additional cost-sharing over that amount. Section 301 reduces from 80 percent to 20 percent the government reinsurance in the catastrophic phase of Part D coverage, and increases plan responsibility from 20 percent to 50 percent. Reinsurance for the catastrophic spending grew by over 500 percent from $8.0 billion in 2007 to nearly $40.9 billion in 2018—and is now the single-largest component of total Part D spending. The shift in plan responsibility will improve incentives for plans to better manage drug spending.

Section 301 also converts the current coverage gap discount program into a benefit-wide responsibility, requiring manufacturers of single source drugs to contribute to payments in both the initial and catastrophic phases of the benefit. Under current law, manufacturers pay 70 percent of the costs for beneficiaries in the coverage gap. Changes made by section 301 require that drug manufacturers be responsible for 30 percent of costs in the catastrophic coverage phase, to ensure that drug companies help pay more of the costs for expensive drugs in catastrophic coverage. Additionally, manufacturers would be required to pay 10 percent costs in the initial coverage phase. The new manufacturer discount program would apply to *applicable drugs,* which would be defined as brand-name drugs, biologics, and biosimilars on the formulary of a Part D plan or otherwise covered by a Part D plan, including through an enrollee exception or appeal. Single source drugs selected by the Secretary for price negotiation under Section 101 of H.R. 3 would be exempt from the manufacturer discount program as long as the drug was covered under a price applicability period. Section 301 program enhancements would be implemented beginning in plan year 2022.

Section 302, "Allowing Certain Enrollees of Prescription Drugs Plans and MA-PD Plans Under Medicare Program to Spread Out Cost-Sharing under Certain Circumstances," amends Part D of title XVIII of the Social Security Act to direct the Secretary to engage in rulemaking in order to allow PDPs to give beneficiaries with high drug costs the option to pay for such costs in installments throughout the year, known as "smoothing." Eligible beneficiaries would be those who would meet the $2000 annual out-of-pocket deductible in a single prescription fill. Section 302 would be implemented beginning in plan year 2022.

Section 303, "Establishment of Pharmacy Quality Measures Under Medicare Part D," amends Part D of title XVIII of the Social Security Act and establishes pharmacy quality measures for the purposes of providing pharmacy incentive payments or price concessions. This section would require the Secretary to establish standardized pharmacy quality metrics that PDPs must use in any pharmacy incentive payment program. The Secretary would require PDPs to use these measures as soon as they are sufficient in number, but no later than in plan year January 1, 2021.

EFFECTIVE DATES

Section 301: Effective beginning on or after January 1, 2022.
Section 302: Effective beginning on or after January 1, 2022.
Section 303: Effective beginning on or after January 1, 2021.

Title IV: Prescription Drug Policies for Low-Income Individuals

PRESENT LAW

Medicare Part D Low Income Subsidy (LIS) Program

Private insurers participating in Part D bear some financial risk, although federal subsidies cover most program costs in an effort to encourage participation and keep benefits affordable. Beneficiaries with limited incomes and resources may qualify for additional Medicare LIS that reduce their out-of-pocket spending by covering all, or some, of the Part D monthly premiums and annual deductible, and limiting co-payments or coinsurance.[46] The LIS is progressive, with lower-income beneficiaries receiving greater assistance.[47]

Certain groups of Medicare beneficiaries automatically qualify (and are *deemed eligible*) for the full LIS including the following: (1) full benefit dual-eligible individuals who qualify for Medicaid based on income and resources; (2) individuals who receive cost-sharing assistance from Medicaid through MSP; and (3) individuals eligible for SSI cash assistance. Medicare beneficiaries may apply to have their LIS eligibility determined by Social Security Administration or by their state Medicaid agency.

For 2019, individuals may qualify for the full LIS if they have annual incomes below 135 percent of FPL (as applicable to family size) and resources that do not exceed $9,230 for a single person and $14,600 for a couple. Individuals may qualify for a partial LIS if they have incomes between 135 percent and 150 percent of FPL (applicable to family size) and resources below $14,390 for a single person and $28,720 for a couple. The resource limits include $1,500 per person for burial expenses.

There is a clear need to improve the programs that provide assistance with Medicare Part D premiums and cost sharing. Currently, an estimated 40 percent of low-income Medicare beneficiaries spend 20 percent or more of their incomes on premiums and health care costs.[48] Roughly 3 in 10, or 13 million, Part D enrollees receive cost sharing assistance through the LIS program. An additional 1 million LIS beneficiaries are paying premiums for Part D coverage even though they may be able to obtain coverage without a premium through a benchmark PDP.[49] One-third (18 million people) had incomes below 150 percent of the federal poverty level (less than $18,000 annually for an individual), and at best, limited assets to last for the duration of their lifetimes.[50]

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[46] Section 1395w-114 of the Social Security Act (42 U.S.C. § 1395w-114).

[47] *Id.*

[48] Cathy Schoen, et al., "A Policy Option to Enhance Access and Affordability for Medicare's Low-Income Beneficiaries," *The Commonwealth Foundation*, (2018). Available at: https://www.commonwealthfund.org/publications/issue-briefs/2018/sep/medicare-low-income-beneficiaries

[49] "10 Essential Facts About Medicare and Prescription Drug Spending," *Henry J. Kaiser Family Foundation*, (2019). Available at: https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug- spending/

[50] Cathy Schoen, et al., "A Policy Option to Enhance Access and Affordability for Medicare's Low-Income Beneficiaries," *The Commonwealth Foundation*, (2018). Available at: https://

For people with incomes near poverty ($12,120 per year for an individual), the sum of the Part A hospital deductible, Part B premium, and deductibles for other medical care could amount to nearly 25 percent of income. Prescription drug premiums and cost-sharing responsibilities are in addition to Part A and B cost-sharing obligations, indicating how critical it is to expand and improve these assistance programs for low- and moderate-income beneficiaries.

State Health Insurance Assistance Program (SHIP)

The SHIP provides funding to states and U.S. territories for outreach, counseling, and information assistance to Medicare beneficiaries and their families and caregivers on Medicare and other health insurance issues. Authorized under Section 4360 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90; P.L. 101–508; 42 U.S.C. 1395b–4), SHIP grants are administered by the Administration for Community Living within HHS. There are SHIP projects in all 50 states, as well as the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.

The majority of SHIP funding is provided annually under discretionary budget authority in appropriations for Labor, Health and Human Services, Education, and Related Agencies (LHHS). SHIPs received $49 million in discretionary appropriations for FY2019 and grants are provided to states (including certain U.S. territories) based on formulas specified in regulation and guidance. In addition to discretionary funding, beginning in FY2009, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) provided funding for specific outreach and assistance activities to Medicare beneficiaries to SHIPs and other entities.[51] This mandatory funding was extended multiple times, most recently under the Bipartisan Budget Act of 2018 through FY2019.[52] MIPPA funding for SHIPs provided for outreach and assistance to low-income Medicare beneficiaries including those who may be eligible for LIS and MSP. The HHS Secretary was required to transfer specified amounts for MIPPA program activities from the Medicare Trust Funds. SHIPs received $13 million in mandatory funding for FY2019 which was provided to states based on a statutory funding formula.

REASONS FOR CHANGES

To make modifications to Medicare at Title XVIII of the SSA to refine eligibility standards and administration of the Low Income Subsidy (LIS) program under Part D.

EXPLANATION OF PROVISIONS

Section 401, "Adjustments to Medicare Part D Cost-Sharing Reductions for Low-Income Individuals," amends section 1860D–14 of title XVIII of the Social Security Act to eliminate cost-sharing for beneficiaries who receive generic drugs under Part D. PDP sponsors are required under current law to apply specific copayments

www.commonwealthfund.org/publications/issue-briefs/2018/sep/medicare-low-income-beneficiaries

[51] Medicare Improvements for Patients and Providers Act of 2008, (H.R. 6331; P.L. 110–275) (July 15, 2008).

[52] Bipartisan Budget Act of 2018, (H.R. 1892; P.L. 115–123) (February 9, 2018).

for generic drugs obtained by LIS eligible enrollees and enrollees with spending above the out-of-pocket threshold (catastrophic coverage). PDPs must ensure that the appropriate cost-sharing is applied to the generic drug as defined under CMS regulations, and when a drug is provided across multiple phases of Part D, each requiring different co-payments, Part D sponsors charge beneficiaries only one copayment per prescription. Section 401 fully incorporates H.R. 2757, the *Creating Lower Cost Alternative for Your Prescription Drugs Act.*

Section 402, "Dissemination to Medicare Part D Subsidy Eligible Individuals of Information Comparing Premiums of Certain Prescription Drug Plans," amends section 1860D–1 of title XVIII of the Social Security Act to require CMS to send a "choosers notice" to all LIS beneficiaries with *any* premium under their current plan, not just those who opt to retain their existing PDP. Under current law, LIS enrolled beneficiaries receive an annual notice prior to each plan year if their plan requires a premium, but they actively chose to retain their current plan instead of a $0 premium plan. CMS refers to these beneficiaries as "choosers." Medicare beneficiaries on LIS are eligible for premium-free prescription drug plans. The chooser's notice would outline the out-of-pocket costs associated with coverage under comparable PDPs. Section 402 fully incorporates H.R. 4632, the *Better Transparency in Information for Medicare Beneficiaries Act.*

Section 403, "Providing for Intelligent Assignment of Certain Subsidy Eligible Individuals Auto-Enrolled Under Medicare Prescription Drug Plans and MA–PD Plans," amends section 1860D–1 of title XVIII of the Social Security Act to require "intelligent assignment" of LIS-eligible individuals so Medicare can better prioritize enrolling patients into high-quality plans that can reduce the costs and improve access to the drugs that individual needs. Under current law, CMS annually automatically enrolls certain Medicare beneficiaries who have not already chosen a plan into a Part D plan. CMS auto-enrolls full-benefit dual eligible individuals who have not elected a Part D plan, and also "passively enrolls" low-income beneficiaries from plans with premiums above the regional LIS benchmark and those that are terminating. These passively enrolled beneficiaries are reassigned into a plan with premiums below the regional LIS benchmark. Unless the plan in which a beneficiary is enrolled is terminating or reducing its service area and the beneficiary would be without Part D coverage, CMS does not reassign beneficiaries that are eligible for a full LIS premium subsidy and who have voluntarily elected a plan. Section 403 fully incorporates H.R. 4669, the *Maximizing Drug Coverage for Low-Income Seniors Act.*

Section 404, "Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program," amends section 1860D–14 of title XVIII of the Social Security Act to authorize expansion of the income eligibility thresholds for the LIS Program. The bill increases the income thresholds for partial subsidy LIS benefits from 150 percent to 200 percent of the federal poverty level (FPL) (or from $25,365 to $33,820 for a married couple, and for full LIS program benefits, from 135 to 150 percent of FPL ($22,829 to $25,365 for a married couple), beginning January 1, 2022. Most beneficiaries who are dually eligible for Medicare and Medicaid are

"deemed eligible" for LIS and automatically enrolled into the program. Those who are not dually eligible individuals may also receive subsidies, but they must apply for the LIS program and demonstrate that their income and assets meet the program's thresholds. Section 404 fully incorporates H.R. 4620, the *More Help for Seniors Act.*

Section 405, "Automatic Eligibility of Certain Low-Income Territorial Residents for Premium and Cost-Sharing Subsidies under the Medicare Program; Sunset of Enhanced Allotment Program," amends sections 1860D–14 and 1860D–31of title XVIII and section 1935 of the Social Security Act, to make territorial residents to eligible for the Medicare Part D LIS program, beginning January 1, 2021. Currently, territorial residents are prohibited under law from receiving LIS under Part D. In lieu of LIS, territories receive a fixed amount of funding to provide Medicaid covered prescription drugs for low-income beneficiaries. This funding is provided under the enhanced allotment program and can be substantially less than the amount of out-of-pocket assistance low-income territorial residents would receive if were eligible for the LIS program.

Section 406, "Automatic Qualification of Certain Medicaid Beneficiaries for Premium and Cost-Sharing Subsidies Under Part D of the Medicare Program," amends section 1860D–14 of title XVIII of the Social Security Act to require automatic enrollment into LIS for all adults who reach age 65 with incomes below 200 percent of FPL and who were enrolled in Medicaid, either through the State Plan or after January 1, 2014 under the ACA Medicaid expansion. The LIS program automatic enrollment on or after January 1, 2022, will be for a limited period of time, to be defined by the Secretary of the Department of Health and Human Services.

The Patient Protection and Affordable Care Act (ACA) directed states to cover lower income adults with incomes up to 133 percent of the FPL, and offered states the option to add coverage for adults whose incomes exceed 133 percent of FPL. This "Medicaid expansion" created a pathway to coverage for millions of Americans with lower incomes. While individuals on Medicaid expansion are likely eligible for LIS because of the income thresholds, when individuals reach age 65 and enroll in Medicare, they experience an unnecessary delay in LIS enrollment. This delay not only has an adverse impact on one's ability to afford and adhere to prescription drugs, but it also exposes the individual to late enrollment penalties when they do eventually apply to the LIS program. Section 406 fully incorporates H.R. 4661, the *Advancing Enrollment and Reducing Drug Costs Act.*

Section 407, "Eliminating the Resource Requirement with Respect to Subsidy Eligible Individuals Under Part D of the Medicare Program," amends section 1860D–14 of title XVIII of the Social Security Act to reduce red tape by eliminating the resource and asset requirement to streamline the eligibility process for the Part D LIS program. LIS program eligibility includes income and asset requirements, and the application process is administered through the Social Security Administration and state governments. Section 407 fully incorporates H.R. 4628, the *Better Tools to Lower Costs Act.*

Section 408, "Providing for Certain Rules Regarding the Treatment of Eligible Retirement Plans in Determining the Eligibility of

Individuals for Premium and Cost-Sharing Subsidies Under Part D of the Medicare Program," amends section 1860D–14 of title XVIII of the Social Security Act to include disbursements from covered retirement accounts as income for LIS eligibility determinations. Section 408 partially incorporates H.R. 4655, the *Enhancing Retirement Security for Medicare Beneficiaries Act*, and in conjunction with Section 407, will to help incentivize savings and provide more out-of-pocket protection for Medicare beneficiaries by counting disbursements from those accounts in income calculations for prescription drug plan years beginning 2022.

EFFECTIVE DATES

Section 401: Effective beginning on or after date January 1, 2021.
Section 402: Effective beginning after the of enactment.
Section 403: Effective beginning on or after date January 1, 2022.
Section 404: Effective beginning on or after date January 1, 2022.
Section 405: Effective beginning on or after date January 1, 2021.
Section 406: Effective beginning on or after date January 1, 2022.
Section 407: Effective beginning on or after date January 1, 2022.
Section 408: Effective beginning on or after date January 1, 2022.

Title V: Drug Price Transparency

PRESENT LAW

Drug prices have been increasing astronomically over the past 20 years, and the lack of transparency around pricing leaves patients and the public at the mercy of drug manufacturers. Pharmaceutical companies are free to price their drugs as they wish, knowing there will be few to no repercussions. The recent scandals surrounding pricing of EpiPen and Daraprim were among the few times a drug company has been publicly shamed for drug prices. The dramatic 50 percent drop in price just announced by Eli Lilly also highlights exactly how unnecessary and unjustifiable the price was to begin with. The discount cost is still a significant jump in price from just a few years ago and may still be unaffordable to many diabetic patients. These realities spurred a demand for public accountability and transparency into the rationale behind prescription drug cost increases and high launch prices.

REASONS FOR CHANGES

To make modifications to Medicare at Title XVIII of the SSA to require manufacturer transparency in prescription drug price setting.

EXPLANATION OF PROVISIONS

Section 501, "Drug Price Transparency," amends Part A of title XI of the Social Security Act to require drug manufacturers to submit a report to the Secretary 30 days before increasing the wholesale acquisition cost (WAC) of a qualifying drug if the estimated price of a qualifying drug for an applicable year per course of treatment is at least $26,000; if the manufacturer increases the price by 10 percent or more over a 12-month period or by 25 percent or more over a 36-month period; or if there was an increase in the price of the qualifying drug that resulted in an increase of the

WAC that is equal to 10 percent or more within a 12 month period in the 5 year period preceding January 1, 2021, or 25 percent or more within a 26 month period that begins and ends during the five year period preceding January 1, 2021. Qualifying drugs have a WAC of $100 and for which during the previous calendar year at least $1 of total sales were for individuals enrolled under Part D or Medicaid.

In addition, a manufacturer of a qualifying drug will be required to report the total expenditures for manufacturing the drug, the research and development expenditures for the drug, and total revenue and net profit generated by the drug, as well as other documentation as applicable. The information provided by the manufacturer will be published unless it is considered trade secret and confidential. Section 501 also includes a civil monetary penalty of $75,000 per day should a manufacturer fail to comply. Section 501 incorporates elements of H.R. 2069, the *Stopping the Pharmaceutical Industry from Keeping drugs Expensive Act*.

EFFECTIVE DATE

Section 501: Effective beginning after the of enactment.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the House of Representatives, the following statement is made concerning the votes of the Committee on Ways and Means during the markup consideration of H.R. 3, the "Lower Drug Costs Act Now Act of 2019" on October 23, 2019.

An amendment to the amendment in the nature of a substitute to change the name of the bill to "Elijah E. Cummings Lower Drug Costs Now Act" was offered by Rep. Pascrell. The amendment was agreed to by voice vote (with a quorum being present).

An amendment to the amendment in the nature of a substitute offered by Mr. Brady was ruled nongermane. Mr. Brady moved to appeal the ruling of the Chair and Mr. Thompson moved to table the appeal. Mr. Thompson's motion to table the appeal of the ruling of the Chair was agreed to by a vote of 25 yeas to 16 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal	X			Mr. Brady		X	
Mr. Lewis	X			Mr. Nunes			
Mr. Doggett	X			Mr. Buchanan		X	
Mr. Thompson	X			Mr. Smith		X	
Mr. Larson	X			Mr. Marchant		X	
Mr. Blumenauer	X			Mr. Reed		X	
Mr. Kind	X			Mr. Kelly		X	
Mr. Pascrell	X			Mr. Holding		X	
Mr. Davis	X			Mr. Smith		X	
Ms. Sánchez	X			Mr. Rice		X	
Mr. Higgins	X			Mr. Schweikert		X	
Ms. Sewell	X			Ms. Walorski		X	
Ms. DelBene	X			Mr. LaHood (IL)		X	
Ms. Chu (CA)	X			Mr. Wenstrup		X	
Ms. Moore	X			Mr. Arrington		X	
Mr. Kildee	X			Mr. Ferguson		X	
Mr. Boyle	X			Mr. Estes		X	
Mr. Beyer	X						
Mr. Evans	X						

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Schneider	X						
Mr. Suozzi	X						
Mr. Panetta	X						
Ms. Murphy	X						
Mr. Gomez	X						
Mr. Horsford	X						

An amendment to the amendment in the nature of a substitute that would redesign and modernize the Medicare Part D program to add an out-of-office pocket spending cap for beneficiaries and for other purposes was offered by Mr. Brady. The amendment was defeated by a vote of 16 yeas to 24 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady	X		
Mr. Lewis				Mr. Nunes			
Mr. Doggett		X		Mr. Buchanan	X		
Mr. Thompson		X		Mr. Smith (NE)	X		
Mr. Larson		X		Mr. Marchant	X		
Mr. Blumenauer		X		Mr. Reed	X		
Mr. Kind		X		Mr. Kelly	X		
Mr. Pascrell		X		Mr. Holding	X		
Mr. Davis		X		Mr. Smith	X		
Ms. Sánchez		X		Mr. Rice	X		
Mr. Higgins		X		Mr. Schweikert	X		
Ms. Sewell		X		Ms. Walorski	X		
Ms. DelBene		X		Mr. LaHood (IL)	X		
Ms. Chu (CA)		X		Mr. Wenstrup	X		
Ms. Moore		X		Mr. Arrington	X		
Mr. Kildee		X		Mr. Ferguson	X		
Mr. Boyle		X		Mr. Estes	X		
Mr. Beyer		X					
Mr. Evans		X					
Mr. Schneider		X					
Mr. Suozzi		X		.			
Mr. Panetta		X					
Ms. Murphy		X					
Mr. Gomez		X					
Mr. Horsford		X					

An amendment to the amendment in the nature of a substitute that would improve incentives of the add-on payment and cap the add-on amount for Part B drugs was offered by Mr. Smith of Nebraska. The amendment was defeated by a vote of 17 yeas to 24 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady	X		
Mr. Lewis				Mr. Nunes	X		
Mr. Doggett		X		Mr. Buchanan	X		
Mr. Thompson		X		Mr. Smith	X		
Mr. Larson		X		Mr. Marchant	X		
Mr. Blumenauer		X		Mr. Reed	X		
Mr. Kind		X		Mr. Kelly	X		
Mr. Pascrell		X		Mr. Holding	X		
Mr. Davis		X		Mr. Smith	X		
Ms. Sánchez		X		Mr. Rice	X		
Mr. Higgins		X		Mr. Schweikert	X		
Ms. Sewell		X		Ms. Walorski	X		
Ms. DelBene		X		Mr. LaHood (IL)	X		
Ms. Chu (CA)		X		Mr. Wenstrup	X		
Ms. Moore		X		Mr. Arrington	X		
Mr. Kildee		X		Mr. Ferguson	X		

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Boyle		X		Mr. Estes	X		
Mr. Beyer		X					
Mr. Evans		X					
Mr. Schneider		X					
Mr. Suozzi		X					
Mr. Panetta		X					
Ms. Murphy		X					
Mr. Gomez		X					
Mr. Horsford		X					

An amendment to the amendment in the nature of a substitute that would improve transparency of out-of-pocket costs for patients getting their Part B drugs in certain hospital settings or in a hospital-owned physician practice was offered by Mr. Wenstrup. The amendment was defeated by a vote of 19 yeas to 23 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady	X		
Mr. Lewis		X		Mr. Nunes	X		
Mr. Doggett	X			Mr. Buchanan	X		
Mr. Thompson		X		Mr. Smith	X		
Mr. Larson		X		Mr. Marchant	X		
Mr. Blumenauer		X		Mr. Reed	X		
Mr. Kind		X		Mr. Kelly	X		
Mr. Pascrell		X		Mr. Holding	X		
Mr. Davis		X		Mr. Smith	X		
Ms. Sánchez		X		Mr. Rice	X		
Mr. Higgins		X		Mr. Schweikert	X		
Ms. Sewell		X		Ms. Walorski	X		
Ms. DelBene		X		Mr. LaHood (IL)	X		
Ms. Chu (CA)		X		Mr. Wenstrup	X		
Ms. Moore		X		Mr. Arrington	X		
Mr. Kildee		X		Mr. Ferguson	X		
Mr. Boyle		X		Mr. Estes	X		
Mr. Beyer	X						
Mr. Evans		X					
Mr. Schneider		X					
Mr. Suozzi		X					
Mr. Panetta		X					
Ms. Murphy		X					
Mr. Gomez		X					
Mr. Horsford		X					

An amendment to the amendment in the nature of a substitute that would require a partial passthrough of Part D rebates at the point of sale was offered by Mr. Arrington. The amendment was defeated by voice vote (with a quorum being present).

An amendment to the amendment in the nature of a substitute that would expand the cap on PDP offerings from three to four and allow plans that passthrough a portion of rebates at the point of sale to offer PDP's was offered by Mr. Reed. The amendment was defeated by a vote of 17 yeas to 23 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady	X		
Mr. Lewis		X		Mr. Nunes	X		
Mr. Doggett		X		Mr. Buchanan	X		
Mr. Thompson		X		Mr. Smith	X		
Mr. Larson		X		Mr. Marchant	X		
Mr. Blumenauer				Mr. Reed	X		
Mr. Kind		X		Mr. Kelly	X		

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Pascrell		X		Mr. Holding	X		
Mr. Davis		X		Mr. Smith	X		
Ms. Sánchez		X		Mr. Rice	X		
Mr. Higgins		X		Mr. Schweikert	X		
Ms. Sewell		X		Ms. Walorski	X		
Ms. DelBene		X		Mr. LaHood (IL)	X		
Ms. Chu (CA)		X		Mr. Wenstrup	X		
Ms. Moore		X		Mr. Arrington	X		
Mr. Kildee		X		Mr. Ferguson	X		
Mr. Boyle		X		Mr. Estes	X		
Mr. Beyer		X					
Mr. Evans		X					
Mr. Schneider		X					
Mr. Suozzi		X					
Mr. Panetta		X					
Ms. Murphy							
Mr. Gomez		X					
Mr. Horsford		X					

An amendment to the amendment in the nature of a substitute that would require rebates on insulin products in Part D to be delivered at the point of sale was offered by Mr. Reed. The amendment was defeated by a vote of 17 yeas to 24 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady	X		
Mr. Lewis		X		Mr. Nunes	X		
Mr. Doggett		X		Mr. Buchanan	X		
Mr. Thompson		X		Mr. Smith	X		
Mr. Larson		X		Mr. Marchant	X		
Mr. Blumenauer		X		Mr. Reed	X		
Mr. Kind		X		Mr. Kelly	X		
Mr. Pascrell		X		Mr. Holding	X		
Mr. Davis		X		Mr. Smith	X		
Ms. Sánchez		X		Mr. Rice	X		
Mr. Higgins		X		Mr. Schweikert	X		
Ms. Sewell		X		Ms. Walorski	X		
Ms. DelBene		X		Mr. LaHood (IL)	X		
Ms. Chu (CA)		X		Mr. Wenstrup	X		
Ms. Moore		X		Mr. Arrington	X		
Mr. Kildee		X		Mr. Ferguson	X		
Mr. Boyle		X		Mr. Estes	X		
Mr. Beyer		X					
Mr. Evans		X					
Mr. Schneider		X					
Mr. Suozzi		X					
Mr. Panetta		X					
Ms. Murphy							
Mr. Gomez		X					
Mr. Horsford		X					

An amendment to the amendment in the nature of a substitute that would require hospitals to pass along savings from the 340B program directly to consumers to help lower their out of pocket costs for drugs was offered by Mr. Wenstrup. The amendment was withdrawn.

An amendment to the amendment in the nature of a substitute that would promote competition in the market for drugs and biological products by stopping anti-competitive practices and reforming certain exclusivity conditions was offered by Mr. Ferguson. The amendment was withdrawn.

An amendment to the amendment in the nature of a substitute that would strike the 95% excise tax imposed on certain drug manufacturers during noncompliance periods, repeal the 2.3 percent excise tax on certain medical devices, and set the income threshold for the medical expense deduction at 7.5 percent of adjusted gross income was offered by Ms. Walorski. The amendment was withdrawn.

An amendment to the amendment in the nature of a substitute that would strike Title I of H.R. 3 was offered by Mr. Nunes. The amendment was defeated by a vote of 17 yeas to 24 nays.

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady	X		
Mr. Lewis		X		Mr. Nunes	X		
Mr. Doggett		X		Mr. Buchanan	X		
Mr. Thompson		X		Mr. Smith	X		
Mr. Larson		X		Mr. Marchant	X		
Mr. Blumenauer		X		Mr. Reed	X		
Mr. Kind		X		Mr. Kelly	X		
Mr. Pascrell		X		Mr. Holding	X		
Mr. Davis		X		Mr. Smith	X		
Ms. Sánchez		X		Mr. Rice	X		
Mr. Higgins		X		Mr. Schweikert	X		
Ms. Sewell		X		Ms. Walorski	X		
Ms. DelBene		X		Mr. LaHood (IL)	X		
Ms. Chu (CA)		X		Mr. Wenstrup	X		
Ms. Moore		X		Mr. Arrington	X		
Mr. Kildee		X		Mr. Ferguson	X		
Mr. Boyle		X		Mr. Estes	X		
Mr. Beyer		X					
Mr. Evans		X					
Mr. Schneider		X					
Mr. Suozzi		X					
Mr. Panetta		X					
Ms. Murphy		X					
Mr. Gomez							
Mr. Horsford		X					

An amendment to the amendment in the nature of a substitute that would eliminate international reference pricing from H.R. 3 was offered by Mr. Holding. The amendment was defeated by a vote of 17 yeas to 25 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady	X		
Mr. Lewis		X		Mr. Nunes	X		
Mr. Doggett		X		Mr. Buchanan	X		
Mr. Thompson		X		Mr. Smith	X		
Mr. Larson		X		Mr. Marchant	X		
Mr. Blumenauer		X		Mr. Reed	X		
Mr. Kind		X		Mr. Kelly	X		
Mr. Pascrell		X		Mr. Holding	X		
Mr. Davis		X		Mr. Smith	X		
Ms. Sánchez		X		Mr. Rice	X		
Mr. Higgins		X		Mr. Schweikert	X		
Ms. Sewell		X		Ms. Walorski	X		
Ms. DelBene		X		Mr. LaHood (IL)	X		
Ms. Chu (CA)		X		Mr. Wenstrup	X		
Ms. Moore		X		Mr. Arrington	X		
Mr. Kildee		X		Mr. Ferguson	X		
Mr. Boyle		X		Mr. Estes	X		
Mr. Beyer		X					
Mr. Evans		X					
Mr. Schneider		X					

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Suozzi		X					
Mr. Panetta		X					
Ms. Murphy		X					
Mr. Gomez		X					
Mr. Horsford		X					

An amendment to the amendment in the nature of a substitute that would exempt any drug used to treat Alzheimer's disease from price setting was offered by Mr. LaHood. The amendment was defeated by a vote of 17 yeas to 23 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady	X		
Mr. Lewis		X		Mr. Nunes			
Mr. Doggett		X		Mr. Buchanan			
Mr. Thompson		X		Mr. Smith	X		
Mr. Larson		X		Mr. Marchant	X		
Mr. Blumenauer		X		Mr. Reed	X		
Mr. Kind		X		Mr. Kelly	X		
Mr. Pascrell				Mr. Holding	X		
Mr. Davis		X		Mr. Smith	X		
Ms. Sánchez		X		Mr. Rice	X		
Mr. Higgins		X		Mr. Schweikert	X		
Ms. Sewell		X		Ms. Walorski	X		
Ms. DelBene		X		Mr. LaHood (IL)	X		
Ms. Chu (CA)		X		Mr. Wenstrup	X		
Ms. Moore		X		Mr. Arrington	X		
Mr. Kildee		X		Mr. Ferguson	X		
Mr. Boyle		X		Mr. Estes	X		
Mr. Beyer		X					
Mr. Evans		X					
Mr. Schneider		X					
Mr. Suozzi							
Mr. Panetta		X					
Ms. Murphy		X					
Mr. Gomez		X					
Mr. Horsford		X					

An amendment to the amendment in the nature of a substitute that would exempt any drug used to treat or cure Cancer from price setting was offered by Ms. Walorski. The amendment was defeated by a vote of 16 yeas to 24 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady	X		
Mr. Lewis		X		Mr. Nunes	X		
Mr. Doggett		X		Mr. Buchanan	X		
Mr. Thompson		X		Mr. Smith	X		
Mr. Larson		X		Mr. Marchant	X		
Mr. Blumenauer		X		Mr. Reed	X		
Mr. Kind		X		Mr. Kelly	X		
Mr. Pascrell				Mr. Holding	X		
Mr. Davis		X		Mr. Smith	X		
Ms. Sánchez		X		Mr. Rice	X		
Mr. Higgins		X		Mr. Schweikert	X		
Ms. Sewell		X		Ms. Walorski	X		
Ms. DelBene		X		Mr. LaHood (IL)	X		
Ms. Chu (CA)		X		Mr. Wenstrup	X		
Ms. Moore		X		Mr. Arrington	X		
Mr. Kildee		X		Mr. Ferguson			
Mr. Boyle		X		Mr. Estes	X		
Mr. Beyer		X					
Mr. Evans		X					
Mr. Schneider		X					

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Suozzi		X					
Mr. Panetta		X					
Ms. Murphy		X					
Mr. Gomez		X					
Mr. Horsford		X					

An amendment to the amendment in the nature of a substitute that would exempt any drug used to treat or cure any disease or any other disease most prevalent to seniors from price setting was offered by Mr. Smith of Nebraska. The amendment was defeated by a voice vote (with a quorum being present).

An amendment to the amendment in the nature of a substitute that would allow New Drug applications for unmet medical needs that benefit Medicare beneficiaries was offered by Mr. Kelly. The amendment was defeated by a voice vote (with a quorum being present).

An amendment to the amendment in the nature of a substitute offered by Mr. LaHood was ruled nongermane. Mr. LaHood moved to appeal the ruling of the Chair and Mr. Thompson moved to table the appeal. Mr. Thompson's motion to table the appeal of the ruling of the Chair was agreed to by a vote of 24 yeas to 16 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal	X			Mr. Brady		X	
Mr. Lewis	X			Mr. Nunes		X	
Mr. Doggett	X			Mr. Buchanan		X	
Mr. Thompson	X			Mr. Smith		X	
Mr. Larson	X			Mr. Marchant		X	
Mr. Blumenauer	X			Mr. Reed		X	
Mr. Kind	X			Mr. Kelly		X	
Mr. Pascrell	X			Mr. Holding		X	
Mr. Davis	X			Mr. Smith		X	
Ms. Sánchez				Mr. Rice		X	
Mr. Higgins	X			Mr. Schweikert		X	
Ms. Sewell	X			Ms. Walorski			
Ms. DelBene	X			Mr. LaHood (IL)		X	
Ms. Chu (CA)	X			Mr. Wenstrup		X	
Ms. Moore	X			Mr. Arrington		X	
Mr. Kildee	X			Mr. Ferguson		X	
Mr. Boyle	X			Mr. Estes		X	
Mr. Beyer	X						
Mr. Evans	X						
Mr. Schneider	X						
Mr. Suozzi	X						
Mr. Panetta	X						
Ms. Murphy	X						
Mr. Gomez	X						
Mr. Horsford	X						

An amendment to the amendment in the nature of a substitute that would require no provision of H.R. 3 be implemented until the Secretary of Health and Human Services certifies in writing that H.R. 3 will not reduce access to life-saving medications in rural areas within the United States was offered by Mr. Smith of Missouri. The amendment was defeated by a vote of 17 yeas to 25 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady	X		

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Lewis		X		Mr. Nunes	X		
Mr. Doggett		X		Mr. Buchanan	X		
Mr. Thompson		X		Mr. Smith	X		
Mr. Larson		X		Mr. Marchant	X		
Mr. Blumenauer		X		Mr. Reed	X		
Mr. Kind		X		Mr. Kelly	X		
Mr. Pascrell		X		Mr. Holding	X		
Mr. Davis		X		Mr. Smith	X		
Ms. Sánchez				Mr. Rice	X		
Mr. Higgins		X		Mr. Schweikert	X		
Ms. Sewell		X		Ms. Walorski	X		
Ms. DelBene		X		Mr. LaHood (IL)	X		
Ms. Chu (CA)		X		Mr. Wenstrup	X		
Ms. Moore		X		Mr. Arrington	X		
Mr. Kildee		X		Mr. Ferguson	X		
Mr. Boyle		X		Mr. Estes	X		
Mr. Beyer		X					
Mr. Evans		X					
Mr. Schneider		X					
Mr. Suozzi		X					
Mr. Panetta		X					
Ms. Murphy		X					
Mr. Gomez		X					
Mr. Horsford		X					

An amendment to the amendment in the nature of a substitute offered by Mr. Ferguson was ruled nongermane. Mr. Ferguson moved to appeal the ruling of the Chair and Mr. Thompson moved to table the appeal. Mr. Thompson's motion to table the appeal of the ruling of the Chair was agreed to by a vote of 25 yeas to 17 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal	X			Mr. Brady		X	
Mr. Lewis	X			Mr. Nunes		X	
Mr. Doggett	X			Mr. Buchanan		X	
Mr. Thompson	X			Mr. Smith		X	
Mr. Larson	X			Mr. Marchant		X	
Mr. Blumenauer	X			Mr. Reed		X	
Mr. Kind	X			Mr. Kelly		X	
Mr. Pascrell	X			Mr. Holding		X	
Mr. Davis	X			Mr. Smith		X	
Ms. Sánchez	X			Mr. Rice		X	
Mr. Higgins	X			Mr. Schweikert		X	
Ms. Sewell	X			Ms. Walorski		X	
Ms. DelBene	X			Mr. LaHood (IL)		X	
Ms. Chu (CA)	X			Mr. Wenstrup		X	
Ms. Moore	X			Mr. Arrington		X	
Mr. Kildee	X			Mr. Ferguson		X	
Mr. Boyle	X			Mr. Estes		X	
Mr. Beyer	X						
Mr. Evans	X						
Mr. Schneider	X						
Mr. Suozzi	X						
Mr. Panetta	X						
Ms. Murphy	X						
Mr. Gomez	X						
Mr. Horsford	X						

An amendment to the amendment in the nature of a substitute that would create a Chief Pharmaceutical Negotiator at the Office of the United States Trade Representative was offered by Mr. Arrington. The amendment was withdrawn.

An amendment to the amendment in the nature of a substitute that would create a technical expert panel to provide recommendations on alternative payment models under Medicare in order to encourage the development of cures was offered by Mr. Schweikert. The amendment was withdrawn.

An amendment to the amendment in the nature of a substitute that would create a medication adherence pilot program was offered by Mr. Schweikert. The amendment was withdrawn.

An amendment to the amendment in the nature of a substitute offered by Mr. Kelly was ruled nongermane. Mr. Kelly moved to appeal the ruling of the Chair and Mr. Thompson moved to table the appeal. Mr. Thompson's motion to table the appeal of the ruling of the Chair was agreed to by a vote of 25 yeas to 17 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal	X			Mr. Brady		X	
Mr. Lewis	X			Mr. Nunes		X	
Mr. Doggett	X			Mr. Buchanan		X	
Mr. Thompson	X			Mr. Smith		X	
Mr. Larson	X			Mr. Marchant		X	
Mr. Blumenauer	X			Mr. Reed		X	
Mr. Kind	X			Mr. Kelly		X	
Mr. Pascrell	X			Mr. Holding		X	
Mr. Davis	X			Mr. Smith		X	
Ms. Sánchez	X			Mr. Rice		X	
Mr. Higgins	X			Mr. Schweikert		X	
Ms. Sewell	X			Ms. Walorski		X	
Ms. DelBene	X			Mr. LaHood (IL)		X	
Ms. Chu (CA)	X			Mr. Wenstrup		X	
Ms. Moore	X			Mr. Arrington		X	
Mr. Kildee	X			Mr. Ferguson		X	
Mr. Boyle	X			Mr. Estes		X	
Mr. Beyer	X						
Mr. Evans	X						
Mr. Schneider	X						
Mr. Suozzi	X						
Mr. Panetta	X						
Ms. Murphy	X						
Mr. Gomez	X						
Mr. Horsford	X						

An amendment to the amendment in the nature of a substitute offered by Mr. Estes was ruled nongermane. Mr. Estes moved to appeal the ruling of the Chair and Mr. Thompson moved to table the appeal. Mr. Thompson's motion to table the appeal of the ruling of the Chair was agreed to by a vote of 25 yeas to 16 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal	X			Mr. Brady		X	
Mr. Lewis	X			Mr. Nunes		X	
Mr. Doggett	X			Mr. Buchanan		X	
Mr. Thompson	X			Mr. Smith		X	
Mr. Larson	X			Mr. Marchant		X	
Mr. Blumenauer	X			Mr. Reed		X	
Mr. Kind	X			Mr. Kelly		X	
Mr. Pascrell	X			Mr. Holding		X	
Mr. Davis	X			Mr. Smith		X	
Ms. Sánchez	X			Mr. Rice		X	
Mr. Higgins	X			Mr. Schweikert			
Ms. Sewell	X			Ms. Walorski		X	
Ms. DelBene	X			Mr. LaHood (IL)		X	

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Ms. Chu (CA)	X			Mr. Wenstrup		X	
Ms. Moore	X			Mr. Arrington		X	
Mr. Kildee	X			Mr. Ferguson		X	
Mr. Boyle	X			Mr. Estes		X	
Mr. Beyer	X						
Mr. Evans	X						
Mr. Schneider	X						
Mr. Suozzi	X						
Mr. Panetta	X						
Ms. Murphy	X						
Mr. Gomez	X						
Mr. Horsford	X						

An amendment to the amendment in the nature of a substitute that would provide relief from Obamacare's tax on branded drugs was offered by Mr. Rice. The amendment was defeated by a vote of 17 yeas to 25 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady	X		
Mr. Lewis		X		Mr. Nunes	X		
Mr. Doggett		X		Mr. Buchanan	X		
Mr. Thompson		X		Mr. Smith	X		
Mr. Larson		X		Mr. Marchant	X		
Mr. Blumenauer		X		Mr. Reed	X		
Mr. Kind		X		Mr. Kelly	X		
Mr. Pascrell		X		Mr. Holding	X		
Mr. Davis		X		Mr. Smith	X		
Ms. Sánchez		X		Mr. Rice	X		
Mr. Higgins		X		Mr. Schweikert	X		
Ms. Sewell		X		Ms. Walorski	X		
Ms. DelBene		X		Mr. LaHood (IL)	X		
Ms. Chu (CA)		X		Mr. Wenstrup	X		
Ms. Moore		X		Mr. Arrington	X		
Mr. Kildee		X		Mr. Ferguson	X		
Mr. Boyle		X		Mr. Estes	X		
Mr. Beyer		X					
Mr. Evans		X					
Mr. Schneider		X					
Mr. Suozzi		X					
Mr. Panetta		X					
Ms. Murphy		X					
Mr. Gomez		X					
Mr. Horsford		X					

An amendment to the amendment in the nature of a substitute that would amend the "Fair Price Eligible Individual" definition to include the uninsured was offered by Mr. Doggett. The amendment was defeated by a vote of 4 yeas to 20 nays, with 17 voting present. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady			X
Mr. Lewis		X		Mr. Nunes			X
Mr. Doggett	X			Mr. Buchanan			X
Mr. Thompson		X		Mr. Smith			X
Mr. Larson		X		Mr. Marchant			X
Mr. Blumenauer		X		Mr. Reed			X
Mr. Kind		X		Mr. Kelly			X
Mr. Pascrell		X		Mr. Holding			X
Mr. Davis		X		Mr. Smith			X
Ms. Sánchez				Mr. Rice			X
Mr. Higgins		X		Mr. Schweikert			X

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Ms. Sewell		X		Ms. Walorski			X
Ms. DelBene		X		Mr. LaHood (IL)			X
Ms. Chu (CA)	X			Mr. Wenstrup			X
Ms. Moore	X			Mr. Arrington			X
Mr. Kildee		X		Mr. Ferguson			X
Mr. Boyle				Mr. Estes			X
Mr. Beyer	X						
Mr. Evans		X					
Mr. Schneider		X					
Mr. Suozzi		X					
Mr. Panetta		X					
Ms. Murphy		X					
Mr. Gomez		X					
Mr. Horsford		X					

An amendment to the amendment in the nature of a substitute that would increase the minimum number of drugs to be negotiated to 50 within 5 years and 100 within 10 years was offered by Mr. Doggett. The amendment was defeated by a vote of 3 yeas to 39 nays. The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal		X		Mr. Brady		X	
Mr. Lewis		X		Mr. Nunes		X	
Mr. Doggett	X			Mr. Buchanan		X	
Mr. Thompson		X		Mr. Smith		X	
Mr. Larson		X		Mr. Marchant		X	
Mr. Blumenauer		X		Mr. Reed		X	
Mr. Kind		X		Mr. Kelly		X	
Mr. Pascrell		X		Mr. Holding		X	
Mr. Davis		X		Mr. Smith		X	
Ms. Sánchez				Mr. Rice		X	
Mr. Higgins		X		Mr. Schweikert		X	
Ms. Sewell		X		Ms. Walorski		X	
Ms. DelBene		X		Mr. LaHood (IL)		X	
Ms. Chu (CA)	X			Mr. Wenstrup		X	
Ms. Moore		X		Mr. Arrington		X	
Mr. Kildee		X		Mr. Ferguson		X	
Mr. Boyle				Mr. Estes		X	
Mr. Beyer	X						
Mr. Evans		X					
Mr. Schneider		X					
Mr. Suozzi		X					
Mr. Panetta		X					
Ms. Murphy		X					
Mr. Gomez		X					
Mr. Horsford		X					

The amendment in the nature of a substitute to H.R. 3 was agreed to by voice vote (with a quorum being present).

H.R. 3 was ordered favorably reported to the House of Representatives as amended by an amendment in the nature of a substitute offered by Chairman Neal by a vote of 24 yeas to 17 nays, with one voting present.

The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Neal	X			Mr. Brady		X	
Mr. Lewis	X			Mr. Nunes		X	
Mr. Doggett			X	Mr. Buchanan		X	
Mr. Thompson	X			Mr. Smith (NE)		X	
Mr. Larson	X			Mr. Marchant		X	
Mr. Blumenauer	X			Mr. Reed		X	

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Kind	X			Mr. Kelly		X	
Mr. Pascrell	X			Mr. Holding		X	
Mr. Davis	X			Mr. Smith (MO)		X	
Ms. Sánchez	X			Mr. Rice		X	
Mr. Higgins	X			Mr. Schweikert		X	
Ms. Sewell	X			Ms. Walorski		X	
Ms. DelBene	X			Mr. LaHood (IL)		X	
Ms. Chu (CA)	X			Mr. Wenstrup		X	
Ms. Moore	X			Mr. Arrington		X	
Mr. Kildee	X			Mr. Ferguson		X	
Mr. Boyle	X			Mr. Estes		X	
Mr. Beyer	X						
Mr. Evans	X						
Mr. Schneider	X						
Mr. Suozzi	X						
Mr. Panetta	X						
Ms. Murphy	X						
Mr. Gomez	X						
Mr. Horsford	X						

III. BUDGET EFFECTS OF THE BILL

A. Committee Estimate of Budgetary Effects

Clause 3(d)(1) of the Rules of the House of Representatives requires an estimate and a comparison of costs that would be incurred in carrying out H.R. 3. The Committee traditionally adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office (CBO) pursuant to section 402 of the Congressional Budget Act of 1974. The Committee reports that because this cost estimate was not timely submitted to the Committee before the filing of this report, the Committee is not in a position to make a cost estimate for H.R. 3, as amended.

B. Statement Regarding New Budget Authority and Tax Expenditures Budget Authority

Pursuant to clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the bill involves no new or increased budget authority. The Committee further states that the bill involves no new tax expenditure.

C. Cost Estimate Prepared by the Congressional Budget Office

With respect to the requirements of clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the Committee has requested but not received a cost estimate for the bill from the Director of the Congressional Budget Office.

IV. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

A. Committee Oversight Findings and Recommendations

With respect to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the Committee made findings and recommendations that are reflected in this report.

B. Statement of General Performance Goals and Objectives

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill contains no measure that authorizes funding, so no statement of general performance goals and objectives for which any measure authorizes funding is required.

C. Information Relating to Unfunded Mandates

This information is provided in accordance with section 423 of the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104–4).

The Committee has determined that the bill does not contain Federal mandates on the private sector. The Committee has determined that the bill does not impose a Federal intergovernmental mandate on State, local, or tribal governments.

D. Congressional Earmarks, Limited Tax Benefits, and Limited Tariff Benefits

With respect to clause 9 of rule XXI of the Rules of the House of Representatives, the Committee has carefully reviewed the provisions of the bill, and states that the provisions of the bill do not contain any congressional earmarks, limited tax benefits, or limited tariff benefits within the meaning of the rule.

E. Duplication of Federal Programs

In compliance with clause 3(c)(5) of rule XIII of the Rules of the House of Representatives, the Committee states that no provision of the bill establishes or reauthorizes: (1) a program of the Federal Government known to be duplicative of another Federal program; (2) a program included in any report to Congress pursuant to section 21 of Public Law 111–139; or (3) a program related to a program identified in the most recent Catalog of Federal Domestic Assistance, published pursuant section 6104 of title 31, United States Code.

F. Hearings

In compliance with Sec. 103(i) of H. Res. 6 (116th Congress) the following hearing was used to develop or consider H.R. 3:

(1) On October 17, 2019, the Committee on Ways and Means held a full committee hearing entitled, "Investing in the U.S. Health system by lowering drug prices, reducing out-of-pocket costs, and improving Medicare benefits" to discuss how H.R. 3, the Lower Drug Costs Now Act, will lower prescription drug prices in Medicare and the commercial market, improve affordability of medicine, and reduce costs for patients and taxpayers in addition to ways savings from H.R. 3 can be reinvested to improve care and lower costs for seniors and people with disabilities enrolled in Medicare.

(2) the following related hearings were also held:

On February 12, 2019, the Committee on Ways and Means held a full committee hearing entitled, "The Cost of Rising Prescription Drug Prices," to discuss the drug pricing crisis.

On March 7, 2019, the Committee on Ways and Means held a health subcommittee hearing entitled, "Promoting Competition to Lower Medicare Drug Prices," to discuss the com-

plicated drug pricing landscape, including how to lower prescription drug prices through competition, pay for value, and lower out-of-pocket costs for patients.

On June 4, 2019, the Committee on Ways and Means held a full committee Member Day hearing to discuss the range of issues, concerns, and proposals among on-committee and off-committee members.

V. Changes in Existing Law Made by the Bill, as Reported

In compliance with clause 3(e)(1)(B) of rule XIII of the Rules of the House of Representatives, changes in existing law proposed by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Changes in Existing Law Made by the Bill, as Reported

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

* * * * * * *

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

* * * * * * *

Part A—General Provisions

* * * * * * *

SEC. 1150C. REPORTING ON DRUG PRICES.

(a) Definitions.—In this section:

(1) Manufacturer.—The term "manufacturer" means the person—

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

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

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

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

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

(ii) not a preventative vaccine; and

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

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

(b) REPORT.—

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

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

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

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

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

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

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

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

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

(A) in the case of a report with respect to an increase in the price of a qualifying drug that occurs during the period beginning on January 1, 2019, and ending on the day that is 60 days after the date of the enactment of this section, not later than 90 days after such date of enactment;

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

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

(D) in the case of a report with respect to an increase in the price of a qualifying drug that occurs during a 12-

month or 36-month period described in paragraph (1)(C), not later than April 1, 2021.

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

(1) with respect to the qualifying drug—

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

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

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

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

(i) the sponsor or sponsors of any investigational new drug applications under section 505(i) of the Federal Food, Drug, and Cosmetic Act for clinical investigations with respect to such drug, for which the full reports are submitted as part of the application—

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

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

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

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

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

(G) the total expenditures of the manufacturer on—

(i) materials and manufacturing for such drug;

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

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

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

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

(J) the total expenditures of the manufacturer on pursuing new or expanded indications or dosage changes for such drug under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act;

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

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

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

(2) with respect to the manufacturer—

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

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

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

(i) drug research and development; or

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

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

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

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

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

(g) PUBLIC POSTING.—

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

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

(A) user-friendly to the public; and

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

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

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

SEC. 1150D. ANNUAL REPORT TO CONGRESS.

(a) IN GENERAL.—Subject to subsection (b), the Secretary shall submit to the Committees on Energy and Commerce and Ways and Means of the House of Representatives and the Committees on Health, Education, Labor, and Pensions and Finance of the Senate, and post on the public website of the Department of Health and Human Services in a way that is user-friendly to the public and written in plain language that consumers can readily understand, an annual report—

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

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

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

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

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

* * * * * * *

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

SEC. 1191. ESTABLISHMENT OF PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a Fair Price Negotiation Program (in this part referred to as the "program"). Under the program, with respect to each price applicability period, the Secretary shall—

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

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

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

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

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

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

(2) PRICE APPLICABILITY PERIOD.—The term "price applicability period" means, with respect to a drug, the period beginning with the initial price applicability year with respect to which such drug is a selected drug and ending with the last plan year during which the drug is a selected drug.

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

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

(A) beginning on the sooner of—

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

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

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

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

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

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

(i) an individual who is enrolled under a prescription drug plan under part D of title XVIII or an MA–

PD plan under part C of such title under which coverage is provided for such drug; and

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

(B) in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier—

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

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

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

(3) AVERAGE INTERNATIONAL MARKET PRICE DEFINED.—

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

(B) APPLICABLE COUNTRIES.—

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

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

(I) Australia.

(II) Canada.

(III) France.

(IV) Germany.
(V) Japan.
(VI) The United Kingdom.

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

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

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

(1)(A) with respect to an initial price applicability year during the period beginning with 2023 and ending with 2027, at least 25 negotiation-eligible drugs described in subparagraphs (A) and (B), but not subparagraph (C), of subsection (d)(1) (or, with respect to an initial price applicability year during such period beginning after 2023, the maximum number (if such number is less than 25) of such negotiation-eligible drugs for the year) with respect to such year;

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

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

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

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

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

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

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

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

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

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

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

(2) continue to be marketed.

(d) NEGOTIATION-ELIGIBLE DRUG.—

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

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

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

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

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

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

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

(1) DRUG PRODUCTS.—A drug that—

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

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

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

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

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

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

SEC. 1193. MANUFACTURER AGREEMENTS.

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

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

(A) to fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1191(c)(1) and are furnished or dispensed such drug during, subject to subparagraph (2), the price applicability period; and

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

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

(A) to fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1191(c)(1) and are furnished or dispensed such drug during any year during the price applicability period (beginning after such renegotiation) with respect to such selected drug; and

(B) to hospitals, physicians, and other providers of services and suppliers with respect to fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or admin-

istered such drug during any year described in subparagraph (A);

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

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

(A) for the voluntary negotiation period for the price applicability period (and, if applicable, before any period of renegotiation specified pursuant to paragraph (2)) with respect to such drug all information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part, including information described in section 1192(f) and section 1194(d)(1); and

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

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

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

(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO LONGER A SELECTED DRUG.—An agreement entered into under this section shall be effective, with respect to a drug, until such drug is no longer considered a selected drug under section 1192(c).

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

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

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

(B) the number of units of such drug sold in the United States, including the 50 States, the District of Columbia, and the territories of the United States, during the period described in paragraph (2)(B).

(2) AMOUNTS DESCRIBED.—

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

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

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

(e) REGULATIONS.—

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

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

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

SEC. 1194. NEGOTIATION AND RENEGOTIATION PROCESS.

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

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

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

(b) NEGOTIATING METHODOLOGY AND OBJECTIVE.—

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

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

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

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

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

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

(3) REQUIREMENT.—

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

(B) TARGET PRICE.—

(i) IN GENERAL.—Subject to clause (ii), the target price described in this subparagraph for a selected drug with respect to a year, is the average price (which shall be the net average price, if practicable, and volume-weighted, if practicable) for a unit of such drug for sales of such drug, as computed (across different dosage forms and strengths of the drug and not based on the specific formulation or package size or package type of the drug) in the applicable country described in section 1191(c)(3)(B) with respect to such drug that, with respect to such year, has the lowest average price for such drug as compared to the average prices (as so computed) of such drug with respect to such year in the other applicable countries described in such section with respect to such drug.

(ii) SELECTED DRUGS WITHOUT AIM PRICE.—In applying this paragraph in the case of negotiating the max-

imum 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 shall, consistent with subsection (b)(2), take into consideration the following factors:

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

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

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

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

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

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

(F) National sales data for the drug.

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

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

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

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

(C) Information on comparative effectiveness analysis for such products, taking into consideration the effects of such products on specific populations, such as individuals with disabilities, the elderly, terminally ill, children, and other patient populations.

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

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

(4) ADDITIONAL INFORMATION.—Information submitted to the Secretary, in accordance with a process specified by the Secretary, by other parties that are affected by the establishment of a maximum fair price for the selected drug.

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

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

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

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

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

(i) the lesser of—

(I) the wholesale acquisition cost of the drug;

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

(III) any other similar determination of pharmacy acquisition costs of the drug, as determined by the Secretary; and

(ii) the maximum fair price for the drug.

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

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

(ii) any other discounts.

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

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

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

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

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

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

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

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

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

(2) MONITORING COMPLIANCE.—

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

(B) NOTIFICATION.—If a third party with a contract under subsection (c)(1) determines that the manufacturer is not in compliance with such agreement, the third party shall notify the Secretary of such noncompliance for appropriate enforcement under section 4192 of the Internal Revenue Code of 1986 or section 1198, as applicable.

(b) COLLECTION OF DATA.—

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

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

(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 health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act), with respect to a price applicability period and a selected drug with respect to such period—

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

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

(2) OPTING OUT OF AGREEMENT.—The Secretary shall not be treated as having in effect an agreement under the program under this part with a group health plan or health insurance issuer offering 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 issuer of 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, 2025, the National Academy of Medicine shall conduct a study, and submit to Congress a report, on recommendations for improvements to the program under this part, including the determination of the limits applied under section 1194(c).

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

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

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

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

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

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

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

(f) DATA SHARING.—The Secretary shall share with the Secretary of the Treasury such information as is necessary to determine the tax imposed by section 4192 of the Internal Revenue Code of 1986.

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TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

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

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PAYMENT OF BENEFITS

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

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

(H) with respect to services of a certified registered nurse anesthetist under section 1861(s)(11), the amounts paid shall be 80 percent of the least of the actual charge, the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1848) if the services had been performed by an anesthesiologist, or the fee schedule for such services established by the Secretary in accordance with subsection (l), (I) with respect to covered items (described in section 1834(a)(13)), the amounts paid shall be the amounts described in section 1834(a)(1), and(J) with respect to expenses incurred for radiologist services (as defined in section 1834(b)(6)), subject to section 1848, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount provided under the fee schedule established under section 1834(b), (K) with respect to certified nurse-midwife services under section 1861(s)(2)(L), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph (but in no event shall such fee schedule exceed 65 percent of the prevailing charge that would be allowed for the same service performed by a physician, or, for services furnished on or after January 1, 1992, 65 percent (or 100 percent for services furnished on or after January 1, 2011) of the fee schedule amount provided under section 1848 for the same service performed by a physician), (L) with respect to qualified psychologist services under section 1861(s)(2)(M), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, (M) with respect to prosthetic devices and orthotics and prosthetics (as defined in section 1834(h)(4)), the amounts paid shall be the amounts described in section 1834(h)(1), (N) with respect to expenses incurred for physicians' services (as defined in section 1848(j)(3)) other than personalized prevention plan services (as defined in section 1861(hhh)(1)), the amounts paid shall be 80 percent of the payment basis determined under section 1848(a)(1), (O) with respect to services described in section 1861(s)(2)(K) (relating to services furnished by physician assistants, nurse practitioners, or clinic nurse specialists), the amounts paid shall be equal to 80 percent of (i) the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1848, or (ii) in the case of services as an assistant at surgery, the lesser of the actual charge or 85 percent of the amount that would oth-

erwise be recognized if performed by a physician who is serving as an assistant at surgery, (P) with respect to surgical dressings, the amounts paid shall be the amounts determined under section 1834(i), (Q) with respect to items or services for which fee schedules are established pursuant to section 1842(s), the amounts paid shall be 80 percent of the lesser of the actual charge or the fee schedule established in such section, (R) with respect to ambulance services, (i) the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary under section 1834(l) and (ii) with respect to ambulance services described in section 1834(l)(8), the amounts paid shall be the amounts determined under section 1834(g) for outpatient critical access hospital services, (S) [with respect to] *subject to subparagraph (DD), with respect to* drugs and biologicals (including intravenous immune globulin (as defined in section 1861(zz))) not paid on a cost or prospective payment basis as otherwise provided in this part (other than items and services described in subparagraph (B)), the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1842(o) (or, if applicable, under section 1847, 1847A, or 1847B), (T) with respect to medical nutrition therapy services (as defined in section 1861(vv)), the amount paid shall be 80 percent (or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual) of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) for the same services if furnished by a physician, (U) with respect to facility fees described in section 1834(m)(2)(B), the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section, (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1842(s) items), with respect to competitively priced items and services (described in section 1847(a)(2)) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1847(b)(5), (W) with respect to additional preventive services (as defined in section 1861(ddd)(1)), the amount paid shall be (i) in the case of such services which are clinical diagnostic laboratory tests, the amount determined under subparagraph (D) (if such subparagraph were applied, by substituting "100 percent" for "80 percent"), and (ii) in the case of all other such services, 100 percent of the lesser of the actual charge for the service or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph, (X) with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)), the amount paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined under the payment basis determined under section 1848, (Y) with respect to preventive services described in subparagraphs (A) and (B) of section 1861(ddd)(3) that are appro-

priate for the individual and, in the case of such services described in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population, the amount paid shall be 100 percent of (i) except as provided in clause (ii), the lesser of the actual charge for the services or the amount determined under the fee schedule that applies to such services under this part, and (ii) in the case of such services that are covered OPD services (as defined in subsection (t)(1)(B)), the amount determined under subsection (t), (Z) with respect to Federally qualified health center services for which payment is made under section 1834(o), the amounts paid shall be 80 percent of the lesser of the actual charge or the amount determined under such section, (AA) with respect to an applicable disposable device (as defined in paragraph (2) of section 1834(s)) furnished to an individual pursuant to paragraph (1) of such section, the amount paid shall be equal to 80 percent of the lesser of the actual charge or the amount determined under paragraph (3) of such section, (BB) with respect to home infusion therapy, the amount paid shall be an amount equal to 80 percent of the lesser of the actual charge for the services or the amount determined under section 1834(u), ❚and (CC)❚ *(CC)* with respect to opioid use disorder treatment services furnished during an episode of care, the amount paid shall be equal to the amount payable under section 1834(w) less any copayment required as specified by the Secretary*, and (DD) with respect to a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) for which the payment amount for a calendar quarter under paragraph (3)(A)(ii)(I) of such section for such quarter exceeds the inflation-adjusted payment under paragraph (3)(A)(ii)(II) of such section for such quarter, the amounts paid shall be the difference between (i) the payment amount under paragraph (3)(A)(ii)(I) of such section for such drug, and (ii) 20 percent of the inflation-adjusted payment amount under paragraph (3)(A)(ii)(II) of such section for such drug*;

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

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

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

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

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

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

services exceed 80 percent of such reasonable cost, or

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

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

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

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

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

(E) with respect to—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(8) in the case of—

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

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

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

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

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

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

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

the amounts described in section 1834(k); and

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

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

For purposes of applying paragraph (1)(DD), subsections (i)(9) and (t)(3)(H), and section 1834(x)(5), the Secretary shall make such estimates and use such data as the Secretary determines appropriate, and notwithstanding any other provision of law, may do so by program instruction or otherwise.

(b) Before applying subsection (a) with respect to expenses incurred by an individual during any calendar year, the total amount of the expenses incurred by such individual during such year (which would, except for this subsection, constitute incurred expenses from which benefits payable under subsection (a) are determinable) shall be reduced by a deductible of $75 for calendar years before 1991, $100 for 1991 through 2004, $110 for 2005, and for a

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

to expenses incurred with respect to services furnished after December 31, 2017.

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

(2) The amount specified in this paragraph—

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

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

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

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

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

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

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

within 10 business days of the date of the Secretary's receipt of the request made in accordance with such requirement, the Secretary shall be deemed to have found the services to be medically necessary.

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

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

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

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

(II) for occupational therapy services.

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

(ii) Such factors may include the following:

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

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

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

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

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

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

contractor under section 1893(h) for medical reviews under this subparagraph.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(II) for occupational therapy services.

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

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

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

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

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

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

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

such other adjustments as the Secretary determines are justified by technological changes.

(ii) Notwithstanding clause (i)—

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

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

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

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

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

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

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

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

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

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

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

(3) In addition to the amounts provided under the fee schedules (for tests furnished before January 1, 2017)or under section 1834A (for tests furnished on or afterJanuary 1, 2017), subject to subsection (b)(5) of such section, the Secretary shall provide for and establish (A) a nominal fee to cover the appropriate costs in collecting the sample on which a clinical diagnostic laboratory test was performed and for which payment is made under this part, except that not more than one such fee may be provided under this paragraph

with respect to samples collected in the same encounter, and (B) a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). In establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample, but the Secretary shall only be required to apply such method in the case of tests furnished during the period beginning on April 1, 1989, and ending on December 31, 1990, by a laboratory that establishes to the satisfaction of the Secretary (based on data for the 12-month period ending June 30, 1988) that (i) the laboratory is dependent upon payments under this title for at least 80 percent of its collected revenues for clinical diagnostic laboratory tests, (ii) at least 85 percent of its gross revenues for such tests are attributable to tests performed with respect to individuals who are homebound or who are residents in a nursing facility, and (iii) the laboratory provided such tests for residents in nursing facilities representing at least 20 percent of the number of such facilities in the State in which the laboratory is located.

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

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

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

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

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

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

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

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

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

(viii) after December 31, 1997, is equal to 74 percent of such median (or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1,

2001, that the Secretary determines is a new test for which no limitation amount has previously been established under this subparagraph).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of final determinations of the payment

amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

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

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

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

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

(E) For purposes of this paragraph:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(II) the ASC proportion (as defined in clause (ii)(II)) of the standard overhead amount payable with respect to the same surgical procedure as if it were provided in an ambulatory surgical center in the same area, as determined under paragraph (2)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A).

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

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

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

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

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

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

(iii) on October 1, 1987—

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

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

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

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

(5)(A) The Secretary is authorized to provide by regulations that in the case of a surgical procedure, specified by the Secretary pursuant to paragraph (1)(A), performed in an ambulatory surgical center described in such paragraph, there shall be paid (in lieu of

any amounts otherwise payable under this part) with respect to the facility services furnished by such center and with respect to all related services (including physicians' services, laboratory, X-ray, and diagnostic services) a single all-inclusive fee established pursuant to subparagraph (B), if all parties furnishing all such services agree to accept such fee (to be divided among the parties involved in such manner as they shall have previously agreed upon) as full payment for the services furnished.

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

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

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

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

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

(9) In the case of a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) furnished on or after July 1, 2021, under the system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under

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

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

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

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

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

(C) The provisions of this subsection shall not apply to certain services furnished in certain hospitals in rural areas under the provisions of section 9320(k) of the Omnibus Budget Reconciliation Act of 1986, as amended by section 6132 of the Omnibus Budget Reconciliation Act of 1989.

(2) Except as provided in paragraph (3), the fee schedule established under paragraph (1) shall be initially based on audited data from cost reporting periods ending in fiscal year 1985 and such other data as the Secretary determines necessary.

(3)(A) In establishing the initial fee schedule for those services, the Secretary shall adjust the fee schedule to the extent necessary to ensure that the estimated total amount which will be paid under this title for those services plus applicable coinsurance in 1989 will equal the estimated total amount which would be paid under this title for those services in 1989 if the services were included as inpatient hospital services and payment for such services was made under part A in the same manner as payment was made in fiscal year 1987, adjusted to take into account changes in prices and technology relating to the administration of anesthesia.

(B) The Secretary shall also reduce the prevailing charge of physicians for medical direction of a certified registered nurse anesthetist, or the fee schedule for services of certified registered nurse anesthetists, or both, to the extent necessary to ensure that the estimated total amount which will be paid under this title plus applicable coinsurance for such medical direction and such services in 1989 and 1990 will not exceed the estimated total amount which would have been paid plus applicable coinsurance but for the enactment of the amendments made by section 9320 of the Omnibus

Budget Reconciliation Act of 1986. A reduced prevailing charge under this subparagraph shall become the prevailing charge but for subsequent years for purposes of applying the economic index under the fourth sentence of section 1842(b)(3).

(4)(A) Except as provided in subparagraphs (C) and (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, by a certified registered nurse anesthetist who is not medically directed—

(i) the conversion factor shall be—

(I) for services furnished in 1991, $15.50,

(II) for services furnished in 1992, $15.75,

(III) for services furnished in 1993, $16.00,

(IV) for services furnished in 1994, $16.25,

(V) for services furnished in 1995, $16.50,

(VI) for services furnished in 1996, $16.75, and

(VII) for services furnished in calendar years after 1996, the previous year's conversion factor increased by the update determined under section 1848(d) for physician anesthesia services for that year;

(ii) the payment areas to be used shall be the fee schedule areas used under section 1848 (or, in the case of services furnished during 1991, the localities used under section 1842(b)) for purposes of computing payments for physicians' services that are anesthesia services;

(iii) the geographic adjustment factors to be applied to the conversion factor under clause (i) for services in a fee schedule area or locality is—

(I) in the case of services furnished in 1991, the geographic work index value and the geographic practice cost index value specified in section 1842(q)(1)(B) for physicians' services that are anesthesia services furnished in the area or locality, and

(II) in the case of services furnished after 1991, the geographic work index value, the geographic practice cost index value, and the geographic malpractice index value used for determining payments for physicians' services that are anesthesia services under section 1848,

with 70 percent of the conversion factor treated as attributable to work and 30 percent as attributable to overhead for services furnished in 1991 (and the portions attributable to work, practice expenses, and malpractice expenses in 1992 and thereafter being the same as is applied under section 1848).

(B)(i) Except as provided in clause (ii) and subparagraph (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, and before January 1, 1994, by a certified registered nurse anesthetist who is medically directed, the Secretary shall apply the same methodology specified in subparagraph (A).

(ii) The conversion factor used under clause (i) shall be—

(I) for services furnished in 1991, $10.50,

(II) for services furnished in 1992, $10.75, and

(III) for services furnished in 1993, $11.00.

(iii) In the case of services of a certified registered nurse anesthetist who is medically directed or medically supervised by a physician which are furnished on or after January 1, 1994, the fee

schedule amount shall be one-half of the amount described in section 1848(a)(5)(B) with respect to the physician.

(C) Notwithstanding subclauses (I) through (V) of subparagraph (A)(i)—

(i) in the case of a 1990 conversion factor that is greater than $16.50, the conversion factor for a calendar year after 1990 and before 1996 shall be the 1990 conversion factor reduced by the product of the last digit of the calendar year and one-fifth of the amount by which the 1990 conversion factor exceeds $16.50; and

(ii) in the case of a 1990 conversion factor that is greater than $15.49 but less than $16.51, the conversion factor for a calendar year after 1990 and before 1996 shall be the greater of—

(I) the 1990 conversion factor, or

(II) the conversion factor specified in subparagraph (A)(i) for the year involved.

(D) Notwithstanding subparagraph (C), in no case may the conversion factor used to determine payment for services in a fee schedule area or locality under this subsection, as adjusted by the adjustment factors specified in subparagraphs (A)(iii), exceed the conversion factor used to determine the amount paid for physicians' services that are anesthesia services in the area or locality.

(5)(A) Payment for the services of a certified registered nurse anesthetist (for which payment may otherwise be made under this part) may be made on the basis of a claim or request for payment presented by the certified registered nurse anesthetist furnishing such services, or by a hospital, critical access hospital, physician, group practice, or ambulatory surgical center with which the certified registered nurse anesthetist furnishing such services has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, critical access hospital, physician, group practice, or ambulatory surgical center.

(B) No hospital or critical access hospital that presents a claim or request for payment for services of a certified nurse anesthetist under this part may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital or critical access hospital for purposes of this title.

(6) If an adjustment under paragraph (3)(B) results in a reduction in the reasonable charge for a physicians' service and a nonparticipating physician furnishes the service to an individual entitled to benefits under this part after the effective date of the reduction, the physician's actual charge is subject to a limit under section 1842(j)(1)(D).

(m)(1) In the case of physicians' services furnished in a year to an individual, who is covered under the insurance program established by this part and who incurs expenses for such services, in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area as identified by the Secretary prior to the beginning of such year, in addition to the amount otherwise paid under this part, there also shall be paid to the physician (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance

Trust Fund an amount equal to 10 percent of the payment amount for the service under this part.

(2) For each health professional shortage area identified in paragraph (1) that consists of an entire county, the Secretary shall provide for the additional payment under paragraph (1) without any requirement on the physician to identify the health professional shortage area involved. The Secretary may implement the previous sentence using the method specified in subsection (u)(4)(C).

(3) The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a list of the health professional shortage areas identified in paragraph (1) that consist of a partial county to facilitate the additional payment under paragraph (1) in such areas.

(4) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, respecting—

(A) the identification of a county or area;

(B) the assignment of a specialty of any physician under this paragraph;

(C) the assignment of a physician to a county under this subsection; or

(D) the assignment of a postal ZIP Code to a county or other area under this subsection.

(n)(1)(A) The aggregate amount of the payments to be made for all or part of a cost reporting period for services described in subsection (a)(2)(E)(i) furnished under this part on or after October 1, 1988, and before January 1, 1999, and for services described in subsection (a)(2)(E)(ii) furnished under this part on or after October 1, 1989, and before January 1, 1999, shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B), or

(ii) the blend amount for radiology services and diagnostic procedures determined in accordance with subparagraph (B).

(B)(i) The blend amount for radiology services and diagnostic procedures for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)) of the amount described in subparagraph (A)(i); and

(II) the charge proportion (as defined in clause (ii)(II)) of 62 percent (for services described in subsection (a)(2)(E)(i)), or (for procedures described in subsection (a)(2)(E)(ii)), 42 percent or such other percent established by the Secretary (or carriers acting pursuant to guidelines issued by the Secretary) based on prevailing charges established with actual charge data, of the prevailing charge or (for services described in subsection (a)(2)(E)(i) furnished on or after January 1, 1989) the fee schedule amount established for participating physicians for the same services as if they were furnished in a physician's office in the same locality as determined under section 1842(b), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A).

(ii) In this subparagraph:

(I) The term "cost proportion" means 50 percent, except that such term means 65 percent in the case of outpatient radiology services for portions of cost reporting periods which occur in fiscal year 1989 and in the case of diagnostic procedures de-

scribed in subsection (a)(2)(E)(ii) for portions of cost reporting periods which occur in fiscal year 1990, and such term means 42 percent in the case of outpatient radiology services for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term "charge proportion" means 100 percent minus the cost proportion.

(o)(1) In the case of shoes described in section 1861(s)(12)—

(A) no payment may be made under this part, with respect to any individual for any year, for the furnishing of—

(i) more than one pair of custom molded shoes (including inserts provided with such shoes) and 2 additional pairs of inserts for such shoes, or

(ii) more than one pair of extra-depth shoes (not including inserts provided with such shoes) and 3 pairs of inserts for such shoes, and

(B) with respect to expenses incurred in any calendar year, no more than the amount of payment applicable under paragraph (2) shall be considered as incurred expenses for purposes of subsections (a) and (b).

Payment for shoes (or inserts) under this part shall be considered to include payment for any expenses for the fitting of such shoes (or inserts).

(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra-depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1834(h).

(B) The Secretary may establish payment amounts for shoes and inserts that are lower than the amount established under section 1834(h) if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

(C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1861(s)(12) may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1834(h), a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.

(3) In this title, the term "shoes" includes, except for purposes of subparagraphs (A)(ii) and (B) of paragraph (2), inserts for extra-depth shoes.

(q)(1) Each request for payment, or bill submitted, for an item or service furnished by an entity for which payment may be made under this part and for which the entity knows or has reason to believe there has been a referral by a referring physician (within the meaning of section 1877) shall include the name and unique physician identification number for the referring physician.

(2)(A) In the case of a request for payment for an item or service furnished by an entity under this part on an assignment-related basis and for which information is required to be provided under

paragraph (1) but not included, payment may be denied under this part.

(B) In the case of a request for payment for an item or service furnished by an entity under this part not submitted on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included—

(i) if the entity knowingly and willfully fails to provide such information promptly upon request of the Secretary or a carrier, the entity may be subject to a civil money penalty in an amount not to exceed $2,000, and

(ii) if the entity knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection to provide the information required under paragraph (1), the entity may be subject to exclusion from participation in the programs under this Act for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1128.

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under clause (i) in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(r)(1) With respect to services described in section 1861(s)(2)(K)(ii) (relating to nurse practitioner or clinical nurse specialist services), payment may be made on the basis of a claim or request for payment presented by the nurse practitioner or clinical nurse specialist furnishing such services, or by a hospital, critical access hospital, skilled nursing facility or nursing facility (as defined in section 1919(a)), physician, group practice, or ambulatory surgical center with which the nurse practitioner or clinical nurse specialist has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, physician, group practice, or ambulatory surgical center.

(2) No hospital or critical access hospital that presents a claim or request for payment under this part for services described in section 1861(s)(2)(K)(ii) may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital for purposes of this title.

(s) The Secretary may not provide for payment under subsection (a)(1)(A) with respect to an organization unless the organization provides assurances satisfactory to the Secretary that the organization meets the requirement of section 1866(f) (relating to maintaining written policies and procedures respecting advance directives).

(t) PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.—

(1) AMOUNT OF PAYMENT.—

(A) IN GENERAL.—With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.

(B) DEFINITION OF COVERED OPD SERVICES.—For purposes of this subsection, the term "covered OPD services"—

(i) means hospital outpatient services designated by the Secretary;

(ii) subject to clause (iv), includes inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (I) is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (II) is not so entitled;

(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1861(s);

(iv) does not include any therapy services described in subsection (a)(8) or ambulance services, for which payment is made under a fee schedule described in section 1834(k) or section 1834(l) and does not include screening mammography (as defined in section 1861(jj)), diagnostic mammography, or personalized prevention plan services (as defined in section 1861(hhh)(1)); and

(v) does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph).

(2) SYSTEM REQUIREMENTS.—Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

For purposes of subparagraph (B), items and services within a group shall not be treated as "comparable with respect to the use of resources" if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the group; except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.

(3) CALCULATION OF BASE AMOUNTS.—

(A) AGGREGATE AMOUNTS THAT WOULD BE PAYABLE IF DEDUCTIBLES WERE DISREGARDED.—The Secretary shall estimate the sum of—

(i) the total amounts that would be payable from the Trust Fund under this part for covered OPD services in 1999, determined without regard to this subsection, as though the deductible under section 1833(b) did not apply, and

(ii) the total amounts of copayments estimated to be paid under this subsection by beneficiaries to hospitals for covered OPD services in 1999, as though the deductible under section 1833(b) did not apply.

(B) UNADJUSTED COPAYMENT AMOUNT.—

(i) IN GENERAL.—For purposes of this subsection, subject to clause (ii), the "unadjusted copayment amount" applicable to a covered OPD service (or group of such services) is 20 percent of the national median of the charges for the service (or services within the group) furnished during 1996, updated to 1999 using the Secretary's estimate of charge growth during the period.

(ii) ADJUSTED TO BE 20 PERCENT WHEN FULLY PHASED IN.—If the pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year would be equal to or exceed 80

percent, then the unadjusted copayment amount shall be 20 percent of amount determined under subparagraph (D).

(iii) RULES FOR NEW SERVICES.—The Secretary shall establish rules for establishment of an unadjusted copayment amount for a covered OPD service not furnished during 1996, based upon its classification within a group of such services.

(C) CALCULATION OF CONVERSION FACTORS.—

(i) FOR 1999.—

(I) IN GENERAL.—The Secretary shall establish a 1999 conversion factor for determining the medicare OPD fee schedule amounts for each covered OPD service (or group of such services) furnished in 1999. Such conversion factor shall be established on the basis of the weights and frequencies described in paragraph (2)(C) and in such a manner that the sum for all services and groups of the products (described in subclause (II) for each such service or group) equals the total projected amount described in subparagraph (A).

(II) PRODUCT DESCRIBED.—The Secretary shall determine for each service or group the product of the medicare OPD fee schedule amounts (taking into account appropriate adjustments described in paragraphs (2)(D) and (2)(E)) and the estimated frequencies for such service or group.

(ii) SUBSEQUENT YEARS.—Subject to paragraph (8)(B), the Secretary shall establish a conversion factor for covered OPD services furnished in subsequent years in an amount equal to the conversion factor established under this subparagraph and applicable to such services furnished in the previous year increased by the OPD fee schedule increase factor specified under clause (iv) for the year involved.

(iii) ADJUSTMENT FOR SERVICE MIX CHANGES.—Insofar as the Secretary determines that the adjustments for service mix under paragraph (2) for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments under this subsection during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service mix, the Secretary may adjust the conversion factor computed under this subparagraph for subsequent years so as to eliminate the effect of such coding or classification changes.

(iv) OPD FEE SCHEDULE INCREASE FACTOR.—For purposes of this subparagraph, subject to paragraph (17) and subparagraph (F) of this paragraph, the "OPD fee schedule increase factor" for services furnished in a year is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such fac-

tor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.

(D) CALCULATION OF MEDICARE OPD FEE SCHEDULE AMOUNTS.—The Secretary shall compute a medicare OPD fee schedule amount for each covered OPD service (or group of such services) furnished in a year, in an amount equal to the product of—

(i) the conversion factor computed under subparagraph (C) for the year, and

(ii) the relative payment weight (determined under paragraph (2)(C)) for the service or group.

(E) PRE-DEDUCTIBLE PAYMENT PERCENTAGE.—The pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year is equal to the ratio of—

(i) the medicare OPD fee schedule amount established under subparagraph (D) for the year, minus the unadjusted copayment amount determined under subparagraph (B) for the service or group, to

(ii) the medicare OPD fee schedule amount determined under subparagraph (D) for the year for such service or group.

(F) PRODUCTIVITY AND OTHER ADJUSTMENT.—After determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor—

(i) for 2012 and subsequent years, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(ii) for each of 2010 through 2019, by the adjustment described in subparagraph (G).

The application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment rates under the payment system under this subsection for a year being less than such payment rates for the preceding year.

(G) OTHER ADJUSTMENT.—For purposes of subparagraph (F)(ii), the adjustment described in this subparagraph is—

(i) for each of 2010 and 2011, 0.25 percentage point;

(ii) for each of 2012 and 2013, 0.1 percentage point;

(iii) for 2014, 0.3 percentage point;

(iv) for each of 2015 and 2016, 0.2 percentage point; and

(v) for each of 2017, 2018, and 2019, 0.75 percentage point.

(H) PART B REBATABLE DRUGS.—In the case of a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) furnished on or after July 1, 2021, under the sys-

tem under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1834(x)(5), paragraph (1)(DD) of subsection (a), and the flush left matter following paragraph (9) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1834(x)(5) and subsection (a) apply under such section and subsection.

(4) MEDICARE PAYMENT AMOUNT.—The amount of payment made from the Trust Fund under this part for a covered OPD service (and such services classified within a group) furnished in a year is determined, subject to paragraph (7), as follows:

(A) FEE SCHEDULE ADJUSTMENTS.—The medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).

(B) SUBTRACT APPLICABLE DEDUCTIBLE.—Reduce the adjusted amount determined under subparagraph (A) by the amount of the deductible under section 1833(b), to the extent applicable.

(C) APPLY PAYMENT PROPORTION TO REMAINDER.—The amount of payment is the amount so determined under subparagraph (B) multiplied by the pre-deductible payment percentage (as determined under paragraph (3)(E)) for the service or group and year involved, plus the amount of any reduction in the copayment amount attributable to paragraph (8)(C).

(5) OUTLIER ADJUSTMENT.—

(A) IN GENERAL.—Subject to subparagraph (D), the Secretary shall provide for an additional payment for each covered OPD service (or group of services) for which a hospital's charges, adjusted to cost, exceed—

(i) a fixed multiple of the sum of—

(I) the applicable medicare OPD fee schedule amount determined under paragraph (3)(D), as adjusted under paragraph (4)(A) (other than for adjustments under this paragraph or paragraph (6)); and

(II) any transitional pass-through payment under paragraph (6); and

(ii) at the option of the Secretary, such fixed dollar amount as the Secretary may establish.

(B) AMOUNT OF ADJUSTMENT.—The amount of the additional payment under subparagraph (A) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the applicable cutoff point under such subparagraph.

(C) LIMIT ON AGGREGATE OUTLIER ADJUSTMENTS.—

(i) IN GENERAL.—The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not ex-

ceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term "applicable percentage" means a percentage specified by the Secretary up to (but not to exceed)—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, 3.0 percent.

(D) TRANSITIONAL AUTHORITY.—In applying subparagraph (A) for covered OPD services furnished before January 1, 2002, the Secretary may—

(i) apply such subparagraph to a bill for such services related to an outpatient encounter (rather than for a specific service or group of services) using OPD fee schedule amounts and transitional pass-through payments covered under the bill; and

(ii) use an appropriate cost-to-charge ratio for the hospital involved (as determined by the Secretary), rather than for specific departments within the hospital.

(E) EXCLUSION OF SEPARATE DRUG AND BIOLOGICAL APCS FROM OUTLIER PAYMENTS.—No additional payment shall be made under subparagraph (A) in the case of ambulatory payment classification groups established separately for drugs or biologicals.

(6) TRANSITIONAL PASS-THROUGH FOR ADDITIONAL COSTS OF INNOVATIVE MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—

(A) IN GENERAL.—The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):

(i) CURRENT ORPHAN DRUGS.—A drug or biological that is used for a rare disease or condition with respect to which the drug or biological has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this subsection is implemented.

(ii) CURRENT CANCER THERAPY DRUGS AND BIOLOGICALS AND BRACHYTHERAPY.—A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy or temperature monitored cryoablation, if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.

(iii) CURRENT RADIOPHARMACEUTICAL DRUGS AND BIOLOGICAL PRODUCTS.—A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part was being made on such first date.

(iv) NEW MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—A medical device, drug, or biological not described in clause (i), (ii), or (iii) if—

(I) payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and

(II) the cost of the drug or biological or the average cost of the category of devices is not insignificant in relation to the OPD fee schedule amount (as calculated under paragraph (3)(D)) payable for the service (or group of services) involved.

(B) USE OF CATEGORIES IN DETERMINING ELIGIBILITY OF A DEVICE FOR PASS-THROUGH PAYMENTS.—The following provisions apply for purposes of determining whether a medical device qualifies for additional payments under clause (ii) or (iv) of subparagraph (A):

(i) ESTABLISHMENT OF INITIAL CATEGORIES.—

(I) IN GENERAL.—The Secretary shall initially establish under this clause categories of medical devices based on type of device by April 1, 2001. Such categories shall be established in a manner such that each medical device that meets the requirements of clause (ii) or (iv) of subparagraph (A) as of January 1, 2001, is included in such a category and no such device is included in more than one category. For purposes of the preceding sentence, whether a medical device meets such requirements as of such date shall be determined on the basis of the program memoranda issued before such date.

(II) AUTHORIZATION OF IMPLEMENTATION OTHER THAN THROUGH REGULATIONS.—The categories may be established under this clause by program memorandum or otherwise, after consultation with groups representing hospitals, manufacturers of medical devices, and other affected parties.

(ii) ESTABLISHING CRITERIA FOR ADDITIONAL CATEGORIES.—

(I) IN GENERAL.—The Secretary shall establish criteria that will be used for creation of additional categories (other than those established under clause (i)) through rulemaking (which may include use of an interim final rule with comment period).

(II) STANDARD.—Such categories shall be established under this clause in a manner such that no medical device is described by more than one category. Such criteria shall include a test of whether the average cost of devices that would be included

in a category and are in use at the time the category is established is not insignificant, as described in subparagraph (A)(iv)(II).

(III) DEADLINE.—Criteria shall first be established under this clause by July 1, 2001. The Secretary may establish in compelling circumstances categories under this clause before the date such criteria are established.

(IV) ADDING CATEGORIES.—The Secretary shall promptly establish a new category of medical devices under this clause for any medical device that meets the requirements of subparagraph (A)(iv) and for which none of the categories in effect (or that were previously in effect) is appropriate.

(iii) PERIOD FOR WHICH CATEGORY IS IN EFFECT.—A category of medical devices established under clause (i) or (ii) shall be in effect for a period of at least 2 years, but not more than 3 years, that begins—

(I) in the case of a category established under clause (i), on the first date on which payment was made under this paragraph for any device described by such category (including payments made during the period before April 1, 2001); and

(II) in the case of any other category, on the first date on which payment is made under this paragraph for any medical device that is described by such category.

(iv) REQUIREMENTS TREATED AS MET.—A medical device shall be treated as meeting the requirements of subparagraph (A)(iv), regardless of whether the device meets the requirement of subclause (I) of such subparagraph, if—

(I) the device is described by a category established and in effect under clause (i); or

(II) the device is described by a category established and in effect under clause (ii) and an application under section 515 of the Federal Food, Drug, and Cosmetic Act has been approved with respect to the device, or the device has been cleared for market under section 510(k) of such Act, or the device is exempt from the requirements of section 510(k) of such Act pursuant to subsection (l) or (m) of section 510 of such Act or section 520(g) of such Act.

Nothing in this clause shall be construed as requiring an application or prior approval (other than that described in subclause (II)) in order for a covered device described by a category to qualify for payment under this paragraph.

(C) LIMITED PERIOD OF PAYMENT.—

(i) DRUGS AND BIOLOGICALS.—Subject to subparagraph (G), the payment under this paragraph with respect to a drug or biological shall only apply during a period of at least 2 years, but not more than 3 years, that begins—

(I) on the first date this subsection is implemented in the case of a drug or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug or biological described in subparagraph (A)(iv) and for which payment under this part is made as an outpatient hospital service before such first date; or

(II) in the case of a drug or biological described in subparagraph (A)(iv) not described in subclause (I), on the first date on which payment is made under this part for the drug or biological as an outpatient hospital service.

(ii) MEDICAL DEVICES.—Payment shall be made under this paragraph with respect to a medical device only if such device—

(I) is described by a category of medical devices established and in effect under subparagraph (B); and

(II) is provided as part of a service (or group of services) paid for under this subsection and provided during the period for which such category is in effect under such subparagraph.

(D) AMOUNT OF ADDITIONAL PAYMENT.—Subject to subparagraph (E)(iii), the amount of the payment under this paragraph with respect to a device, drug, or biological provided as part of a covered OPD service is—

(i) subject to subparagraph (H), in the case of a drug or biological, the amount by which the amount determined under section 1842(o) (or if the drug or biological is covered under a competitive acquisition contract under section 1847B, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph) for the drug or biological exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

(ii) in the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the device.

(E) LIMIT ON AGGREGATE ANNUAL ADJUSTMENT.—

(i) IN GENERAL.—The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall

apply only to the portion of such year. This clause shall not apply for 2018.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term "applicable percentage" means—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

(iii) UNIFORM PROSPECTIVE REDUCTION IF AGGREGATE LIMIT PROJECTED TO BE EXCEEDED.—If the Secretary estimates before the beginning of a year that the amount of the additional payments under this paragraph for the year (or portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause, the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed such limit.

(F) LIMITATION OF APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.—

(i) IN GENERAL.—The Secretary may not publish regulations that apply a functional equivalence standard to a drug or biological under this paragraph.

(ii) APPLICATION.—Clause (i) shall apply to the application of a functional equivalence standard to a drug or biological on or after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 unless—

(I) such application was being made to such drug or biological prior to such date of enactment; and

(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this title.

(iii) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to effect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.

(G) PASS-THROUGH EXTENSION FOR CERTAIN DRUGS AND BIOLOGICALS.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, such pass-through status shall be extended for a 2-year period beginning on October 1, 2018.

(H) TEMPORARY PAYMENT RULE FOR CERTAIN DRUGS AND BIOLOGICALS.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, the payment amount for such drug or biological under this subsection that is furnished during the period beginning on October 1, 2018, and ending on March 31, 2019, shall be the greater of—

(i) the payment amount that would otherwise apply under subparagraph (D)(i) for such drug or biological during such period; or

(ii) the payment amount that applied under such subparagraph (D)(i) for such drug or biological on December 31, 2017.

(I) SPECIAL PAYMENT ADJUSTMENT RULES FOR LAST QUARTER OF 2018.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment amount for a covered OPD service (or group of services) beginning January 1, 2018, the following rules shall apply with respect to payment amounts under this subsection for covered a OPD service (or group of services) furnished during the period beginning on October 1, 2018, and ending on December 31, 2018:

(i) The Secretary shall remove the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged.

(ii) The Secretary shall not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (i).

(7) TRANSITIONAL ADJUSTMENT TO LIMIT DECLINE IN PAYMENT.—

(A) BEFORE 2002.—Subject to subparagraph (D), for covered OPD services furnished before January 1, 2002, for which the PPS amount (as defined in subparagraph (E)) is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in subparagraph (F)), the amount of payment under this subsection shall be increased by 80 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.71 and the pre-BBA amount, exceeds (II) the product of 0.70 and the PPS amount;

(iii) at least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by

which (I) the product of 0.63 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iv) less than 70 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 21 percent of the pre-BBA amount.

(B) 2002.—Subject to subparagraph (D), for covered OPD services furnished during 2002, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 70 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.61 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iii) less than 80 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 13 percent of the pre-BBA amount.

(C) 2003.—Subject to subparagraph (D), for covered OPD services furnished during 2003, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 60 percent of the amount of such difference; or

(ii) less than 90 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 6 percent of the pre-BBA amount.

(D) HOLD HARMLESS PROVISIONS.—

(i) TEMPORARY TREATMENT FOR CERTAIN RURAL HOSPITALS.—(I) In the case of a hospital located in a rural area and that has not more than 100 beds or a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) located in a rural area, for covered OPD services furnished before January 1, 2006, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(II) In the case of a hospital located in a rural area and that has not more than 100 beds and that is not a sole community hospital (as defined in section 1886(d)(5)(D)(iii)), for covered OPD services furnished on or after January 1, 2006, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the applicable percentage of the amount of such difference. For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to

such services furnished in 2008, 2009, 2010, 2011, or 2012.

(III) In the case of a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) that has not more than 100 beds, for covered OPD services furnished on or after January 1, 2009, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by 85 percent of the amount of such difference. In the case of covered OPD services furnished on or after January 1, 2010, and before March 1, 2012, the preceding sentence shall be applied without regard to the 100-bed limitation.

(ii) PERMANENT TREATMENT FOR CANCER HOSPITALS AND CHILDREN'S HOSPITALS.—In the case of a hospital described in clause (iii) or (v) of section 1886(d)(1)(B), for covered OPD services for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(E) PPS AMOUNT DEFINED.—In this paragraph, the term "PPS amount" means, with respect to covered OPD services, the amount payable under this title for such services (determined without regard to this paragraph), including amounts payable as copayment under paragraph (8), coinsurance under section 1866(a)(2)(A)(ii), and the deductible under section 1833(b).

(F) PRE-BBA AMOUNT DEFINED.—

(i) IN GENERAL.—In this paragraph, the "pre-BBA amount" means, with respect to covered OPD services furnished by a hospital in a year, an amount equal to the product of the reasonable cost of the hospital for such services for the portions of the hospital's cost reporting period (or periods) occurring in the year and the base OPD payment-to-cost ratio for the hospital (as defined in clause (ii)).

(ii) BASE PAYMENT-TO-COST-RATIO DEFINED.—For purposes of this subparagraph, the "base payment-to-cost ratio" for a hospital means the ratio of—

(I) the hospital's reimbursement under this part for covered OPD services furnished during the cost reporting period ending in 1996 (or in the case of a hospital that did not submit a cost report for such period, during the first subsequent cost reporting period ending before 2001 for which the hospital submitted a cost report), including any reimbursement for such services through cost-sharing described in subparagraph (E), to

(II) the reasonable cost of such services for such period.

The Secretary shall determine such ratios as if the amendments made by section 4521 of the Balanced Budget Act of 1997 were in effect in 1996.

(G) INTERIM PAYMENTS.—The Secretary shall make payments under this paragraph to hospitals on an interim

basis, subject to retrospective adjustments based on settled cost reports.

(H) NO EFFECT ON COPAYMENTS.—Nothing in this paragraph shall be construed to affect the unadjusted copayment amount described in paragraph (3)(B) or the copayment amount under paragraph (8).

(I) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The additional payments made under this paragraph—

(i) shall not be considered an adjustment under paragraph (2)(E); and

(ii) shall not be implemented in a budget neutral manner.

(8) COPAYMENT AMOUNT.—

(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), the copayment amount under this subsection is the amount by which the amount described in paragraph (4)(B) exceeds the amount of payment determined under paragraph (4)(C).

(B) ELECTION TO OFFER REDUCED COPAYMENT AMOUNT.—The Secretary shall establish a procedure under which a hospital, before the beginning of a year (beginning with 1999), may elect to reduce the copayment amount otherwise established under subparagraph (A) for some or all covered OPD services to an amount that is not less than 20 percent of the medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service involved. Under such procedures, such reduced copayment amount may not be further reduced or increased during the year involved and the hospital may disseminate information on the reduction of copayment amount effected under this subparagraph.

(C) LIMITATION ON COPAYMENT AMOUNT.—

(i) TO INPATIENT HOSPITAL DEDUCTIBLE AMOUNT.—In no case shall the copayment amount for a procedure performed in a year exceed the amount of the inpatient hospital deductible established under section 1813(b) for that year.

(ii) TO SPECIFIED PERCENTAGE.—The Secretary shall reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed the following percentage:

(I) For procedures performed in 2001, on or after April 1, 2001, 57 percent.

(II) For procedures performed in 2002 or 2003, 55 percent.

(III) For procedures performed in 2004, 50 percent.

(IV) For procedures performed in 2005, 45 percent.

(V) For procedures performed in 2006 and thereafter, 40 percent.

(D) NO IMPACT ON DEDUCTIBLES.—Nothing in this paragraph shall be construed as affecting a hospital's authority to waive the charging of a deductible under section 1833(b).

(E) COMPUTATION IGNORING OUTLIER AND PASS-THROUGH ADJUSTMENTS.—The copayment amount shall be computed under subparagraph (A) as if the adjustments under paragraphs (5) and (6) (and any adjustment made under paragraph (2)(E) in relation to such adjustments) had not occurred.

(9) PERIODIC REVIEW AND ADJUSTMENTS COMPONENTS OF PROSPECTIVE PAYMENT SYSTEM.—

(A) PERIODIC REVIEW.—The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) BUDGET NEUTRALITY ADJUSTMENT.—If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

(C) UPDATE FACTOR.—If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

(10) SPECIAL RULE FOR AMBULANCE SERVICES.—The Secretary shall pay for hospital outpatient services that are ambulance services on the basis described in section 1861(v)(1)(U), or, if applicable, the fee schedule established under section 1834(l).

(11) SPECIAL RULES FOR CERTAIN HOSPITALS.—In the case of hospitals described in clause (iii) or (v) of section 1886(d)(1)(B)—

(A) the system under this subsection shall not apply to covered OPD services furnished before January 1, 2000; and

(B) the Secretary may establish a separate conversion factor for such services in a manner that specifically takes into account the unique costs incurred by such hospitals by virtue of their patient population and service intensity.

(12) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise of—

(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

(13) AUTHORIZATION OF ADJUSTMENT FOR RURAL HOSPITALS.—

(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals located in rural areas by ambulatory payment classification groups (APCs) exceed those costs incurred by hospitals located in urban areas.

(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.

(14) DRUG APC PAYMENT RATES.—

(A) IN GENERAL.—The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

(i) in 2004, in the case of—

(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

(ii) in 2005, in the case of—

(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

(iii) in a subsequent year, shall be equal, subject to subparagraph (E)—

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

(B) SPECIFIED COVERED OUTPATIENT DRUG DEFINED.—

(i) IN GENERAL.—In this paragraph, the term "specified covered outpatient drug" means, subject to clause (ii), a covered outpatient drug (as defined in section 1927(k)(2)) for which a separate ambulatory payment classification group (APC) has been established and that is—

(I) a radiopharmaceutical; or

(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

(ii) EXCEPTION.—Such term does not include—

(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

(C) PAYMENT FOR DESIGNATED ORPHAN DRUGS DURING 2004 AND 2005.—The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B)(ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

(D) ACQUISITION COST SURVEY FOR HOSPITAL OUTPATIENT DRUGS.—

(i) ANNUAL GAO SURVEYS IN 2004 AND 2005.—

(I) IN GENERAL.—The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General shall furnish data from such surveys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

(II) RECOMMENDATIONS.—Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii).

(ii) SUBSEQUENT SECRETARIAL SURVEYS.—The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph (A).

(iii) SURVEY REQUIREMENTS.—The surveys conducted under clauses (i) and (ii) shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the justification for the size of the sample used in order to assure the validity of such estimates.

(iv) DIFFERENTIATION IN COST.—In conducting surveys under clause (i), the Comptroller General shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

(v) COMMENT ON PROPOSED RATES.—Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates based on the surveys the Comptroller General has conducted under clause (i).

(E) ADJUSTMENT IN PAYMENT RATES FOR OVERHEAD COSTS.—

(i) MEDPAC REPORT ON DRUG APC DESIGN.—The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

(I) a description and analysis of the data available with regard to such expenses;

(II) a recommendation as to whether such a payment adjustment should be made; and

(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

(ii) ADJUSTMENT AUTHORIZED.—The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i).

(F) CLASSES OF DRUGS.—For purposes of this paragraph:

(i) SOLE SOURCE DRUGS.—The term "sole source drug" means—

(I) a biological product (as defined under section 1861(t)(1)); or

(II) a single source drug (as defined in section 1927(k)(7)(A)(iv)).

(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—The term "innovator multiple source drug" has the meaning given such term in section 1927(k)(7)(A)(ii).

(iii) NONINNOVATOR MULTIPLE SOURCE DRUGS.—The term "noninnovator multiple source drug" has the meaning given such term in section 1927(k)(7)(A)(iii).

(G) REFERENCE AVERAGE WHOLESALE PRICE.—The term "reference average wholesale price" means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1842(o) as of May 1, 2003.

(H) INAPPLICABILITY OF EXPENDITURES IN DETERMINING CONVERSION, WEIGHTING, AND OTHER ADJUSTMENT FACTORS.—Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.

(15) PAYMENT FOR NEW DRUGS AND BIOLOGICALS UNTIL HCPCS CODE ASSIGNED.—With respect to payment under this part for an outpatient drug or biological that is covered under this part and is furnished as part of covered OPD services for which a HCPCS code has not been assigned, the amount provided for payment for such drug or biological under this part shall be equal to 95 percent of the average wholesale price for the drug or biological.

(16) MISCELLANEOUS PROVISIONS.—

(A) APPLICATION OF RECLASSIFICATION OF CERTAIN HOSPITALS.—If a hospital is being treated as being located in a rural area under section 1886(d)(8)(E), that hospital shall be treated under this subsection as being located in that rural area.

(B) THRESHOLD FOR ESTABLISHMENT OF SEPARATE APCS FOR DRUGS.—The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs or biologicals

to $50 per administration for drugs and biologicals furnished in 2005 and 2006.

(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY AND THERAPEUTIC RADIOPHARMACEUTICALS AT CHARGES ADJUSTED TO COST.—Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before January 1, 2010, and for therapeutic radiopharmaceuticals furnished on or after January 1, 2008, and before January 1, 2010, the payment basis for the device or therapeutic radiopharmaceutical under this subsection shall be equal to the hospital's charges for each device or therapeutic radiopharmaceutical furnished, adjusted to cost. Charges for such devices or therapeutic radiopharmaceuticals shall not be included in determining any outlier payment under this subsection.

(D) SPECIAL PAYMENT RULE.—

(i) IN GENERAL.—In the case of covered OPD services furnished on or after April 1, 2013, in a hospital described in clause (ii), if—

(I) the payment rate that would otherwise apply under this subsection for stereotactic radiosurgery, complete course of treatment of cranial lesion(s) consisting of 1 session that is multisource Cobalt 60 based (identified as of January 1, 2013, by HCPCS code 77371 (and any succeeding code) and reimbursed as of such date under APC 0127 (and any succeeding classification group)); exceeds

(II) the payment rate that would otherwise apply under this subsection for linear accelerator based stereotactic radiosurgery, complete course of therapy in one session (identified as of January 1, 2013, by HCPCS code G0173 (and any succeeding code) and reimbursed as of such date under APC 0067 (and any succeeding classification group)),

the payment rate for the service described in subclause (I) shall be reduced to an amount equal to the payment rate for the service described in subclause (II).

(ii) HOSPITAL DESCRIBED.—A hospital described in this clause is a hospital that is not—

(I) located in a rural area (as defined in section 1886(d)(2)(D));

(II) classified as a rural referral center under section 1886(d)(5)(C); or

(III) a sole community hospital (as defined in section 1886(d)(5)(D)(iii)).

(iii) NOT BUDGET NEUTRAL.—In making any budget neutrality adjustments under this subsection for 2013 (with respect to covered OPD services furnished on or after April 1, 2013, and before January 1, 2014) or a subsequent year, the Secretary shall not take into ac-

count the reduced expenditures that result from the application of this subparagraph.

(E) APPLICATION OF APPROPRIATE USE CRITERIA FOR CERTAIN IMAGING SERVICES.—For provisions relating to the application of appropriate use criteria for certain imaging services, see section 1834(q).

(F) PAYMENT INCENTIVE FOR THE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY.—Notwithstanding the previous provisions of this subsection:

(i) LIMITATION ON PAYMENT FOR FILM X-RAY IMAGING SERVICES.—In the case of an imaging service that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 20 percent.

(ii) PHASED-IN LIMITATION ON PAYMENT FOR COMPUTED RADIOGRAPHY IMAGING SERVICES.—In the case of an imaging service that is an X-ray taken using computed radiography technology (as defined in section 1848(b)(9)(C))—

(I) in the case of such a service furnished during 2018, 2019, 2020, 2021, or 2022, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 7 percent; and

(II) in the case of such a service furnished during 2023 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 10 percent.

(iii) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The reductions made under this subparagraph—

(I) shall not be considered an adjustment under paragraph (2)(E); and

(II) shall not be implemented in a budget neutral manner.

(iv) IMPLEMENTATION.—In order to implement this subparagraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.

(17) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—For purposes of paragraph (3)(C)(iv) for 2009 and each subsequent year, in the case of a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to such a year, the OPD fee schedule increase factor under paragraph (3)(C)(iv) for such year shall be reduced by 2.0 percentage points.

(ii) NON-CUMULATIVE APPLICATION.—A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing the OPD fee schedule increase factor for a subsequent year.

(B) FORM AND MANNER OF SUBMISSION.—Each subsection (d) hospital shall submit data on measures selected under this paragraph to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this paragraph.

(C) DEVELOPMENT OF OUTPATIENT MEASURES.—

(i) IN GENERAL.—The Secretary shall develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(ii) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the Secretary from selecting measures that are the same as (or a subset of) the measures for which data are required to be submitted under section 1886(b)(3)(B)(viii).

(D) REPLACEMENT OF MEASURES.—For purposes of this paragraph, the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(E) AVAILABILITY OF DATA.—The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(18) AUTHORIZATION OF ADJUSTMENT FOR CANCER HOSPITALS.—

(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals described in section 1886(d)(1)(B)(v)

with respect to ambulatory payment classification groups exceed those costs incurred by other hospitals furnishing services under this subsection (as determined appropriate by the Secretary). In conducting the study under this subparagraph, the Secretary shall take into consideration the cost of drugs and biologicals incurred by such hospitals.

(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals described in section 1886(d)(1)(B)(v) exceed those costs incurred by other hospitals furnishing services under this subsection, the Secretary shall, subject to subparagraph (C), provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.

(C) TARGET PCR ADJUSTMENT.—In applying section 419.43(i) of title 42 of the Code of Federal Regulations to implement the appropriate adjustment under this paragraph for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage points less than the target PCR that would otherwise apply. In addition to the percentage point reduction under the previous sentence, the Secretary may consider making an additional percentage point reduction to such target PCR that takes into account payment rates for applicable items and services described in paragraph (21)(C) other than for services furnished by hospitals described in section 1886(d)(1)(B)(v). In making any budget neutrality adjustments under this subsection for 2018 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(19) FLOOR ON AREA WAGE ADJUSTMENT FACTOR FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES IN FRONTIER STATES.—

(A) IN GENERAL.—Subject to subparagraph (B), with respect to covered OPD services furnished on or after January 1, 2011, the area wage adjustment factor applicable under the payment system established under this subsection to any hospital outpatient department which is located in a frontier State (as defined in section 1886(d)(3)(E)(iii)(II)) may not be less than 1.00. The preceding sentence shall not be applied in a budget neutral manner.

(B) LIMITATION.—This paragraph shall not apply to any hospital outpatient department located in a State that receives a non-labor related share adjustment under section 1886(d)(5)(H).

(20) NOT BUDGET NEUTRAL APPLICATION OF REDUCED EXPENDITURES RESULTING FROM QUALITY INCENTIVES FOR COMPUTED TOMOGRAPHY.—The Secretary shall not take into account the reduced expenditures that result from the application of section 1834(p) in making any budget neutrality adjustments this subsection.

(21) SERVICES FURNISHED BY AN OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.—

(A) APPLICABLE ITEMS AND SERVICES.—For purposes of paragraph (1)(B)(v) and this paragraph, the term "applicable items and services" means items and services other than items and services furnished by a dedicated emergency department (as defined in section 489.24(b) of title 42 of the Code of Federal Regulations).

(B) OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.—

(i) IN GENERAL.—For purposes of paragraph (1)(B)(v) and this paragraph, subject to the subsequent provisions of this subparagraph, the term "off-campus outpatient department of a provider" means a department of a provider (as defined in section 413.65(a)(2) of title 42 of the Code of Federal Regulations, as in effect as of the date of the enactment of this paragraph) that is not located—

(I) on the campus (as defined in such section 413.65(a)(2)) of such provider; or

(II) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section 413.65(a)(2)).

(ii) EXCEPTION.—For purposes of paragraph (1)(B)(v) and this paragraph, the term "off-campus outpatient department of a provider" shall not include a department of a provider (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to the date of the enactment of this paragraph.

(iii) DEEMED TREATMENT FOR 2017.—For purposes of applying clause (ii) with respect to applicable items and services furnished during 2017, a department of a provider (as so defined) not described in such clause is deemed to be billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015, if the Secretary received from the provider prior to December 2, 2015, an attestation (pursuant to section 413.65(b)(3) of title 42 of the Code of Federal Regulations) that such department was a department of a provider (as so defined).

(iv) ALTERNATIVE EXCEPTION BEGINNING WITH 2018.—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2018 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if—

(I) the Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than December 31, 2016 (or, if later, 60 days after the date of the enactment of this clause), that such department met the requirements of a department of a provider specified in section 413.65 of title 42 of the Code of Federal Regulations;

(II) the provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1866(j); and

(III) the department met the mid-build requirement of clause (v) and the Secretary receives, not later than 60 days after the date of the enactment of this clause, from the chief executive officer or chief operating officer of the provider a written certification that the department met such requirement.

(v) MID-BUILD REQUIREMENT DESCRIBED.—The mid-build requirement of this clause is, with respect to a department of a provider, that before November 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

(vi) EXCLUSION FOR CERTAIN CANCER HOSPITALS.—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2017 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if the provider is a hospital described in section 1886(d)(1)(B)(v) and—

(I) in the case of a department that met the requirements of section 413.65 of title 42 of the Code of Federal Regulations after November 1, 2015, and before the date of the enactment of this clause, the Secretary receives from the provider an attestation that such department met such requirements not later than 60 days after such date of enactment; or

(II) in the case of a department that meets such requirements after such date of enactment, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.

(vii) AUDIT.—Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance with such requirements with respect to the department. If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the department shall not be excluded from the term "off-

campus outpatient department of a provider" under such clause.

(viii) IMPLEMENTATION.—For purposes of implementing clauses (iii) through (vii):

(I) Notwithstanding any other provision of law, the Secretary may implement such clauses by program instruction or otherwise.

(II) Subchapter I of chapter 35 of title 44, United States Code, shall not apply.

(III) For purposes of carrying out this subparagraph with respect to clauses (iii) and (iv) (and clause (vii) insofar as it relates to clause (iv)), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until December 31, 2018. For purposes of carrying out this subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), $2,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until expended.

(C) AVAILABILITY OF PAYMENT UNDER OTHER PAYMENT SYSTEMS.—Payments for applicable items and services furnished by an off-campus outpatient department of a provider that are described in paragraph (1)(B)(v) shall be made under the applicable payment system under this part (other than under this subsection) if the requirements for such payment are otherwise met.

(D) INFORMATION NEEDED FOR IMPLEMENTATION.—Each hospital shall provide to the Secretary such information as the Secretary determines appropriate to implement this paragraph and paragraph (1)(B)(v) (which may include reporting of information on a hospital claim using a code or modifier and reporting information about off-campus outpatient departments of a provider on the enrollment form described in section 1866(j)).

(E) LIMITATIONS.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(i) The determination of the applicable items and services under subparagraph (A) and applicable payment systems under subparagraph (C).

(ii) The determination of whether a department of a provider meets the term described in subparagraph (B).

(iii) Any information that hospitals are required to report pursuant to subparagraph (D).

(iv) The determination of an audit under subparagraph (B)(vii).

(22) REVIEW AND REVISIONS OF PAYMENTS FOR NON-OPIOID ALTERNATIVE TREATMENTS.—

(A) IN GENERAL.—With respect to payments made under this subsection for covered OPD services (or groups of services), including covered OPD services assigned to a com-

prehensive ambulatory payment classification, the Secretary—

(i) shall, as soon as practicable, conduct a review (part of which may include a request for information) of payments for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives;

(ii) may, as the Secretary determines appropriate, conduct subsequent reviews of such payments; and

(iii) shall consider the extent to which revisions under this subsection to such payments (such as the creation of additional groups of covered OPD services to classify separately those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management.

(B) PRIORITY.—In conducting the review under clause (i) of subparagraph (A) and considering revisions under clause (iii) of such subparagraph, the Secretary shall focus on covered OPD services (or groups of services) assigned to a comprehensive ambulatory payment classification, ambulatory payment classifications that primarily include surgical services, and other services determined by the Secretary which generally involve treatment for pain management.

(C) REVISIONS.—If the Secretary identifies revisions to payments pursuant to subparagraph (A)(iii), the Secretary shall, as determined appropriate, begin making such revisions for services furnished on or after January 1, 2020. Revisions under the previous sentence shall be treated as adjustments for purposes of application of paragraph (9)(B).

(D) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed to preclude the Secretary—

(i) from conducting a demonstration before making the revisions described in subparagraph (C); or

(ii) prior to implementation of this paragraph, from changing payments under this subsection for covered OPD services (or groups of services) which include opioids or non-opioid alternatives for pain management.

(u) INCENTIVE PAYMENTS FOR PHYSICIAN SCARCITY AREAS.—

(1) IN GENERAL.—In the case of physicians' services furnished on or after January 1, 2005, and before July 1, 2008—

(A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or

(B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid

an amount equal to 5 percent of the payment amount for the service under this part.

(2) DETERMINATION OF RATIOS OF PHYSICIANS TO MEDICARE BENEFICIARIES IN AREA.—Based upon available data, the Secretary shall establish for each county or equivalent area in the United States, the following:

(A) NUMBER OF PHYSICIANS PRACTICING IN THE AREA.—The number of physicians who furnish physicians' services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are—

(i) primary care physicians; or

(ii) physicians who are not primary care physicians.

(B) NUMBER OF MEDICARE BENEFICIARIES RESIDING IN THE AREA.—The number of individuals who are residing in the county and are entitled to benefits under part A or enrolled under this part, or both (in this subsection referred to as "individuals").

(C) DETERMINATION OF RATIOS.—

(i) PRIMARY CARE RATIO.—The ratio (in this paragraph referred to as the "primary care ratio") of the number of primary care physicians (determined under subparagraph (A)(i)), to the number of individuals determined under subparagraph (B).

(ii) SPECIALIST CARE RATIO.—The ratio (in this paragraph referred to as the "specialist care ratio") of the number of other physicians (determined under subparagraph (A)(ii)), to the number of individuals determined under subparagraph (B).

(3) RANKING OF COUNTIES.—The Secretary shall rank each such county or area based separately on its primary care ratio and its specialist care ratio.

(4) IDENTIFICATION OF COUNTIES.—

(A) IN GENERAL.—The Secretary shall identify—

(i) those counties and areas (in this paragraph referred to as "primary care scarcity counties") with the lowest primary care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph; and

(ii) those counties and areas (in this subsection referred to as "specialist care scarcity counties") with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph.

(B) PERIODIC REVISIONS.—The Secretary shall periodically revise the counties or areas identified in subparagraph (A) (but not less often than once every three years) unless the Secretary determines that there is no new data

available on the number of physicians practicing in the county or area or the number of individuals residing in the county or area, as identified in paragraph (2).

(C) IDENTIFICATION OF COUNTIES WHERE SERVICE IS FURNISHED.—For purposes of paying the additional amount specified in paragraph (1), if the Secretary uses the 5-digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code (as determined by the United States Postal Service, or otherwise) shall be used to determine whether the postal ZIP Code is in a scarcity county identified in subparagraph (A) or revised in subparagraph (B).

(D) SPECIAL RULE.—With respect to physicians' services furnished on or after January 1, 2008, and before July 1, 2008, for purposes of this subsection, the Secretary shall use the primary care scarcity counties and the specialty care scarcity counties (as identified under the preceding provisions of this paragraph) that the Secretary was using under this subsection with respect to physicians' services furnished on December 31, 2007.

(E) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting—

116.(i) the identification of a county or area;

(ii) the assignment of a specialty of any physician under this paragraph;

(iii) the assignment of a physician to a county under paragraph (2); or

(iv) the assignment of a postal ZIP Code to a county or other area under this subsection.

(5) RURAL CENSUS TRACTS.—To the extent feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), as an equivalent area for purposes of qualifying as a primary care scarcity county or specialist care scarcity county under this subsection.

(6) PHYSICIAN DEFINED.—For purposes of this paragraph, the term "physician" means a physician described in section 1861(r)(1) and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

(7) PUBLICATION OF LIST OF COUNTIES; POSTING ON WEBSITE.—With respect to a year for which a county or area is identified or revised under paragraph (4), the Secretary shall identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the applicable year. The Secretary shall post the list of counties identified or revised under paragraph (4) on the Internet website of the Centers for Medicare & Medicaid Services.

(v) INCREASE OF FQHC PAYMENT LIMITS.—In the case of services furnished by Federally qualified health centers (as defined in sec-

tion 1861(aa)(4)), the Secretary shall establish payment limits with respect to such services under this part for services furnished—

(1) in 2010, at the limits otherwise established under this part for such year increased by $5; and

(2) in a subsequent year, at the limits established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year.

(w) METHODS OF PAYMENT.—The Secretary may develop alternative methods of payment for items and services provided under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health and Human Services, as determined by the Secretary, to those that would otherwise apply under this section, to the extent such alternative methods are necessary to preserve the scientific validity of such trials or studies, such as in the case where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design.

(x) INCENTIVE PAYMENTS FOR PRIMARY CARE SERVICES.—

(1) IN GENERAL.—In the case of primary care services furnished on or after January 1, 2011, and before January 1, 2016, by a primary care practitioner, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) DEFINITIONS.—In this subsection:

(A) PRIMARY CARE PRACTITIONER.—The term "primary care practitioner" means an individual—

(i) who—

(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)); and

(ii) for whom primary care services accounted for at least 60 percent of the allowed charges under this part for such physician or practitioner in a prior period as determined appropriate by the Secretary.

(B) PRIMARY CARE SERVICES.—The term "primary care services" means services identified, as of January 1, 2009, by the following HCPCS codes (and as subsequently modified by the Secretary):

(i) 99201 through 99215.

(ii) 99304 through 99340.

(iii) 99341 through 99350.

(3) COORDINATION WITH OTHER PAYMENTS.—The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z) shall be

determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

(4) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the identification of primary care practitioners under this subsection.

(y) INCENTIVE PAYMENTS FOR MAJOR SURGICAL PROCEDURES FURNISHED IN HEALTH PROFESSIONAL SHORTAGE AREAS.—

(1) IN GENERAL.—In the case of major surgical procedures furnished on or after January 1, 2011, and before January 1, 2016, by a general surgeon in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area as identified by the Secretary prior to the beginning of the year involved, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) DEFINITIONS.—In this subsection:

(A) GENERAL SURGEON.—In this subsection, the term "general surgeon" means a physician (as described in section 1861(r)(1)) who has designated CMS specialty code 02–General Surgery as their primary specialty code in the physician's enrollment under section 1866(j).

(B) MAJOR SURGICAL PROCEDURES.—The term "major surgical procedures" means physicians' services which are surgical procedures for which a 10-day or 90-day global period is used for payment under the fee schedule under section 1848(b).

(3) COORDINATION WITH OTHER PAYMENTS.—The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

(4) APPLICATION.—The provisions of paragraph (2) and (4) of subsection (m) shall apply to the determination of additional payments under this subsection in the same manner as such provisions apply to the determination of additional payments under subsection (m).

(z) INCENTIVE PAYMENTS FOR PARTICIPATION IN ELIGIBLE ALTERNATIVE PAYMENT MODELS.—

(1) PAYMENT INCENTIVE.—

(A) IN GENERAL.—In the case of covered professional services furnished by an eligible professional during a year that is in the period beginning with 2019 and ending with 2024 and for which the professional is a qualifying APM participant with respect to such year, in addition to the amount of payment that would otherwise be made for such covered professional services under this part for such year, there also shall be paid to such professional an amount equal to 5 percent of the estimated aggregate payment amounts for such covered professional services under this

part for the preceding year. For purposes of the previous sentence, the payment amount for the preceding year may be an estimation for the full preceding year based on a period of such preceding year that is less than the full year. The Secretary shall establish policies to implement this subparagraph in cases in which payment for covered professional services furnished by a qualifying APM participant in an alternative payment model—

(i) is made to an eligible alternative payment entity rather than directly to the qualifying APM participant; or

(ii) is made on a basis other than a fee-for-service basis (such as payment on a capitated basis).

(B) FORM OF PAYMENT.—Payments under this subsection shall be made in a lump sum, on an annual basis, as soon as practicable.

(C) TREATMENT OF PAYMENT INCENTIVE.—Payments under this subsection shall not be taken into account for purposes of determining actual expenditures under an alternative payment model and for purposes of determining or rebasing any benchmarks used under the alternative payment model.

(D) COORDINATION.—The amount of the additional payment under this subsection or subsection (m) shall be determined without regard to any additional payment under subsection (m) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (x) shall be determined without regard to any additional payment under subsection (x) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (y) shall be determined without regard to any additional payment under subsection (y) and this subsection, respectively.

(2) QUALIFYING APM PARTICIPANT.—For purposes of this subsection, the term "qualifying APM participant" means the following:

(A) 2019 AND 2020.—With respect to 2019 and 2020, an eligible professional for whom the Secretary determines that at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(B) 2021 AND 2022.—With respect to 2021 and 2022, an eligible professional described in either of the following clauses:

(i) MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional for whom the Secretary determines that at least 50 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) COMBINATION ALL-PAYER AND MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year), that at least 50 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under title XIX in a State in which no medical home or alternative payment model is available under the State program under that title),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause (iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) REQUIREMENT.—For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i) apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds expected aggregate expenditures; or

(BB) with respect to beneficiaries under title XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1115A(c).

(C) BEGINNING IN 2023.—With respect to 2023 and each subsequent year, an eligible professional described in either of the following clauses:

(i) MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional for whom the Secretary determines that at least 75 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) COMBINATION ALL-PAYER AND MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year), that at least 75 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under title XIX in a State in which no medical home or alternative payment model is available under the State program under that title),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause (iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) REQUIREMENT.—For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i) apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds expected aggregate expenditures; or

(BB) with respect to beneficiaries under title XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1115A(c).

(D) USE OF PATIENT APPROACH.—The Secretary may base the determination of whether an eligible professional is a qualifying APM participant under this subsection and the determination of whether an eligible professional is a partial qualifying APM participant under section 1848(q)(1)(C)(iii) by using counts of patients in lieu of using payments and using the same or similar percentage criteria (as specified in this subsection and such section, respectively), as the Secretary determines appropriate.

(3) ADDITIONAL DEFINITIONS.—In this subsection:

(A) COVERED PROFESSIONAL SERVICES.—The term "covered professional services" has the meaning given that term in section 1848(k)(3)(A).

(B) ELIGIBLE PROFESSIONAL.—The term "eligible professional" has the meaning given that term in section 1848(k)(3)(B) and includes a group that includes such professionals.

(C) ALTERNATIVE PAYMENT MODEL (APM).—The term "alternative payment model" means, other than for purposes of subparagraphs (B)(ii)(I)(bb) and (C)(ii)(I)(bb) of paragraph (2), any of the following:

(i) A model under section 1115A (other than a health care innovation award).

(ii) The shared savings program under section 1899.

(iii) A demonstration under section 1866C.

(iv) A demonstration required by Federal law.

(D) ELIGIBLE ALTERNATIVE PAYMENT ENTITY.—The term "eligible alternative payment entity" means, with respect to a year, an entity that—

(i) participates in an alternative payment model that—

(I) requires participants in such model to use certified EHR technology (as defined in subsection (o)(4)); and

(II) provides for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i); and

(ii)(I) bears financial risk for monetary losses under such alternative payment model that are in excess of a nominal amount; or

(II) is a medical home expanded under section 1115A(c).

(4) LIMITATION.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, of the following:

(A) The determination that an eligible professional is a qualifying APM participant under paragraph (2) and the determination that an entity is an eligible alternative payment entity under paragraph (3)(D).

(B) The determination of the amount of the 5 percent payment incentive under paragraph (1)(A), including any estimation as part of such determination.

(aa) MEDICAL REVIEW OF SPINAL SUBLUXATION SERVICES.—

(1) IN GENERAL.—The Secretary shall implement a process for the medical review (as described in paragraph (2)) of treatment by a chiropractor described in section 1861(r)(5) by means of manual manipulation of the spine to correct a subluxation (as described in such section) of an individual who is enrolled under this part and apply such process to such services furnished on or after January 1, 2017, focusing on services such as—

(A) services furnished by a such a chiropractor whose pattern of billing is aberrant compared to peers; and

(B) services furnished by such a chiropractor who, in a prior period, has a services denial percentage in the 85th percentile or greater, taking into consideration the extent that service denials are overturned on appeal.

(2) MEDICAL REVIEW.—

(A) PRIOR AUTHORIZATION MEDICAL REVIEW.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary shall use prior authorization medical review for services described in paragraph (1) that are furnished to an individual by a chiropractor described in section 1861(r)(5) that are part of an episode of treatment that includes more than 12 services. For purposes of the preceding sentence, an episode of treatment shall be determined by the underlying cause that justifies the need for services, such as a diagnosis code.

(ii) ENDING APPLICATION OF PRIOR AUTHORIZATION MEDICAL REVIEW.—The Secretary shall end the application of prior authorization medical review under clause (i) to services described in paragraph (1) by such a chiropractor if the Secretary determines that the chiropractor has a low denial rate under such prior authorization medical review. The Secretary may subsequently reapply prior authorization medical review to such chiropractor if the Secretary determines it to be appropriate and the chiropractor has, in the time period subsequent to the determination by the Secretary of a low denial rate with respect to the chiropractor, furnished such services described in paragraph (1).

(iii) EARLY REQUEST FOR PRIOR AUTHORIZATION REVIEW PERMITTED.—Nothing in this subsection shall be construed to prevent such a chiropractor from requesting prior authorization for services described in paragraph (1) that are to be furnished to an individual before the chiropractor furnishes the twelfth such service to such individual for an episode of treatment.

(B) TYPE OF REVIEW.—The Secretary may use pre-payment review or post-payment review of services described in section 1861(r)(5) that are not subject to prior authorization medical review under subparagraph (A).

(C) RELATIONSHIP TO LAW ENFORCEMENT ACTIVITIES.—The Secretary may determine that medical review under this subsection does not apply in the case where potential fraud may be involved.

(3) NO PAYMENT WITHOUT PRIOR AUTHORIZATION.—With respect to a service described in paragraph (1) for which prior authorization medical review under this subsection applies, the following shall apply:

(A) PRIOR AUTHORIZATION DETERMINATION.—The Secretary shall make a determination, prior to the service being furnished, of whether the service would or would not meet the applicable requirements of section 1862(a)(1)(A).

(B) DENIAL OF PAYMENT.—Subject to paragraph (5), no payment may be made under this part for the service unless the Secretary determines pursuant to subparagraph (A) that the service would meet the applicable requirements of such section 1862(a)(1)(A).

(4) SUBMISSION OF INFORMATION.—A chiropractor described in section 1861(r)(5) may submit the information necessary for medical review by fax, by mail, or by electronic means. The Secretary shall make available the electronic means described in the preceding sentence as soon as practicable.

(5) TIMELINESS.—If the Secretary does not make a prior authorization determination under paragraph (3)(A) within 14 business days of the date of the receipt of medical documentation needed to make such determination, paragraph (3)(B) shall not apply.

(6) APPLICATION OF LIMITATION ON BENEFICIARY LIABILITY.—Where payment may not be made as a result of the application of paragraph (2)(B), section 1879 shall apply in the same manner as such section applies to a denial that is made by reason of section 1862(a)(1).

(7) REVIEW BY CONTRACTORS.—The medical review described in paragraph (2) may be conducted by medicare administrative contractors pursuant to section 1874A(a)(4)(G) or by any other contractor determined appropriate by the Secretary that is not a recovery audit contractor.

(8) MULTIPLE SERVICES.—The Secretary shall, where practicable, apply the medical review under this subsection in a manner so as to allow an individual described in paragraph (1) to obtain, at a single time rather than on a service-by-service basis, an authorization in accordance with paragraph (3)(A) for multiple services.

(9) CONSTRUCTION.—With respect to a service described in paragraph (1) that has been affirmed by medical review under this subsection, nothing in this subsection shall be construed to preclude the subsequent denial of a claim for such service that does not meet other applicable requirements under this Act.

(10) IMPLEMENTATION.—

(A) AUTHORITY.—The Secretary may implement the provisions of this subsection by interim final rule with comment period.

(B) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to medical review under this subsection.

(bb) ADDITIONAL PAYMENTS FOR CERTAIN RURAL HEALTH CLINICS WITH PHYSICIANS OR PRACTITIONERS RECEIVING DATA 2000 WAIVERS.—

(1) IN GENERAL.—In the case of a rural health clinic with respect to which, beginning on or after January 1, 2019, rural health clinic services (as defined in section 1861(aa)(1)) are furnished for the treatment of opioid use disorder by a physician or practitioner who meets the requirements described in paragraph (3), the Secretary shall, subject to availability of funds under paragraph (4), make a payment (at such time and in such manner as specified by the Secretary) to such rural health clinic after receiving and approving an application described in paragraph (2). Such payment shall be in an amount determined by the Secretary, based on an estimate of the average costs of training for purposes of receiving a waiver described in paragraph (3)(B). Such payment may be made only one time with respect to each such physician or practitioner.

(2) APPLICATION.—In order to receive a payment described in paragraph (1), a rural health clinic shall submit to the Secretary an application for such a payment at such time, in such manner, and containing such information as specified by the Secretary. A rural health clinic may apply for such a payment for each physician or practitioner described in paragraph (1) furnishing services described in such paragraph at such clinic.

(3) REQUIREMENTS.—For purposes of paragraph (1), the requirements described in this paragraph, with respect to a physician or practitioner, are the following:

(A) The physician or practitioner is employed by or working under contract with a rural health clinic described in paragraph (1) that submits an application under paragraph (2).

(B) The physician or practitioner first receives a waiver under section 303(g) of the Controlled Substances Act on or after January 1, 2019.

(4) FUNDING.—For purposes of making payments under this subsection, there are appropriated, out of amounts in the Treasury not otherwise appropriated, $2,000,000, which shall remain available until expended.

SPECIAL PAYMENT RULES FOR PARTICULAR ITEMS AND SERVICES

SEC. 1834. (a) PAYMENT FOR DURABLE MEDICAL EQUIPMENT.—

(1) GENERAL RULE FOR PAYMENT.—

(A) IN GENERAL.—With respect to a covered item (as defined in paragraph (13)) for which payment is determined under this subsection, payment shall be made in the frequency specified in paragraphs (2) through (7) and in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) PAYMENT BASIS.—Subject to subparagraph (F)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item, or

(ii) the payment amount recognized under paragraphs (2) through (7) of this subsection for the item;

except that clause (i) shall not apply if the covered item is furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(C) EXCLUSIVE PAYMENT RULE.—Subject to subparagraph (F)(ii), this subsection shall constitute the exclusive provision of this title for payment for covered items under this part or under part A to a home health agency.

(D) REDUCTION IN FEE SCHEDULES FOR CERTAIN ITEMS.—With respect to a seat-lift chair or transcutaneous electrical nerve stimulator furnished on or after April 1, 1990, the Secretary shall reduce the payment amount applied under subparagraph (B)(ii) for such an item by 15 percent, and, in the case of a transcutaneous electrical nerve stimulator furnished on or after January 1, 1991, the Secretary shall further reduce such payment amount (as previously reduced) by 45 percent.

(E) CLINICAL CONDITIONS FOR COVERAGE.—

(i) IN GENERAL.—The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

(ii) REQUIREMENTS.—The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1861(r)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) and a prescription for the item.

(iii) PRIORITY OF ESTABLISHMENT OF STANDARDS.—In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.

(iv) STANDARDS FOR POWER WHEELCHAIRS.—Effective on the date of the enactment of this subparagraph, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) has

conducted a face-to-face examination of the individual and written a prescription for the item.

(v) LIMITATION ON PAYMENT FOR COVERED ITEMS.—Payment may not be made for a covered item under this subsection unless the item meets any standards established under this subparagraph for clinical condition of coverage.

(F) APPLICATION OF COMPETITIVE ACQUISITION; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of covered items furnished on or after January 1, 2011, subject to subparagraphs (G) and (H), that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program;

(ii) the Secretary may (and, in the case of covered items furnished on or after January 1, 2016, subject to clause (iii), shall) use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 and in the case of such adjustment, paragraph (10)(B) shall not be applied; and

(iii) in the case of covered items furnished on or after January 1, 2016, the Secretary shall continue to make such adjustments described in clause (ii) as, under such competitive acquisition programs, additional covered items are phased in or information is updated as contracts under section 1847 are recompeted in accordance with section 1847(b)(3)(B).

(G) USE OF INFORMATION ON COMPETITIVE BID RATES.—The Secretary shall specify by regulation the methodology to be used in applying the provisions of subparagraph (F)(ii) and subsection (h)(1)(H)(ii). In promulgating such regulation, the Secretary shall consider the costs of items and services in areas in which such provisions would be applied compared to the payment rates for such items and services in competitive acquisition areas.In the case of items and services furnished on or after January 1, 2019, in making any adjustments under clause (ii) or (iii) of subparagraph (F), under subsection (h)(1)(H)(ii), or under section 1842(s)(3)(B), the Secretary shall—

(i) solicit and take into account stakeholder input; and

(ii) take into account the highest amount bid by a winning supplier in a competitive acquisition area and a comparison of each of the following with respect to non-competitive acquisition areas and competitive acquisition areas:

(I) The average travel distance and cost associated with furnishing items and services in the area.

(II) The average volume of items and services furnished by suppliers in the area.

(III) The number of suppliers in the area.

(H) DIABETIC SUPPLIES.—

(i) IN GENERAL.—On or after the date described in clause (ii), the payment amount under this part for diabetic supplies, including testing strips, that are non-mail order items (as defined by the Secretary) shall be equal to the single payment amounts established under the national mail order competition for diabetic supplies under section 1847.

(ii) DATE DESCRIBED.—The date described in this clause is the date of the implementation of the single payment amounts under the national mail order competition for diabetic supplies under section 1847.

(I) TREATMENT OF VACUUM ERECTION SYSTEMS.—Effective for items and services furnished on and after July 1, 2015, vacuum erection systems described as prosthetic devices described in section 1861(s)(8) shall be treated in the same manner as erectile dysfunction drugs are treated for purposes of section 1860D-2(e)(2)(A).

(2) PAYMENT FOR INEXPENSIVE AND OTHER ROUTINELY PURCHASED DURABLE MEDICAL EQUIPMENT.—

(A) IN GENERAL.—Payment for an item of durable medical equipment (as defined in paragraph (13))—

(i) the purchase price of which does not exceed $150,

(ii) which the Secretary determines is acquired at least 75 percent of the time by purchase,

(iii) which is an accessory used in conjunction with a nebulizer, aspirator, or a ventilator excluded under paragraph (3)(A), or

(iv) in the case of devices furnished on or after October 1, 2015, which serves as a speech generating device or which is an accessory that is needed for the individual to effectively utilize such a device,

shall be made on a rental basis or in a lump-sum amount for the purchase of the item. The payment amount recognized for purchase or rental of such equipment is the amount specified in subparagraph (B) for purchase or rental, except that the total amount of payments with respect to an item may not exceed the payment amount specified in subparagraph (B) with respect to the purchase of the item.

(B) PAYMENT AMOUNT.—For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to the purchase or rental of an item furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the purchase or rental, respectively, of the item for the 12-month period ending on June 30, 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year (reduced by 10 percent, in the case of a blood glucose testing strip furnished after 1997 for an individual with diabetes).

(C) COMPUTATION OF LOCAL PAYMENT AMOUNT AND NATIONAL LIMITED PAYMENT AMOUNT.—For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994 the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(3) PAYMENT FOR ITEMS REQUIRING FREQUENT AND SUBSTANTIAL SERVICING.—

(A) IN GENERAL.—Payment for a covered item (such as IPPB machines and ventilators, excluding ventilators that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices) for which there must be frequent and substantial servicing in order to avoid risk to the patient's health shall be made on a monthly basis for the rental of the item and the amount recognized is the amount specified in subparagraph (B).

(B) PAYMENT AMOUNT.—For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to an item or device furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the rental of the item or device for the 12-month period ending with June 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year.

(C) COMPUTATION OF LOCAL PAYMENT AMOUNT AND NATIONAL LIMITED PAYMENT AMOUNT.—For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994 the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(4) PAYMENT FOR CERTAIN CUSTOMIZED ITEMS.—Payment with respect to a covered item that is uniquely constructed or substantially modified to meet the specific needs of an individual patient, and for that reason cannot be grouped with similar items for purposes of payment under this title, shall be made in a lump-sum amount (A) for the purchase of the item in a payment amount based upon the carrier's individual consideration for that item, and (B) for the reasonable and necessary maintenance and servicing for parts and labor not covered by the supplier's or manufacturer's warranty, when necessary during the period of medical need, and the amount recognized for such maintenance and servicing shall be paid on a lump-sum, as needed basis based upon the carrier's individual consideration for that item. In the case of a wheelchair furnished on or after January 1, 1992, the wheelchair shall be treated as a customized item for purposes of this paragraph if the wheelchair has been measured, fitted, or adapted in consideration of the patient's body size, disability, period of need, or intended use, and has been assembled by a supplier or ordered from a manufacturer who makes available customized features, modifications, or components for wheelchairs that are intended for an individual patient's use in accordance with instructions from the patient's physician.

(5) PAYMENT FOR OXYGEN AND OXYGEN EQUIPMENT.—

(A) IN GENERAL.—Payment for oxygen and oxygen equipment shall be made on a monthly basis in the monthly payment amount recognized under paragraph (9) for oxygen and oxygen equipment (other than portable oxygen equipment), subject to subparagraphs (B), (C), (E), and (F).

(B) ADD-ON FOR PORTABLE OXYGEN EQUIPMENT.—When portable oxygen equipment is used, but subject to subparagraph (D), the payment amount recognized under subparagraph (A) shall be increased by the monthly payment amount recognized under paragraph (9) for portable oxygen equipment.

(C) VOLUME ADJUSTMENT.—When the attending physician prescribes an oxygen flow rate—

(i) exceeding 4 liters per minute, the payment amount recognized under subparagraph (A), subject to subparagraph (D), shall be increased by 50 percent, or

(ii) of less than 1 liter per minute, the payment amount recognized under subparagraph (A) shall be decreased by 50 percent.

(D) LIMIT ON ADJUSTMENT.—When portable oxygen equipment is used and the attending physician prescribes an oxygen flow rate exceeding 4 liters per minute, there shall only be an increase under either subparagraph (B) or (C), whichever increase is larger, and not under both such subparagraphs.

(E) RECERTIFICATION FOR PATIENTS RECEIVING HOME OXYGEN THERAPY.—In the case of a patient receiving home oxygen therapy services who, at the time such services are initiated, has an initial arterial blood gas value at or above a partial pressure of 56 or an arterial oxygen saturation at or above 89 percent (or such other values, pressures, or criteria as the Secretary may specify) no payment may be made under this part for such services after the expiration of the 90-day period that begins on the date the patient first receives such services unless the patient's attending physician certifies that, on the basis of a follow-up test of the patient's arterial blood gas value or arterial oxygen saturation conducted during the final 30 days of such 90-day period, there is a medical need for the patient to continue to receive such services.

(F) RENTAL CAP.—

(i) IN GENERAL.—Payment for oxygen equipment (including portable oxygen equipment) under this paragraph may not extend over a period of continuous use (as determined by the Secretary) of longer than 36 months.

(ii) PAYMENTS AND RULES AFTER RENTAL CAP.—After the 36th continuous month during which payment is made for the equipment under this paragraph—

(I) the supplier furnishing such equipment under this subsection shall continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime of the equipment, as determined by the Secretary;

(II) payments for oxygen shall continue to be made in the amount recognized for oxygen under paragraph (9) for the period of medical need; and

(III) maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and

labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(6) PAYMENT FOR OTHER COVERED ITEMS (OTHER THAN DURABLE MEDICAL EQUIPMENT).—Payment for other covered items (other than durable medical equipment and other covered items described in paragraph (3), (4), or (5)) shall be made in a lump-sum amount for the purchase of the item in the amount of the purchase price recognized under paragraph (8).

(7) PAYMENT FOR OTHER ITEMS OF DURABLE MEDICAL EQUIPMENT.—

(A) PAYMENT.—In the case of an item of durable medical equipment not described in paragraphs (2) through (6), the following rules shall apply:

(i) RENTAL.—

(I) IN GENERAL.—Except as provided in clause (iii), payment for the item shall be made on a monthly basis for the rental of the item during the period of medical need (but payments under this clause may not extend over a period of continuous use (as determined by the Secretary) of longer than 13 months).

(II) PAYMENT AMOUNT.—Subject to subclause (III) and subparagraph (B), the amount recognized for the item, for each of the first 3 months of such period, is 10 percent of the purchase price recognized under paragraph (8) with respect to the item, and, for each of the remaining months of such period, is 7.5 percent of such purchase price.

(III) SPECIAL RULE FOR POWER-DRIVEN WHEELCHAIRS.—For purposes of payment for power-driven wheelchairs, subclause (II) shall be applied by substituting "15 percent" and "6 percent" for "10 percent" and "7.5 percent", respectively.

(ii) OWNERSHIP AFTER RENTAL.—On the first day that begins after the 13th continuous month during which payment is made for the rental of an item under clause (i), the supplier of the item shall transfer title to the item to the individual.

(iii) PURCHASE AGREEMENT OPTION FOR COMPLEX, REHABILITATIVE POWER-DRIVEN WHEELCHAIRS.—In the case of a complex, rehabilitative power-driven wheelchair, at the time the supplier furnishes the item, the supplier shall offer the individual the option to purchase the item, and payment for such item shall be made on a lump-sum basis if the individual exercises such option.

(iv) MAINTENANCE AND SERVICING.—After the supplier transfers title to the item under clause (ii) or in the case of a power-driven wheelchair for which a purchase agreement has been entered into under clause (iii), maintenance and servicing payments shall, if the Secretary determines such payments are reasonable

and necessary, be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the particular type of durable medical equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(B) RANGE FOR RENTAL AMOUNTS.—

(i) FOR 1989.—For items furnished during 1989, the payment amount recognized under subparagraph (A)(i) shall not be more than 115 percent, and shall not be less than 85 percent, of the prevailing charge established for rental of the item in January 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987.

(ii) FOR 1990.—For items furnished during 1990, clause (i) shall apply in the same manner as it applies to items furnished during 1989.

(C) REPLACEMENT OF ITEMS.—

(i) ESTABLISHMENT OF REASONABLE USEFUL LIFETIME.—In accordance with clause (iii), the Secretary shall determine and establish a reasonable useful lifetime for items of durable medical equipment for which payment may be made under this paragraph.

(ii) PAYMENT FOR REPLACEMENT ITEMS.—If the reasonable lifetime of such an item, as so established, has been reached during a continuous period of medical need, or the carrier determines that the item is lost or irreparably damaged, the patient may elect to have payment for an item serving as a replacement for such item made—

(I) on a monthly basis for the rental of the replacement item in accordance with subparagraph (A); or

(II) in the case of an item for which a purchase agreement has been entered into under subparagraph (A)(iii), in a lump-sum amount for the purchase of the item.

(iii) LENGTH OF REASONABLE USEFUL LIFETIME.—The reasonable useful lifetime of an item of durable medical equipment under this subparagraph shall be equal to 5 years, except that, if the Secretary determines that, on the basis of prior experience in making payments for such an item under this title, a reasonable useful lifetime of 5 years is not appropriate with respect to a particular item, the Secretary shall establish an alternative reasonable lifetime for such item.

(8) PURCHASE PRICE RECOGNIZED FOR MISCELLANEOUS DEVICES AND ITEMS.—For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for a covered item is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) COMPUTATION OF LOCAL PURCHASE PRICE.—Each carrier under section 1842 shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price, for each item described—

(I) in paragraph (6) equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987, or

(II) in paragraph (7) equal to the average of the purchase prices on the claims submitted on an assignment-related basis for the unused item supplied during the 6-month period ending with December 1986.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item—

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987,

(II) in 1991, equal to the local purchase price computed under this clause for the previous year, increased by the covered item update for 1991, and decreased by the percentage by which the average of the reasonable charges for claims paid for all items described in paragraph (7) is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988; or

(III) in 1992, 1993, and 1994 equal to the local purchase price computed under this clause for the previous year increased by the covered item update for the year.

(B) COMPUTATION OF NATIONAL LIMITED PURCHASE PRICE.—With respect to the furnishing of a particular item in a year, the Secretary shall compute a national limited purchase price—

(i) for 1991, equal to the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the median of all local purchase prices computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local purchase prices com-

puted under such subparagraph for the item for the year; and

(iv) for each subsequent year, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year.

(C) PURCHASE PRICE RECOGNIZED.—For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for each item furnished—

(i) in 1989 or 1990, is 100 percent of the local purchase price computed under subparagraph (A)(ii)(I);

(ii) in 1991, is the sum of (I) 67 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1991, and (II) 33 percent of the national limited purchase price computed under subparagraph (B) for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local purchase price computed under subparagraph (A)(ii)(III) for 1992, and (II) 67 percent of the national limited purchase price computed under subparagraph (B) for 1992; and

(iv) in 1993 or a subsequent year, is the national limited purchase price computed under subparagraph (B) for that year.

(9) MONTHLY PAYMENT AMOUNT RECOGNIZED WITH RESPECT TO OXYGEN AND OXYGEN EQUIPMENT.—For purposes of paragraph (5), the amount that is recognized under this paragraph for payment for oxygen and oxygen equipment is the monthly payment amount described in subparagraph (C) of this paragraph. Such amount shall be computed separately (i) for all items of oxygen and oxygen equipment (other than portable oxygen equipment) and (ii) for portable oxygen equipment (each such group referred to in this paragraph as an "item").

(A) COMPUTATION OF LOCAL MONTHLY PAYMENT RATE.—Each carrier under this section shall compute a base local payment rate for each item as follows:

(i) The carrier shall compute a base local average monthly payment rate per beneficiary as an amount equal to (I) the total reasonable charges for the item during the 12-month period ending with December 1986, divided by (II) the total number of months for all beneficiaries receiving the item in the area during the 12-month period for which the carrier made payment for the item under this title.

(ii) The carrier shall compute a local average monthly payment rate for the item applicable—

(I) to 1989 and 1990, equal to 95 percent of the base local average monthly payment rate computed under clause (i) for the item increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987, or

(II) to 1991, 1992, 1993, and 1994 equal to the local average monthly payment rate computed under this clause for the item for the previous year increased by the covered item increase for the year.

(B) COMPUTATION OF NATIONAL LIMITED MONTHLY PAYMENT RATE.—With respect to the furnishing of an item in a year, the Secretary shall compute a national limited monthly payment rate equal to—

(i) for 1991, the local monthly payment rate computed under subparagraph (A)(ii)(II) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local monthly payment rate computed under subparagraph (A)(ii) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year;

(iv) for 1995, 1996, and 1997, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(v) for 1998, 75 percent of the amount determined under this subparagraph for 1997; and

(vi) for 1999 and each subsequent year, 70 percent of the amount determined under this subparagraph for 1997.

(C) MONTHLY PAYMENT AMOUNT RECOGNIZED.—For purposes of paragraph (5), the amount that is recognized under this paragraph as the base monthly payment amount for each item furnished—

(i) in 1989 and in 1990, is 100 percent of the local average monthly payment rate computed under subparagraph (A)(ii) for the item;

(ii) in 1991, is the sum of (I) 67 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1991, and (II) 33 percent of the national limited monthly payment rate computed under subparagraph (B)(i) for the item for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local average monthly payment rate computed under sub-

paragraph (A)(ii)(II) for the item for 1992, and (II) 67 percent of the national limited monthly payment rate computed under subparagraph (B)(ii) for the item for 1992; and

(iv) in a subsequent year, is the national limited monthly payment rate computed under subparagraph (B) for the item for that year.

(10) EXCEPTIONS AND ADJUSTMENTS.—

(A) AREAS OUTSIDE CONTINENTAL UNITED STATES.—Exceptions to the amounts recognized under the previous provisions of this subsection shall be made to take into account the unique circumstances of covered items furnished in Alaska, Hawaii, or Puerto Rico.

(B) ADJUSTMENT FOR INHERENT REASONABLENESS.—The Secretary is authorized to apply the provisions of paragraphs (8) and (9) of section 1842(b) to covered items and suppliers of such items and payments under this subsection in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(F).

(C) TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (TENS).—In order to permit an attending physician time to determine whether the purchase of a transcutaneous electrical nerve stimulator is medically appropriate for a particular patient, the Secretary may determine an appropriate payment amount for the initial rental of such item for a period of not more than 2 months. If such item is subsequently purchased, the payment amount with respect to such purchase is the payment amount determined under paragraph (2).

(11) IMPROPER BILLING AND REQUIREMENT OF PHYSICIAN ORDER.—

(A) IMPROPER BILLING FOR CERTAIN RENTAL ITEMS.—Notwithstanding any other provision of this title, a supplier of a covered item for which payment is made under this subsection and which is furnished on a rental basis shall continue to supply the item without charge (other than a charge provided under this subsection for the maintenance and servicing of the item) after rental payments may no longer be made under this subsection. If a supplier knowingly and willfully violates the previous sentence, the Secretary may apply sanctions against the supplier under section 1842(j)(2) in the same manner such sanctions may apply with respect to a physician.

(B) REQUIREMENT OF PHYSICIAN ORDER.—

(i) IN GENERAL.—The Secretary is authorized to require, for specified covered items, that payment may be made under this subsection with respect to the item only if a physician enrolled under section 1866(j) or an eligible professional under section 1848(k)(3)(B) that is enrolled under section 1866(j) has communicated to the supplier, before delivery of the item, a written order for the item.

(ii) REQUIREMENT FOR FACE TO FACE ENCOUNTER.—The Secretary shall require that such an order be

written pursuant to a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) documenting such physician, physician assistant, practitioner, or specialist has had a face-to-face encounter (including through use of telehealth under subsection (m) and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary.

(12) REGIONAL CARRIERS.—The Secretary may designate, by regulation under section 1842, one carrier for one or more entire regions to process all claims within the region for covered items under this section.

(13) COVERED ITEM.—In this subsection, the term "covered item" means durable medical equipment (as defined in section 1861(n)), including such equipment described in section 1861(m)(5), but not including implantable items for which payment may be made under section 1833(t).

(14) COVERED ITEM UPDATE.—In this subsection, the term "covered item update" means, with respect to a year—

(A) for 1991 and 1992, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced by 1 percentage point;

(B) for 1993, 1994, 1995, 1996, and 1997, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year;

(C) for each of the years 1998 through 2000, 0 percentage points;

(D) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(E) for 2002, 0 percentage points;

(F) for 2003, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of 2002;

(G) for 2004 through 2006—

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) for the year involved; and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(H) for 2007—

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section

302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(I) for 2008—

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(J) for 2009—

(i) in the case of items and services furnished in any geographic area, if such items or services were selected for competitive acquisition in any area under the competitive acquisition program under section 1847(a)(1)(B)(i)(I) before July 1, 2008, including related accessories but only if furnished with such items and services selected for such competition and diabetic supplies but only if furnished through mail order, - 9.5 percent; or

(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2008;

(K) for 2010, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year; and

(L) for 2011 and each subsequent year—

(i) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—

(ii) the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

The application of subparagraph (L)(ii) may result in the covered item update under this paragraph being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.

(15) ADVANCE DETERMINATIONS OF COVERAGE FOR CERTAIN ITEMS.—

(A) DEVELOPMENT OF LISTS OF ITEMS BY SECRETARY.—The Secretary may develop and periodically update a list of items for which payment may be made under this subsection that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization throughout a carrier's entire service area or a portion of such area.

(B) DEVELOPMENT OF LISTS OF SUPPLIERS BY SECRETARY.—The Secretary may develop and periodically up-

date a list of suppliers of items for which payment may be made under this subsection with respect to whom—

(i) the Secretary has found that a substantial number of claims for payment under this part for items furnished by the supplier have been denied on the basis of the application of section 1862(a)(1); or

(ii) the Secretary has identified a pattern of overutilization resulting from the business practice of the supplier.

(C) DETERMINATIONS OF COVERAGE IN ADVANCE.—A carrier shall determine in advance of delivery of an item whether payment for the item may not be made because the item is not covered or because of the application of section 1862(a)(1) if—

(i) the item is included on the list developed by the Secretary under subparagraph (A);

(ii) the item is furnished by a supplier included on the list developed by the Secretary under subparagraph (B); or

(iii) the item is a customized item (other than inexpensive items specified by the Secretary) and the patient to whom the item is to be furnished or the supplier requests that such advance determination be made.

(16) DISCLOSURE OF INFORMATION AND SURETY BOND.—The Secretary shall not provide for the issuance (or renewal) of a provider number for a supplier of durable medical equipment, for purposes of payment under this part for durable medical equipment furnished by the supplier, unless the supplier provides the Secretary on a continuing basis—

(A) with—

(i) full and complete information as to the identity of each person with an ownership or control interest (as defined in section 1124(a)(3)) in the supplier or in any subcontractor (as defined by the Secretary in regulations) in which the supplier directly or indirectly has a 5 percent or more ownership interest; and

(ii) to the extent determined to be feasible under regulations of the Secretary, the name of any disclosing entity (as defined in section 1124(a)(2)) with respect to which a person with such an ownership or control interest in the supplier is a person with such an ownership or control interest in the disclosing entity; and

(B) with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000 that the Secretary determines is commensurate with the volume of the billing of the supplier.

The Secretary may waive the requirement of a bond under subparagraph (B) in the case of a supplier that provides a comparable surety bond under State law. The Secretary, at the Secretary's discretion, may impose the requirements of the first sentence with respect to some or all providers of items or services under part A or some or all suppliers or other persons (other than physicians or other practitioners, as defined in sec-

tion 1842(b)(18)(C)) who furnish items or services under this part.

(17) PROHIBITION AGAINST UNSOLICITED TELEPHONE CONTACTS BY SUPPLIERS.—

(A) IN GENERAL.—A supplier of a covered item under this subsection may not contact an individual enrolled under this part by telephone regarding the furnishing of a covered item to the individual unless 1 of the following applies:

(i) The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a covered item.

(ii) The supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such covered item.

(iii) If the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least 1 covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

(B) PROHIBITING PAYMENT FOR ITEMS FURNISHED SUBSEQUENT TO UNSOLICITED CONTACTS.—If a supplier knowingly contacts an individual in violation of subparagraph (A), no payment may be made under this part for any item subsequently furnished to the individual by the supplier.

(C) EXCLUSION FROM PROGRAM FOR SUPPLIERS ENGAGING IN PATTERN OF UNSOLICITED CONTACTS.—If a supplier knowingly contacts individuals in violation of subparagraph (A) to such an extent that the supplier's conduct establishes a pattern of contacts in violation of such subparagraph, the Secretary shall exclude the supplier from participation in the programs under this Act, in accordance with the procedures set forth in subsections (c), (f), and (g) of section 1128.

(18) REFUND OF AMOUNTS COLLECTED FOR CERTAIN DISALLOWED ITEMS.—

(A) IN GENERAL.—If a nonparticipating supplier furnishes to an individual enrolled under this part a covered item for which no payment may be made under this part by reason of paragraph (17)(B), the supplier shall refund on a timely basis to the patient (and shall be liable to the patient for) any amounts collected from the patient for the item, unless—

(i) the supplier establishes that the supplier did not know and could not reasonably have been expected to know that payment may not be made for the item by reason of paragraph (17)(B), or

(ii) before the item was furnished, the patient was informed that payment under this part may not be made for that item and the patient has agreed to pay for that item.

(B) SANCTIONS.—If a supplier knowingly and willfully fails to make refunds in violation of subparagraph (A), the

Secretary may apply sanctions against the supplier in accordance with section 1842(j)(2).

(C) NOTICE.—Each carrier with a contract in effect under this part with respect to suppliers of covered items shall send any notice of denial of payment for covered items by reason of paragraph (17)(B) and for which payment is not requested on an assignment-related basis to the supplier and the patient involved.

(D) TIMELY BASIS DEFINED.—A refund under subparagraph (A) is considered to be on a timely basis only if—

(i) in the case of a supplier who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the supplier receives a denial notice under subparagraph (C), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the supplier receives notice of an adverse determination on reconsideration or appeal.

(19) CERTAIN UPGRADED ITEMS.—

(A) INDIVIDUAL'S RIGHT TO CHOOSE UPGRADED ITEM.—Notwithstanding any other provision of this title, the Secretary may issue regulations under which an individual may purchase or rent from a supplier an item of upgraded durable medical equipment for which payment would be made under this subsection if the item were a standard item.

(B) PAYMENTS TO SUPPLIER.—In the case of the purchase or rental of an upgraded item under subparagraph (A)—

(i) the supplier shall receive payment under this subsection with respect to such item as if such item were a standard item; and

(ii) the individual purchasing or renting the item shall pay the supplier an amount equal to the difference between the supplier's charge and the amount under clause (i).

In no event may the supplier's charge for an upgraded item exceed the applicable fee schedule amount (if any) for such item.

(C) CONSUMER PROTECTION SAFEGUARDS.—Any regulations under subparagraph (A) shall provide for consumer protection standards with respect to the furnishing of upgraded equipment under subparagraph (A). Such regulations shall provide for—

(i) determination of fair market prices with respect to an upgraded item;

(ii) full disclosure of the availability and price of standard items and proof of receipt of such disclosure information by the beneficiary before the furnishing of the upgraded item;

(iii) conditions of participation for suppliers in the billing arrangement;

(iv) sanctions of suppliers who are determined to engage in coercive or abusive practices, including exclusion; and

(v) such other safeguards as the Secretary determines are necessary.

(20) IDENTIFICATION OF QUALITY STANDARDS.—

(A) IN GENERAL.—Subject to subparagraph (C), the Secretary shall establish and implement quality standards for suppliers of items and services described in subparagraph (D) to be applied by recognized independent accreditation organizations (as designated under subparagraph (B)) and with which such suppliers shall be required to comply in order to—

(i) furnish any such item or service for which payment is made under this part; and

(ii) receive or retain a provider or supplier number used to submit claims for reimbursement for any such item or service for which payment may be made under this title.

(B) DESIGNATION OF INDEPENDENT ACCREDITATION ORGANIZATIONS.—Not later than the date that is 1 year after the date on which the Secretary implements the quality standards under subparagraph (A), notwithstanding section 1865(a), the Secretary shall designate and approve one or more independent accreditation organizations for purposes of such subparagraph.

(C) QUALITY STANDARDS.—The quality standards described in subparagraph (A) may not be less stringent than the quality standards that would otherwise apply if this paragraph did not apply and shall include consumer services standards.

(D) ITEMS AND SERVICES DESCRIBED.—The items and services described in this subparagraph are the following items and services, as the Secretary determines appropriate:

(i) Covered items (as defined in paragraph (13)) for which payment may otherwise be made under this subsection.

(ii) Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4).

(iii) Items and services described in section 1842(s)(2).

(E) IMPLEMENTATION.—The Secretary may establish by program instruction or otherwise the quality standards under this paragraph, including subparagraph (F), after consultation with representatives of relevant parties. Such standards shall be applied prospectively and shall be published on the Internet website of the Centers for Medicare & Medicaid Services.

(F) APPLICATION OF ACCREDITATION REQUIREMENT.—In implementing quality standards under this paragraph—

(i) subject to clause (ii) and subparagraph (G), the Secretary shall require suppliers furnishing items and services described in subparagraph (D) on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted to the Secretary evidence of accreditation by an accreditation organization designated under subparagraph (B) as meeting appli-

cable quality standards, except that the Secretary shall not require under this clause pharmacies to obtain such accreditation before January 1, 2010, except that the Secretary shall not require a pharmacy to have submitted to the Secretary such evidence of accreditation prior to January 1, 2011; and

(ii) in applying such standards and the accreditation requirement of clause (i) with respect to eligible professionals (as defined in section 1848(k)(3)(B)), and including such other persons, such as orthotists and prosthetists, as specified by the Secretary, furnishing such items and services—

(I) such standards and accreditation requirement shall not apply to such professionals and persons unless the Secretary determines that the standards being applied are designed specifically to be applied to such professionals and persons; and

(II) the Secretary may exempt such professionals and persons from such standards and requirement if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons with respect to the furnishing of such items and services.

(G) APPLICATION OF ACCREDITATION REQUIREMENT TO CERTAIN PHARMACIES.—

(i) IN GENERAL.—With respect to items and services furnished on or after January 1, 2011, in implementing quality standards under this paragraph—

(I) subject to subclause (II), in applying such standards and the accreditation requirement of subparagraph (F)(i) with respect to pharmacies described in clause (ii) furnishing such items and services, such standards and accreditation requirement shall not apply to such pharmacies; and

(II) the Secretary may apply to such pharmacies an alternative accreditation requirement established by the Secretary if the Secretary determines such alternative accreditation requirement is more appropriate for such pharmacies.

(ii) PHARMACIES DESCRIBED.—A pharmacy described in this clause is a pharmacy that meets each of the following criteria:

(I) The total billings by the pharmacy for such items and services under this title are less than 5 percent of total pharmacy sales, as determined based on the average total pharmacy sales for the previous 3 calendar years, 3 fiscal years, or other yearly period specified by the Secretary.

(II) The pharmacy has been enrolled under section 1866(j) as a supplier of durable medical equipment, prosthetics, orthotics, and supplies, has been issued (which may include the renewal

of) a provider number for at least 5 years, and for which a final adverse action (as defined in section 424.57(a) of title 42, Code of Federal Regulations) has not been imposed in the past 5 years.

(III) The pharmacy submits to the Secretary an attestation, in a form and manner, and at a time, specified by the Secretary, that the pharmacy meets the criteria described in subclauses (I) and (II). Such attestation shall be subject to section 1001 of title 18, United States Code.

(IV) The pharmacy agrees to submit materials as requested by the Secretary, or during the course of an audit conducted on a random sample of pharmacies selected annually, to verify that the pharmacy meets the criteria described in subclauses (I) and (II). Materials submitted under the preceding sentence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods, as requested by the Secretary.

(21) SPECIAL PAYMENT RULE FOR SPECIFIED ITEMS AND SUPPLIES.—

(A) IN GENERAL.—Notwithstanding the preceding provisions of this subsection, for specified items and supplies (described in subparagraph (B)) furnished during 2005, the payment amount otherwise determined under this subsection for such specified items and supplies shall be reduced by the percentage difference between—

(i) the amount of payment otherwise determined for the specified item or supply under this subsection for 2002, and

(ii) the amount of payment for the specified item or supply under chapter 89 of title 5, United States Code, as identified in the column entitled "Median FEHP Price" in the table entitled "SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS" included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002, or any subsequent report by the Inspector General.

(B) SPECIFIED ITEM OR SUPPLY DESCRIBED.—For purposes of subparagraph (A), a specified item or supply means oxygen and oxygen equipment, standard wheelchairs (including standard power wheelchairs), nebulizers, diabetic supplies consisting of lancets and testing strips, hospital beds, and air mattresses, but only if the HCPCS code for the item or supply is identified in a table referred to in subparagraph (A)(ii).

(C) APPLICATION OF UPDATE TO SPECIAL PAYMENT AMOUNT.—The covered item update under paragraph (14) for specified items and supplies for 2006 and each subsequent year shall be applied to the payment amount under subparagraph (A) unless payment is made for such items and supplies under section 1847.

(22) SPECIAL PAYMENT RULE FOR DIABETIC SUPPLIES.—Notwithstanding the preceding provisions of this subsection, for purposes of determining the payment amount under this subsection for diabetic supplies furnished on or after the first day of the calendar quarter during 2013 that is at least 30 days after the date of the enactment of this paragraph and before the date described in paragraph (1)(H)(ii), the Secretary shall recalculate and apply the covered item update under paragraph (14) as if subparagraph (J)(i) of such paragraph was amended by striking "but only if furnished through mail order".

(b) FEE SCHEDULES FOR RADIOLOGIST SERVICES.—

(1) DEVELOPMENT.—The Secretary shall develop—

(A) a relative value scale to serve as the basis for the payment for radiologist services under this part, and

(B) using such scale and appropriate conversion factors and subject to subsection (c)(1)(A), fee schedules (on a regional, statewide, locality, or carrier service area basis) for payment for radiologist services under this part, to be implemented for such services furnished during 1989.

(2) CONSULTATION.—In carrying out paragraph (1), the Secretary shall regularly consult closely with the Physician Payment Review Commission, the American College of Radiology, and other organizations representing physicians or suppliers who furnish radiologist services and shall share with them the data and data analysis being used to make the determinations under paragraph (1), including data on variations in current medicare payments by geographic area, and by service and physician specialty.

(3) CONSIDERATIONS.—In developing the relative value scale and fee schedules under paragraph (1), the Secretary—

(A) shall take into consideration variations in the cost of furnishing such services among geographic areas and among different sites where services are furnished, and

(B) may also take into consideration such other factors respecting the manner in which physicians in different specialties furnish such services as may be appropriate to assure that payment amounts are equitable and designed to promote effective and efficient provision of radiologist services by physicians in the different specialties.

(4) SAVINGS.—

(A) BUDGET NEUTRAL FEE SCHEDULES.—The Secretary shall develop preliminary fee schedules for 1989, which are designed to result in the same amount of aggregate payments (net of any coinsurance and deductibles under sections 1833(a)(1)(J) and 1833(b)) for radiologist services furnished in 1989 as would have been made if this subsection had not been enacted.

(B) INITIAL SAVINGS.—The fee schedules established for payment purposes under this subsection for services furnished in 1989 shall be 97 percent of the amounts permitted under these preliminary fee schedules developed under subparagraph (A).

(C) 1990 FEE SCHEDULES.—For radiologist services (other than portable X-ray services) furnished under this part

during 1990, after March 31 of such year, the conversion factors used under this subsection shall be 96 percent of the conversion factors that applied under this subsection as of December 31, 1989.

(D) 1991 FEE SCHEDULES.—For radiologist services (other than portable X-ray services) furnished under this part during 1991, the conversion factors used in a locality under this subsection shall, subject to clause (vii), be reduced to the adjusted conversion factor for the locality determined as follows:

(i) NATIONAL WEIGHTED AVERAGE CONVERSION FACTOR.—The Secretary shall estimate the national weighted average of the conversion factors used under this subsection for services furnished during 1990 beginning on April 1, using the best available data.

(ii) REDUCED NATIONAL WEIGHTED AVERAGE.—The national weighted average estimated under clause (i) shall be reduced by 13 percent.

(iii) COMPUTATION OF 1990 LOCALITY INDEX RELATIVE TO NATIONAL AVERAGE.—The Secretary shall establish an index which reflects, for each locality, the ratio of the conversion factor used in the locality under this subsection to the national weighted average estimated under clause (i).

(iv) ADJUSTED CONVERSION FACTOR.—The adjusted conversion factor for the professional or technical component of a service in a locality is the sum of ½ of the locally-adjusted amount determined under clause (v) and ½ of the GPCI-adjusted amount determined under clause (vi).

(v) LOCALLY-ADJUSTED AMOUNT.—For purposes of clause (iv), the locally adjusted amount determined under this clause is the product of (I) the national weighted average conversion factor computed under clause (ii), and (II) the index value established under clause (iii) for the locality.

(vi) GPCI-ADJUSTED AMOUNT.—For purposes of clause (iv), the GPCI-adjusted amount determined under this clause is the sum of—

(I) the product of (a) the portion of the reduced national weighted average conversion factor computed under clause (ii) which is attributable to physician work and (b) the geographic work index value for the locality (specified in Addendum C to the Model Fee Schedule for Physician Services (published on September 4, 1990, 55 Federal Register pp. 36238–36243)); and

(II) the product of (a) the remaining portion of the reduced national weighted average conversion factor computed under clause (ii), and (b) the geographic practice cost index value specified in section 1842(b)(14)(C)(iv) for the locality.

In applying this clause with respect to the professional component of a service, 80 percent of the conversion factor shall be considered to be attributable to physi-

cian work and with respect to the technical component of the service, 0 percent shall be considered to be attributable to physician work.

(vii) LIMITS ON CONVERSION FACTOR.—The conversion factor to be applied to a locality to the professional or technical component of a service shall not be reduced under this subparagraph by more than 9.5 percent below the conversion factor applied in the locality under subparagraph (C) to such component, but in no case shall the conversion factor be less than 60 percent of the national weighted average of the conversion factors (computed under clause (i)).

(E) RULE FOR CERTAIN SCANNING SERVICES.—In the case of the technical components of magnetic resonance imaging (MRI) services and computer assisted tomography (CAT) services furnished after December 31, 1990, the amount otherwise payable shall be reduced by 10 percent.

(F) SUBSEQUENT UPDATING.—For radiologist services furnished in subsequent years, the fee schedules shall be the schedules for the previous year updated by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year.

(G) NONPARTICIPATING PHYSICIANS AND SUPPLIERS.—Each fee schedule so established shall provide that the payment rate recognized for nonparticipating physicians and suppliers is equal to the appropriate percent (as defined in section 1842(b)(4)(A)(iv)) of the payment rate recognized for participating physicians and suppliers.

(5) LIMITING CHARGES OF NONPARTICIPATING PHYSICIANS AND SUPPLIERS.—

(A) IN GENERAL.—In the case of radiologist services furnished after January 1, 1989, for which payment is made under a fee schedule under this subsection, if a nonparticipating physician or supplier furnishes the service to an individual entitled to benefits under this part, the physician or supplier may not charge the individual more than the limiting charge (as defined in subparagraph (B)).

(B) LIMITING CHARGE DEFINED.—In subparagraph (A), the term "limiting charge" means, with respect to a service furnished—

(i) in 1989, 125 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1),

(ii) in 1990, 120 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1), and

(iii) after 1990, 115 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1).

(C) ENFORCEMENT.—If a physician or supplier knowingly and willfully bills in violation of subparagraph (A), the Secretary may apply sanctions against such physician or supplier in accordance with section 1842(j)(2) in the same manner as such sanctions may apply to a physician.

(6) RADIOLOGIST SERVICES DEFINED.—For the purposes of this subsection and section 1833(a)(1)(J), the term "radiologist services" only includes radiology services performed by, or under the direction or supervision of, a physician—

(A) who is certified, or eligible to be certified, by the American Board of Radiology, or

(B) for whom radiology services account for at least 50 percent of the total amount of charges made under this part.

(c) PAYMENT AND STANDARDS FOR SCREENING MAMMOGRAPHY.—

(1) IN GENERAL.—With respect to expenses incurred for screening mammography (as defined in section 1861(jj)), payment may be made only—

(A) for screening mammography conducted consistent with the frequency permitted under paragraph (2); and

(B) if the screening mammography is conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act.

(2) FREQUENCY COVERED.—

(A) IN GENERAL.—Subject to revision by the Secretary under subparagraph (B)—

(i) no payment may be made under this part for screening mammography performed on a woman under 35 years of age;

(ii) payment may be made under this part for only one screening mammography performed on a woman over 34 years of age, but under 40 years of age; and

(iii) in the case of a woman over 39 years of age, payment may not be made under this part for screening mammography performed within 11 months following the month in which a previous screening mammography was performed.

(B) REVISION OF FREQUENCY.—

(i) REVIEW.—The Secretary, in consultation with the Director of the National Cancer Institute, shall review periodically the appropriate frequency for performing screening mammography, based on age and such other factors as the Secretary believes to be pertinent.

(ii) REVISION OF FREQUENCY.—The Secretary, taking into consideration the review made under clause (i), may revise from time to time the frequency with which screening mammography may be paid for under this subsection.

(d) FREQUENCY LIMITS AND PAYMENT FOR COLORECTAL CANCER SCREENING TESTS.—

(1) SCREENING FECAL-OCCULT BLOOD TESTS.—

(A) PAYMENT AMOUNT.—The payment amount for colorectal cancer screening tests consisting of screening fecal-occult blood tests is equal to the payment amount established for diagnostic fecal-occult blood tests under section 1833(h).

(B) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening fecal-occult blood test—

(i) if the individual is under 50 years of age; or

(ii) if the test is performed within the 11 months after a previous screening fecal-occult blood test.

(2) SCREENING FLEXIBLE SIGMOIDOSCOPIES.—

(A) FEE SCHEDULE.—With respect to colorectal cancer screening tests consisting of screening flexible sigmoidoscopies, payment under section 1848 shall be consistent with payment under such section for similar or related services.

(B) PAYMENT LIMIT.—In the case of screening flexible sigmoidoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic flexible sigmoidoscopy services.

(C) FACILITY PAYMENT LIMIT.—

(i) IN GENERAL.—Notwithstanding subsections (i)(2)(A) and (t) of section 1833, in the case of screening flexible sigmoidoscopy services furnished on or after January 1, 1999, that—

(I) in accordance with regulations, may be performed in an ambulatory surgical center and for which the Secretary permits ambulatory surgical center payments under this part, and

(II) are performed in an ambulatory surgical center or hospital outpatient department,

payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) LIMITATION ON COINSURANCE.—Notwithstanding any other provision of this title, in the case of a beneficiary who receives the services described in clause (i)—

(I) in computing the amount of any applicable copayment, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) SPECIAL RULE FOR DETECTED LESIONS.—If during the course of such screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening flexible sigmoidoscopy but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal.

(E) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening flexible sigmoidoscopy—

(i) if the individual is under 50 years of age; or

(ii) if the procedure is performed within the 47 months after a previous screening flexible

sigmoidoscopy or, in the case of an individual who is not at high risk for colorectal cancer, if the procedure is performed within the 119 months after a previous screening colonoscopy.

(3) SCREENING COLONOSCOPY.—

(A) FEE SCHEDULE.—With respect to colorectal cancer screening test consisting of a screening colonoscopy, payment under section 1848 shall be consistent with payment amounts under such section for similar or related services.

(B) PAYMENT LIMIT.—In the case of screening colonoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic colonoscopy services.

(C) FACILITY PAYMENT LIMIT.—

(i) IN GENERAL.—Notwithstanding subsections (i)(2)(A) and (t) of section 1833, in the case of screening colonoscopy services furnished on or after January 1, 1999, that are performed in an ambulatory surgical center or a hospital outpatient department, payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) LIMITATION ON COINSURANCE.—Notwithstanding any other provision of this title, in the case of a beneficiary who receives the services described in clause (i)—

(I) in computing the amount of any applicable coinsurance, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) SPECIAL RULE FOR DETECTED LESIONS.—If during the course of such screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal.

(E) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening colonoscopy for individuals at high risk for colorectal cancer if the procedure is performed within the 23 months after a previous screening colonoscopy or for other individuals if the procedure is performed within the 119 months after a previous screening colonoscopy or within 47 months after a previous screening flexible sigmoidoscopy.

(e) ACCREDITATION REQUIREMENT FOR ADVANCED DIAGNOSTIC IMAGING SERVICES.—

(1) IN GENERAL.—

(A) IN GENERAL.—Beginning with January 1, 2012, with respect to the technical component of advanced diagnostic imaging services for which payment is made under the fee schedule established under section 1848(b) and that are furnished by a supplier, payment may only be made if such supplier is accredited by an accreditation organization designated by the Secretary under paragraph (2)(B)(i).

(B) ADVANCED DIAGNOSTIC IMAGING SERVICES DEFINED.—In this subsection, the term "advanced diagnostic imaging services" includes—

(i) diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and

(ii) such other diagnostic imaging services, including services described in section 1848(b)(4)(B) (excluding X-ray, ultrasound, and fluoroscopy), as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

(C) SUPPLIER DEFINED.—In this subsection, the term "supplier" has the meaning given such term in section 1861(d).

(2) ACCREDITATION ORGANIZATIONS.—

(A) FACTORS FOR DESIGNATION OF ACCREDITATION ORGANIZATIONS.—The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B)(i) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

(i) The ability of the organization to conduct timely reviews of accreditation applications.

(ii) Whether the organization has established a process for the timely integration of new advanced diagnostic imaging services into the organization's accreditation program.

(iii) Whether the organization uses random site visits, site audits, or other strategies for ensuring accredited suppliers maintain adherence to the criteria described in paragraph (3).

(iv) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D)).

(v) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

(vi) Such other factors as the Secretary determines appropriate.

(B) DESIGNATION.—Not later than January 1, 2010, the Secretary shall designate organizations to accredit suppliers furnishing the technical component of advanced diagnostic imaging services. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

(C) REVIEW AND MODIFICATION OF LIST OF ACCREDITATION ORGANIZATIONS.—

(i) IN GENERAL.—The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

(ii) SPECIAL RULE FOR ACCREDITATIONS DONE PRIOR TO REMOVAL FROM LIST OF DESIGNATED ACCREDITATION ORGANIZATIONS.—In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

(3) CRITERIA FOR ACCREDITATION.—The Secretary shall establish procedures to ensure that the criteria used by an accreditation organization designated under paragraph (2)(B) to evaluate a supplier that furnishes the technical component of advanced diagnostic imaging services for the purpose of accreditation of such supplier is specific to each imaging modality. Such criteria shall include—

(A) standards for qualifications of medical personnel who are not physicians and who furnish the technical component of advanced diagnostic imaging services;

(B) standards for qualifications and responsibilities of medical directors and supervising physicians, including standards that recognize the considerations described in paragraph (4);

(C) procedures to ensure that equipment used in furnishing the technical component of advanced diagnostic imaging services meets performance specifications;

(D) standards that require the supplier have procedures in place to ensure the safety of persons who furnish the technical component of advanced diagnostic imaging services and individuals to whom such services are furnished;

(E) standards that require the establishment and maintenance of a quality assurance and quality control program by the supplier that is adequate and appropriate to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by such supplier; and

(F) any other standards or procedures the Secretary determines appropriate.

(4) RECOGNITION IN STANDARDS FOR THE EVALUATION OF MEDICAL DIRECTORS AND SUPERVISING PHYSICIANS.—The standards described in paragraph (3)(B) shall recognize whether a medical director or supervising physician—

(A) in a particular specialty receives training in advanced diagnostic imaging services in a residency program;

(B) has attained, through experience, the necessary expertise to be a medical director or a supervising physician;

(C) has completed any continuing medical education courses relating to such services; or

(D) has met such other standards as the Secretary determines appropriate.

(5) RULE FOR ACCREDITATIONS MADE PRIOR TO DESIGNATION.—In the case of a supplier that is accredited before January 1, 2010, by an accreditation organization designated by the Secretary under paragraph (2)(B) as of January 1, 2010, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2012, for the remaining period such accreditation is in effect.

(f) REDUCTION IN PAYMENTS FOR PHYSICIAN PATHOLOGY SERVICES DURING 1991.—

(1) IN GENERAL.—For physician pathology services furnished under this part during 1991, the prevailing charges used in a locality under this part shall be 7 percent below the prevailing charges used in the locality under this part in 1990 after March 31.

(2) LIMITATION.—The prevailing charge for the technical and professional components of an physician pathology service furnished by a physician through an independent laboratory shall not be reduced pursuant to paragraph (1) to the extent that such reduction would reduce such prevailing charge below 115 percent of the prevailing charge for the professional component of such service when furnished by a hospital-based physician in the same locality. For purposes of the preceding sentence, an independent laboratory is a laboratory that is independent of a hospital and separate from the attending or consulting physicians' office.

(g) PAYMENT FOR OUTPATIENT CRITICAL ACCESS HOSPITAL SERVICES.—

(1) IN GENERAL.—The amount of payment for outpatient critical access hospital services of a critical access hospital is equal to 101 percent of the reasonable costs of the hospital in providing such services, unless the hospital makes the election under paragraph (2).

(2) ELECTION OF COST-BASED HOSPITAL OUTPATIENT SERVICE PAYMENT PLUS FEE SCHEDULE FOR PROFESSIONAL SERVICES.—A critical access hospital may elect to be paid for outpatient critical access hospital services amounts equal to the sum of the following, less the amount that such hospital may charge as described in section 1866(a)(2)(A):

(A) FACILITY FEE.—With respect to facility services, not including any services for which payment may be made under subparagraph (B), 101 percent of the reasonable costs of the critical access hospital in providing such services.

(B) FEE SCHEDULE FOR PROFESSIONAL SERVICES.—With respect to professional services otherwise included within outpatient critical access hospital services, 115 percent of such amounts as would otherwise be paid under this part if such services were not included in outpatient critical ac-

cess hospital services. Subsections (x) and (y) of section 1833 shall not be taken into account in determining the amounts that would otherwise be paid pursuant to the preceding sentence.

The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician or other practitioner providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to those physicians and practitioners who have not assigned such billing rights.

(3) DISREGARDING CHARGES.—The payment amounts under this subsection shall be determined without regard to the amount of the customary or other charge.

(4) TREATMENT OF CLINICAL DIAGNOSTIC LABORATORY SERVICES.—No coinsurance, deductible, copayment, or other cost-sharing otherwise applicable under this part shall apply with respect to clinical diagnostic laboratory services furnished as an outpatient critical access hospital service. Nothing in this title shall be construed as providing for payment for clinical diagnostic laboratory services furnished as part of outpatient critical access hospital services, other than on the basis described in this subsection. For purposes of the preceding sentence and section 1861(mm)(3), clinical diagnostic laboratory services furnished by a critical access hospital shall be treated as being furnished as part of outpatient critical access services without regard to whether the individual with respect to whom such services are furnished is physically present in the critical access hospital, or in a skilled nursing facility or a clinic (including a rural health clinic) that is operated by a critical access hospital, at the time the specimen is collected.

(5) COVERAGE OF COSTS FOR CERTAIN EMERGENCY ROOM ON-CALL PROVIDERS.—In determining the reasonable costs of outpatient critical access hospital services under paragraphs (1) and (2)(A), the Secretary shall recognize as allowable costs, amounts (as defined by the Secretary) for reasonable compensation and related costs for physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services but who are not present on the premises of the critical access hospital involved, and are not otherwise furnishing services covered under this title and are not on-call at any other provider or facility.

(h) PAYMENT FOR PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS.—

(1) GENERAL RULE FOR PAYMENT.—

(A) IN GENERAL.—Payment under this subsection for prosthetic devices and orthotics and prosthetics shall be made in a lump-sum amount for the purchase of the item in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) PAYMENT BASIS.—Except as provided in subparagraphs (C), (E), and (H)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item; or

(ii) the amount recognized under paragraph (2) as the purchase price for the item.

(C) EXCEPTION FOR CERTAIN PUBLIC HOME HEALTH AGENCIES.—Subparagraph (B)(i) shall not apply to an item furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(D) EXCLUSIVE PAYMENT RULE.—Subject to subparagraph (H)(ii), this subsection shall constitute the exclusive provision of this title for payment for prosthetic devices, orthotics, and prosthetics under this part or under part A to a home health agency.

(E) EXCEPTION FOR CERTAIN ITEMS.—Payment for ostomy supplies, tracheostomy supplies, and urologicals shall be made in accordance with subparagraphs (B) and (C) of section 1834(a)(2).

(F) SPECIAL PAYMENT RULES FOR CERTAIN PROSTHETICS AND CUSTOM-FABRICATED ORTHOTICS.—

(i) IN GENERAL.—No payment shall be made under this subsection for an item of custom-fabricated orthotics described in clause (ii) or for an item of prosthetics unless such item is—

(I) furnished by a qualified practitioner; and

(II) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate.

(ii) DESCRIPTION OF CUSTOM-FABRICATED ITEM.—

(I) IN GENERAL.—An item described in this clause is an item of custom-fabricated orthotics that requires education, training, and experience to custom-fabricate and that is included in a list established by the Secretary in subclause (II). Such an item does not include shoes and shoe inserts.

(II) LIST OF ITEMS.—The Secretary, in consultation with appropriate experts in orthotics (including national organizations representing manufacturers of orthotics), shall establish and update as appropriate a list of items to which this subparagraph applies. No item may be included in such list unless the item is individually fabricated for the patient over a positive model of the patient.

(iii) QUALIFIED PRACTITIONER DEFINED.—In this subparagraph, the term "qualified practitioner" means a physician or other individual who—

(I) is a qualified physical therapist or a qualified occupational therapist;

(II) in the case of a State that provides for the licensing of orthotics and prosthetics, is licensed in orthotics or prosthetics by the State in which the item is supplied; or

(III) in the case of a State that does not provide for the licensing of orthotics and prosthetics, is

specifically trained and educated to provide or manage the provision of prosthetics and custom-designed or -fabricated orthotics, and is certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or is credentialed and approved by a program that the Secretary determines, in consultation with appropriate experts in orthotics and prosthetics, has training and education standards that are necessary to provide such prosthetics and orthotics.

(iv) QUALIFIED SUPPLIER DEFINED.—In this subparagraph, the term "qualified supplier" means any entity that is accredited by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or accredited and approved by a program that the Secretary determines has accreditation and approval standards that are essentially equivalent to those of such Board.

(G) REPLACEMENT OF PROSTHETIC DEVICES AND PARTS.—

(i) IN GENERAL.—Payment shall be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the provision of a replacement device, or a replacement part of such a device, is necessary because of any of the following:

(I) A change in the physiological condition of the patient.

(II) An irreparable change in the condition of the device, or in a part of the device.

(III) The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

(ii) CONFIRMATION MAY BE REQUIRED IF DEVICE OR PART BEING REPLACED IS LESS THAN 3 YEARS OLD.—If a physician determines that a replacement device, or a replacement part, is necessary pursuant to clause (i)—

(I) such determination shall be controlling; and

(II) such replacement device or part shall be deemed to be reasonable and necessary for purposes of section 1862(a)(1)(A);

except that if the device, or part, being replaced is less than 3 years old (calculated from the date on which the beneficiary began to use the device or part), the Secretary may also require confirmation of necessity of the replacement device or replacement part, as the case may be.

(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph

(2)(C) of section 1847(a) furnished on or after January 1, 2009, subject to subsection (a)(1)(G), that are included in a competitive acquisition program in a competitive acquisition area under such section—

(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(ii) subject to subsection (a)(1)(G), the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.

(2) PURCHASE PRICE RECOGNIZED.—For purposes of paragraph (1), the amount that is recognized under this paragraph as the purchase price for prosthetic devices, orthotics, and prosthetics is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) COMPUTATION OF LOCAL PURCHASE PRICE.—Each carrier under section 1842 shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price for each item equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item—

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 6-month period ending with December 1987, or

(II) in 1991, 1992 or 1993, equal to the local purchase price computed under this clause for the previous year increased by the applicable percentage increase for the year.

(B) COMPUTATION OF REGIONAL PURCHASE PRICE.—With respect to the furnishing of a particular item in each region (as defined by the Secretary), the Secretary shall compute a regional purchase price—

(i) for 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local purchase prices for the carriers in the region computed under subparagraph (A)(ii)(II) for the year, and

(ii) for each subsequent year, equal to the regional purchase price computed under this subparagraph for the previous year increased by the applicable percentage increase for the year.

(C) PURCHASE PRICE RECOGNIZED.—For purposes of paragraph (1) and subject to subparagraph (D), the amount

that is recognized under this paragraph as the purchase price for each item furnished—

(i) in 1989, 1990, or 1991, is 100 percent of the local purchase price computed under subparagraph (A)(ii);

(ii) in 1992, is the sum of (I) 75 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1992, and (II) 25 percent of the regional purchase price computed under subparagraph (B) for 1992;

(iii) in 1993, is the sum of (I) 50 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1993, and (II) 50 percent of the regional purchase price computed under subparagraph (B) for 1993; and

(iv) in 1994 or a subsequent year, is the regional purchase price computed under subparagraph (B) for that year.

(D) RANGE ON AMOUNT RECOGNIZED.—The amount that is recognized under subparagraph (C) as the purchase price for an item furnished—

(i) in 1992, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year; and

(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year.

(3) APPLICABILITY OF CERTAIN PROVISIONS RELATING TO DURABLE MEDICAL EQUIPMENT.—Paragraphs (12) and (17) and subparagraphs (A) and (B) of paragraph (10) and paragraph (11) of subsection (a) shall apply to prosthetic devices, orthotics, and prosthetics in the same manner as such provisions apply to covered items under such subsection.

(4) DEFINITIONS.—In this subsection—

(A) the term "applicable percentage increase" means—

(i) for 1991, 0 percent;

(ii) for 1992 and 1993, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(iii) for 1994 and 1995, 0 percent;

(iv) for 1996 and 1997, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(v) for each of the years 1998 through 2000, 1 percent;

(vi) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(vii) for 2002, 1 percent;

(viii) for 2003, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(ix) for 2004, 2005, and 2006, 0 percent;

(x) for for each of 2007 through 2010, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year; and

(xi) for 2011 and each subsequent year—

(I) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—

(II) the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

(B) the term "prosthetic devices" has the meaning given such term in section 1861(s)(8), except that such term does not include parenteral and enteral nutrition nutrients, supplies, and equipment and does not include an implantable item for which payment may be made under section 1833(t); and

(C) the term "orthotics and prosthetics" has the meaning given such term in section 1861(s)(9) (and includes shoes described in section 1861(s)(12)), but does not include intraocular lenses or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1861(m)(5).

The application of subparagraph (A)(xi)(II) may result in the applicable percentage increase under subparagraph (A) being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.

(5) DOCUMENTATION CREATED BY ORTHOTISTS AND PROSTHETISTS.—For purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by eligible professionals described in section 1848(k)(3)(B).

(i) PAYMENT FOR SURGICAL DRESSINGS.—

(1) IN GENERAL.—Payment under this subsection for surgical dressings (described in section 1861(s)(5)) shall be made in a lump sum amount for the purchase of the item in an amount equal to 80 percent of the lesser of—

(A) the actual charge for the item; or

(B) a payment amount determined in accordance with the methodology described in subparagraphs (B) and (C) of subsection (a)(2) (except that in applying such methodology, the national limited payment amount referred to in such subparagraphs shall be initially computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, in-

creased by the covered item updates described in such subsection for 1993 and 1994).

(2) EXCEPTIONS.—Paragraph (1) shall not apply to surgical dressings that are—

(A) furnished as an incident to a physician's professional service; or

(B) furnished by a home health agency.

(j) REQUIREMENTS FOR SUPPLIERS OF MEDICAL EQUIPMENT AND SUPPLIES.—

(1) ISSUANCE AND RENEWAL OF SUPPLIER NUMBER.—

(A) PAYMENT.—Except as provided in subparagraph (C), no payment may be made under this part after the date of the enactment of the Social Security Act Amendments of 1994 for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number.

(B) STANDARDS FOR POSSESSING A SUPPLIER NUMBER.—A supplier may not obtain a supplier number unless—

(i) for medical equipment and supplies furnished on or after the date of the enactment of the Social Security Act Amendments of 1994 and before January 1, 1996, the supplier meets standards prescribed by the Secretary in regulations issued on June 18, 1992; and

(ii) for medical equipment and supplies furnished on or after January 1, 1996, the supplier meets revised standards prescribed by the Secretary (in consultation with representatives of suppliers of medical equipment and supplies, carriers, and consumers) that shall include requirements that the supplier—

(I) comply with all applicable State and Federal licensure and regulatory requirements;

(II) maintain a physical facility on an appropriate site;

(III) have proof of appropriate liability insurance; and

(IV) meet such other requirements as the Secretary may specify.

(C) EXCEPTION FOR ITEMS FURNISHED AS INCIDENT TO A PHYSICIAN'S SERVICE.—Subparagraph (A) shall not apply with respect to medical equipment and supplies furnished incident to a physician's service.

(D) PROHIBITION AGAINST MULTIPLE SUPPLIER NUMBERS.—The Secretary may not issue more than one supplier number to any supplier of medical equipment and supplies unless the issuance of more than one number is appropriate to identify subsidiary or regional entities under the supplier's ownership or control.

(E) PROHIBITION AGAINST DELEGATION OF SUPPLIER DETERMINATIONS.—The Secretary may not delegate (other than by contract under section 1842) the responsibility to determine whether suppliers meet the standards necessary to obtain a supplier number.

(2) CERTIFICATES OF MEDICAL NECESSITY.—

(A) LIMITATION ON INFORMATION PROVIDED BY SUPPLIERS ON CERTIFICATES OF MEDICAL NECESSITY.—

(i) IN GENERAL.—Effective 60 days after the date of the enactment of the Social Security Act Amendments of 1994, a supplier of medical equipment and supplies may distribute to physicians, or to individuals entitled to benefits under this part, a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier:

(I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.

(II) A description of such medical equipment and supplies.

(III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary.

(ii) INFORMATION ON PAYMENT AMOUNT AND CHARGES.—If a supplier distributes a certificate of medical necessity containing any of the information permitted to be supplied under clause (i), the supplier shall also list on the certificate of medical necessity the fee schedule amount and the supplier's charge for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician.

(iii) PENALTY.—Any supplier of medical equipment and supplies who knowingly and willfully distributes a certificate of medical necessity in violation of clause (i) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an amount not to exceed $1,000 for each such certificate of medical necessity so distributed. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(B) DEFINITION.—For purposes of this paragraph, the term "certificate of medical necessity" means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(3) COVERAGE AND REVIEW CRITERIA.—The Secretary shall annually review the coverage and utilization of items of medical equipment and supplies to determine whether such items should be made subject to coverage and utilization review criteria, and if appropriate, shall develop and apply such criteria to such items.

(4) LIMITATION ON PATIENT LIABILITY.—If a supplier of medical equipment and supplies (as defined in paragraph (5))—

(A) furnishes an item or service to a beneficiary for which no payment may be made by reason of paragraph (1);

(B) furnishes an item or service to a beneficiary for which payment is denied in advance under subsection (a)(15); or

(C) furnishes an item or service to a beneficiary for which payment is denied under section 1862(a)(1);

any expenses incurred for items and services furnished to an individual by such a supplier not on an assigned basis shall be the responsibility of such supplier. The individual shall have no financial responsibility for such expenses and the supplier shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected from the individual for such items or services. The provisions of subsection (a)(18) shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such subsection.

(5) DEFINITION.—The term "medical equipment and supplies" means—

(A) durable medical equipment (as defined in section 1861(n));

(B) prosthetic devices (as described in section 1861(s)(8));

(C) orthotics and prosthetics (as described in section 1861(s)(9));

(D) surgical dressings (as described in section 1861(s)(5));

(E) such other items as the Secretary may determine; and

(F) for purposes of paragraphs (1) and (3)—

(i) home dialysis supplies and equipment (as described in section 1861(s)(2)(F)),

(ii) immunosuppressive drugs (as described in section 1861(s)(2)(J)),

(iii) therapeutic shoes for diabetics (as described in section 1861(s)(12)),

(iv) oral drugs prescribed for use as an anticancer therapeutic agent (as described in section 1861(s)(2)(Q)), and

(v) self-administered erythropoetin (as described in section 1861(s)(2)(P)).

(k) PAYMENT FOR OUTPATIENT THERAPY SERVICES AND COMPREHENSIVE OUTPATIENT REHABILITATION SERVICES.—

(1) IN GENERAL.—With respect to services described in section 1833(a)(8) or 1833(a)(9) for which payment is determined under this subsection, the payment basis shall be—

(A) for services furnished during 1998, the amount determined under paragraph (2); or

(B) for services furnished during a subsequent year, 80 percent of the lesser of—

(i) the actual charge for the services, or

(ii) the applicable fee schedule amount (as defined in paragraph (3)) for the services.

(2) PAYMENT IN 1998 BASED UPON ADJUSTED REASONABLE COSTS.—The amount under this paragraph for services is the lesser of—

(A) the charges imposed for the services, or

(B) the adjusted reasonable costs (as defined in paragraph (4)) for the services,

less 20 percent of the amount of the charges imposed for such services.

(3) APPLICABLE FEE SCHEDULE AMOUNT.—In this subsection, the term "applicable fee schedule amount" means, with respect to services furnished in a year, the amount determined under the fee schedule established under section 1848 for such services furnished during the year or, if there is no such fee schedule established for such services, the amount determined under the fee schedule established for such comparable services as the Secretary specifies.

(4) ADJUSTED REASONABLE COSTS.—In paragraph (2), the term "adjusted reasonable costs" means, with respect to any services, reasonable costs determined for such services, reduced by 10 percent. The 10-percent reduction shall not apply to services described in section 1833(a)(8)(B) (relating to services provided by hospitals).

(5) UNIFORM CODING.—For claims for services submitted on or after April 1, 1998, for which the amount of payment is determined under this subsection, the claim shall include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(6) RESTRAINT ON BILLING.—The provisions of subparagraphs (A) and (B) of section 1842(b)(18) shall apply to therapy services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1842(b)(18)(C).

(7) ADJUSTMENT IN DISCOUNT FOR CERTAIN MULTIPLE THERAPY SERVICES.—In the case of therapy services furnished on or after April 1, 2013, and for which payment is made under this subsection pursuant to the applicable fee schedule amount (as defined in paragraph (3)), instead of the 25 percent multiple procedure payment reduction specified in the final rule published by the Secretary in the Federal Register on November 29, 2010, the reduction percentage shall be 50 percent.

(l) ESTABLISHMENT OF FEE SCHEDULE FOR AMBULANCE SERVICES.—

(1) IN GENERAL.—The Secretary shall establish a fee schedule for payment for ambulance services whether provided directly by a supplier or provider or under arrangement with a provider under this part through a negotiated rulemaking process described in title 5, United States Code, and in accordance with the requirements of this subsection.

(2) CONSIDERATIONS.—In establishing such fee schedule, the Secretary shall—

(A) establish mechanisms to control increases in expenditures for ambulance services under this part;

(B) establish definitions for ambulance services which link payments to the type of services provided;

(C) consider appropriate regional and operational differences;

(D) consider adjustments to payment rates to account for inflation and other relevant factors; and

(E) phase in the application of the payment rates under the fee schedule in an efficient and fair manner consistent with paragraph (11), except that such phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported.

(3) SAVINGS.—In establishing such fee schedule, the Secretary shall—

(A) ensure that the aggregate amount of payments made for ambulance services under this part during 2000 does not exceed the aggregate amount of payments which would have been made for such services under this part during such year if the amendments made by section 4531(a) of the Balanced Budget Act of 1997 continued in effect, except that in making such determination the Secretary shall assume an update in such payments for 2002 equal to percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points;

(B) set the payment amounts provided under the fee schedule for services furnished in 2001 and each subsequent year at amounts equal to the payment amounts under the fee schedule for services furnished during the previous year, increased, subject to subparagraph (C) and the succeeding sentence of this paragraph, by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points; and

(C) for 2011 and each subsequent year, after determining the percentage increase under subparagraph (B) for the year, reduce such percentage increase by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

The application of subparagraph (C) may result in the percentage increase under subparagraph (B) being less than 0.0 for a year, and may result in payment rates under the fee schedule under this subsection for a year being less than such payment rates for the preceding year.

(4) CONSULTATION.—In establishing the fee schedule for ambulance services under this subsection, the Secretary shall consult with various national organizations representing individuals and entities who furnish and regulate ambulance services and share with such organizations relevant data in establishing such schedule.

(5) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869 or otherwise of the amounts established under the fee schedule for ambulance services under this subsection, including matters described in paragraph (2).

(6) RESTRAINT ON BILLING.—The provisions of subparagraphs (A) and (B) of section 1842(b)(18) shall apply to ambulance services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1842(b)(18)(C).

(7) CODING SYSTEM.—The Secretary may require the claim for any services for which the amount of payment is determined under this subsection to include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(8) SERVICES FURNISHED BY CRITICAL ACCESS HOSPITALS.—Notwithstanding any other provision of this subsection, the Secretary shall pay 101 percent of the reasonable costs incurred in furnishing ambulance services if such services are furnished—

(A) by a critical access hospital (as defined in section 1861(mm)(1)), or

(B) by an entity that is owned and operated by a critical access hospital,

but only if the critical access hospital or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of such critical access hospital.

(9) TRANSITIONAL ASSISTANCE FOR RURAL PROVIDERS.—In the case of ground ambulance services furnished on or after July 1, 2001, and before January 1, 2004, for which the transportation originates in a rural area (as defined in section 1886(d)(2)(D)) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 17 miles, and up to 50 miles, the rate otherwise established shall be increased by not less than ½ of the additional payment per mile established for the first 17 miles of such a trip originating in a rural area.

(10) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In carrying out the phase-in under paragraph (2)(E) for each level of ground service furnished in a year, the portion of the payment amount that is based on the fee schedule shall be the greater of the amount determined under such fee schedule (without regard to this paragraph) or the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

(A) For 2004 (for services furnished on or after July 1, 2004), the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

(B) For 2005, the blended rate shall be based 40 percent on the fee schedule under paragraph (1) and 60 percent on the regional fee schedule.

(C) For 2006, the blended rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

(D) For 2007, 2008, and 2009, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

(E) For 2010 and each succeeding year, the blended rate shall be based 100 percent on the fee schedule under paragraph (1).

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the nine census divisions (referred to in section 1886(d)(2)) using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.

(11) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2009, regardless of where the transportation originates, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by ¼ of the payment per mile otherwise applicable to miles in excess of 50 miles in such trip.

(12) ASSISTANCE FOR RURAL PROVIDERS FURNISHING SERVICES IN LOW POPULATION DENSITY AREAS.—

(A) IN GENERAL.—In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2023, for which the transportation originates in a qualified rural area (identified under subparagraph (B)(iii)), the Secretary shall provide for a percent increase in the base rate of the fee schedule for a trip established under this subsection. In establishing such percent increase, the Secretary shall estimate the average cost per trip for such services (not taking into account mileage) in the lowest quartile as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of all rural county populations.

(B) IDENTIFICATION OF QUALIFIED RURAL AREAS.—

(i) DETERMINATION OF POPULATION DENSITY IN AREA.—Based upon data from the United States decennial census for the year 2000, the Secretary shall determine, for each rural area, the population density for that area.

(ii) RANKING OF AREAS.—The Secretary shall rank each such area based on such population density.

(iii) IDENTIFICATION OF QUALIFIED RURAL AREAS.—The Secretary shall identify those areas (in subparagraph (A) referred to as "qualified rural areas") with the lowest population densities that represent, if each

such area were weighted by the population of such area (as used in computing such population densities), an aggregate total of 25 percent of the total of the population of all such areas.

(iv) RURAL AREA.—For purposes of this paragraph, the term "rural area" has the meaning given such term in section 1886(d)(2)(D). If feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725) as a rural area for purposes of this paragraph.

(v) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the identification of an area under this subparagraph.

(13) TEMPORARY INCREASE FOR GROUND AMBULANCE SERVICES.—

(A) IN GENERAL.—After computing the rates with respect to ground ambulance services under the other applicable provisions of this subsection, in the case of such services furnished on or after July 1, 2004, and before January 1, 2007, and for such services furnished on or after July 1, 2008, and before January 1, 2023, for which the transportation originates in—

(i) a rural area described in paragraph (9) or in a rural census tract described in such paragraph, the fee schedule established under this section shall provide that the rate for the service otherwise established, after the application of any increase under paragraphs (11) and (12), shall be increased by 2 percent (or 3 percent if such service is furnished on or after July 1, 2008, and before January 1, 2023); and

(ii) an area not described in clause (i), the fee schedule established under this subsection shall provide that the rate for the service otherwise established, after the application of any increase under paragraph (11), shall be increased by 1 percent (or 2 percent if such service is furnished on or after July 1, 2008, and before January 1, 2023).

(B) APPLICATION OF INCREASED PAYMENTS AFTER APPLICABLE PERIOD.—The increased payments under subparagraph (A) shall not be taken into account in calculating payments for services furnished after the applicable period specified in such subparagraph.

(14) PROVIDING APPROPRIATE COVERAGE OF RURAL AIR AMBULANCE SERVICES.—

(A) IN GENERAL.—The regulations described in section 1861(s)(7) shall provide, to the extent that any ambulance services (whether ground or air) may be covered under such section, that a rural air ambulance service (as defined in subparagraph (C)) is reimbursed under this subsection at the air ambulance rate if the air ambulance service—

(i) is reasonable and necessary based on the health condition of the individual being transported at or immediately prior to the time of the transport; and

(ii) complies with equipment and crew requirements established by the Secretary.

(B) SATISFACTION OF REQUIREMENT OF MEDICALLY NECESSARY.—The requirement of subparagraph (A)(i) is deemed to be met for a rural air ambulance service if—

(i) subject to subparagraph (D), such service is requested by a physician or other qualified medical personnel (as specified by the Secretary) who certifies or reasonably determines that the individual's condition is such that the time needed to transport the individual by land or the instability of transportation by land poses a threat to the individual's survival or seriously endangers the individual's health; or

(ii) such service is furnished pursuant to a protocol that is established by a State or regional emergency medical service (EMS) agency and recognized or approved by the Secretary under which the use of an air ambulance is recommended, if such agency does not have an ownership interest in the entity furnishing such service.

(C) RURAL AIR AMBULANCE SERVICE DEFINED.—For purposes of this paragraph, the term "rural air ambulance service" means fixed wing and rotary wing air ambulance service in which the point of pick up of the individual occurs in a rural area (as defined in section 1886(d)(2)(D)) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)).

(D) LIMITATION.—

(i) IN GENERAL.—Subparagraph (B)(i) shall not apply if there is a financial or employment relationship between the person requesting the rural air ambulance service and the entity furnishing the ambulance service, or an entity under common ownership with the entity furnishing the air ambulance service, or a financial relationship between an immediate family member of such requester and such an entity.

(ii) EXCEPTION.—Where a hospital and the entity furnishing rural air ambulance services are under common ownership, clause (i) shall not apply to remuneration (through employment or other relationship) by the hospital of the requester or immediate family member if the remuneration is for provider-based physician services furnished in a hospital (as described in section 1887) which are reimbursed under part A and the amount of the remuneration is unrelated directly or indirectly to the provision of rural air ambulance services.

(15) PAYMENT ADJUSTMENT FOR NON-EMERGENCY AMBULANCE TRANSPORTS FOR ESRD BENEFICIARIES.—The fee schedule amount otherwise applicable under the preceding provisions of

this subsection shall be reduced by 10 percent for ambulance services furnished during the period beginning on October 1, 2013, and ending on September 30, 2018, and by 23 percent for such services furnished on or after October 1, 2018, consisting of non-emergency basic life support services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B)) furnished other than on an emergency basis by a provider of services or a renal dialysis facility.

(16) PRIOR AUTHORIZATION FOR REPETITIVE SCHEDULED NON-EMERGENT AMBULANCE TRANSPORTS.—

(A) IN GENERAL.—Beginning January 1, 2017, if the expansion to all States of the model of prior authorization described in paragraph (2) of section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015 meets the requirements described in paragraphs (1) through (3) of section 1115A(c), then the Secretary shall expand such model to all States.

(B) FUNDING.—The Secretary shall use funds made available under section 1893(h)(10) to carry out this paragraph.

(C) CLARIFICATION REGARDING BUDGET NEUTRALITY.—Nothing in this paragraph may be construed to limit or modify the application of section 1115A(b)(3)(B) to models described in such section, including with respect to the model described in subparagraph (A) and expanded beginning on January 1, 2017, under such subparagraph.

(17) SUBMISSION OF COST AND OTHER INFORMATION.—

(A) DEVELOPMENT OF DATA COLLECTION SYSTEM.—The Secretary shall develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary with respect to providers of services (in this paragraph referred to as "providers") and suppliers of ground ambulance services. Such system shall be designed to collect information—

(i) needed to evaluate the extent to which reported costs relate to payment rates under this subsection;

(ii) on the utilization of capital equipment and ambulance capacity, including information consistent with the type of information described in section 1121(a); and

(iii) on different types of ground ambulance services furnished in different geographic locations, including rural areas and low population density areas described in paragraph (12).

(B) SPECIFICATION OF DATA COLLECTION SYSTEM.—

(i) IN GENERAL.—The Secretary shall—

(I) not later than December 31, 2019, specify the data collection system under subparagraph (A); and

(II) identify the providers and suppliers of ground ambulance services that would be required to submit information under such data collection

system, including the representative sample described in clause (ii).

(ii) DETERMINATION OF REPRESENTATIVE SAMPLE.—

(I) IN GENERAL.—Not later than December 31, 2019, with respect to the data collection for the first year under such system, and for each subsequent year through 2024, the Secretary shall determine a representative sample to submit information under the data collection system.

(II) REQUIREMENTS.—The sample under subclause (I) shall be representative of the different types of providers and suppliers of ground ambulance services (such as those providers and suppliers that are part of an emergency service or part of a government organization) and the geographic locations in which ground ambulance services are furnished (such as urban, rural, and low population density areas).

(III) LIMITATION.—The Secretary shall not include an individual provider or supplier of ground ambulance services in the sample under subclause (I) in 2 consecutive years, to the extent practicable.

(C) REPORTING OF COST INFORMATION.—For each year, a provider or supplier of ground ambulance services identified by the Secretary under subparagraph (B)(i)(II) as being required to submit information under the data collection system with respect to a period for the year shall submit to the Secretary information specified under the system. Such information shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) PAYMENT REDUCTION FOR FAILURE TO REPORT.—

(i) IN GENERAL.—Beginning January 1, 2022, subject to clause (ii), a 10 percent reduction to payments under this subsection shall be made for the applicable period (as defined in clause (ii)) to a provider or supplier of ground ambulance services that—

(I) is required to submit information under the data collection system with respect to a period under subparagraph (C); and

(II) does not sufficiently submit such information, as determined by the Secretary.

(ii) APPLICABLE PERIOD DEFINED.—For purposes of clause (i), the term "applicable period" means, with respect to a provider or supplier of ground ambulance services, a year specified by the Secretary not more than 2 years after the end of the period with respect to which the Secretary has made a determination under clause (i)(II) that the provider or supplier of ground ambulance services failed to sufficiently submit information under the data collection system.

(iii) HARDSHIP EXEMPTION.—The Secretary may exempt a provider or supplier from the payment reduction under clause (i) with respect to an applicable pe-

riod in the event of significant hardship, such as a natural disaster, bankruptcy, or other similar situation that the Secretary determines interfered with the ability of the provider or supplier of ground ambulance services to submit such information in a timely manner for the specified period.

(iv) INFORMAL REVIEW.—The Secretary shall establish a process under which a provider or supplier of ground ambulance services may seek an informal review of a determination that the provider or supplier is subject to the payment reduction under clause (i).

(E) ONGOING DATA COLLECTION.—

(i) REVISION OF DATA COLLECTION SYSTEM.—The Secretary may, as the Secretary determines appropriate and, if available, taking into consideration the report (or reports) under subparagraph (F), revise the data collection system under subparagraph (A).

(ii) SUBSEQUENT DATA COLLECTION.—In order to continue to evaluate the extent to which reported costs relate to payment rates under this subsection and for other purposes the Secretary deems appropriate, the Secretary shall require providers and suppliers of ground ambulance services to submit information for years after 2024 as the Secretary determines appropriate, but in no case less often than once every 3 years.

(F) GROUND AMBULANCE DATA COLLECTION SYSTEM STUDY.—

(i) IN GENERAL.—Not later than March 15, 2023, and as determined necessary by the Medicare Payment Advisory Commission thereafter, such Commission shall assess, and submit to Congress a report on, information submitted by providers and suppliers of ground ambulance services through the data collection system under subparagraph (A), the adequacy of payments for ground ambulance services under this subsection, and geographic variations in the cost of furnishing such services.

(ii) CONTENTS.—A report under clause (i) shall contain the following:

(I) An analysis of information submitted through the data collection system.

(II) An analysis of any burden on providers and suppliers of ground ambulance services associated with the data collection system.

(III) A recommendation as to whether information should continue to be submitted through such data collection system or if such system should be revised under subparagraph (E)(i).

(IV) Other information determined appropriate by the Commission.

(G) PUBLIC AVAILABILITY.—The Secretary shall post information on the results of the data collection under this paragraph on the Internet website of the Centers for Medi-

care & Medicaid Services, as determined appropriate by the Secretary.

(H) IMPLEMENTATION.—The Secretary shall implement this paragraph through notice and comment rulemaking.

(I) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information required under this subsection.

(J) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the data collection system or identification of respondents under this paragraph.

(K) FUNDING FOR IMPLEMENTATION.—For purposes of carrying out subparagraph (A), the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $15,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for fiscal year 2018. Amounts transferred under this subparagraph shall remain available until expended.

(m) PAYMENT FOR TELEHEALTH SERVICES.—

(1) IN GENERAL.—The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician (as defined in section 1861(r)) or a practitioner (described in section 1842(b)(18)(C)) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary. For purposes of the preceding sentence, in the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term "telecommunications system" includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.

(2) PAYMENT AMOUNT.—

(A) DISTANT SITE.—The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system.

(B) FACILITY FEE FOR ORIGINATING SITE.—

(i) IN GENERAL.—Subject to clause (ii) and paragraph (6)(C), with respect to a telehealth service, subject to section 1833(a)(1)(U), there shall be paid to the originating site a facility fee equal to—

(I) for the period beginning on October 1, 2001, and ending on December 31, 2001, and for 2002, $20; and

(II) for a subsequent year, the facility fee specified in subclause (I) or this subclause for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year.

(ii) NO FACILITY FEE IF ORIGINATING SITE IS THE HOME.—No facility fee shall be paid under this subparagraph to an originating site described in paragraph (4)(C)(ii)(X).

(C) TELEPRESENTER NOT REQUIRED.—Nothing in this subsection shall be construed as requiring an eligible telehealth individual to be presented by a physician or practitioner at the originating site for the furnishing of a service via a telecommunications system, unless it is medically necessary (as determined by the physician or practitioner at the distant site).

(3) LIMITATION ON BENEFICIARY CHARGES.—

(A) PHYSICIAN AND PRACTITIONER.—The provisions of section 1848(g) and subparagraphs (A) and (B) of section 1842(b)(18) shall apply to a physician or practitioner receiving payment under this subsection in the same manner as they apply to physicians or practitioners under such sections.

(B) ORIGINATING SITE.—The provisions of section 1842(b)(18) shall apply to originating sites receiving a facility fee in the same manner as they apply to practitioners under such section.

(4) DEFINITIONS.—For purposes of this subsection:

(A) DISTANT SITE.—The term "distant site" means the site at which the physician or practitioner is located at the time the service is provided via a telecommunications system.

(B) ELIGIBLE TELEHEALTH INDIVIDUAL.—The term "eligible telehealth individual" means an individual enrolled under this part who receives a telehealth service furnished at an originating site.

(C) ORIGINATING SITE.—

(i) IN GENERAL.—Except as provided in paragraphs (5), (6), and (7), the term"originating site" means only those sites described in clause (ii) at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system and only if such site is located—

(I) in an area that is designated as a rural health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A));

(II) in a county that is not included in a Metropolitan Statistical Area; or

(III) from an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

(ii) SITES DESCRIBED.—The sites referred to in clause (i) are the following sites:

(I) The office of a physician or practitioner.

(II) A critical access hospital (as defined in section 1861(mm)(1)).

(III) A rural health clinic (as defined in section 1861(aa)(2)).

(IV) A Federally qualified health center (as defined in section 1861(aa)(4)).

(V) A hospital (as defined in section 1861(e)).

(VI) A hospital-based or critical access hospital-based renal dialysis center (including satellites).

(VII) A skilled nursing facility (as defined in section 1819(a)).

(VIII) A community mental health center (as defined in section 1861(ff)(3)(B)).

(IX) A renal dialysis facility, but only for purposes of section 1881(b)(3)(B).

(X) The home of an individual, but only for purposes of section 1881(b)(3)(B) or telehealth services described in paragraph (7).

(D) PHYSICIAN.—The term "physician" has the meaning given that term in section 1861(r).

(E) PRACTITIONER.—The term "practitioner" has the meaning given that term in section 1842(b)(18)(C).

(F) TELEHEALTH SERVICE.—

(i) IN GENERAL.—The term "telehealth service" means professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241–99275, 99201–99215, 90804–90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary.

(ii) YEARLY UPDATE.—The Secretary shall establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), as appropriate, to those specified in clause (i) for authorized payment under paragraph (1).

(5) TREATMENT OF HOME DIALYSIS MONTHLY ESRD-RELATED VISIT.—The geographic requirements described in paragraph (4)(C)(i) shall not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of section 1881(b)(3)(B), at an originating site described in subclause (VI), (IX), or (X) of paragraph (4)(C)(ii).

(6) TREATMENT OF STROKE TELEHEALTH SERVICES.—

(A) NON-APPLICATION OF ORIGINATING SITE REQUIREMENTS.—The requirements described in paragraph (4)(C) shall not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke, as determined by the Secretary.

(B) INCLUSION OF CERTAIN SITES.—With respect to telehealth services described in subparagraph (A), the term "originating site" shall include any hospital (as defined in section 1861(e)) or critical access hospital (as defined in section 1861(mm)(1)), any mobile stroke unit (as defined by the Secretary), or any other site determined appropriate by the Secretary, at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system.

(C) NO ORIGINATING SITE FACILITY FEE FOR NEW SITES.—No facility fee shall be paid under paragraph (2)(B) to an originating site with respect to a telehealth service described in subparagraph (A) if the originating site does not otherwise meet the requirements for an originating site under paragraph (4)(C).

(7) TREATMENT OF SUBSTANCE USE DISORDER SERVICES FURNISHED THROUGH TELEHEALTH.—The geographic requirements described in paragraph (4)(C)(i) shall not apply with respect to telehealth services furnished on or after July 1, 2019, to an eligible telehealth individual with a substance use disorder diagnosis for purposes of treatment of such disorder or co-occurring mental health disorder, as determined by the Secretary, at an originating site described in paragraph (4)(C)(ii) (other than an originating site described in subclause (IX) of such paragraph).

(n) AUTHORITY TO MODIFY OR ELIMINATE COVERAGE OF CERTAIN PREVENTIVE SERVICES.—Notwithstanding any other provision of this title, effective beginning on January 1, 2010, if the Secretary determines appropriate, the Secretary may—

(1) modify—

(A) the coverage of any preventive service described in subparagraph (A) of section 1861(ddd)(3) to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force; and

(B) the services included in the initial preventive physical examination described in subparagraph (B) of such section; and

(2) provide that no payment shall be made under this title for a preventive service described in subparagraph (A) of such section that has not received a grade of A, B, C, or I by such Task Force.

(o) DEVELOPMENT AND IMPLEMENTATION OF PROSPECTIVE PAYMENT SYSTEM.—

(1) DEVELOPMENT.—

(A) IN GENERAL.—The Secretary shall develop a prospective payment system for payment for Federally qualified health center services furnished by Federally qualified health centers under this title. Such system shall include a process for appropriately describing the services furnished by Federally qualified health centers and shall establish payment rates for specific payment codes based on such appropriate descriptions of services. Such system shall be established to take into account the type, intensity, and duration of services furnished by Federally qualified health centers. Such system may include adjustments, including geographic adjustments, determined appropriate by the Secretary.

(B) COLLECTION OF DATA AND EVALUATION.—By not later than January 1, 2011, the Secretary shall require Federally qualified health centers to submit to the Secretary such information as the Secretary may require in order to develop and implement the prospective payment system under this subsection, including the reporting of services using HCPCS codes.

(2) IMPLEMENTATION.—

(A) IN GENERAL.—Notwithstanding section 1833(a)(3)(A), the Secretary shall provide, for cost reporting periods beginning on or after October 1, 2014, for payments of prospective payment rates for Federally qualified health center services furnished by Federally qualified health centers under this title in accordance with the prospective payment system developed by the Secretary under paragraph (1).

(B) PAYMENTS.—

(i) INITIAL PAYMENTS.—The Secretary shall implement such prospective payment system so that the estimated aggregate amount of prospective payment rates (determined prior to the application of section 1833(a)(1)(Z)) under this title for Federally qualified health center services in the first year that such system is implemented is equal to 100 percent of the estimated amount of reasonable costs (determined without the application of a per visit payment limit or productivity screen and prior to the application of section 1866(a)(2)(A)(ii)) that would have occurred for such services under this title in such year if the system had not been implemented.

(ii) PAYMENTS IN SUBSEQUENT YEARS.—Payment rates in years after the year of implementation of such system shall be the payment rates in the previous year increased—

(I) in the first year after implementation of such system, by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year involved; and

(II) in subsequent years, by the percentage increase in a market basket of Federally qualified health center goods and services as promulgated through regulations, or if such an index is not available, by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year involved.

(C) PREPARATION FOR PPS IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may establish and implement by program instruction or otherwise the payment codes to be used under the prospective payment system under this section.

(3) ADDITIONAL PAYMENTS FOR CERTAIN FQHCS WITH PHYSICIANS OR OTHER PRACTITIONERS RECEIVING DATA 2000 WAIVERS.—

(A) IN GENERAL.—In the case of a Federally qualified health center with respect to which, beginning on or after January 1, 2019, Federally qualified health center services (as defined in section 1861(aa)(3)) are furnished for the treatment of opioid use disorder by a physician or practitioner who meets the requirements described in subparagraph (C), the Secretary shall, subject to availability of funds under subparagraph (D), make a payment (at such time and in such manner as specified by the Secretary) to such Federally qualified health center after receiving and

approving an application submitted by such Federally qualified health center under subparagraph (B). Such a payment shall be in an amount determined by the Secretary, based on an estimate of the average costs of training for purposes of receiving a waiver described in subparagraph (C)(ii). Such a payment may be made only one time with respect to each such physician or practitioner.

(B) APPLICATION.—In order to receive a payment described in subparagraph (A), a Federally qualified health center shall submit to the Secretary an application for such a payment at such time, in such manner, and containing such information as specified by the Secretary. A Federally qualified health center may apply for such a payment for each physician or practitioner described in subparagraph (A) furnishing services described in such subparagraph at such center.

(C) REQUIREMENTS.—For purposes of subparagraph (A), the requirements described in this subparagraph, with respect to a physician or practitioner, are the following:

(i) The physician or practitioner is employed by or working under contract with a Federally qualified health center described in subparagraph (A) that submits an application under subparagraph (B).

(ii) The physician or practitioner first receives a waiver under section 303(g) of the Controlled Substances Act on or after January 1, 2019.

(D) FUNDING.—For purposes of making payments under this paragraph, there are appropriated, out of amounts in the Treasury not otherwise appropriated, $6,000,000, which shall remain available until expended.

(p) QUALITY INCENTIVES TO PROMOTE PATIENT SAFETY AND PUBLIC HEALTH IN COMPUTED TOMOGRAPHY.—

(1) QUALITY INCENTIVES.—In the case of an applicable computed tomography service (as defined in paragraph (2)) for which payment is made under an applicable payment system (as defined in paragraph (3)) and that is furnished on or after January 1, 2016, using equipment that is not consistent with the CT equipment standard (described in paragraph (4)), the payment amount for such service shall be reduced by the applicable percentage (as defined in paragraph (5)).

(2) APPLICABLE COMPUTED TOMOGRAPHY SERVICES DEFINED.—In this subsection, the term "applicable computed tomography service" means a service billed using diagnostic radiological imaging codes for computed tomography (identified as of January 1, 2014, by HCPCS codes 70450–70498, 71250–71275, 72125–72133, 72191–72194, 73200–73206, 73700–73706, 74150–74178, 74261–74263, and 75571–75574 (and any succeeding codes).

(3) APPLICABLE PAYMENT SYSTEM DEFINED.—In this subsection, the term "applicable payment system" means the following:

(A) The technical component and the technical component of the global fee under the fee schedule established under section 1848(b).

(B) The prospective payment system for hospital outpatient department services under section 1833(t).

(4) CONSISTENCY WITH CT EQUIPMENT STANDARD.—In this subsection, the term "not consistent with the CT equipment standard" means, with respect to an applicable computed tomography service, that the service was furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled "Standard Attributes on CT Equipment Related to Dose Optimization and Management". Through rulemaking, the Secretary may apply successor standards.

(5) APPLICABLE PERCENTAGE DEFINED.—In this subsection, the term "applicable percentage" means—

(A) for 2016, 5 percent; and

(B) for 2017 and subsequent years, 15 percent.

(6) IMPLEMENTATION.—

(A) INFORMATION.—The Secretary shall require that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable computed tomography service was furnished that was not consistent with the CT equipment standard (described in paragraph (4)). Such information may be included on a claim and may be a modifier. Such information shall be verified, as appropriate, as part of the periodic accreditation of suppliers under section 1834(e) and hospitals under section 1865(a).

(B) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to information described in subparagraph (A).

(q) RECOGNIZING APPROPRIATE USE CRITERIA FOR CERTAIN IMAGING SERVICES.—

(1) PROGRAM ESTABLISHED.—

(A) IN GENERAL.—The Secretary shall establish a program to promote the use of appropriate use criteria (as defined in subparagraph (B)) for applicable imaging services (as defined in subparagraph (C)) furnished in an applicable setting (as defined in subparagraph (D)) by ordering professionals and furnishing professionals (as defined in subparagraphs (E) and (F), respectively).

(B) APPROPRIATE USE CRITERIA DEFINED.—In this subsection, the term "appropriate use criteria" means criteria, only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based.

(C) APPLICABLE IMAGING SERVICE DEFINED.—In this subsection, the term "applicable imaging service" means an advanced diagnostic imaging service (as defined in subsection (e)(1)(B)) for which the Secretary determines—

(i) one or more applicable appropriate use criteria specified under paragraph (2) apply;

(ii) there are one or more qualified clinical decision support mechanisms listed under paragraph (3)(C); and

(iii) one or more of such mechanisms is available free of charge.

(D) APPLICABLE SETTING DEFINED.—In this subsection, the term "applicable setting" means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary.

(E) ORDERING PROFESSIONAL DEFINED.—In this subsection, the term "ordering professional" means a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who orders an applicable imaging service.

(F) FURNISHING PROFESSIONAL DEFINED.—In this subsection, the term "furnishing professional" means a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who furnishes an applicable imaging service.

(2) ESTABLISHMENT OF APPLICABLE APPROPRIATE USE CRITERIA.—

(A) IN GENERAL.—Not later than November 15, 2015, the Secretary shall through rulemaking, and in consultation with physicians, practitioners, and other stakeholders, specify applicable appropriate use criteria for applicable imaging services only from among appropriate use criteria developed or endorsed by national professional medical specialty societies or other provider-led entities.

(B) CONSIDERATIONS.—In specifying applicable appropriate use criteria under subparagraph (A), the Secretary shall take into account whether the criteria—

(i) have stakeholder consensus;

(ii) are scientifically valid and evidence based; and

(iii) are based on studies that are published and reviewable by stakeholders.

(C) REVISIONS.—The Secretary shall review, on an annual basis, the specified applicable appropriate use criteria to determine if there is a need to update or revise (as appropriate) such specification of applicable appropriate use criteria and make such updates or revisions through rulemaking.

(D) TREATMENT OF MULTIPLE APPLICABLE APPROPRIATE USE CRITERIA.—In the case where the Secretary determines that more than one appropriate use criterion applies with respect to an applicable imaging service, the Secretary shall apply one or more applicable appropriate use criteria under this paragraph for the service.

(3) MECHANISMS FOR CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(A) IDENTIFICATION OF MECHANISMS TO CONSULT WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(i) IN GENERAL.—The Secretary shall specify qualified clinical decision support mechanisms that could

be used by ordering professionals to consult with applicable appropriate use criteria for applicable imaging services.

(ii) CONSULTATION.—The Secretary shall consult with physicians, practitioners, health care technology experts, and other stakeholders in specifying mechanisms under this paragraph.

(iii) INCLUSION OF CERTAIN MECHANISMS.—Mechanisms specified under this paragraph may include any or all of the following that meet the requirements described in subparagraph (B)(ii):

(I) Use of clinical decision support modules in certified EHR technology (as defined in section 1848(o)(4)).

(II) Use of private sector clinical decision support mechanisms that are independent from certified EHR technology, which may include use of clinical decision support mechanisms available from medical specialty organizations.

(III) Use of a clinical decision support mechanism established by the Secretary.

(B) QUALIFIED CLINICAL DECISION SUPPORT MECHANISMS.—

(i) IN GENERAL.—For purposes of this subsection, a qualified clinical decision support mechanism is a mechanism that the Secretary determines meets the requirements described in clause (ii).

(ii) REQUIREMENTS.—The requirements described in this clause are the following:

(I) The mechanism makes available to the ordering professional applicable appropriate use criteria specified under paragraph (2) and the supporting documentation for the applicable imaging service ordered.

(II) In the case where there is more than one applicable appropriate use criterion specified under such paragraph for an applicable imaging service, the mechanism indicates the criteria that it uses for the service.

(III) The mechanism determines the extent to which an applicable imaging service ordered is consistent with the applicable appropriate use criteria so specified.

(IV) The mechanism generates and provides to the ordering professional a certification or documentation that documents that the qualified clinical decision support mechanism was consulted by the ordering professional.

(V) The mechanism is updated on a timely basis to reflect revisions to the specification of applicable appropriate use criteria under such paragraph.

(VI) The mechanism meets privacy and security standards under applicable provisions of law.

(VII) The mechanism performs such other functions as specified by the Secretary, which may in-

clude a requirement to provide aggregate feedback to the ordering professional.

(C) LIST OF MECHANISMS FOR CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(i) INITIAL LIST.—Not later than April 1, 2016, the Secretary shall publish a list of mechanisms specified under this paragraph.

(ii) PERIODIC UPDATING OF LIST.—The Secretary shall identify on an annual basis the list of qualified clinical decision support mechanisms specified under this paragraph.

(4) CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(A) CONSULTATION BY ORDERING PROFESSIONAL.—Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service ordered by an ordering professional that would be furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), an ordering professional shall—

(i) consult with a qualified decision support mechanism listed under paragraph (3)(C); and

(ii) provide to the furnishing professional the information described in clauses (i) through (iii) of subparagraph (B).

(B) REPORTING BY FURNISHING PROFESSIONAL.—Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), payment for such service may only be made if the claim for the service includes the following:

(i) Information about which qualified clinical decision support mechanism was consulted by the ordering professional for the service.

(ii) Information regarding—

(I) whether the service ordered would adhere to the applicable appropriate use criteria specified under paragraph (2);

(II) whether the service ordered would not adhere to such criteria; or

(III) whether such criteria was not applicable to the service ordered.

(iii) The national provider identifier of the ordering professional (if different from the furnishing professional).

(C) EXCEPTIONS.—The provisions of subparagraphs (A) and (B) and paragraph (6)(A) shall not apply to the following:

(i) EMERGENCY SERVICES.—An applicable imaging service ordered for an individual with an emergency medical condition (as defined in section 1867(e)(1)).

(ii) INPATIENT SERVICES.—An applicable imaging service ordered for an inpatient and for which payment is made under part A.

(iii) SIGNIFICANT HARDSHIP.—An applicable imaging service ordered by an ordering professional who the Secretary may, on a case-by-case basis, exempt from the application of such provisions if the Secretary determines, subject to annual renewal, that consultation with applicable appropriate use criteria would result in a significant hardship, such as in the case of a professional who practices in a rural area without sufficient Internet access.

(D) APPLICABLE PAYMENT SYSTEM DEFINED.—In this subsection, the term "applicable payment system" means the following:

(i) The physician fee schedule established under section 1848(b).

(ii) The prospective payment system for hospital outpatient department services under section 1833(t).

(iii) The ambulatory surgical center payment systems under section 1833(i).

(5) IDENTIFICATION OF OUTLIER ORDERING PROFESSIONALS.—

(A) IN GENERAL.—With respect to applicable imaging services furnished beginning with 2017, the Secretary shall determine, on an annual basis, no more than five percent of the total number of ordering professionals who are outlier ordering professionals.

(B) OUTLIER ORDERING PROFESSIONALS.—The determination of an outlier ordering professional shall—

(i) be based on low adherence to applicable appropriate use criteria specified under paragraph (2), which may be based on comparison to other ordering professionals; and

(ii) include data for ordering professionals for whom prior authorization under paragraph (6)(A) applies.

(C) USE OF TWO YEARS OF DATA.—The Secretary shall use two years of data to identify outlier ordering professionals under this paragraph.

(D) PROCESS.—The Secretary shall establish a process for determining when an outlier ordering professional is no longer an outlier ordering professional.

(E) CONSULTATION WITH STAKEHOLDERS.—The Secretary shall consult with physicians, practitioners and other stakeholders in developing methods to identify outlier ordering professionals under this paragraph.

(6) PRIOR AUTHORIZATION FOR ORDERING PROFESSIONALS WHO ARE OUTLIERS.—

(A) IN GENERAL.—Beginning January 1, 2020, subject to paragraph (4)(C), with respect to services furnished during a year, the Secretary shall, for a period determined appropriate by the Secretary, apply prior authorization for applicable imaging services that are ordered by an outlier ordering professional identified under paragraph (5).

(B) APPROPRIATE USE CRITERIA IN PRIOR AUTHORIZATION.—In applying prior authorization under subparagraph (A), the Secretary shall utilize only the applicable appropriate use criteria specified under this subsection.

(C) FUNDING.—For purposes of carrying out this paragraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2019 through 2021. Amounts transferred under the preceding sentence shall remain available until expended.

(7) CONSTRUCTION.—Nothing in this subsection shall be construed as granting the Secretary the authority to develop or initiate the development of clinical practice guidelines or appropriate use criteria.

(r) PAYMENT FOR RENAL DIALYSIS SERVICES FOR INDIVIDUALS WITH ACUTE KIDNEY INJURY.—

(1) PAYMENT RATE.—In the case of renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14)) furnished under this part by a renal dialysis facility or provider of services paid under such section during a year (beginning with 2017) to an individual with acute kidney injury (as defined in paragraph (2)), the amount of payment under this part for such services shall be the base rate for renal dialysis services determined for such year under such section, as adjusted by any applicable geographic adjustment factor applied under subparagraph (D)(iv)(II) of such section and may be adjusted by the Secretary (on a budget neutral basis for payments under this paragraph) by any other adjustment factor under subparagraph (D) of such section.

(2) INDIVIDUAL WITH ACUTE KIDNEY INJURY DEFINED.—In this subsection, the term "individual with acute kidney injury" means an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14).

(s) PAYMENT FOR APPLICABLE DISPOSABLE DEVICES.—

(1) SEPARATE PAYMENT.—The Secretary shall make a payment (separate from the payments otherwise made under section 1895) in the amount established under paragraph (3) to a home health agency for an applicable disposable device (as defined in paragraph (2)) when furnished on or after January 1, 2017, to an individual who receives home health services for which payment is made under section 1895(b).

(2) APPLICABLE DISPOSABLE DEVICE.—In this subsection, the term applicable disposable device means a disposable device that, as determined by the Secretary, is—

(A) a disposable negative pressure wound therapy device that is an integrated system comprised of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy; and

(B) a substitute for, and used in lieu of, a negative pressure wound therapy durable medical equipment item that is an integrated system of a negative pressure vacuum pump, a separate exudate collection canister, and dressings that would otherwise be covered for individuals for such wound therapy.

(3) PAYMENT AMOUNT.—The separate payment amount established under this paragraph for an applicable disposable device

for a year shall be equal to the amount of the payment that would be made under section 1833(t) (relating to payment for covered OPD services) for the year for the Level I Healthcare Common Procedure Coding System (HCPCS) code for which the description for a professional service includes the furnishing of such device.

(t) SITE-OF-SERVICE PRICE TRANSPARENCY.—

(1) IN GENERAL.—In order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center under this title, the Secretary shall, for 2018 and each year thereafter, make available to the public via a searchable Internet website, with respect to an appropriate number of such items and services—

(A) the estimated payment amount for the item or service under the outpatient department fee schedule under subsection (t) of section 1833 and the ambulatory surgical center payment system under subsection (i) of such section; and

(B) the estimated amount of beneficiary liability applicable to the item or service.

(2) CALCULATION OF ESTIMATED BENEFICIARY LIABILITY.—For purposes of paragraph (1)(B), the estimated amount of beneficiary liability, with respect to an item or service, is the amount for such item or service for which an individual who does not have coverage under a Medicare supplemental policy certified under section 1882 or any other supplemental insurance coverage is responsible.

(3) IMPLEMENTATION.—In carrying out this subsection, the Secretary—

(A) shall include in the notice described in section 1804(a) a notification of the availability of the estimated amounts made available under paragraph (1); and

(B) may utilize mechanisms in existence on the date of enactment of this subsection, such as the portion of the Internet website of the Centers for Medicare & Medicaid Services on which information comparing physician performance is posted (commonly referred to as the Physician Compare Internet website), to make available such estimated amounts under such paragraph.

(4) FUNDING.—For purposes of implementing this subsection, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of $6,000,000 for fiscal year 2017, to remain available until expended.

(u) PAYMENT AND RELATED REQUIREMENTS FOR HOME INFUSION THERAPY.—

(1) PAYMENT.—

(A) SINGLE PAYMENT.—

(i) IN GENERAL.—Subject to clause (iii) and subparagraphs (B) and (C), the Secretary shall implement a payment system under which a single payment is made under this title to a qualified home infusion therapy supplier for items and services described in

subparagraphs (A) and (B) of section 1861(iii)(2)) furnished by a qualified home infusion therapy supplier (as defined in section 1861(iii)(3)(D)) in coordination with the furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C)) under this part.

(ii) UNIT OF SINGLE PAYMENT.—A unit of single payment under the payment system implemented under this subparagraph is for each infusion drug administration calendar day in the individual's home. The Secretary shall, as appropriate, establish single payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type.

(iii) LIMITATION.—The single payment amount determined under this subparagraph after application of subparagraph (B) and paragraph (3) shall not exceed the amount determined under the fee schedule under section 1848 for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day.

(B) REQUIRED ADJUSTMENTS.—The Secretary shall adjust the single payment amount determined under subparagraph (A) for home infusion therapy services under section 1861(iii)(1) to reflect other factors such as—

(i) a geographic wage index and other costs that may vary by region; and

(ii) patient acuity and complexity of drug administration.

(C) DISCRETIONARY ADJUSTMENTS.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary may adjust the single payment amount determined under subparagraph (A) (after application of subparagraph (B)) to reflect outlier situations and other factors as the Secretary determines appropriate.

(ii) REQUIREMENT OF BUDGET NEUTRALITY.—Any adjustment under this subparagraph shall be made in a budget neutral manner.

(2) CONSIDERATIONS.—In developing the payment system under this subsection, the Secretary may consider the costs of furnishing infusion therapy in the home, consult with home infusion therapy suppliers, consider payment amounts for similar items and services under this part and part A, and consider payment amounts established by Medicare Advantage plans under part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy).

(3) ANNUAL UPDATES.—

(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall update the single payment amount under this subsection from year to year beginning in 2022 by increasing the single payment amount from the prior year by the percentage increase in the Consumer Price Index for all

urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

(B) ADJUSTMENT.—For each year, the Secretary shall reduce the percentage increase described in subparagraph (A) by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

(4) AUTHORITY TO APPLY PRIOR AUTHORIZATION.—The Secretary may, as determined appropriate by the Secretary, apply prior authorization for home infusion therapy services under section 1861(iii)(1).

(5) ACCREDITATION OF QUALIFIED HOME INFUSION THERAPY SUPPLIERS.—

(A) FACTORS FOR DESIGNATION OF ACCREDITATION ORGANIZATIONS.—The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

(i) The ability of the organization to conduct timely reviews of accreditation applications.

(ii) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D)).

(iii) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

(iv) Such other factors as the Secretary determines appropriate.

(B) DESIGNATION.—Not later than January 1, 2021, the Secretary shall designate organizations to accredit suppliers furnishing home infusion therapy. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

(C) REVIEW AND MODIFICATION OF LIST OF ACCREDITATION ORGANIZATIONS.—

(i) IN GENERAL.—The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

(ii) SPECIAL RULE FOR ACCREDITATIONS DONE PRIOR TO REMOVAL FROM LIST OF DESIGNATED ACCREDITATION ORGANIZATIONS.—In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall

be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

(D) RULE FOR ACCREDITATIONS MADE PRIOR TO DESIGNATION.—In the case of a supplier that is accredited before January 1, 2021, by an accreditation organization designated by the Secretary under subparagraph (B) as of January 1, 2019, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2023, for the remaining period such accreditation is in effect.

(6) NOTIFICATION OF INFUSION THERAPY OPTIONS AVAILABLE PRIOR TO FURNISHING HOME INFUSION THERAPY.—Prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan described in section 1861(iii)(1) for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.

(7) HOME INFUSION THERAPY SERVICES TEMPORARY TRANSITIONAL PAYMENT.—

(A) TEMPORARY TRANSITIONAL PAYMENT.—

(i) IN GENERAL.—The Secretary shall, in accordance with the payment methodology described in subparagraph (B) and subject to the provisions of this paragraph, provide a home infusion therapy services temporary transitional payment under this part to an eligible home infusion supplier (as defined in subparagraph (F)) for items and services described in subparagraphs (A) and (B) of section 1861(iii)(2)) furnished during the period specified in clause (ii) by such supplier in coordination with the furnishing of transitional home infusion drugs (as defined in clause (iii)).

(ii) PERIOD SPECIFIED.—For purposes of clause (i), the period specified in this clause is the period beginning on January 1, 2019, and ending on the day before the date of the implementation of the payment system under paragraph (1)(A).

(iii) TRANSITIONAL HOME INFUSION DRUG DEFINED.—For purposes of this paragraph, the term "transitional home infusion drug" has the meaning given to the term "home infusion drug" under section 1861(iii)(3)(C)), except that clause (ii) of such section shall not apply if a drug described in such clause is identified in clauses (i), (ii), (iii) or (iv) of subparagraph (C) as of the date of the enactment of this paragraph.

(B) PAYMENT METHODOLOGY.—For purposes of this paragraph, the Secretary shall establish a payment methodology, with respect to items and services described in subparagraph (A)(i). Under such payment methodology the Secretary shall—

(i) create the three payment categories described in clauses (i), (ii), and (iii) of subparagraph (C);

(ii) assign drugs to such categories, in accordance with such clauses;

(iii) assign appropriate Healthcare Common Procedure Coding System (HCPCS) codes to each payment category; and

(iv) establish a single payment amount for each such payment category, in accordance with subparagraph (D), for each infusion drug administration calendar day in the individual's home for drugs assigned to such category.

(C) PAYMENT CATEGORIES.—

(i) PAYMENT CATEGORY 1.—The Secretary shall create a payment category 1 and assign to such category drugs which are covered under the Local Coverage Determination on External Infusion Pumps (LCD number L33794) and billed with the following HCPCS codes (as identified as of January 1, 2018, and as subsequently modified by the Secretary): J0133, J0285, J0287, J0288, J0289, J0895, J1170, J1250, J1265, J1325, J1455, J1457, J1570, J2175, J2260, J2270, J2274, J2278, J3010, or J3285.

(ii) PAYMENT CATEGORY 2.—The Secretary shall create a payment category 2 and assign to such category drugs which are covered under such local coverage determination and billed with the following HCPCS codes (as identified as of January 1, 2018, and as subsequently modified by the Secretary): J1555 JB, J1559 JB, J1561 JB, J1562 JB, J1569 JB, or J1575 JB.

(iii) PAYMENT CATEGORY 3.—The Secretary shall create a payment category 3 and assign to such category drugs which are covered under such local coverage determination and billed with the following HCPCS codes (as identified as of January 1, 2018, and as subsequently modified by the Secretary): J9000, J9039, J9040, J9065, J9100, J9190, J9200, J9360, or J9370.

(iv) INFUSION DRUGS NOT OTHERWISE INCLUDED.—With respect to drugs that are not included in payment category 1, 2, or 3 under clause (i), (ii), or (iii), respectively, the Secretary shall assign to the most appropriate of such categories, as determined by the Secretary, drugs which are—

(I) covered under such local coverage determination and billed under HCPCS codes J7799 or J7999 (as identified as of July 1, 2017, and as subsequently modified by the Secretary); or

(II) billed under any code that is implemented after the date of the enactment of this paragraph and included in such local coverage determination or included in subregulatory guidance as a home infusion drug described in subparagraph (A)(i).

(D) PAYMENT AMOUNTS.—

(i) IN GENERAL.—Under the payment methodology, the Secretary shall pay eligible home infusion sup-

pliers, with respect to items and services described in subparagraph (A)(i) furnished during the period described in subparagraph (A)(ii) by such supplier to an individual, at amounts equal to the amounts determined under the physician fee schedule established under section 1848 for services furnished during the year for codes and units of such codes described in clauses (ii), (iii), and (iv) with respect to drugs included in the payment category under subparagraph (C) specified in the respective clause, determined without application of the geographic adjustment under subsection (e) of such section.

(ii) PAYMENT AMOUNT FOR CATEGORY 1.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 1 described in subparagraph (C)(i), are one unit of HCPCS code 96365 plus three units of HCPCS code 96366 (as identified as of January 1, 2018, and as subsequently modified by the Secretary).

(iii) PAYMENT AMOUNT FOR CATEGORY 2.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 2 described in subparagraph (C)(i), are one unit of HCPCS code 96369 plus three units of HCPCS code 96370 (as identified as of January 1, 2018, and as subsequently modified by the Secretary).

(iv) PAYMENT AMOUNT FOR CATEGORY 3.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 3 described in subparagraph (C)(i), are one unit of HCPCS code 96413 plus three units of HCPCS code 96415 (as identified as of January 1, 2018, and as subsequently modified by the Secretary).

(E) CLARIFICATIONS.—

(i) INFUSION DRUG ADMINISTRATION DAY.—For purposes of this subsection, with respect to the furnishing of transitional home infusion drugs or home infusion drugs to an individual by an eligible home infusion supplier or a qualified home infusion therapy supplier, a reference to payment to such supplier for an infusion drug administration calendar day in the individual's home shall refer to payment only for the date on which professional services (as described in section 1861(iii)(2)(A)) were furnished to administer such drugs to such individual. For purposes of the previous sentence, an infusion drug administration calendar day shall include all such drugs administered to such individual on such day.

(ii) TREATMENT OF MULTIPLE DRUGS ADMINISTERED ON SAME INFUSION DRUG ADMINISTRATION DAY.—In the case that an eligible home infusion supplier, with respect to an infusion drug administration calendar day in an individual's home, furnishes to such individual transitional home infusion drugs which are not all assigned to the same payment category under subpara-

graph (C), payment to such supplier for such infusion drug administration calendar day in the individual's home shall be a single payment equal to the amount of payment under this paragraph for the drug, among all such drugs so furnished to such individual during such calendar day, for which the highest payment would be made under this paragraph.

(F) ELIGIBLE HOME INFUSION SUPPLIERS.—In this paragraph, the term "eligible home infusion supplier" means a supplier that is enrolled under this part as a pharmacy that provides external infusion pumps and external infusion pump supplies and that maintains all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered.

(G) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(v) PAYMENT FOR OUTPATIENT PHYSICAL THERAPY SERVICES AND OUTPATIENT OCCUPATIONAL THERAPY SERVICES FURNISHED BY A THERAPY ASSISTANT.—

(1) IN GENERAL.—In the case of an outpatient physical therapy service or outpatient occupational therapy service furnished on or after January 1, 2022, for which payment is made under section 1848 or subsection (k), that is furnished in whole or in part by a therapy assistant (as defined by the Secretary), the amount of payment for such service shall be an amount equal to 85 percent of the amount of payment otherwise applicable for the service under this part. Nothing in the preceding sentence shall be construed to change applicable requirements with respect to such services.

(2) USE OF MODIFIER.—

(A) ESTABLISHMENT.—Not later than January 1, 2019, the Secretary shall establish a modifier to indicate (in a form and manner specified by the Secretary), in the case of an outpatient physical therapy service or outpatient occupational therapy service furnished in whole or in part by a therapy assistant (as so defined), that the service was furnished by a therapy assistant.

(B) REQUIRED USE.—Each request for payment, or bill submitted, for an outpatient physical therapy service or outpatient occupational therapy service furnished in whole or in part by a therapy assistant (as so defined) on or after January 1, 2020, shall include the modifier established under subparagraph (A) for each such service.

(3) IMPLEMENTATION.—The Secretary shall implement this subsection through notice and comment rulemaking.

(w) OPIOID USE DISORDER TREATMENT SERVICES.—

(1) IN GENERAL.—The Secretary shall pay to an opioid treatment program (as defined in paragraph (2) of section 1861(jjj)) an amount that is equal to 100 percent of a bundled payment under this part for opioid use disorder treatment services (as defined in paragraph (1) of such section) that are furnished by such program to an individual during an episode of care (as defined by the Secretary) beginning on or after January 1, 2020. The Secretary shall ensure, as determined appropriate by the

Secretary, that no duplicative payments are made under this part or part D for items and services furnished by an opioid treatment program.

(2) CONSIDERATIONS.—The Secretary may implement this subsection through one or more bundles based on the type of medication provided (such as buprenorphine, methadone, naltrexone, or a new innovative drug), the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determine appropriate. In developing such bundles, the Secretary may consider payment rates paid to opioid treatment programs for comparable services under State plans under title XIX or under the TRICARE program under chapter 55 of title 10 of the United States Code.

(3) ANNUAL UPDATES.—The Secretary shall provide an update each year to the bundled payment amounts under this subsection.

(x) REBATE BY MANUFACTURERS FOR SINGLE SOURCE DRUGS WITH PRICES INCREASING FASTER THAN INFLATION.—

(1) REQUIREMENTS.—

(A) SECRETARIAL PROVISION OF INFORMATION.—Not later than 6 months after the end of each calendar quarter beginning on or after July 1, 2021, the Secretary shall, for each part B rebatable drug, report to each manufacturer of such part B rebatable drug the following for such calendar quarter:

(i) Information on the total number of units of the billing and payment code described in subparagraph (A)(i) of paragraph (3) with respect to such drug and calendar quarter.

(ii) Information on the amount (if any) of the excess average sales price 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, 2021, the manufacturer of a part B rebatable drug shall, for such drug, not later than 30 days after the date of receipt from the Secretary of the information described in subparagraph (A) for such calendar quarter, provide to the Secretary a rebate that is equal to the amount specified in paragraph (3) for such drug for such calendar quarter.

(2) PART B REBATABLE DRUG DEFINED.—

(A) IN GENERAL.—In this subsection, the term "part B rebatable drug" means a single source drug or biological (as defined in subparagraph (D) of section 1847A(c)(6)), including a biosimilar biological product (as defined in subparagraph (H) of such section), paid for under this part, except such term shall not include such a drug or biological—

(i) if the average total allowed charges for a year per individual that uses such a drug or biological, as de-

termined by the Secretary, are less than, subject to subparagraph (B), $100; or

(ii) that is a vaccine described in subparagraph (A) or (B) of section 1861(s)(10).

(B) INCREASE.—The dollar amount applied under subparagraph (A)(i)—

(i) for 2022, shall be the dollar amount specified under such subparagraph for 2021, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12 month period ending with June of the previous year; and

(ii) for a subsequent year, shall be the dollar amount specified in this clause (or clause (i)) for the previous year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12 month period ending with June of the previous year.

Any dollar amount specified under this subparagraph that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(3) REBATE AMOUNT.—

(A) IN GENERAL.—For purposes of paragraph (1), the amount specified in this paragraph for a part B rebatable drug assigned to a billing and payment code for a calendar quarter is, subject to paragraph (4), the amount equal to the product of—

(i) subject to subparagraphs (B) and (G), the total number of units of the billing and payment code for such part B rebatable drug furnished under this part during the calendar quarter; and

(ii) the amount (if any) by which—

(I) the payment amount under subparagraph (B) or (C) of section 1847A(b)(1), as applicable, for such part B rebatable drug during the calendar quarter; exceeds

(II) the inflation-adjusted payment amount determined under subparagraph (C) for such part B rebatable drug during the calendar quarter.

(B) EXCLUDED UNITS.—For purposes of subparagraph (A)(i), the total number of units of the billing and payment code for each part B rebatable drug furnished during a calendar quarter shall not include—

(i) units packaged into the payment for a procedure or service under section 1833(t) or under section 1833(i) (instead of separately payable under such respective section);

(ii) units included under the single payment system for renal dialysis services under section 1881(b)(14); or

(iii) units of a part B rebatable drug of a manufacturer furnished to an individual, if such manufacturer, with respect to the furnishing of such units of such drug, provides for discounts under section 340B of the Public Health Service Act or for rebates under section 1927.

(C) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this subparagraph for a part B rebatable drug for a calendar quarter is—

(i) the payment amount for the billing and payment code for such drug in the payment amount benchmark quarter (as defined in subparagraph (D)); increased by

(ii) the percentage by which the rebate period CPI–U (as defined in subparagraph (F)) for the calendar quarter exceeds the benchmark period CPI–U (as defined in subparagraph (E)).

(D) PAYMENT AMOUNT BENCHMARK QUARTER.—The term "payment amount benchmark quarter" means the calendar quarter beginning January 1, 2016.

(E) BENCHMARK PERIOD CPI–U.—The term "benchmark period CPI–U" means the consumer price index for all urban consumers (United States city average) for July 2015.

(F) REBATE PERIOD CPI–U.—The term "rebate period CPI–U" means, with respect to a calendar quarter described in subparagraph (C), the greater of the benchmark period CPI–U and the consumer price index for all urban consumers (United States city average) for the first month of the calendar quarter that is two calendar quarters prior to such described calendar quarter.

(G) COUNTING UNITS.—

(i) CUT-OFF PERIOD TO COUNT UNITS.—For purposes of subparagraph (A)(i), subject to clause (ii), to count the total number of billing units for a part B rebatable drug for a quarter, the Secretary may use a cut-off period in order to exclude from such total number of billing units for such quarter claims for services furnished during such quarter that were not processed at an appropriate time prior to the end of the cut-off period.

(ii) COUNTING UNITS FOR CLAIMS PROCESSED AFTER CUT-OFF PERIOD.—If the Secretary uses a cut-off period pursuant to clause (i), in the case of units of a part B rebatable drug furnished during a quarter but pursuant to application of such cut-off period excluded for purposes of subparagraph (A)(i) from the total number of billing units for the drug for such quarter, the Secretary shall count such units of such drug so furnished in the total number of billing units for such drug for a subsequent quarter, as the Secretary determines appropriate.

(4) SPECIAL TREATMENT OF CERTAIN DRUGS AND EXEMPTION.—

(A) SUBSEQUENTLY APPROVED DRUGS.—Subject to subparagraph (B), in the case of a part B rebatable drug first approved or licensed by the Food and Drug Administration after July 1, 2015, clause (i) of paragraph (3)(C) shall be applied as if the term "payment amount benchmark quarter" were defined under paragraph (3)(D) as the third full calendar quarter after the day on which the drug was first marketed and clause (ii) of paragraph (3)(C) shall be ap-

plied as if the term "benchmark period CPI–U" were defined under paragraph (3)(E) as if the reference to "July 2015" under such paragraph were a reference to "the first month of the first full calendar quarter after the day on which the drug was first marketed".

(B) TIMELINE FOR PROVISION OF REBATES FOR SUBSEQUENTLY APPROVED DRUGS.—In the case of a part B rebatable drug first approved or licensed by the Food and Drug Administration after July 1, 2015, paragraph (1)(B) shall be applied as if the reference to "July 1, 2021" under such paragraph were a reference to the later of the 6th full calendar quarter after the day on which the drug was first marketed or July 1, 2021.

(C) EXEMPTION FOR SHORTAGES.—The Secretary may reduce or waive the rebate amount under paragraph (1)(B) with respect to a part B rebatable drug that is described as currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act or in the case of other exigent circumstances, as determined by the Secretary.

(D) SELECTED DRUGS.—In the case of a part B rebatable drug that is a selected drug (as defined in section 1192(c)) for a price applicability period (as defined in section 1191(b)(2)) and is determined (pursuant to such section 1192(c)) to no longer be a selected drug, for each applicable year beginning after the price applicability period with respect to such drug, clause (i) of paragraph (3)(C) shall be applied as if the term "payment amount benchmark quarter" were defined under paragraph (3)(D) as the calendar quarter beginning January 1 of the last year beginning during such price applicability period with respect to such selected drug and clause (ii) of paragraph (3)(C) shall be applied as if the term "benchmark period CPI–U" were defined under paragraph (3)(E) as if the reference to "July 2015" under such paragraph were a reference to the July of the year preceding such last year.

(5) APPLICATION TO BENEFICIARY COINSURANCE.—In the case of a part B rebatable drug, if the payment amount for a quarter exceeds the inflation adjusted payment for such quarter—

(A) in computing the amount of any coinsurance applicable under this title to an individual with respect to such drug, the computation of such coinsurance shall be based on the inflation-adjusted payment amount determined under paragraph (3)(C) for such part B rebatable drug; and

(B) the amount of such coinsurance is equal to 20 percent of such inflation-adjusted payment amount so determined.

(6) REBATE DEPOSITS.—Amounts paid as rebates under paragraph (1)(B) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

(7) CIVIL MONEY PENALTY.—If a manufacturer of a part B rebatable drug has failed to comply with the requirements under paragraph (1)(B) for such drug for a calendar quarter, the manufacturer shall be subject to, in accordance with a process established by the Secretary pursuant to regulations, a civil

money penalty in an amount equal to at least 125 percent of the amount specified in paragraph (3) for such drug for such calendar quarter. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(8) STUDY AND REPORT.—

(A) STUDY.—The Secretary shall conduct a study of the feasibility of and operational issues involved with the following:

(i) Including multiple source drugs (as defined in section 1847A(c)(6)(C)) in the rebate system under this subsection.

(ii) Including drugs and biologicals paid for under MA plans under part C in the rebate system under this subsection.

(iii) Including drugs excluded under paragraph (2)(A) and units of the billing and payment code of the drugs excluded under paragraph (3)(B) in the rebate system under this subsection.

(B) REPORT.—Not later than 3 years after the date of the enactment of this subsection, the Secretary shall submit to Congress a report on the study conducted under subparagraph (A).

(9) APPLICATION TO MULTIPLE SOURCE DRUGS.—The Secretary may, based on the report submitted under paragraph (8) and pursuant to rulemaking, apply the provisions of this subsection to multiple source drugs (as defined in section 1847A(c)(6)(C)), including, for purposes of determining the rebate amount under paragraph (3), by calculating manufacturer-specific average sales prices for the benchmark period and the rebate period.

* * * * * * *

USE OF AVERAGE SALES PRICE PAYMENT METHODOLOGY

SEC. 1847A. (a) APPLICATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), this section shall apply to payment for drugs and biologicals that are described in section 1842(o)(1)(C) and that are furnished on or after January 1, 2005.

(2) ELECTION.—This section shall not apply in the case of a physician who elects under subsection (a)(1)(A)(ii) of section 1847B for that section to apply instead of this section for the payment for drugs and biologicals.

(b) PAYMENT AMOUNT.—

(1) IN GENERAL.—Subject to paragraph (7) and subsections (d)(3)(C) and (e), the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), 106 percent of the amount determined under paragraph (3) for a multiple source drug furnished before April 1, 2008, or 106 percent of the amount

determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008;

(B) in the case of a single source drug or biological (as defined in subsection (c)(6)(D)), 106 percent of the amount determined under paragraph (4) *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*; or

(C) in the case of a biosimilar biological product (as defined in subsection (c)(6)(H)), the amount determined under paragraph (8).

(2) SPECIFICATION OF UNIT.—

(A) SPECIFICATION BY MANUFACTURER.—The manufacturer of a drug or biological shall specify the unit associated with each National Drug Code (including package size) as part of the submission of data under section 1927(b)(3)(A)(iii).

(B) UNIT DEFINED.—In this section, the term "unit" means, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. For years after 2004, the Secretary may establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section.

(3) MULTIPLE SOURCE DRUG.—For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) determined by—

(A) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(i) the manufacturer's average sales price (as defined in subsection (c)); and

(ii) the total number of units specified under paragraph (2) sold; and

(B) dividing the sum determined under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all National Drug Codes assigned to such drug products.

(4) SINGLE SOURCE DRUG OR BIOLOGICAL.—The amount specified in this paragraph for a single source drug or biological is the lesser of the following:

(A) AVERAGE SALES PRICE.—The average sales price as determined using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(B) WHOLESALE ACQUISITION COST (WAC).—The wholesale acquisition cost (as defined in subsection (c)(6)(B)) using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(5) BASIS FOR PAYMENT AMOUNT.—The payment amount shall be determined under this subsection based on information reported under subsection (f) and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(6) USE OF VOLUME-WEIGHTED AVERAGE SALES PRICES IN CALCULATION OF AVERAGE SALES PRICE.—

(A) IN GENERAL.—For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) determined by—

(i) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(I) the manufacturer's average sales price (as defined in subsection (c)), determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code; and

(II) the total number of units specified under paragraph (2) sold; and

(ii) dividing the sum determined under clause (i) by the sum of the products (for each National Drug Code assigned to such drug products) of—

(I) the total number of units specified under paragraph (2) sold; and

(II) the total number of billing units for the National Drug Code for the billing and payment code.

(B) BILLING UNIT DEFINED.—For purposes of this subsection, the term "billing unit" means the identifiable quantity associated with a billing and payment code, as established by the Secretary.

(7) SPECIAL RULE.—Beginning with April 1, 2008, the payment amount for—

(A) each single source drug or biological described in section 1842(o)(1)(G) that is treated as a multiple source drug because of the application of subsection (c)(6)(C)(ii) is the lower of—

(i) the payment amount that would be determined for such drug or biological applying such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied; and

(B) a multiple source drug described in section 1842(o)(1)(G) (excluding a drug or biological that is treated

as a multiple source drug because of the application of such subsection) is the lower of—

(i) the payment amount that would be determined for such drug or biological taking into account the application of such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied.

(8) BIOSIMILAR BIOLOGICAL PRODUCT.—The amount specified in this paragraph for a biosimilar biological product described in paragraph (1)(C) is the sum of—

(A) the average sales price as determined using the methodology described under paragraph (6) applied to a biosimilar biological product for all National Drug Codes assigned to such product in the same manner as such paragraph is applied to drugs described in such paragraph; and

(B) 6 percent of the amount determined under paragraph (4) for the reference biological product (as defined in subsection (c)(6)(I)).

(c) MANUFACTURER'S AVERAGE SALES PRICE.—

(1) IN GENERAL.—For purposes of this section, subject to paragraphs (2) and (3), the manufacturer's "average sales price" means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit—

(A) the manufacturer's sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological in the calendar quarter; divided by

(B) the total number of such units of such drug or biological sold by the manufacturer in such quarter.

(2) CERTAIN SALES EXEMPTED FROM COMPUTATION.—In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

(A) SALES EXEMPT FROM BEST PRICE.—Sales exempt from the inclusion in the determination of "best price' under section 1927(c)(1)(C)(i).

(B) SALES AT NOMINAL CHARGE.—Such other sales as the Secretary identifies as sales to an entity that are merely nominal in amount (as applied for purposes of section 1927(c)(1)(C)(ii)(III), except as the Secretary may otherwise provide).

(3) SALE PRICE NET OF DISCOUNTS.—In calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under ⟦section 1927⟧ *section 1927, section 1834(x), or section 1860D–14B*). For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.

(4) PAYMENT METHODOLOGY IN CASES WHERE AVERAGE SALES PRICE DURING FIRST QUARTER OF SALES IS UNAVAILABLE.—In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for

sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section—

(A) in the case of a drug or biological furnished prior to January 1, 2019, based on—

(i) the wholesale acquisition cost; or

(ii) the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals; and

(B) in the case of a drug or biological furnished on or after January 1, 2019—

(i) at an amount not to exceed 103 percent of the wholesale acquisition cost; or

(ii) based on the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals.

(5) FREQUENCY OF DETERMINATIONS.—

(A) IN GENERAL ON A QUARTERLY BASIS.—The manufacturer's average sales price, for a drug or biological of a manufacturer, shall be calculated by such manufacturer under this subsection on a quarterly basis. In making such calculation insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks. For years after 2004, the Secretary may establish a uniform methodology under this subparagraph to estimate and apply such costs.

(B) UPDATES IN PAYMENT AMOUNTS.—The payment amounts under subsection (b) shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer's average sales price calculated for the most recent calendar quarter for which data is available.

(C) USE OF CONTRACTORS; IMPLEMENTATION.—The Secretary may contract with appropriate entities to calculate the payment amount under subsection (b). Notwithstanding any other provision of law, the Secretary may implement, by program instruction or otherwise, any of the provisions of this section.

(6) DEFINITIONS AND OTHER RULES.—In this section:

(A) MANUFACTURER.—The term "manufacturer" means, with respect to a drug or biological, the manufacturer (as defined in section 1927(k)(5)).

(B) WHOLESALE ACQUISITION COST.—The term "wholesale acquisition cost" means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price

guides or other publications of drug or biological pricing data.

(C) MULTIPLE SOURCE DRUG.—

(i) IN GENERAL.—The term "multiple source drug" means, for a calendar quarter, a drug for which there are 2 or more drug products which—

(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

(III) are sold or marketed in the United States during the quarter.

(ii) EXCEPTION.—With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs.

(D) SINGLE SOURCE DRUG OR BIOLOGICAL.—The term "single source drug or biological" means—

(i) a biological; or

(ii) a drug which is not a multiple source drug and which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(E) EXCEPTION FROM PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE REQUIREMENT.—Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

(F) DETERMINATION OF PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE.—For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

(G) INCLUSION OF VACCINES.—In applying provisions of section 1927 under this section, "other than a vaccine" is deemed deleted from section 1927(k)(2)(B).

(H) BIOSIMILAR BIOLOGICAL PRODUCT.—The term "biosimilar biological product" means a biological product ap-

proved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act.

(I) REFERENCE BIOLOGICAL PRODUCT.—The term "reference biological product" means the biological product licensed under such section 351 that is referred to in the application described in subparagraph (H) of the biosimilar biological product.

(d) MONITORING OF MARKET PRICES.—

(1) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.

(2) COMPARISON OF PRICES.—Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the average sales price under this section for drugs and biologicals with—

(A) the widely available market price for such drugs and biologicals (if any); and

(B) the average manufacturer price (as determined under section 1927(k)(1)) for such drugs and biologicals.

(3) LIMITATION ON AVERAGE SALES PRICE.—

(A) IN GENERAL.—The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).

(B) APPLICABLE THRESHOLD PERCENTAGE DEFINED.—In this paragraph, the term "applicable threshold percentage" means—

(i) in 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; and

(ii) in 2006 and subsequent years, the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both.

(C) AUTHORITY TO ADJUST AVERAGE SALES PRICE.—If the Inspector General finds that the average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of—

(i) the widely available market price for the drug or biological (if any); or

(ii) 103 percent of the average manufacturer price (as determined under section 1927(k)(1)) for the drug or biological.

(4) CIVIL MONEY PENALTY.—

(A) IN GENERAL.—If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of the manufacturer's average sales price for a drug or biological, the Secretary may apply a civil money penalty in an amount of up to $10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied.

(B) PROCEDURES.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (B) in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(5) WIDELY AVAILABLE MARKET PRICE.—

(A) IN GENERAL.—In this subsection, the term "widely available market price" means the price that a prudent physician or supplier would pay for the drug or biological. In determining such price, the Inspector General shall take into account the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals.

(B) CONSIDERATIONS.—In determining the price under subparagraph (A), the Inspector General shall consider information from one or more of the following sources:

(i) Manufacturers.

(ii) Wholesalers.

(iii) Distributors.

(iv) Physician supply houses.

(v) Specialty pharmacies.

(vi) Group purchasing arrangements.

(vii) Surveys of physicians.

(viii) Surveys of suppliers.

(ix) Information on such market prices from insurers.

(x) Information on such market prices from private health plans.

(e) AUTHORITY TO USE ALTERNATIVE PAYMENT IN RESPONSE TO PUBLIC HEALTH EMERGENCY.—In the case of a public health emergency under section 319 of the Public Health Service Act in which there is a documented inability to access drugs and biologicals, and a concomitant increase in the price, of a drug or biological which is not reflected in the manufacturer's average sales price for one or more quarters, the Secretary may use the wholesale acquisition cost (or other reasonable measure of drug or biological price) instead of the manufacturer's average sales price for such quarters and for subsequent quarters until the price and availability of the drug or biological has stabilized and is substantially reflected in the applicable manufacturer's average sales price.

(f) QUARTERLY REPORT ON AVERAGE SALES PRICE.—For requirements for reporting the manufacturer's average sales price (and, if required to make payment, the manufacturer's wholesale acquisi-

tion cost) for the drug or biological under this section, see section 1927(b)(3).

(g) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

(1) determinations of payment amounts under this section, including the assignment of National Drug Codes to billing and payment codes;

(2) the identification of units (and package size) under subsection (b)(2);

(3) the method to allocate rebates, chargebacks, and other price concessions to a quarter if specified by the Secretary;

(4) the manufacturer's average sales price when it is used for the determination of a payment amount under this section; and

(5) the disclosure of the average manufacturer price by reason of an adjustment under subsection (d)(3)(C) or (e).

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PART C—MEDICARE+CHOICE PROGRAM

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CONTRACTS WITH MEDICARE+CHOICE ORGANIZATIONS

SEC. 1857. (a) IN GENERAL.—The Secretary shall not permit the election under section 1851 of a Medicare+Choice plan offered by a Medicare+Choice organization under this part, and no payment shall be made under section 1853 to an organization, unless the Secretary has entered into a contract under this section with the organization with respect to the offering of such plan. Such a contract with an organization may cover more than 1 Medicare+Choice plan. Such contract shall provide that the organization agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(b) MINIMUM ENROLLMENT REQUIREMENTS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may not enter into a contract under this section with a Medicare+Choice organization unless the organization has—

(A) at least 5,000 individuals (or 1,500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization, or

(B) at least 1,500 individuals (or 500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization if the organization primarily serves individuals residing outside of urbanized areas.

(2) APPLICATION TO MSA PLANS.—In applying paragraph (1) in the case of a Medicare+Choice organization that is offering an MSA plan, paragraph (1) shall be applied by substituting covered lives for individuals.

(3) ALLOWING TRANSITION.—The Secretary may waive the requirement of paragraph (1) during the first 3 contract years with respect to an organization.

(c) CONTRACT PERIOD AND EFFECTIVENESS.—

(1) PERIOD.—Each contract under this section shall be for a term of at least 1 year, as determined by the Secretary, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term.

(2) TERMINATION AUTHORITY.—In accordance with procedures established under subsection (h), the Secretary may at any time terminate any such contract if the Secretary determines that the organization—

(A) has failed substantially to carry out the contract;

(B) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part; or

(C) no longer substantially meets the applicable conditions of this part.

(3) EFFECTIVE DATE OF CONTRACTS.—The effective date of any contract executed pursuant to this section shall be specified in the contract, except that in no case shall a contract under this section which provides for coverage under an MSA plan be effective before January 1999 with respect to such coverage.

(4) PREVIOUS TERMINATIONS.—

(A) IN GENERAL.—The Secretary may not enter into a contract with a Medicare+Choice organization if a previous contract with that organization under this section was terminated at the request of the organization within the preceding 2-year period, except as provided in subparagraph (B) and except in such other circumstances which warrant special consideration, as determined by the Secretary.

(B) EARLIER RE-ENTRY PERMITTED WHERE CHANGE IN PAYMENT POLICY.—Subparagraph (A) shall not apply with respect to the offering by a Medicare+Choice organization of a Medicare+Choice plan in a Medicare+Choice payment area if during the 6-month period beginning on the date the organization notified the Secretary of the intention to terminate the most recent previous contract, there was a legislative change enacted (or a regulatory change adopted) that has the effect of increasing payment amounts under section 1853 for that Medicare+Choice payment area.

(5) CONTRACTING AUTHORITY.—The authority vested in the Secretary by this part may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this title.

(d) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—

(1) PERIODIC AUDITING.—The Secretary shall provide for the annual auditing of the financial records (including data relating to medicare utilization and costs, including allowable costs under section 1858(c)) of at least one-third of the Medicare+Choice organizations offering Medicare+Choice plans under this part. The Comptroller General shall monitor auditing activities conducted under this subsection.

(2) INSPECTION AND AUDIT.—Each contract under this section shall provide that the Secretary, or any person or organization designated by the Secretary—

(A) shall have the right to timely inspect or otherwise evaluate (i) the quality, appropriateness, and timeliness of services performed under the contract, and (ii) the facilities of the organization when there is reasonable evidence of some need for such inspection, and

(B) shall have the right to timely audit and inspect any books and records of the Medicare+Choice organization that pertain (i) to the ability of the organization to bear the risk of potential financial losses, or (ii) to services performed or determinations of amounts payable under the contract.

(3) ENROLLEE NOTICE AT TIME OF TERMINATION.—Each contract under this section shall require the organization to provide (and pay for) written notice in advance of the contract's termination, as well as a description of alternatives for obtaining benefits under this title, to each individual enrolled with the organization under this part.

(4) DISCLOSURE.—

(A) IN GENERAL.—Each Medicare+Choice organization shall, in accordance with regulations of the Secretary, report to the Secretary financial information which shall include the following:

(i) Such information as the Secretary may require demonstrating that the organization has a fiscally sound operation.

(ii) A copy of the report, if any, filed with the Secretary containing the information required to be reported under section 1124 by disclosing entities.

(iii) A description of transactions, as specified by the Secretary, between the organization and a party in interest. Such transactions shall include—

(I) any sale or exchange, or leasing of any property between the organization and a party in interest;

(II) any furnishing for consideration of goods, services (including management services), or facilities between the organization and a party in interest, but not including salaries paid to employees for services provided in the normal course of their employment and health services provided to members by hospitals and other providers and by staff, medical group (or groups), individual practice association (or associations), or any combination thereof; and

(III) any lending of money or other extension of credit between an organization and a party in interest.

The Secretary may require that information reported respecting an organization which controls, is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(B) PARTY IN INTEREST DEFINED.—For the purposes of this paragraph, the term "party in interest" means—

(i) any director, officer, partner, or employee responsible for management or administration of a Medicare+Choice organization, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the organization, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the organization, and, in the case of a Medicare+Choice organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

(ii) any entity in which a person described in clause (i)—

(I) is an officer or director;

(II) is a partner (if such entity is organized as a partnership);

(III) has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(IV) has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(iii) any person directly or indirectly controlling, controlled by, or under common control with an organization; and

(iv) any spouse, child, or parent of an individual described in clause (i).

(C) ACCESS TO INFORMATION.—Each Medicare+Choice organization shall make the information reported pursuant to subparagraph (A) available to its enrollees upon reasonable request.

(5) LOAN INFORMATION.—The contract shall require the organization to notify the Secretary of loans and other special financial arrangements which are made between the organization and subcontractors, affiliates, and related parties.

(6) REVIEW TO ENSURE COMPLIANCE WITH CARE MANAGEMENT REQUIREMENTS FOR SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS INDIVIDUALS.—In conjunction with the periodic audit of a specialized Medicare Advantage plan for special needs individuals under paragraph (1), the Secretary shall conduct a review to ensure that such organization offering the plan meets the requirements described in section 1859(f)(5).

(e) ADDITIONAL CONTRACT TERMS.—

(1) IN GENERAL.—The contract shall contain such other terms and conditions not inconsistent with this part (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.

(2) COST-SHARING IN ENROLLMENT-RELATED COSTS.—

(A) IN GENERAL.—A Medicare+Choice organization and a PDP sponsor under part D shall pay the fee established by the Secretary under subparagraph (B).

(B) AUTHORIZATION.—The Secretary is authorized to charge a fee to each Medicare+Choice organization with a contract under this part and each PDP sponsor with a contract under part D that is equal to the organization' or sponsor's pro rata share (as determined by the Secretary) of the aggregate amount of fees which the Secretary is directed to collect in a fiscal year. Any amounts collected shall be available without further appropriation to the Secretary for the purpose of carrying out section 1851 (relating to enrollment and dissemination of information), section 1860D-1(c), and section 4360 of the Omnibus Budget Reconciliation Act of 1990 (relating to the health insurance counseling and assistance program).

(C) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the purposes described in subparagraph (B) for each fiscal year beginning with fiscal year 2001 and ending with fiscal year 2005 an amount equal to $100,000,000, and for each fiscal year beginning with fiscal year 2006 an amount equal to $200,000,000, reduced by the amount of fees authorized to be collected under this paragraph and section 1860D–12(b)(3)(D) for the fiscal year.

(D) LIMITATION.—In any fiscal year the fees collected by the Secretary under subparagraph (B) shall not exceed the lesser of—

(i) the estimated costs to be incurred by the Secretary in the fiscal year in carrying out the activities described in section 1851 and section 1860D–1(c) and section 4360 of the Omnibus Budget Reconciliation Act of 1990; or

(ii)(I) $200,000,000 in fiscal year 1998;

(II) $150,000,000 in fiscal year 1999;

(III) $100,000,000 in fiscal year 2000;

(IV) the Medicare+Choice portion (as defined in subparagraph (E)) of $100,000,000 in fiscal year 2001 and each succeeding fiscal year before fiscal year 2006; and

(V) the applicable portion (as defined in subparagraph (F)) of $200,000,000 in fiscal year 2006 and each succeeding fiscal year.

(E) MEDICARE+CHOICE PORTION DEFINED.—In this paragraph, the term "Medicare+Choice portion" means, for a fiscal year, the ratio, as estimated by the Secretary, of—

(i) the average number of individuals enrolled in Medicare+Choice plans during the fiscal year, to

(ii) the average number of individuals entitled to benefits under part A, and enrolled under part B, during the fiscal year.

(F) APPLICABLE PORTION DEFINED.—In this paragraph, the term "applicable portion" means, for a fiscal year—

(i) with respect to MA organizations, the Secretary's estimate of the total proportion of expenditures under this title that are attributable to expenditures made under this part (including payments under part D that are made to such organizations); or

(ii) with respect to PDP sponsors, the Secretary's estimate of the total proportion of expenditures under this title that are attributable to expenditures made to such sponsors under part D.

(3) AGREEMENTS WITH FEDERALLY QUALIFIED HEALTH CENTERS.—

(A) PAYMENT LEVELS AND AMOUNTS.—A contract under this section with an MA organization shall require the organization to provide, in any written agreement described in section 1853(a)(4) between the organization and a federally qualified health center, for a level and amount of payment to the federally qualified health center for services provided by such health center that is not less than the level and amount of payment that the plan would make for such services if the services had been furnished by a entity providing similar services that was not a federally qualified health center.

(B) COST-SHARING.—Under the written agreement referred to in subparagraph (A), a federally qualified health center must accept the payment amount referred to in such subparagraph plus the Federal payment provided for in section 1833(a)(3)(B) as payment in full for services covered by the agreement, except that such a health center may collect any amount of cost-sharing permitted under the contract under this section, so long as the amounts of any deductible, coinsurance, or copayment comply with the requirements under section 1854(e).

(4) REQUIREMENT FOR MINIMUM MEDICAL LOSS RATIO.—If the Secretary determines for a contract year (beginning with 2014) that an MA plan has failed to have a medical loss ratio of at least .85—

(A) the MA plan shall remit to the Secretary an amount equal to the product of—

(i) the total revenue of the MA plan under this part for the contract year; and

(ii) the difference between .85 and the medical loss ratio;

(B) for 3 consecutive contract years, the Secretary shall not permit the enrollment of new enrollees under the plan for coverage during the second succeeding contract year; and

(C) the Secretary shall terminate the plan contract if the plan fails to have such a medical loss ratio for 5 consecutive contract years.

(5) COMMUNICATING PLAN CORRECTIVE ACTIONS AGAINST OPIOIDS OVER-PRESCRIBERS.—

(A) IN GENERAL.—Beginning with plan years beginning on or after January 1, 2021, a contract under this section with an MA organization shall require the organization to submit to the Secretary, through the process established under subparagraph (B), information on the investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier related to fraud, and other actions taken by such plans related to inappropriate prescribing of opioids.

(B) PROCESS.—Not later than January 1, 2021, the Secretary shall, in consultation with stakeholders, establish a process under which MA plans and prescription drug plans shall submit to the Secretary information described in subparagraph (A).

(C) REGULATIONS.—For purposes of this paragraph, including as applied under section 1860D–12(b)(3)(D), the Secretary shall, pursuant to rulemaking—

(i) specify a definition for the term "inappropriate prescribing" and a method for determining if a provider of services prescribes inappropriate prescribing; and

(ii) establish the process described in subparagraph (B) and the types of information that shall be submitted through such process.

(f) PROMPT PAYMENT BY MEDICARE+CHOICE ORGANIZATION.—

(1) REQUIREMENT.—A contract under this part shall require a Medicare+Choice organization to provide prompt payment (consistent with the provisions of sections 1816(c)(2) and 1842(c)(2)) of claims submitted for services and supplies furnished to enrollees pursuant to the contract, if the services or supplies are not furnished under a contract between the organization and the provider or supplier (or in the case of a Medicare+Choice private fee-for-service plan, if a claim is submitted to such organization by an enrollee).

(2) SECRETARY'S OPTION TO BYPASS NONCOMPLYING ORGANIZATION.—In the case of a Medicare+Choice eligible organization which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with paragraph (1), the Secretary may provide for direct payment of the amounts owed to providers and suppliers (or, in the case of a Medicare+Choice private fee-for-service plan, amounts owed to the enrollees) for covered services and supplies furnished to individuals enrolled under this part under the contract. If the Secretary provides for the direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this part to reflect the amount of the Secretary's payments (and the Secretary's costs in making the payments).

(3) INCORPORATION OF CERTAIN PRESCRIPTION DRUG PLAN CONTRACT REQUIREMENTS.—The following provisions shall apply to contracts with a Medicare Advantage organization offering an MA–PD plan in the same manner as they apply to contracts with a PDP sponsor offering a prescription drug plan under part D:

(A) PROMPT PAYMENT.—Section 1860D–12(b)(4).

(B) SUBMISSION OF CLAIMS BY PHARMACIES LOCATED IN OR CONTRACTING WITH LONG-TERM CARE FACILITIES.—Section 1860D–12(b)(5).

(C) REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD.—Section 1860D–12(b)(6).

(D) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.—Section 1860D–12(b)(7).

(E) PROVISION OF INFORMATION RELATED TO MAXIMUM FAIR PRICES.—Section 1860D–12(b)(8).

(g) INTERMEDIATE SANCTIONS.—

(1) IN GENERAL.—If the Secretary determines that a Medicare+Choice organization with a contract under this section—

(A) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(B) imposes premiums on individuals enrolled under this part in excess of the amount of the Medicare+Choice monthly basic and supplemental beneficiary premiums permitted under section 1854;

(C) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this part;

(D) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(E) misrepresents or falsifies information that is furnished—

(i) to the Secretary under this part, or

(ii) to an individual or to any other entity under this part;

(F) fails to comply with the applicable requirements of section 1852(j)(3) or 1852(k)(2)(A)(ii);

(G) employs or contracts with any individual or entity that is excluded from participation under this title under section 1128 or 1128A for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services;

(H) except as provided under subparagraph (C) or (D) of section 1860D–1(b)(1), enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual;

(I) transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission;

(J) fails to comply with marketing restrictions described in subsections (h) and (j) of section 1851 or applicable implementing regulations or guidance; or

(K) employs or contracts with any individual or entity who engages in the conduct described in subparagraphs (A) through (J) of this paragraph;

the Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2). The Secretary may provide, in addition to any other

remedies authorized by law, for any of the remedies described in paragraph (2), if the Secretary determines that any employee or agent of such organization, or any provider or supplier who contracts with such organization, has engaged in any conduct described in subparagraphs (A) through (K) of this paragraph.

(2) REMEDIES.—The remedies described in this paragraph are—

(A) civil money penalties of not more than $25,000 for each determination under paragraph (1) or, with respect to a determination under subparagraph (D) or (E)(i) of such paragraph, of not more than $100,000 for each such determination, except with respect to a determination under subparagraph (E), an assessment of not more than the amount claimed by such plan or plan sponsor based upon the misrepresentation or falsified information involved, plus, with respect to a determination under paragraph (1)(B), double the excess amount charged in violation of such paragraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under paragraph (1)(D), $15,000 for each individual not enrolled as a result of the practice involved,

(B) suspension of enrollment of individuals under this part after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur, or

(C) suspension of payment to the organization under this part for individuals enrolled after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

(3) OTHER INTERMEDIATE SANCTIONS.—In the case of a Medicare+Choice organization for which the Secretary makes a determination under subsection (c)(2) the basis of which is not described in paragraph (1), the Secretary may apply the following intermediate sanctions:

(A) Civil money penalties of not more than $25,000 for each determination under subsection (c)(2) if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

(B) Civil money penalties of not more than $10,000 for each week beginning after the initiation of civil money penalty procedures by the Secretary during which the deficiency that is the basis of a determination under subsection (c)(2) exists.

(C) Suspension of enrollment of individuals under this part after the date the Secretary notifies the organization of a determination under subsection (c)(2) and until the Secretary is satisfied that the deficiency that is the basis

for the determination has been corrected and is not likely to recur.

(D) Civil monetary penalties of not more than $100,000, or such higher amount as the Secretary may establish by regulation, where the finding under subsection (c)(2)(A) is based on the organization's termination of its contract under this section other than at a time and in a manner provided for under subsection (a).

(4) CIVIL MONEY PENALTIES.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under paragraph (2) or (3) in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).

(h) PROCEDURES FOR TERMINATION.—

(1) IN GENERAL.—The Secretary may terminate a contract with a Medicare+Choice organization under this section in accordance with formal investigation and compliance procedures established by the Secretary under which—

(A) the Secretary provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under subsection (c)(2); and

(B) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before terminating the contract.

(2) EXCEPTION FOR IMMINENT AND SERIOUS RISK TO HEALTH.—Paragraph (1) shall not apply if the Secretary determines that a delay in termination, resulting from compliance with the procedures specified in such paragraph prior to termination, would pose an imminent and serious risk to the health of individuals enrolled under this part with the organization.

(3) DELAY IN CONTRACT TERMINATION AUTHORITY FOR PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATING.—During the period beginning on the date of the enactment of this paragraph and through the end of plan year 2018, the Secretary may not terminate a contract under this section with respect to the offering of an MA plan by a Medicare Advantage organization solely because the MA plan has failed to achieve a minimum quality rating under the 5-star rating system under section 1853(o)(4).

(i) MEDICARE+CHOICE PROGRAM COMPATIBILITY WITH EMPLOYER OR UNION GROUP HEALTH PLANS.—

(1) CONTRACTS WITH MA ORGANIZATIONS.—To facilitate the offering of Medicare+Choice plans under contracts between Medicare+Choice organizations and employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such Medicare+Choice plans.

(2) EMPLOYER SPONSORED MA PLANS.—To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such MA plans. Notwithstanding section 1851(g), an MA plan described in the previous sentence may restrict the enrollment of individuals under this part to individuals who are beneficiaries and participants in such plan.

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PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

Subpart 1—Part D Eligible Individuals and Prescription Drug Benefits

ELIGIBILITY, ENROLLMENT, AND INFORMATION

SEC. 1860D–1. (a) PROVISION OF QUALIFIED PRESCRIPTION DRUG COVERAGE THROUGH ENROLLMENT IN PLANS.—

(1) IN GENERAL.—Subject to the succeeding provisions of this part, each part D eligible individual (as defined in paragraph (3)(A)) is entitled to obtain qualified prescription drug coverage (described in section 1860D–2(a)) as follows:

(A) FEE-FOR-SERVICE ENROLLEES MAY RECEIVE COVERAGE THROUGH A PRESCRIPTION DRUG PLAN.—A part D eligible individual who is not enrolled in an MA plan may obtain qualified prescription drug coverage through enrollment in a prescription drug plan (as defined in section 1860D–41(a)(14)).

(B) MEDICARE ADVANTAGE ENROLLEES.—

(i) ENROLLEES IN A PLAN PROVIDING QUALIFIED PRESCRIPTION DRUG COVERAGE RECEIVE COVERAGE THROUGH THE PLAN.—A part D eligible individual who is enrolled in an MA–PD plan obtains such coverage through such plan.

(ii) LIMITATION ON ENROLLMENT OF MA PLAN ENROLLEES IN PRESCRIPTION DRUG PLANS.—Except as provided in clauses (iii) and (iv), a part D eligible individual who is enrolled in an MA plan may not enroll in a prescription drug plan under this part.

(iii) PRIVATE FEE-FOR-SERVICE ENROLLEES IN MA PLANS NOT PROVIDING QUALIFIED PRESCRIPTION DRUG COVERAGE PERMITTED TO ENROLL IN A PRESCRIPTION DRUG PLAN.—A part D eligible individual who is enrolled in an MA private fee-for-service plan (as defined in section 1859(b)(2)) that does not provide qualified prescription drug coverage may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

(iv) ENROLLEES IN MSA PLANS PERMITTED TO ENROLL IN A PRESCRIPTION DRUG PLAN.—A part D eligible indi-

vidual who is enrolled in an MSA plan (as defined in section 1859(b)(3)) may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

(2) COVERAGE FIRST EFFECTIVE JANUARY 1, 2006.—Coverage under prescription drug plans and MA–PD plans shall first be effective on January 1, 2006.

(3) DEFINITIONS.—For purposes of this part:

(A) PART D ELIGIBLE INDIVIDUAL.—The term "part D eligible individual" means an individual who is entitled to benefits under part A or enrolled under part B.

(B) MA PLAN.—The term "MA plan" has the meaning given such term in section 1859(b)(1).

(C) MA–PD PLAN.—The term "MA–PD plan" means an MA plan that provides qualified prescription drug coverage.

(b) ENROLLMENT PROCESS FOR PRESCRIPTION DRUG PLANS.—

(1) ESTABLISHMENT OF PROCESS.—

(A) IN GENERAL.—The Secretary shall establish a process for the enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in prescription drug plans consistent with this subsection.

(B) APPLICATION OF MA RULES.—In establishing such process, the Secretary shall use rules similar to (and coordinated with) the rules for enrollment, disenrollment, termination, and change of enrollment with an MA–PD plan under the following provisions of section 1851:

(i) RESIDENCE REQUIREMENTS.—Section 1851(b)(1)(A), relating to residence requirements.

(ii) EXERCISE OF CHOICE.—Section 1851(c) (other than paragraph (3)(A) and paragraph (4) of such section), relating to exercise of choice.

(iii) COVERAGE ELECTION PERIODS.—Subject to paragraphs (2) and (3) of this subsection, section 1851(e) (other than subparagraphs (B), (C), (E), and (F) of paragraph (2) and the second sentence of paragraph (4) of such section), relating to coverage election periods, including initial periods, annual coordinated election periods, special election periods, and election periods for exceptional circumstances.

(iv) COVERAGE PERIODS.—Section 1851(f), relating to effectiveness of elections and changes of elections.

(v) GUARANTEED ISSUE AND RENEWAL.—Section 1851(g) (other than paragraph (2) of such section and clause (i) and the second sentence of clause (ii) of paragraph (3)(C) of such section), relating to guaranteed issue and renewal.

(vi) MARKETING MATERIAL AND APPLICATION FORMS.—Section 1851(h), relating to approval of marketing material and application forms.

In applying clauses (ii), (iv), and (v) of this subparagraph, any reference to section 1851(e) shall be treated as a reference to such section as applied pursuant to clause (iii) of this subparagraph.

(C) SPECIAL RULE.—The process established under subparagraph (A) shall include, except as provided in subparagraph (D), in the case of a part D eligible individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)) who has failed to enroll in a prescription drug plan or an MA–PD plan, for the enrollment in a prescription drug plan that has a monthly beneficiary premium that does not exceed the premium assistance available under section 1860D–14(a)(1)(A)). If there is more than one such plan available, the Secretary shall enroll such an individual on a random basis among all such plans in the PDP region *or through use of an intelligent assignment process that is designed to maximize the access of such individual to necessary prescription drugs while minimizing costs to such individual and to the program under this part to the greatest extent possible. In the case the Secretary enrolls such individuals through use of an intelligent assignment process, such process shall take into account the extent to which prescription drugs necessary for the individual are covered in the case of a PDP sponsor of a prescription drug plan that uses a formulary, the use of prior authorization or other restrictions on access to coverage of such prescription drugs by such a sponsor, and the overall quality of a prescription drug plan as measured by quality ratings established by the Secretary*. ❚Nothing in the previous sentence❚ *Nothing in this subparagraph* shall prevent such an individual from declining or changing such enrollment.

(D) SPECIAL RULE FOR PLANS THAT WAIVE DE MINIMIS PREMIUMS.—The process established under subparagraph (A) may include, in the case of a part D eligible individual who is a subsidy eligible individual (as defined in section 1860D–14(a)(3)) who has failed to enroll in a prescription drug plan or an MA–PD plan, for the enrollment in a prescription drug plan or MA–PD plan that has waived the monthly beneficiary premium for such subsidy eligible individual under section 1860D–14(a)(5). If there is more than one such plan available, the Secretary shall enroll such an individual under the preceding sentence on a random basis among all such plans in the PDP region *or through use of an intelligent assignment process that is designed to maximize the access of such individual to necessary prescription drugs while minimizing costs to such individual and to the program under this part to the greatest extent possible. In the case the Secretary enrolls such individuals through use of an intelligent assignment process, such process shall take into account the extent to which prescription drugs necessary for the individual are covered in the case of a PDP sponsor of a prescription drug plan that uses a formulary, the use of prior authorization or other restrictions on access to coverage of such prescription drugs by such a sponsor, and the overall quality of a prescription drug plan as measured by quality ratings established by the Secretary*. ❚Nothing in the previous sentence❚ *Nothing*

in this subparagraph shall prevent such an individual from declining or changing such enrollment.

(2) INITIAL ENROLLMENT PERIOD.—

(A) PROGRAM INITIATION.—In the case of an individual who is a part D eligible individual as of November 15, 2005, there shall be an initial enrollment period that shall be the same as the annual, coordinated open election period described in section 1851(e)(3)(B)(iii), as applied under paragraph (1)(B)(iii).

(B) CONTINUING PERIODS.—In the case of an individual who becomes a part D eligible individual after November 15, 2005, there shall be an initial enrollment period which is the period under section 1851(e)(1), as applied under paragraph (1)(B)(iii) of this section, as if "entitled to benefits under part A or enrolled under part B" were substituted for "entitled to benefits under part A and enrolled under part B", but in no case shall such period end before the period described in subparagraph (A).

(3) ADDITIONAL SPECIAL ENROLLMENT PERIODS.—The Secretary shall establish special enrollment periods, including the following:

(A) INVOLUNTARY LOSS OF CREDITABLE PRESCRIPTION DRUG COVERAGE.—

(i) IN GENERAL.—In the case of a part D eligible individual who involuntarily loses creditable prescription drug coverage (as defined in section 1860D–13(b)(4)).

(ii) NOTICE.—In establishing special enrollment periods under clause (i), the Secretary shall take into account when the part D eligible individuals are provided notice of the loss of creditable prescription drug coverage.

(iii) FAILURE TO PAY PREMIUM.—For purposes of clause (i), a loss of coverage shall be treated as voluntary if the coverage is terminated because of failure to pay a required beneficiary premium.

(iv) REDUCTION IN COVERAGE.—For purposes of clause (i), a reduction in coverage so that the coverage no longer meets the requirements under section 1860D–13(b)(5) (relating to actuarial equivalence) shall be treated as an involuntary loss of coverage.

(B) ERRORS IN ENROLLMENT.—In the case described in section 1837(h) (relating to errors in enrollment), in the same manner as such section applies to part B.

(C) EXCEPTIONAL CIRCUMSTANCES.—In the case of part D eligible individuals who meet such exceptional conditions (in addition to those conditions applied under paragraph (1)(B)(iii)) as the Secretary may provide.

(D) MEDICAID COVERAGE.—In the case of an individual (as determined by the Secretary, subject to such limits as the Secretary may establish for individuals identified pursuant to section 1860D–4(c)(5)) who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)).

(E) DISCONTINUANCE OF MA–PD ELECTION DURING FIRST YEAR OF ELIGIBILITY.—In the case of a part D eligible individual who discontinues enrollment in an MA–PD plan

under the second sentence of section 1851(e)(4) at the time of the election of coverage under such sentence under the original medicare fee-for-service program.

(4) INFORMATION TO FACILITATE ENROLLMENT.—

(A) IN GENERAL.—Notwithstanding any other provision of law but subject to subparagraph (B), the Secretary may provide to each PDP sponsor and MA organization such identifying information about part D eligible individuals as the Secretary determines to be necessary to facilitate efficient marketing of prescription drug plans and MA–PD plans to such individuals and enrollment of such individuals in such plans.

(B) LIMITATION.—

(i) PROVISION OF INFORMATION.—The Secretary may provide the information under subparagraph (A) only to the extent necessary to carry out such subparagraph.

(ii) USE OF INFORMATION.—Such information provided by the Secretary to a PDP sponsor or an MA organization may be used by such sponsor or organization only to facilitate marketing of, and enrollment of part D eligible individuals in, prescription drug plans and MA–PD plans.

(5) REFERENCE TO ENROLLMENT PROCEDURES FOR MA–PD PLANS.—For rules applicable to enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in MA–PD plans, see section 1851.

(6) REFERENCE TO PENALTIES FOR LATE ENROLLMENT.—Section 1860D–13(b) imposes a late enrollment penalty for part D eligible individuals who—

(A) enroll in a prescription drug plan or an MA–PD plan after the initial enrollment period described in paragraph (2); and

(B) fail to maintain continuous creditable prescription drug coverage during the period of non-enrollment.

(c) PROVIDING INFORMATION TO BENEFICIARIES.—

(1) ACTIVITIES.—The Secretary shall conduct activities that are designed to broadly disseminate information to part D eligible individuals (and prospective part D eligible individuals) regarding the coverage provided under this part. Such activities shall ensure that such information is first made available at least 30 days prior to the initial enrollment period described in subsection (b)(2)(A).

(2) REQUIREMENTS.—The activities described in paragraph (1) shall—

(A) be similar to the activities performed by the Secretary under section 1851(d), including dissemination (including through the toll-free telephone number 1–800–MEDICARE) of comparative information for prescription drug plans and MA–PD plans; and

(B) be coordinated with the activities performed by the Secretary under such section and under section 1804.

(3) COMPARATIVE INFORMATION.—

(A) IN GENERAL.—Subject to subparagraph (B), the comparative information referred to in paragraph (2)(A) shall

include a comparison of the following with respect to qualified prescription drug coverage:

(i) BENEFITS.—The benefits provided under the plan.

(ii) MONTHLY BENEFICIARY PREMIUM.—The monthly beneficiary premium under the plan.

(iii) QUALITY AND PERFORMANCE.—The quality and performance under the plan.

(iv) BENEFICIARY COST-SHARING.—The cost-sharing required of part D eligible individuals under the plan.

(v) CONSUMER SATISFACTION SURVEYS.—The results of consumer satisfaction surveys regarding the plan conducted pursuant to section 1860D–4(d).

(B) EXCEPTION FOR UNAVAILABILITY OF INFORMATION.—The Secretary is not required to provide comparative information under clauses (iii) and (v) of subparagraph (A) with respect to a plan—

(i) for the first plan year in which it is offered; and

(ii) for the next plan year if it is impracticable or the information is otherwise unavailable.

(C) INFORMATION ON PREMIUMS FOR SUBSIDY ELIGIBLE INDIVIDUALS.—

(i) IN GENERAL.—For plan year 2022 and each subsequent plan year, the Secretary shall disseminate to each subsidy eligible individual (as defined in section 1860D–14(a)(3)) information under this paragraph comparing premiums that would apply to such individual for prescription drug coverage under LIS benchmark plans, including, in the case of an individual enrolled in a prescription drug plan under this part, information that compares the premium that would apply if such individual were to remain enrolled in such plan to premiums that would apply if the individual were to enroll in other LIS benchmark plans.

(ii) LIS BENCHMARK PLAN.—For purposes of clause (i), the term "LIS benchmark plan" means, with respect to an individual, a prescription drug plan under this part that is offered in the region in which the individual resides and—

(I) that provides for a premium that is not more than the low-income benchmark premium amount (as defined in section 1860D–14(b)(2)) for such region; or

(II) with respect to which the premium would be waived as de minimis pursuant to section 1860D–14(a)(5) for such individual.

(4) INFORMATION ON LATE ENROLLMENT PENALTY.—The information disseminated under paragraph (1) shall include information concerning the methodology for determining the late enrollment penalty under section 1860D–13(b).

PRESCRIPTION DRUG BENEFITS

SEC. 1860D–2. (a) REQUIREMENTS.—

(1) IN GENERAL.—For purposes of this part and part C, the term "qualified prescription drug coverage" means either of the following:

(A) STANDARD PRESCRIPTION DRUG COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Standard prescription drug coverage (as defined in subsection (b)) and access to negotiated prices under subsection (d).

(B) ALTERNATIVE PRESCRIPTION DRUG COVERAGE WITH AT LEAST ACTUARIALLY EQUIVALENT BENEFITS AND ACCESS TO NEGOTIATED PRICES.—Coverage of covered part D drugs which meets the alternative prescription drug coverage requirements of subsection (c) and access to negotiated prices under subsection (d), but only if the benefit design of such coverage is approved by the Secretary, as provided under subsection (c).

(2) PERMITTING SUPPLEMENTAL PRESCRIPTION DRUG COVERAGE.—

(A) IN GENERAL.—Subject to subparagraph (B), qualified prescription drug coverage may include supplemental prescription drug coverage consisting of either or both of the following:

(i) CERTAIN REDUCTIONS IN COST-SHARING.—

(I) IN GENERAL.—A reduction in the annual deductible, a reduction in the coinsurance percentage[, or an increase in the initial] *or, for a year preceding 2022, an increase in the initial* coverage limit with respect to covered part D drugs, or any combination thereof, insofar as such a reduction or increase increases the actuarial value of benefits above the actuarial value of basic prescription drug coverage.

(II) CONSTRUCTION.—Nothing in this paragraph shall be construed as affecting the application of subsection (c)(3).

(ii) OPTIONAL DRUGS.—Coverage of any product that would be a covered part D drug but for the application of subsection (e)(2)(A).

(B) REQUIREMENT.—A PDP sponsor may not offer a prescription drug plan that provides supplemental prescription drug coverage pursuant to subparagraph (A) in an area unless the sponsor also offers a prescription drug plan in the area that only provides basic prescription drug coverage.

(3) BASIC PRESCRIPTION DRUG COVERAGE.—For purposes of this part and part C, the term "basic prescription drug coverage" means either of the following:

(A) Coverage that meets the requirements of paragraph (1)(A).

(B) Coverage that meets the requirements of paragraph (1)(B) but does not have any supplemental prescription drug coverage described in paragraph (2)(A).

(4) APPLICATION OF SECONDARY PAYOR PROVISIONS.—The provisions of section 1852(a)(4) shall apply under this part in the same manner as they apply under part C.

(5) CONSTRUCTION.—Nothing in this subsection shall be construed as changing the computation of incurred costs under subsection (b)(4).

(b) STANDARD PRESCRIPTION DRUG COVERAGE.—For purposes of this part and part C, the term "standard prescription drug coverage" means coverage of covered part D drugs that meets the following requirements:

(1) DEDUCTIBLE.—

(A) IN GENERAL.—The coverage has an annual deductible—

(i) for 2006, that is equal to $250; or

(ii) for a subsequent year, that is equal to the amount specified under this paragraph for the previous year increased by the percentage specified in paragraph (6) for the year involved.

(B) ROUNDING.—Any amount determined under subparagraph (A)(ii) that is not a multiple of $5 shall be rounded to the nearest multiple of $5.

(2) BENEFIT STRUCTURE.—

(A) 25 PERCENT COINSURANCE.—[Subject to subparagraphs (C) and (D)] *Subject to subparagraphs (C), (D), and (E)*, the coverage has coinsurance (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3) *for a year preceding 2022 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2022 and each subsequent year*) that is—

(i) equal to 25 percent; or

(ii) actuarially equivalent (using processes and methods established under section 1860D–11(c)) to an average expected payment of 25 percent of such costs.

(B) USE OF TIERS.—Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization from applying tiered copayments under a plan, so long as such tiered copayments are consistent with subparagraphs (A)(ii), (C), and (D).

(C) COVERAGE FOR GENERIC DRUGS IN COVERAGE GAP.—

(i) IN GENERAL.—Except as provided in paragraph (4), *for a year preceding 2022,* the coverage for an applicable beneficiary (as defined in section 1860D–14A(g)(1)) has coinsurance (for costs above the initial coverage limit under paragraph (3) and below the out-of-pocket threshold) for covered part D drugs that are not applicable drugs under section 1860D–14A(g)(2) that is—

(I) equal to the generic-gap coinsurance percentage (specified in clause (ii)) for the year; or

(II) actuarially equivalent (using processes and methods established under section 1860D–11(c)) to an average expected payment of such percentage of such costs for covered part D drugs that are not applicable drugs under section 1860D–14A(g)(2).

(ii) GENERIC-GAP COINSURANCE PERCENTAGE.—The generic-gap coinsurance percentage specified in this clause for—

(I) 2011 is 93 percent;

(II) 2012 and each succeeding year before 2020 is the generic-gap coinsurance percentage under this clause for the previous year decreased by 7 percentage points; and

(III) 2020 [and each subsequent year] *and 2021* is 25 percent.

(D) COVERAGE FOR APPLICABLE DRUGS IN COVERAGE GAP.—

(i) IN GENERAL.—Except as provided in paragraph (4), *for a year preceding 2022,* the coverage for an applicable beneficiary (as defined in section 1860D–14A(g)(1)) has coinsurance (for costs above the initial coverage limit under paragraph (3) and below the out-of-pocket threshold) for the negotiated price (as defined in section 1860D–14A(g)(6)) of covered part D drugs that are applicable drugs under section 1860D–14A(g)(2) that is—

(I) equal to the difference between—

(aa) the applicable gap percentage (specified in clause (ii) for the year); and

(bb) the discount percentage specified in section 1860D–14A(g)(4)(A) for such applicable drugs (or, in the case of [a year after 2018] *each of years 2018 through 2021*, 50 percent); or

(II) actuarially equivalent (using processes and methods established under section 1860D–11(c)) to an average expected payment of such percentage of such costs, for covered part D drugs that are applicable drugs under section 1860D–14A(g)(2).

(ii) APPLICABLE GAP PERCENTAGE.—The applicable gap percentage specified in this clause for—

(I) 2013 and 2014 is 97.5 percent;

(II) 2015 and 2016 is 95 percent;

(III) 2017 is 90 percent;

(IV) 2018 is 85 percent; and

(V) [2019 and each subsequent year] *each of years 2019 through 2021* is 75 percent.

(E) ENROLLEE OPTION REGARDING SPREADING COST-SHARING.—The Secretary shall establish by regulation a process under which, with respect to plan year 2022 and subsequent plan years, a prescription drug plan or an MA–PD plan shall, in the case of a part D eligible individual enrolled with such plan for such plan year who is not a subsidy eligible individual (as defined in section 1860D–14(a)(3)) and with respect to whom the plan projects that the dispensing of the first fill of a covered part D drug to such individual will result in the individual incurring costs that are equal to or above the annual out-of-pocket threshold specified in paragraph (4)(B) for such plan year, provide such individual with the option to make the coinsurance payment required under subparagraph (A) (for the portion of such costs that are not above such annual out-of-pocket threshold) in the form of periodic installments over the remainder of such plan year.

(3) INITIAL COVERAGE LIMIT.—

(A) IN GENERAL.—Except as provided in paragraphs (2)(C), (2)(D), and (4), *for a year preceding 2022,* the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes (including the annual deductible)—

(i) for 2006, that is equal to $2,250; or

(ii) [for a subsequent year] *for each of years 2007 through 2021*, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

(B) ROUNDING.—Any amount determined under subparagraph (A)(ii) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(4) PROTECTION AGAINST HIGH OUT-OF-POCKET EXPENDITURES.—

(A) IN GENERAL.—

(i) IN GENERAL.—The coverage provides benefits, after the part D eligible individual has incurred costs (as described in subparagraph (C)) for covered part D drugs in a year equal to the annual out-of-pocket threshold specified in subparagraph (B), with cost-sharing that [is equal to the greater of—] *is equal to—*

(I) for a year preceding 2022, the greater of—

[(I)] *(aa)* a copayment of $2 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i)) and $5 for any other drug; or

[(II)] *(bb)* coinsurance that is equal to 5 percent[.]*; and*

(II) for 2022 and each succeeding year, $0.

(ii) ADJUSTMENT OF AMOUNT.—For a year after 2006, the dollar amounts specified in [clause (i)(I)] *clause (i)(I)(aa)* shall be equal to the dollar amounts specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved. Any amount established under this clause that is not a multiple of a 5 cents shall be rounded to the nearest multiple of 5 cents.

(B) ANNUAL OUT-OF-POCKET THRESHOLD.—

(i) IN GENERAL.—For purposes of this part, the "annual out-of-pocket threshold" specified in this subparagraph—

(I) for 2006, is equal to $3,600;

(II) for each of years 2007 through 2013, 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;

(III) for 2014 and 2015, 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, minus 0.25 percentage point;

(IV) for each of years 2016 through 2019, is equal to the amount specified in this subparagraph for the previous year, increased by the lesser of—

(aa) the annual percentage increase described in paragraph (7) for the year involved, plus 2 percentage points; or

(bb) the annual percentage increase described in paragraph (6) for the year;

(V) for 2020, is equal to the amount that would have been applied under this subparagraph for 2020 if the amendments made by section 1101(d)(1) of the Health Care and Education Reconciliation Act of 2010 had not been enacted; [or]

(VI) [for a subsequent year] *for 2021*, 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[.]*;*

(VII) for 2022, is equal to $2,000; or

(VIII) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

(ii) ROUNDING.—Any amount determined under [clause (i)(II)] *clause (i)* that is not a multiple of $50 shall be rounded to the nearest multiple of $50.

(C) APPLICATION.—Except as provided in subparagraph (E), in applying subparagraph (A)—

(i) incurred costs shall only include costs incurred with respect to covered part D drugs for the annual deductible described in paragraph (1), for cost-sharing described in paragraph (2), [and for amounts] *and, for a year preceding 2022, for amounts* for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3), but does not include any costs incurred for covered part D drugs which are not included (or treated as being included) in the plan's formulary;

(ii) subject to clause (iii), such costs shall be treated as incurred only if they are paid by the part D eligible individual (or by another person, such as a family member, on behalf of the individual) and the part D eligible individual (or other person) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement (other than under such section or such a Program) for such costs; and

(iii) such costs shall be treated as incurred and shall not be considered to be reimbursed under clause (ii) if such costs are borne or paid—

(I) under section 1860D–14;

(II) under a State Pharmaceutical Assistance Program;

(III) by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act); or

(IV) under an AIDS Drug Assistance Program under part B of title XXVI of the Public Health Service Act.

(D) INFORMATION REGARDING THIRD-PARTY REIMBURSEMENT.—

(i) PROCEDURES FOR EXCHANGING INFORMATION.—In order to accurately apply the requirements of subparagraph (C)(ii), the Secretary is authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor—

(I) for determining whether costs for part D eligible individuals are being reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement; and

(II) for alerting the PDP sponsors and MA organizations that offer the prescription drug plans and MA–PD plans in which such individuals are enrolled about such reimbursement arrangements.

(ii) AUTHORITY TO REQUEST INFORMATION FROM ENROLLEES.—A PDP sponsor or an MA organization may periodically ask part D eligible individuals enrolled in a prescription drug plan or an MA–PD plan offered by the sponsor or organization whether such individuals have or expect to receive such third-party reimbursement. A material misrepresentation of the information described in the preceding sentence by an individual (as defined in standards set by the Secretary and determined through a process established by the Secretary) shall constitute grounds for termination of enrollment in any plan under section 1851(g)(3)(B) (and as applied under this part under section 1860D–1(b)(1)(B)(v)) for a period specified by the Secretary.

(E) INCLUSION OF COSTS OF APPLICABLE DRUGS UNDER MEDICARE COVERAGE GAP DISCOUNT PROGRAM.—[In applying] *For each of years 2011 through 2021, in applying* subparagraph (A), incurred costs shall include the negotiated price (as defined in paragraph (6) of section 1860D–14A(g)) of an applicable drug (as defined in paragraph (2) of such section) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1860D–14A, regardless of whether part of such costs were paid by a manufacturer under such program, except that incurred costs shall not include the portion of the negotiated price that represents the reduction in coinsurance resulting from the application of paragraph (2)(D).

(5) CONSTRUCTION.—Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization offering

an MA–PD plan from reducing to zero the cost-sharing otherwise applicable to preferred or generic drugs.

(6) ANNUAL PERCENTAGE INCREASE.—The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered part D drugs in the United States for part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify.

(7) ADDITIONAL ANNUAL PERCENTAGE INCREASE.—The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending in July of the previous year.

(c) ALTERNATIVE PRESCRIPTION DRUG COVERAGE REQUIREMENTS.—A prescription drug plan or an MA–PD plan may provide a different prescription drug benefit design from standard prescription drug coverage so long as the Secretary determines (consistent with section 1860D–11(c)) that the following requirements are met and the plan applies for, and receives, the approval of the Secretary for such benefit design:

(1) ASSURING AT LEAST ACTUARIALLY EQUIVALENT COVERAGE.—

(A) ASSURING EQUIVALENT VALUE OF TOTAL COVERAGE.—The actuarial value of the total coverage is at least equal to the actuarial value of standard prescription drug coverage.

(B) ASSURING EQUIVALENT UNSUBSIDIZED VALUE OF COVERAGE.—The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under section 1860D–15 with respect to such coverage.

(C) ASSURING STANDARD PAYMENT FOR COSTS [AT INITIAL COVERAGE LIMIT].—The coverage is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3) for the year *for a year preceding 2022 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2022 and each subsequent year*, of an amount equal to at least the product of—

(i) the amount by which the initial coverage limit described in subsection (b)(3) for the year *for a year preceding 2022 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2022 and each subsequent year* exceeds the deductible described in subsection (b)(1) for the year; and

(ii) 100 percent minus the coinsurance percentage specified in subsection (b)(2)(A)(i).

(2) MAXIMUM REQUIRED DEDUCTIBLE.—The deductible under the coverage shall not exceed the deductible amount specified under subsection (b)(1) for the year.

(3) SAME PROTECTION AGAINST HIGH OUT-OF-POCKET EXPENDITURES.—The coverage provides the coverage required under subsection (b)(4).

(d) ACCESS TO NEGOTIATED PRICES.—

(1) ACCESS.—

(A) IN GENERAL.—Under qualified prescription drug coverage offered by a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan, the sponsor or organization shall provide enrollees with access to negotiated prices used for payment for covered part D drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing [or an initial] *or, for a year preceding 2022, an initial* coverage limit (described in subsection (b)(3)).

(B) NEGOTIATED PRICES.—For purposes of this part, negotiated prices*, subject to subparagraph (D),* shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs.

(C) MEDICAID-RELATED PROVISIONS.—The prices negotiated by a prescription drug plan, by an MA–PD plan with respect to covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2)) with respect to such drugs on behalf of part D eligible individuals, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

(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.

(2) DISCLOSURE.—A PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall disclose to the Secretary (in a manner specified by the Secretary) the aggregate negotiated price concessions described in paragraph (1)(B) made available to the sponsor or organization by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers. The provisions of section 1927(b)(3)(D) apply to information disclosed to the Secretary under this paragraph.

(3) AUDITS.—To protect against fraud and abuse and to ensure proper disclosures and accounting under this part and in accordance with section 1857(d)(2)(B) (as applied under section 1860D–12(b)(3)(C)), the Secretary may conduct periodic audits, directly or through contracts, of the financial statements and records of PDP sponsors with respect to prescription drug plans and MA organizations with respect to MA–PD plans.

(e) COVERED PART D DRUG DEFINED.—

(1) IN GENERAL.—Except as provided in this subsection, for purposes of this part, the term "covered part D drug" means—

(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2); or

(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary),

and such term includes a vaccine licensed under section 351 of the Public Health Service Act (and, for vaccines administered on or after January 1, 2008, its administration) and any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4)).

(2) EXCLUSIONS.—

(A) IN GENERAL.—Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), other than subparagraph (E) of such section (relating to smoking cessation agents), other than subparagraph (I) of such section (relating to barbiturates) if the barbiturate is used in the treatment of epilepsy, cancer, or a chronic mental health disorder, and other than subparagraph (J) of such section (relating to benzodiazepines), or under section 1927(d)(3), as such sections were in effect on the date of the enactment of this part. Such term also does not include a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration.

(B) MEDICARE COVERED DRUGS.—A drug prescribed for a part D eligible individual that would otherwise be a covered part D drug under this part shall not be so considered if payment for such drug as so prescribed and dispensed or administered with respect to that individual is available (or would be available but for the application of a deductible) under part A or B for that individual.

(3) APPLICATION OF GENERAL EXCLUSION PROVISIONS.—A prescription drug plan or an MA–PD plan may exclude from qualified prescription drug coverage any covered part D drug—

(A) for which payment would not be made if section 1862(a) applied to this part; or

(B) which is not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to subsections (g) and (h), respectively, of section 1860D–4.

(4) MEDICALLY ACCEPTED INDICATION DEFINED.—

(A) IN GENERAL.—For purposes of paragraph (1), the term "medically accepted indication" has the meaning given that term—

(i) in the case of a covered part D drug used in an anticancer chemotherapeutic regimen, in section 1861(t)(2)(B), except that in applying such section—

(I) "prescription drug plan or MA–PD plan" shall be substituted for "carrier" each place it appears; and

(II) subject to subparagraph (B), the compendia described in section 1927(g)(1)(B)(i)(III) shall be included in the list of compendia described in clause (ii)(I) section 1861(t)(2)(B); and

(ii) in the case of any other covered part D drug, in section 1927(k)(6).

(B) CONFLICT OF INTEREST.—On and after January 1, 2010, subparagraph (A)(i)(II) shall not apply unless the compendia described in section 1927(g)(1)(B)(i)(III) meets the requirement in the third sentence of section 1861(t)(2)(B).

(C) UPDATE.—For purposes of applying subparagraph (A)(ii), the Secretary shall revise the list of compendia described in section 1927(g)(1)(B)(i) as is appropriate for identifying medically accepted indications for drugs. Any such revision shall be done in a manner consistent with the process for revising compendia under section 1861(t)(2)(B).

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BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

SEC. 1860D–4. (a) DISSEMINATION OF INFORMATION.—

(1) GENERAL INFORMATION.—

(A) APPLICATION OF MA INFORMATION.—A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan, insofar as the Secretary determines appropriate with respect to benefits provided under this part, and, subject to subparagraph (C), including the information described in subparagraph (B).

(B) DRUG SPECIFIC INFORMATION.—The information described in this subparagraph is information concerning the following:

(i) Access to specific covered part D drugs, including access through pharmacy networks.

(ii) How any formulary (including any tiered formulary structure) used by the sponsor functions, including a description of how a part D eligible individual may obtain information on the formulary consistent with paragraph (3).

(iii) Beneficiary cost-sharing requirements and how a part D eligible individual may obtain information on such requirements, including tiered or other copayment level applicable to each drug (or class of drugs), consistent with paragraph (3).

(iv) The medication therapy management program required under subsection (c).

(v) The drug management program for at-risk beneficiaries under subsection (c)(5).

(vi) For plan year 2021 and each subsequent plan year, subject to subparagraph (C), with respect to the treatment of pain—

(I) the risks associated with prolonged opioid use; and

(II) coverage of nonpharmacological therapies, devices, and nonopioid medications—

(aa) in the case of an MA–PD plan under part C, under such plan; and

(bb) in the case of a prescription drug plan, under such plan and under parts A and B.

(C) TARGETED PROVISION OF INFORMATION.—A PDP sponsor of a prescription drug plan may, in lieu of disclosing the information described in subparagraph (B)(vi) to each enrollee under the plan, disclose such information through mail or electronic communications to a subset of enrollees under the plan, such as enrollees who have been prescribed an opioid in the previous 2-year period.

(2) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of a part D eligible individual who is eligible to enroll in a prescription drug plan, the PDP sponsor offering such plan shall provide information similar (as determined by the Secretary) to the information described in subparagraphs (A), (B), and (C) of section 1852(c)(2) to such individual.

(3) PROVISION OF SPECIFIC INFORMATION.—

(A) RESPONSE TO BENEFICIARY QUESTIONS.—Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information on a timely basis to enrollees upon request. Such mechanism shall include access to information through the use of a toll-free telephone number and, upon request, the provision of such information in writing.

(B) AVAILABILITY OF INFORMATION ON CHANGES IN FORMULARY THROUGH THE INTERNET.—A PDP sponsor offering a prescription drug plan shall make available on a timely basis through an Internet website information on specific changes in the formulary under the plan (including changes to tiered or preferred status of covered part D drugs).

(4) CLAIMS INFORMATION.—A PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees—

(A) an explanation of benefits (in accordance with section 1806(a) or in a comparable manner); and

(B) when prescription drug benefits are provided under this part, a notice of the benefits in relation to—

(i) [the initial] *for a year preceding 2022, the initial* coverage limit for the current year; and

(ii) the annual out-of-pocket threshold for the current year.

Notices under subparagraph (B) need not be provided more often than as specified by the Secretary and notices under subparagraph (B)(ii) shall take into account the application of section 1860D–2(b)(4)(C) to the extent practicable, as specified by the Secretary.

(b) ACCESS TO COVERED PART D DRUGS.—

(1) ASSURING PHARMACY ACCESS.—

(A) PARTICIPATION OF ANY WILLING PHARMACY.—A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.

(B) DISCOUNTS ALLOWED FOR NETWORK PHARMACIES.—For covered part D drugs dispensed through in-network pharmacies, a prescription drug plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required. In no case shall such a reduction result in an increase in payments made by the Secretary under section 1860D–15 to a plan.

(C) CONVENIENT ACCESS FOR NETWORK PHARMACIES.—

(i) IN GENERAL.—The PDP sponsor of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary).

(ii) APPLICATION OF TRICARE STANDARDS.—The Secretary shall establish rules for convenient access to in-network pharmacies under this subparagraph that are no less favorable to enrollees than the rules for convenient access to pharmacies included in the statement of work of solicitation (#MDA906–03–R–0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

(iii) ADEQUATE EMERGENCY ACCESS.—Such rules shall include adequate emergency access for enrollees.

(iv) CONVENIENT ACCESS IN LONG-TERM CARE FACILITIES.—Such rules may include standards with respect to access for enrollees who are residing in long-term care facilities and for pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 4 of the Indian Health Care Improvement Act).

(D) LEVEL PLAYING FIELD.—Such a sponsor shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail order pharmacy), with any differential in charge paid by such enrollees.

(E) NOT REQUIRED TO ACCEPT INSURANCE RISK.—The terms and conditions under subparagraph (A) may not require participating pharmacies to accept insurance risk as a condition of participation.

(2) USE OF STANDARDIZED TECHNOLOGY.—

(A) IN GENERAL.—The PDP sponsor of a prescription drug plan shall issue (and reissue, as appropriate) such a

card (or other technology) that may be used by an enrollee to assure access to negotiated prices under section 1860D–2(d).

(B) STANDARDS.—

(i) IN GENERAL.—The Secretary shall provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology required under subparagraph (A). Such standards shall be compatible with part C of title XI and may be based on standards developed by an appropriate standard setting organization.

(ii) CONSULTATION.—In developing the standards under clause (i), the Secretary shall consult with the National Council for Prescription Drug Programs and other standard setting organizations determined appropriate by the Secretary.

(iii) IMPLEMENTATION.—The Secretary shall develop, adopt, or recognize the standards under clause (i) by such date as the Secretary determines shall be sufficient to ensure that PDP sponsors utilize such standards beginning January 1, 2006.

(3) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—If a PDP sponsor of a prescription drug plan uses a formulary (including the use of tiered cost-sharing), the following requirements must be met:

(A) DEVELOPMENT AND REVISION BY A PHARMACY AND THERAPEUTIC (P&T) COMMITTEE.—

(i) IN GENERAL.—The formulary must be developed and reviewed by a pharmacy and therapeutic committee. A majority of the members of such committee shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

(ii) INCLUSION OF INDEPENDENT EXPERTS.—Such committee shall include at least one practicing physician and at least one practicing pharmacist, each of whom—

(I) is independent and free of conflict with respect to the sponsor and plan; and

(II) has expertise in the care of elderly or disabled persons.

(B) FORMULARY DEVELOPMENT.—In developing and reviewing the formulary, the committee shall—

(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate; and

(ii) take into account whether including in the formulary (or in a tier in such formulary) particular covered part D drugs has therapeutic advantages in terms of safety and efficacy.

(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES AND CLASSES.—

(i) IN GENERAL.—Subject to subparagraph (G), the formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.

(ii) MODEL GUIDELINES.—The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.

(iii) LIMITATION ON CHANGES IN THERAPEUTIC CLASSIFICATION.—The PDP sponsor of a prescription drug plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as the Secretary may permit to take into account new therapeutic uses and newly approved covered part D drugs.

(D) PROVIDER AND PATIENT EDUCATION.—The PDP sponsor shall establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

(E) NOTICE BEFORE REMOVING DRUG FROM FORMULARY OR CHANGING PREFERRED OR TIER STATUS OF DRUG.—Any removal of a covered part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3)) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists.

(F) PERIODIC EVALUATION OF PROTOCOLS.—In connection with the formulary, the sponsor of a prescription drug plan shall provide for the periodic evaluation and analysis of treatment protocols and procedures.

(G) REQUIRED INCLUSION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

(i) FORMULARY REQUIREMENTS.—

(I) IN GENERAL.—Subject to subclause (II), a PDP sponsor offering a prescription drug plan shall be required to include all covered part D drugs in the categories and classes identified by the Secretary under clause (ii)(I).

(II) EXCEPTIONS.—The Secretary may establish exceptions that permit a PDP sponsor offering a prescription drug plan to exclude from its formulary a particular covered part D drug in a category or class that is otherwise required to be included in the formulary under subclause (I) (or to otherwise limit access to such a drug, including through prior authorization or utilization management).

(ii) IDENTIFICATION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

(I) IN GENERAL.—Subject to clause (iv), the Secretary shall identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern.

(II) CRITERIA.—The Secretary shall use criteria established by the Secretary in making any determination under subclause (I).

(iii) IMPLEMENTATION.—The Secretary shall establish the criteria under clause (ii)(II) and any exceptions under clause (i)(II) through the promulgation of a regulation which includes a public notice and comment period.

(iv) REQUIREMENT FOR CERTAIN CATEGORIES AND CLASSES UNTIL CRITERIA ESTABLISHED.—Until such time as the Secretary establishes the criteria under clause (ii)(II) the following categories and classes of drugs shall be identified under clause (ii)(I):

(I) Anticonvulsants.

(II) Antidepressants.

(III) Antineoplastics.

(IV) Antipsychotics.

(V) Antiretrovirals.

(VI) Immunosuppressants for the treatment of transplant rejection.

(H) USE OF SINGLE, UNIFORM EXCEPTIONS AND APPEALS PROCESS.—Notwithstanding any other provision of this part, each PDP sponsor of a prescription drug plan shall—

(i) use a single, uniform exceptions and appeals process (including, to the extent the Secretary determines feasible, a single, uniform model form for use under such process) with respect to the determination of prescription drug coverage for an enrollee under the plan; and

(ii) provide instant access to such process by enrollees through a toll-free telephone number and an Internet website.

(c) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

(1) IN GENERAL.—The PDP sponsor shall have in place, directly or through appropriate arrangements, with respect to covered part D drugs, the following:

(A) A cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs (as defined in section 1927(k)(7)(A)(i)).

(B) Quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

(C) A medication therapy management program described in paragraph (2).

(D) A program to control fraud, abuse, and waste.

(E) A utilization management tool to prevent drug abuse (as described in paragraph (6)(A)).

(F) With respect to plan years beginning on or after January 1, 2022, a drug management program for at-risk beneficiaries described in paragraph (5).

Nothing in this section shall be construed as impairing a PDP sponsor from utilizing cost management tools (including differential payments) under all methods of operation.

(2) MEDICATION THERAPY MANAGEMENT PROGRAM.—

(A) DESCRIPTION.—

(i) IN GENERAL.—A medication therapy management program described in this paragraph is a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure, with respect to targeted beneficiaries described in clause (ii), that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Such a program may distinguish between services in ambulatory and institutional settings.

(ii) TARGETED BENEFICIARIES DESCRIBED.—Targeted beneficiaries described in this clause are the following:

(I) Part D eligible individuals who—

(aa) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure);

(bb) are taking multiple covered part D drugs; and

(cc) are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by the Secretary.

(II) Beginning January 1, 2021, at-risk beneficiaries for prescription drug abuse (as defined in paragraph (5)(C)).

(B) ELEMENTS.—Such program—

(i) may include elements that promote—

(I) enhanced enrollee understanding to promote the appropriate use of medications by enrollees and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, and other appropriate means;

(II) increased enrollee adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs and other appropriate means; and

(III) detection of adverse drug events and patterns of overuse and underuse of prescription drugs; and

(ii) with respect to plan years beginning on or after January 1, 2021, shall provide for—

(I) the provision of information to the enrollee on the safe disposal of prescription drugs that are controlled substances that meets the criteria es-

tablished under section 1852(n)(2), including information on drug takeback programs that meet such requirements determined appropriate by the Secretary and information on in-home disposal; and

(II) cost-effective means by which an enrollee may so safely dispose of such drugs.

(C) REQUIRED INTERVENTIONS.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Patient Protection and Affordable Care Act, prescription drug plan sponsors shall offer medication therapy management services to targeted beneficiaries described in subparagraph (A)(ii) that include, at a minimum, the following to increase adherence to prescription medications or other goals deemed necessary by the Secretary:

(i) An annual comprehensive medication review furnished person-to-person or using telehealth technologies (as defined by the Secretary) by a licensed pharmacist or other qualified provider. The comprehensive medication review—

(I) shall include a review of the individual's medications and may result in the creation of a recommended medication action plan or other actions in consultation with the individual and with input from the prescriber to the extent necessary and practicable; and

(II) shall include providing the individual with a written or printed summary of the results of the review.

The Secretary, in consultation with relevant stakeholders, shall develop a standardized format for the action plan under subclause (I) and the summary under subclause (II).

(ii) Follow-up interventions as warranted based on the findings of the annual medication review or the targeted medication enrollment and which may be provided person-to-person or using telehealth technologies (as defined by the Secretary).

(D) ASSESSMENT.—The prescription drug plan sponsor shall have in place a process to assess, at least on a quarterly basis, the medication use of individuals who are at risk but not enrolled in the medication therapy management program, including individuals who have experienced a transition in care, if the prescription drug plan sponsor has access to that information.

(E) AUTOMATIC ENROLLMENT WITH ABILITY TO OPT-OUT.—The prescription drug plan sponsor shall have in place a process to—

(i) subject to clause (ii), automatically enroll targeted beneficiaries described in subparagraph (A)(ii), including beneficiaries identified under subparagraph (D), in the medication therapy management program required under this subsection; and

(ii) permit such beneficiaries to opt-out of enrollment in such program.

(E) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—Such program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

(F) COORDINATION WITH CARE MANAGEMENT PLANS.—The Secretary shall establish guidelines for the coordination of any medication therapy management program under this paragraph with respect to a targeted beneficiary with any care management plan established with respect to such beneficiary under a chronic care improvement program under section 1807.

(G) CONSIDERATIONS IN PHARMACY FEES.—The PDP sponsor of a prescription drug plan shall take into account, in establishing fees for pharmacists and others providing services under such plan, the resources used, and time required to, implement the medication therapy management program under this paragraph. Each such sponsor shall disclose to the Secretary upon request the amount of any such management or dispensing fees. The provisions of section 1927(b)(3)(D) apply to information disclosed under this subparagraph.

(3) REDUCING WASTEFUL DISPENSING OF OUTPATIENT PRESCRIPTION DRUGS IN LONG-TERM CARE FACILITIES.—The Secretary shall require PDP sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, as determined by the Secretary, in consultation with relevant stakeholders (including representatives of nursing facilities, residents of nursing facilities, pharmacists, the pharmacy industry (including retail and long-term care pharmacy), prescription drug plans, MA–PD plans, and any other stakeholders the Secretary determines appropriate), such as weekly, daily, or automated dose dispensing, when dispensing covered part D drugs to enrollees who reside in a long-term care facility in order to reduce waste associated with 30-day fills.

(4) REQUIRING VALID PRESCRIBER NATIONAL PROVIDER IDENTIFIERS ON PHARMACY CLAIMS.—

(A) IN GENERAL.—For plan year 2016 and subsequent plan years, the Secretary shall require a claim for a covered part D drug for a part D eligible individual enrolled in a prescription drug plan under this part or an MA–PD plan under part C to include a prescriber National Provider Identifier that is determined to be valid under the procedures established under subparagraph (B)(i).

(B) PROCEDURES.—

(i) VALIDITY OF PRESCRIBER NATIONAL PROVIDER IDENTIFIERS.—The Secretary, in consultation with appropriate stakeholders, shall establish procedures for determining the validity of prescriber National Provider Identifiers under subparagraph (A).

(ii) INFORMING BENEFICIARIES OF REASON FOR DENIAL.—The Secretary shall establish procedures to ensure that, in the case that a claim for a covered part D drug of an individual described in subparagraph (A) is denied because the claim does not meet the requirements of this paragraph, the individual is properly in-

formed at the point of service of the reason for the denial.

(C) REPORT.—Not later than January 1, 2018, the Inspector General of the Department of Health and Human Services shall submit to Congress a report on the effectiveness of the procedures established under subparagraph (B)(i).

(D) NOTIFICATION AND ADDITIONAL REQUIREMENTS WITH RESPECT TO OUTLIER PRESCRIBERS OF OPIOIDS.—

(i) NOTIFICATION.—Not later than January 1, 2021, the Secretary shall, in the case of a prescriber identified by the Secretary under clause (ii) to be an outlier prescriber of opioids, provide, subject to clause (iv), an annual notification to such prescriber that such prescriber has been so identified and that includes resources on proper prescribing methods and other information as specified in accordance with clause (iii).

(ii) IDENTIFICATION OF OUTLIER PRESCRIBERS OF OPIOIDS.—

(I) IN GENERAL.—The Secretary shall, subject to subclause (III), using the valid prescriber National Provider Identifiers included pursuant to subparagraph (A) on claims for covered part D drugs for part D eligible individuals enrolled in prescription drug plans under this part or MA–PD plans under part C and based on the thresholds established under subclause (II), identify prescribers that are outlier opioids prescribers for a period of time specified by the Secretary.

(II) ESTABLISHMENT OF THRESHOLDS.—For purposes of subclause (I) and subject to subclause (III), the Secretary shall, after consultation with stakeholders, establish thresholds, based on prescriber specialty and geographic area, for identifying whether a prescriber in a specialty and geographic area is an outlier prescriber of opioids as compared to other prescribers of opioids within such specialty and area.

(III) EXCLUSIONS.—The following shall not be included in the analysis for identifying outlier prescribers of opioids under this clause:

(aa) Claims for covered part D drugs for part D eligible individuals who are receiving hospice care under this title.

(bb) Claims for covered part D drugs for part D eligible individuals who are receiving oncology services under this title.

(cc) Prescribers who are the subject of an investigation by the Centers for Medicare & Medicaid Services or the Inspector General of the Department of Health and Human Services.

(iii) CONTENTS OF NOTIFICATION.—The Secretary shall include the following information in the notifications provided under clause (i):

(I) Information on how such prescriber compares to other prescribers within the same specialty and geographic area.

(II) Information on opioid prescribing guidelines, based on input from stakeholders, that may include the Centers for Disease Control and Prevention guidelines for prescribing opioids for chronic pain and guidelines developed by physician organizations.

(III) Other information determined appropriate by the Secretary.

(iv) MODIFICATIONS AND EXPANSIONS.—

(I) FREQUENCY.—Beginning 5 years after the date of the enactment of this subparagraph, the Secretary may change the frequency of the notifications described in clause (i) based on stakeholder input and changes in opioid prescribing utilization and trends.

(II) EXPANSION TO OTHER PRESCRIPTIONS.—The Secretary may expand notifications under this subparagraph to include identifications and notifications with respect to concurrent prescriptions of covered Part D drugs used in combination with opioids that are considered to have adverse side effects when so used in such combination, as determined by the Secretary.

(v) ADDITIONAL REQUIREMENTS FOR PERSISTENT OUTLIER PRESCRIBERS.—In the case of a prescriber who the Secretary determines is persistently identified under clause (ii) as an outlier prescriber of opioids, the following shall apply:

(I) Such prescriber may be required to enroll in the program under this title under section 1866(j) if such prescriber is not otherwise required to enroll, but only after other appropriate remedies have been provided, such as the provision of education funded through section 6052 of the SUPPORT for Patients and Communities Act, for a period determined by the Secretary as sufficient to correct the prescribing patterns that lead to identification of such prescriber as a persistent outlier prescriber of opioids. The Secretary shall determine the length of the period for which such prescriber is required to maintain such enrollment, which shall be the minimum period necessary to correct such prescribing patterns.

(II) Not less frequently than annually (and in a form and manner determined appropriate by the Secretary), the Secretary, consistent with clause(iv)(I), shall communicate information on such prescribers to sponsors of a prescription drug plan and Medicare Advantage organizations offering an MA–PD plan.

(vi) PUBLIC AVAILABILITY OF INFORMATION.—The Secretary shall make aggregate information under this

subparagraph available on the internet website of the Centers for Medicare & Medicaid Services. Such information shall be in a form and manner determined appropriate by the Secretary and shall not identify any specific prescriber. In carrying out this clause, the Secretary shall consult with interested stakeholders.

(vii) OPIOIDS DEFINED.—For purposes of this subparagraph, the term "opioids" has such meaning as specified by the Secretary.

(viii) OTHER ACTIVITIES.—Nothing in this subparagraph shall preclude the Secretary from conducting activities that provide prescribers with information as to how they compare to other prescribers that are in addition to the activities under this subparagraph, including activities that were being conducted as of the date of the enactment of this subparagraph.

(5) DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.—

(A) AUTHORITY TO ESTABLISH.—A PDP sponsor may (and for plan years beginning on or after January 1, 2022, a PDP sponsor shall) establish a drug management program for at-risk beneficiaries under which, subject to subparagraph (B), the PDP sponsor may, in the case of an at-risk beneficiary for prescription drug abuse who is an enrollee in a prescription drug plan of such PDP sponsor, limit such beneficiary's access to coverage for frequently abused drugs under such plan to frequently abused drugs that are prescribed for such beneficiary by one or more prescribers selected under subparagraph (D), and dispensed for such beneficiary by one or more pharmacies selected under such subparagraph.

(B) REQUIREMENT FOR NOTICES.—

(i) IN GENERAL.—A PDP sponsor may not limit the access of an at-risk beneficiary for prescription drug abuse to coverage for frequently abused drugs under a prescription drug plan until such sponsor—

(I) provides to the beneficiary an initial notice described in clause (ii) and a second notice described in clause (iii); and

(II) verifies with the providers of the beneficiary that the beneficiary is an at-risk beneficiary for prescription drug abuse.

(ii) INITIAL NOTICE.—An initial notice described in this clause is a notice that provides to the beneficiary—

(I) notice that the PDP sponsor has identified the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse;

(II) information describing all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health services and other counseling services;

(III) notice of, and information about, the right of the beneficiary to appeal such identification

under subsection (h), including notice that if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution;

(IV) a request for the beneficiary to submit to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor to select under subparagraph (D) in the case that the beneficiary is identified as an at-risk beneficiary for prescription drug abuse as described in clause (iii)(I);

(V) an explanation of the meaning and consequences of the identification of the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse, including an explanation of the drug management program established by the PDP sponsor pursuant to subparagraph (A);

(VI) clear instructions that explain how the beneficiary can contact the PDP sponsor in order to submit to the PDP sponsor the preferences described in subclause (IV) and any other communications relating to the drug management program for at-risk beneficiaries established by the PDP sponsor; and

(VII) contact information for other organizations that can provide the beneficiary with assistance regarding such drug management program (similar to the information provided by the Secretary in other standardized notices provided to part D eligible individuals enrolled in prescription drug plans under this part).

(iii) SECOND NOTICE.—A second notice described in this clause is a notice that provides to the beneficiary notice—

(I) that the PDP sponsor has identified the beneficiary as an at-risk beneficiary for prescription drug abuse;

(II) that such beneficiary is subject to the requirements of the drug management program for at-risk beneficiaries established by such PDP sponsor for such plan;

(III) of the prescriber (or prescribers) and pharmacy (or pharmacies) selected for such individual under subparagraph (D);

(IV) of, and information about, the beneficiary's right to appeal such identification under subsection (h), including notice that if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution;

(V) that the beneficiary can, in the case that the beneficiary has not previously submitted to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor select under subparagraph (D), submit such preferences to the PDP sponsor; and

(VI) that includes clear instructions that explain how the beneficiary can contact the PDP sponsor.

(iv) TIMING OF NOTICES.—

(I) IN GENERAL.—Subject to subclause (II), a second notice described in clause (iii) shall be provided to the beneficiary on a date that is not less than 30 days after an initial notice described in clause (ii) is provided to the beneficiary.

(II) EXCEPTION.—In the case that the PDP sponsor, in conjunction with the Secretary, determines that concerns identified through rulemaking by the Secretary regarding the health or safety of the beneficiary or regarding significant drug diversion activities require the PDP sponsor to provide a second notice described in clause (iii) to the beneficiary on a date that is earlier than the date described in subclause (I), the PDP sponsor may provide such second notice on such earlier date.

(C) AT-RISK BENEFICIARY FOR PRESCRIPTION DRUG ABUSE.—

(i) IN GENERAL.—Except as provided in clause (v), for purposes of this paragraph, the term "at-risk beneficiary for prescription drug abuse" means a part D eligible individual who is not an exempted individual described in clause (ii) and—

(I) who is identified as such an at-risk beneficiary through the use of clinical guidelines that indicate misuse or abuse of prescription drugs described in subparagraph (G) and that are developed by the Secretary in consultation with PDP sponsors and other stakeholders, including individuals entitled to benefits under part A or enrolled under part B, advocacy groups representing such individuals, physicians, pharmacists, and other clinicians, retail pharmacies, plan sponsors, entities delegated by plan sponsors, and biopharmaceutical manufacturers; or

(II) with respect to whom the PDP sponsor of a prescription drug plan, upon enrolling such individual in such plan, received notice from the Secretary that such individual was identified under this paragraph to be an at-risk beneficiary for prescription drug abuse under the prescription drug plan in which such individual was most recently previously enrolled and such identification has not been terminated under subparagraph (F).

(ii) EXEMPTED INDIVIDUAL DESCRIBED.—An exempted individual described in this clause is an individual who—

(I) receives hospice care under this title;

(II) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

(III) the Secretary elects to treat as an exempted individual for purposes of clause (i).

(iii) PROGRAM SIZE.—The Secretary shall establish policies, including the guidelines developed under clause (i)(I) and the exemptions under clause (ii)(III), to ensure that the population of enrollees in a drug management program for at-risk beneficiaries operated by a prescription drug plan can be effectively managed by such plans.

(iv) CLINICAL CONTACT.—With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by a PDP sponsor, the PDP sponsor shall contact the beneficiary's providers who have prescribed frequently abused drugs regarding whether prescribed medications are appropriate for such beneficiary's medical conditions.

(v) TREATMENT OF ENROLLEES WITH A HISTORY OF OPIOID-RELATED OVERDOSE.—

(I) IN GENERAL.—For plan years beginning not later than January 1, 2021, a part D eligible individual who is not an exempted individual described in clause (ii) and who is identified under this clause as a part D eligible individual with a history of opioid-related overdose (as defined by the Secretary) shall be included as a potentially at-risk beneficiary for prescription drug abuse under the drug management program under this paragraph.

(II) IDENTIFICATION AND NOTICE.—For purposes of this clause, the Secretary shall—

(aa) identify part D eligible individuals with a history of opioid-related overdose (as so defined); and

(bb) notify the PDP sponsor of the prescription drug plan in which such an individual is enrolled of such identification.

(D) SELECTION OF PRESCRIBERS AND PHARMACIES.—

(i) IN GENERAL.—With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by such sponsor, a PDP sponsor shall, based on the preferences submitted to the PDP sponsor by the beneficiary pursuant to clauses (ii)(IV) and (iii)(V) of subparagraph (B) (except as otherwise provided in this subparagraph) select—

(I) one, or, if the PDP sponsor reasonably determines it necessary to provide the beneficiary with reasonable access under clause (ii), more than one, individual who is authorized to prescribe frequently abused drugs (referred to in this para-

graph as a "prescriber") who may write prescriptions for such drugs for such beneficiary; and

(II) one, or, if the PDP sponsor reasonably determines it necessary to provide the beneficiary with reasonable access under clause (ii), more than one, pharmacy that may dispense such drugs to such beneficiary.

For purposes of subclause (II), in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy shall collectively be treated as one pharmacy.

(ii) REASONABLE ACCESS.—In making the selections under this subparagraph—

(I) a PDP sponsor shall ensure that the beneficiary continues to have reasonable access to frequently abused drugs (as defined in subparagraph (G)), taking into account geographic location, beneficiary preference, impact on costsharing, and reasonable travel time; and

(II) a PDP sponsor shall ensure such access (including access to prescribers and pharmacies with respect to frequently abused drugs) in the case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services.

(iii) BENEFICIARY PREFERENCES.—If an at-risk beneficiary for prescription drug abuse submits preferences for which in-network prescribers and pharmacies the beneficiary would prefer the PDP sponsor select in response to a notice under subparagraph (B), the PDP sponsor shall—

(I) review such preferences;

(II) select or change the selection of prescribers and pharmacies for the beneficiary based on such preferences; and

(III) inform the beneficiary of such selection or change of selection.

(iv) EXCEPTION REGARDING BENEFICIARY PREFERENCES.—In the case that the PDP sponsor determines that a change to the selection of prescriber or pharmacy under clause (iii)(II) by the PDP sponsor is contributing or would contribute to prescription drug abuse or drug diversion by the beneficiary, the PDP sponsor may change the selection of prescriber or pharmacy for the beneficiary without regard to the preferences of the beneficiary described in clause (iii). If the PDP sponsor changes the selection pursuant to the preceding sentence, the PDP sponsor shall provide the beneficiary with—

(I) at least 30 days written notice of the change of selection; and

(II) a rationale for the change.

(v) CONFIRMATION.—Before selecting a prescriber or pharmacy under this subparagraph, a PDP sponsor must notify the prescriber and pharmacy that the ben-

eficiary involved has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber and pharmacy has been selected as the beneficiary's designated prescriber and pharmacy.

(E) TERMINATIONS AND APPEALS.—The identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph, a coverage determination made under a drug management program for at-risk beneficiaries, the selection of prescriber or pharmacy under subparagraph (D), and information to be shared under subparagraph (I), with respect to such individual, shall be subject to reconsideration and appeal under subsection (h) and if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution.

(F) TERMINATION OF IDENTIFICATION.—

(i) IN GENERAL.—The Secretary shall develop standards for the termination of identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph. Under such standards such identification shall terminate as of the earlier of—

(I) the date the individual demonstrates that the individual is no longer likely, in the absence of the restrictions under this paragraph, to be an at-risk beneficiary for prescription drug abuse described in subparagraph (C)(i); and

(II) the end of such maximum period of identification as the Secretary may specify.

(ii) RULE OF CONSTRUCTION.—Nothing in clause (i) shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary for prescription drug abuse under subparagraph (C)(i) after such termination on the basis of additional information on drug use occurring after the date of notice of such termination.

(G) FREQUENTLY ABUSED DRUG.—For purposes of this subsection, the term "frequently abused drug" means a drug that is a controlled substance that the Secretary determines to be frequently abused or diverted.

(H) DATA DISCLOSURE.—

(i) DATA ON DECISION TO IMPOSE LIMITATION.—In the case of an at-risk beneficiary for prescription drug abuse (or an individual who is a potentially at-risk beneficiary for prescription drug abuse) whose access to coverage for frequently abused drugs under a prescription drug plan has been limited by a PDP sponsor under this paragraph, the Secretary shall establish rules and procedures to require the PDP sponsor to disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to im-

pose such limitations and the limitations imposed by the sponsor under this part.

(ii) DATA TO REDUCE FRAUD, ABUSE, AND WASTE.—The Secretary shall establish rules and procedures to require PDP sponsors operating a drug management program for at-risk beneficiaries under this paragraph to provide the Secretary with such data as the Secretary determines appropriate for purposes of identifying patterns of prescription drug utilization for plan enrollees that are outside normal patterns and that may indicate fraudulent, medically unnecessary, or unsafe use.

(I) SHARING OF INFORMATION FOR SUBSEQUENT PLAN ENROLLMENTS.—The Secretary shall establish procedures under which PDP sponsors who offer prescription drug plans shall share information with respect to individuals who are at-risk beneficiaries for prescription drug abuse (or individuals who are potentially at-risk beneficiaries for prescription drug abuse) and enrolled in a prescription drug plan and who subsequently disenroll from such plan and enroll in another prescription drug plan offered by another PDP sponsor.

(J) PRIVACY ISSUES.—Prior to the implementation of the rules and procedures under this paragraph, the Secretary shall clarify privacy requirements, including requirements under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), related to the sharing of data under subparagraphs (H) and (I) by PDP sponsors. Such clarification shall provide that the sharing of such data shall be considered to be protected health information in accordance with the requirements of the regulations promulgated pursuant to such section 264(c).

(K) EDUCATION.—The Secretary shall provide education to enrollees in prescription drug plans of PDP sponsors and providers regarding the drug management program for at-risk beneficiaries described in this paragraph, including education—

(i) provided by Medicare administrative contractors through the improper payment outreach and education program described in section 1874A(h); and

(ii) through current education efforts (such as State health insurance assistance programs described in subsection (a)(1)(A) of section 119 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395b–3 note)) and materials directed toward such enrollees.

(L) APPLICATION UNDER MA–PD PLANS.—Pursuant to section 1860D–21(c)(1), the provisions of this paragraph apply under part D to MA organizations offering MA–PD plans to MA eligible individuals in the same manner as such provisions apply under this part to a PDP sponsor offering a prescription drug plan to a part D eligible individual.

(M) CMS COMPLIANCE REVIEW.—The Secretary shall ensure that existing plan sponsor compliance reviews and

audit processes include the drug management programs for at-risk beneficiaries under this paragraph, including appeals processes under such programs.

(6) UTILIZATION MANAGEMENT TOOL TO PREVENT DRUG ABUSE.—

(A) IN GENERAL.—A tool described in this paragraph is any of the following:

(i) A utilization tool designed to prevent the abuse of frequently abused drugs by individuals and to prevent the diversion of such drugs at pharmacies.

(ii) Retrospective utilization review to identify—

(I) individuals that receive frequently abused drugs at a frequency or in amounts that are not clinically appropriate; and

(II) providers of services or suppliers that may facilitate the abuse or diversion of frequently abused drugs by beneficiaries.

(iii) Consultation with the contractor described in subparagraph (B) to verify if an individual enrolling in a prescription drug plan offered by a PDP sponsor has been previously identified by another PDP sponsor as an individual described in clause (ii)(I).

(B) REPORTING.—A PDP sponsor offering a prescription drug plan (and an MA organization offering an MA–PD plan) in a State shall submit to the Secretary and the Medicare drug integrity contractor with which the Secretary has entered into a contract under section 1893 with respect to such State a report, on a monthly basis, containing information on—

(i) any provider of services or supplier described in subparagraph (A)(ii)(II) that is identified by such plan sponsor (or organization) during the 30-day period before such report is submitted; and

(ii) the name and prescription records of individuals described in paragraph (5)(C).

(C) CMS COMPLIANCE REVIEW.—The Secretary shall ensure that plan sponsor compliance reviews and program audits biennially include a certification that utilization management tools under this paragraph are in compliance with the requirements for such tools.

[(6)**]** *(7)* PROVIDING PRESCRIPTION DRUG PLANS WITH PARTS A AND B CLAIMS DATA TO PROMOTE THE APPROPRIATE USE OF MEDICATIONS AND IMPROVE HEALTH OUTCOMES.—

(A) PROCESS.—Subject to subparagraph (B), the Secretary shall establish a process under which a PDP sponsor of a prescription drug plan may submit a request for the Secretary to provide the sponsor, on a periodic basis and in an electronic format, beginning in plan year 2020, data described in subparagraph (D) with respect to enrollees in such plan. Such data shall be provided without regard to whether such enrollees are described in clause (ii) of paragraph (2)(A).

(B) PURPOSES.—A PDP sponsor may use the data provided to the sponsor pursuant to subparagraph (A) for any of the following purposes:

(i) To optimize therapeutic outcomes through improved medication use, as such phrase is used in clause (i) of paragraph (2)(A).

(ii) To improving care coordination so as to prevent adverse health outcomes, such as preventable emergency department visits and hospital readmissions.

(iii) For any other purpose determined appropriate by the Secretary.

(C) LIMITATIONS ON DATA USE.—A PDP sponsor shall not use data provided to the sponsor pursuant to subparagraph (A) for any of the following purposes:

(i) To inform coverage determinations under this part.

(ii) To conduct retroactive reviews of medically accepted indications determinations.

(iii) To facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization.

(iv) To inform marketing of benefits.

(v) For any other purpose that the Secretary determines is necessary to include in order to protect the identity of individuals entitled to, or enrolled for, benefits under this title and to protect the security of personal health information.

(D) DATA DESCRIBED.—The data described in this clause are standardized extracts (as determined by the Secretary) of claims data under parts A and B for items and services furnished under such parts for time periods specified by the Secretary. Such data shall include data as current as practicable.

(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 subparagraph (B) with respect to payment for covered part D drugs dispensed by such pharmacy.

(B) STANDARD PHARMACY QUALITY MEASURES.—The Secretary shall establish or approve standard quality measures from a consensus and evidence-based organization for payments described in subparagraph (A). Such measures shall focus on patient health outcomes and be based on proven criteria measuring pharmacy performance.

(C) EFFECTIVE DATE.—The requirement under subparagraph (A) shall take effect for plan years beginning on or after January 1, 2021, or such earlier date specified by the Secretary if the Secretary determines there are sufficient measures established or approved under subparagraph (B) to meet the requirement under subparagraph (A).

(d) CONSUMER SATISFACTION SURVEYS.—In order to provide for comparative information under section 1860D–1(c)(3)(A)(v), the Secretary shall conduct consumer satisfaction surveys with respect to PDP sponsors and prescription drug plans in a manner similar to the manner such surveys are conducted for MA organizations and MA plans under part C.

(e) ELECTRONIC PRESCRIPTION PROGRAM.—

(1) APPLICATION OF STANDARDS.—As of such date as the Secretary may specify, but not later than 1 year after the date of promulgation of final standards under paragraph (4)(D), prescriptions and other information described in paragraph (2)(A) for covered part D drugs prescribed for part D eligible individuals that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2).

(2) PROGRAM REQUIREMENTS.—Consistent with uniform standards established under paragraph (3)—

(A) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL AND DISPENSING PHARMACIES AND PHARMACISTS.—An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered part D drug:

(i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

(B) APPLICATION TO MEDICAL HISTORY INFORMATION.—Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to carry out this subparagraph, the program shall provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) of information that relates to the medical history concerning the individual and related to a covered part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

(C) LIMITATIONS.—Information shall only be disclosed under subparagraph (A) or (B) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

(D) TIMING.—To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis.

(E) ELECTRONIC PRIOR AUTHORIZATION.—

(i) IN GENERAL.—Not later than January 1, 2021, the program shall provide for the secure electronic transmission of—

(I) a prior authorization request from the prescribing health care professional for coverage of a

covered part D drug for a part D eligible individual enrolled in a part D plan (as defined in section 1860D–23(a)(5)) to the PDP sponsor or Medicare Advantage organization offering such plan; and

(II) a response, in accordance with this subparagraph, from such PDP sponsor or Medicare Advantage organization, respectively, to such professional.

(ii) ELECTRONIC TRANSMISSION.—

(I) EXCLUSIONS.—For purposes of this subparagraph, a facsimile, a proprietary payer portal that does not meet standards specified by the Secretary, or an electronic form shall not be treated as an electronic transmission described in clause (i).

(II) STANDARDS.—In order to be treated, for purposes of this subparagraph, as an electronic transmission described in clause (i), such transmission shall comply with technical standards adopted by the Secretary in consultation with the National Council for Prescription Drug Programs, other standard setting organizations determined appropriate by the Secretary, and stakeholders including PDP sponsors, Medicare Advantage organizations, health care professionals, and health information technology software vendors.

(III) APPLICATION.—Notwithstanding any other provision of law, for purposes of this subparagraph, the Secretary may require the use of such standards adopted under subclause (II) in lieu of any other applicable standards for an electronic transmission described in clause (i) for a covered part D drug for a part D eligible individual.

(3) STANDARDS.—

(A) IN GENERAL.—The Secretary shall provide consistent with this subsection for the promulgation of uniform standards relating to the requirements for electronic prescription drug programs under paragraph (2).

(B) OBJECTIVES.—Such standards shall be consistent with the objectives of improving—

(i) patient safety;

(ii) the quality of care provided to patients; and

(iii) efficiencies, including cost savings, in the delivery of care.

(C) DESIGN CRITERIA.—Such standards shall—

(i) be designed so that, to the extent practicable, the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists;

(ii) be compatible with standards established under part C of title XI, standards established under subsection (b)(2)(B)(i), and with general health information technology standards; and

(iii) be designed so that they permit electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration and the National Library of Medicine.

(D) PERMITTING USE OF APPROPRIATE MESSAGING.—Such standards shall allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems referred to in subsection (c)(1)(B).

(E) PERMITTING PATIENT DESIGNATION OF DISPENSING PHARMACY.—

(i) IN GENERAL.—Consistent with clause (ii), such standards shall permit a part D eligible individual to designate a particular pharmacy to dispense a prescribed drug.

(ii) NO CHANGE IN BENEFITS.—Clause (i) shall not be construed as affecting—

(I) the access required to be provided to pharmacies by a prescription drug plan; or

(II) the application of any differences in benefits or payments under such a plan based on the pharmacy dispensing a covered part D drug.

(4) DEVELOPMENT, PROMULGATION, AND MODIFICATION OF STANDARDS.—

(A) INITIAL STANDARDS.—Not later than September 1, 2005, the Secretary shall develop, adopt, recognize, or modify initial uniform standards relating to the requirements for electronic prescription drug programs described in paragraph (2) taking into consideration the recommendations (if any) from the National Committee on Vital and Health Statistics (as established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k))) under subparagraph (B).

(B) ROLE OF NCVHS.—The National Committee on Vital and Health Statistics shall develop recommendations for uniform standards relating to such requirements in consultation with the following:

(i) Standard setting organizations (as defined in section 1171(8))

(ii) Practicing physicians.

(iii) Hospitals.

(iv) Pharmacies.

(v) Practicing pharmacists.

(vi) Pharmacy benefit managers.

(vii) State boards of pharmacy.

(viii) State boards of medicine.

(ix) Experts on electronic prescribing.

(x) Other appropriate Federal agencies.

(C) PILOT PROJECT TO TEST INITIAL STANDARDS.—

(i) IN GENERAL.—During the 1-year period that begins on January 1, 2006, the Secretary shall conduct a pilot project to test the initial standards developed under subparagraph (A) prior to the promulgation of the final uniform standards under subparagraph (D)

in order to provide for the efficient implementation of the requirements described in paragraph (2).

(ii) EXCEPTION.—Pilot testing of standards is not required under clause (i) where there already is adequate industry experience with such standards, as determined by the Secretary after consultation with effected standard setting organizations and industry users.

(iii) VOLUNTARY PARTICIPATION OF PHYSICIANS AND PHARMACIES.—In order to conduct the pilot project under clause (i), the Secretary shall enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards.

(iv) EVALUATION AND REPORT.—

(I) EVALUATION.—The Secretary shall conduct an evaluation of the pilot project conducted under clause (i).

(II) REPORT TO CONGRESS.—Not later than April 1, 2007, the Secretary shall submit to Congress a report on the evaluation conducted under subclause (I).

(D) FINAL STANDARDS.—Based upon the evaluation of the pilot project under subparagraph (C)(iv)(I) and not later than April 1, 2008, the Secretary shall promulgate uniform standards relating to the requirements described in paragraph (2).

(5) RELATION TO STATE LAWS.—The standards promulgated under this subsection shall supersede any State law or regulation that—

(A) is contrary to the standards or restricts the ability to carry out this part; and

(B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

(6) ESTABLISHMENT OF SAFE HARBOR.—The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1128B(b) and an exception to the prohibition under subsection (a)(1) of section 1877 with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection—

(A) in the case of a hospital, by the hospital to members of its medical staff;

(B) in the case of a group practice (as defined in section 1877(h)(4)), by the practice to prescribing health care professionals who are members of such practice; and

(C) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization, and to prescribing health care professionals.

(7) REQUIREMENT OF E-PRESCRIBING FOR CONTROLLED SUBSTANCES.—

(A) IN GENERAL.—Subject to subparagraph (B), a prescription for a covered part D drug under a prescription drug plan (or under an MA–PD plan) for a schedule II, III, IV, or V controlled substance shall be transmitted by a health care practitioner electronically in accordance with an electronic prescription drug program that meets the requirements of paragraph (2).

(B) EXCEPTION FOR CERTAIN CIRCUMSTANCES.—The Secretary shall, through rulemaking, specify circumstances and processes by which the Secretary may waive the requirement under subparagraph (A), with respect to a covered part D drug, including in the case of—

(i) a prescription issued when the practitioner and dispensing pharmacy are the same entity;

(ii) a prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

(iii) a prescription issued by a practitioner who received a waiver or a renewal thereof for a period of time as determined by the Secretary, not to exceed one year, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;

(iv) a prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;

(v) a prescription issued by a practitioner prescribing a drug under a research protocol;

(vi) a prescription issued by a practitioner for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;

(vii) a prescription issued by a practitioner—

(I) for an individual who receives hospice care under this title; and

(II) that is not covered under the hospice benefit under this title; and

(viii) a prescription issued by a practitioner for an individual who is—

(I) a resident of a nursing facility (as defined in section 1919(a)); and

(II) dually eligible for benefits under this title and title XIX.

(C) DISPENSING.—(i) Nothing in this paragraph shall be construed as requiring a sponsor of a prescription drug plan under this part, MA organization offering an MA–PD plan under part C, or a pharmacist to verify that a practitioner, with respect to a prescription for a covered part D drug, has a waiver (or is otherwise exempt) under subparagraph (B) from the requirement under subparagraph (A).

(ii) Nothing in this paragraph shall be construed as affecting the ability of the plan to cover or the pharmacists' ability to continue to dispense covered part D drugs from otherwise valid written, oral, or fax prescriptions that are consistent with laws and regulations.

(iii) Nothing in this paragraph shall be construed as affecting the ability of an individual who is being prescribed a covered part D drug to designate a particular pharmacy to dispense the covered part D drug to the extent consistent with the requirements under subsection (b)(1) and under this paragraph.

(D) ENFORCEMENT.—The Secretary shall, through rulemaking, have authority to enforce and specify appropriate penalties for non-compliance with the requirement under subparagraph (A).

(f) GRIEVANCE MECHANISM.—Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1852(f).

(g) COVERAGE DETERMINATIONS AND RECONSIDERATIONS.—

(1) APPLICATION OF COVERAGE DETERMINATION AND RECONSIDERATION PROVISIONS.—A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to an MA organization with respect to benefits it offers under an MA plan under part C.

(2) REQUEST FOR A DETERMINATION FOR THE TREATMENT OF TIERED FORMULARY DRUG.—In the case of a prescription drug plan offered by a PDP sponsor that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, a part D eligible individual who is enrolled in the plan may request an exception to the tiered cost-sharing structure. Under such an exception, a nonpreferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual

or both. A PDP sponsor shall have an exceptions process under this paragraph consistent with guidelines established by the Secretary for making a determination with respect to such a request. Denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h).

(h) APPEALS.—

(1) IN GENERAL.—Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1852(g) with respect to benefits (including a determination related to the application of tiered cost-sharing described in subsection (g)(2)) in a manner similar (as determined by the Secretary) to the manner such requirements apply to an MA organization with respect to benefits under the original medicare fee-for-service program option it offers under an MA plan under part C. In applying this paragraph only the part D eligible individual shall be entitled to bring such an appeal.

(2) LIMITATION IN CASES ON NONFORMULARY DETERMINATIONS.—A part D eligible individual who is enrolled in a prescription drug plan offered by a PDP sponsor may appeal under paragraph (1) a determination not to provide for coverage of a covered part D drug that is not on the formulary under the plan only if the prescribing physician determines that all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both.

(3) TREATMENT OF NONFORMULARY DETERMINATIONS.—If a PDP sponsor determines that a plan provides coverage for a covered part D drug that is not on the formulary of the plan, the drug shall be treated as being included on the formulary for purposes of section 1860D–2(b)(4)(C)(i).

(i) PRIVACY, CONFIDENTIALITY, AND ACCURACY OF ENROLLEE RECORDS.—The provisions of section 1852(h) shall apply to a PDP sponsor and prescription drug plan in the same manner as it applies to an MA organization and an MA plan.

(j) TREATMENT OF ACCREDITATION.—Subparagraph (A) of section 1852(e)(4) (relating to treatment of accreditation) shall apply to a PDP sponsor under this part with respect to the following requirements, in the same manner as it applies to an MA organization with respect to the requirements in subparagraph (B) (other than clause (vii) thereof) of such section:

(1) Subsection (b) of this section (relating to access to covered part D drugs).

(2) Subsection (c) of this section (including quality assurance and medication therapy management).

(3) Subsection (i) of this section (relating to confidentiality and accuracy of enrollee records).

(k) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—

(1) IN GENERAL.—A PDP sponsor offering a prescription drug plan shall provide that each pharmacy that dispenses a covered part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan

that is therapeutically equivalent and bioequivalent and available at such pharmacy.

(2) TIMING OF NOTICE.—

(A) IN GENERAL.—Subject to subparagraph (B), the information under paragraph (1) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

(B) WAIVER.—The Secretary may waive subparagraph (A) in such circumstances as the Secretary may specify.

(l) REQUIREMENTS WITH RESPECT TO SALES AND MARKETING ACTIVITIES.—The following provisions shall apply to a PDP sponsor (and the agents, brokers, and other third parties representing such sponsor) in the same manner as such provisions apply to a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization):

(1) The prohibition under section 1851(h)(4)(C) on conducting activities described in section 1851(j)(1).

(2) The requirement under section 1851(h)(4)(D) to conduct activities described in section 1851(j)(2) in accordance with the limitations established under such subsection.

(3) The inclusion of the plan type in the plan name under section 1851(h)(6).

(4) The requirements regarding the appointment of agents and brokers and compliance with State information requests under subparagraphs (A) and (B), respectively, of section 1851(h)(7).

(m) PROHIBITION ON LIMITING CERTAIN INFORMATION ON DRUG PRICES.—A PDP sponsor and a Medicare Advantage organization shall ensure that each prescription drug plan or MA–PD plan offered by the sponsor or organization does not restrict a pharmacy that dispenses a prescription drug or biological from informing, nor penalize such pharmacy for informing, an enrollee in such plan of any differential between the negotiated price of, or copayment or coinsurance for, the drug or biological to the enrollee under the plan and a lower price the individual would pay for the drug or biological if the enrollee obtained the drug without using any health insurance coverage.

(m) PROGRAM INTEGRITY TRANSPARENCY MEASURES.—For program integrity transparency measures applied with respect to prescription drug plan and MA plans, see section 1859(i).

Subpart 2—Prescription Drug Plans; PDP Sponsors; Financing

PDP REGIONS; SUBMISSION OF BIDS; PLAN APPROVAL

SEC. 1860D–11. (a) ESTABLISHMENT OF PDP REGIONS; SERVICE AREAS.—

(1) COVERAGE OF ENTIRE PDP REGION.—The service area for a prescription drug plan shall consist of an entire PDP region established under paragraph (2).

(2) ESTABLISHMENT OF PDP REGIONS.—

(A) IN GENERAL.—The Secretary shall establish, and may revise, PDP regions in a manner that is consistent with the requirements for the establishment and revision of MA regions under subparagraphs (B) and (C) of section 1858(a)(2).

(B) RELATION TO MA REGIONS.—To the extent practicable, PDP regions shall be the same as MA regions under section 1858(a)(2). The Secretary may establish PDP regions which are not the same as MA regions if the Secretary determines that the establishment of different regions under this part would improve access to benefits under this part.

(C) AUTHORITY FOR TERRITORIES.—The Secretary shall establish, and may revise, PDP regions for areas in States that are not within the 50 States or the District of Columbia.

(3) NATIONAL PLAN.—Nothing in this subsection shall be construed as preventing a prescription drug plan from being offered in more than one PDP region (including all PDP regions).

(b) SUBMISSION OF BIDS, PREMIUMS, AND RELATED INFORMATION.—

(1) IN GENERAL.—A PDP sponsor shall submit to the Secretary information described in paragraph (2) with respect to each prescription drug plan it offers. Such information shall be submitted at the same time and in a similar manner to the manner in which information described in paragraph (6) of section 1854(a) is submitted by an MA organization under paragraph (1) of such section.

(2) INFORMATION DESCRIBED.—The information described in this paragraph is information on the following:

(A) COVERAGE PROVIDED.—The prescription drug coverage provided under the plan, including the deductible and other cost-sharing.

(B) ACTUARIAL VALUE.—The actuarial value of the qualified prescription drug coverage in the region for a part D eligible individual with a national average risk profile for the factors described in section 1860D–15(c)(1)(A) (as specified by the Secretary).

(C) BID.—Information on the bid, including an actuarial certification of—

(i) the basis for the actuarial value described in subparagraph (B) assumed in such bid;

(ii) the portion of such bid attributable to basic prescription drug coverage and, if applicable, the portion of such bid attributable to supplemental benefits;

(iii) [assumptions regarding the reinsurance] *assumptions regarding—*

(I) the reinsurance subsidy payments provided under section 1860D–15(b) subtracted from the actuarial value to produce such bid; and

(II) for 2022 and each subsequent year, the manufacturer discounts provided under section 1860D–14C subtracted from the actuarial value to produce such bid; and

(iv) administrative expenses assumed in the bid.

(D) SERVICE AREA.—The service area for the plan.

(E) LEVEL OF RISK ASSUMED.—

(i) IN GENERAL.—Whether the PDP sponsor requires a modification of risk level under clause (ii) and, if so, the extent of such modification. Any such modification

shall apply with respect to all prescription drug plans offered by a PDP sponsor in a PDP region. This subparagraph shall not apply to an MA–PD plan.

(ii) RISK LEVELS DESCRIBED.—A modification of risk level under this clause may consist of one or more of the following:

(I) INCREASE IN FEDERAL PERCENTAGE ASSUMED IN INITIAL RISK CORRIDOR.—An equal percentage point increase in the percents applied under subparagraphs (B)(i), (B)(ii)(I), (C)(i), and (C)(ii)(I) of section 1860D–15(e)(2). In no case shall the application of previous sentence prevent the application of a higher percentage under section 1869D–15(e)(2)(B)(iii).

(II) INCREASE IN FEDERAL PERCENTAGE ASSUMED IN SECOND RISK CORRIDOR.—An equal percentage point increase in the percents applied under subparagraphs (B)(ii)(II) and (C)(ii)(II) of section 1860D–15(e)(2).

(III) DECREASE IN SIZE OF RISK CORRIDORS.—A decrease in the threshold risk percentages specified in section 1860D–15(e)(3)(C).

(F) ADDITIONAL INFORMATION.—Such other information as the Secretary may require to carry out this part.

(3) PAPERWORK REDUCTION FOR OFFERING OF PRESCRIPTION DRUG PLANS NATIONALLY OR IN MULTI-REGION AREAS.—The Secretary shall establish requirements for information submission under this subsection in a manner that promotes the offering of such plans in more than one PDP region (including all regions) through the filing of consolidated information.

(c) ACTUARIAL VALUATION.—

(1) PROCESSES.—For purposes of this part, the Secretary shall establish processes and methods for determining the actuarial valuation of prescription drug coverage, including—

(A) an actuarial valuation of standard prescription drug coverage under section 1860D–2(b);

(B) actuarial valuations relating to alternative prescription drug coverage under section 1860D–2(c)(1);

(C) [an actuarial valuation of the reinsurance] *an actuarial valuation of—*

(i) the reinsurance subsidy payments under section 1860D–15(b); *and*

(ii) for 2022 and each subsequent year, the manufacturer discounts provided under section 1860D–14C;

(D) the use of generally accepted actuarial principles and methodologies; and

(E) applying the same methodology for determinations of actuarial valuations under subparagraphs (A) and (B).

(2) ACCOUNTING FOR DRUG UTILIZATION.—Such processes and methods for determining actuarial valuation shall take into account the effect that providing alternative prescription drug coverage (rather than standard prescription drug coverage) has on drug utilization.

(3) RESPONSIBILITIES.—

(A) PLAN RESPONSIBILITIES.—PDP sponsors and MA organizations are responsible for the preparation and submission of actuarial valuations required under this part for prescription drug plans and MA–PD plans they offer.

(B) USE OF OUTSIDE ACTUARIES.—Under the processes and methods established under paragraph (1), PDP sponsors offering prescription drug plans and MA organizations offering MA–PD plans may use actuarial opinions certified by independent, qualified actuaries to establish actuarial values.

(d) REVIEW OF INFORMATION AND NEGOTIATION.—

(1) REVIEW OF INFORMATION.—The Secretary shall review the information filed under subsection (b) for the purpose of conducting negotiations under paragraph (2).

(2) NEGOTIATION REGARDING TERMS AND CONDITIONS.—Subject to subsection (i), in exercising the authority under paragraph (1), the Secretary—

(A) has the authority to negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan; and

(B) has authority similar to the authority of the Director of the Office of Personnel Management with respect to health benefits plans under chapter 89 of title 5, United States Code.

(3) REJECTION OF BIDS.—Paragraph (5)(C) of section 1854(a) shall apply with respect to bids submitted by a PDP sponsor under subsection (b) in the same manner as such paragraph applies to bids submitted by an MA organization under such section 1854(a).

(e) APPROVAL OF PROPOSED PLANS.—

(1) IN GENERAL.—After review and negotiation under subsection (d), the Secretary shall approve or disapprove the prescription drug plan.

(2) REQUIREMENTS FOR APPROVAL.—The Secretary may approve a prescription drug plan only if the following requirements are met:

(A) COMPLIANCE WITH REQUIREMENTS.—The plan and the PDP sponsor offering the plan comply with the requirements under this part, including the provision of qualified prescription drug coverage.

(B) ACTUARIAL DETERMINATIONS.—The Secretary determines that the plan and PDP sponsor meet the requirements under this part relating to actuarial determinations, including such requirements under section 1860D–2(c).

(C) APPLICATION OF FEHBP STANDARD.—

(i) IN GENERAL.—The Secretary determines that the portion of the bid submitted under subsection (b) that is attributable to basic prescription drug coverage is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial

value of the reinsurance payments under section 1860D–15(b).

(ii) SUPPLEMENTAL COVERAGE.—The Secretary determines that the portion of the bid submitted under subsection (b) that is attributable to supplemental prescription drug coverage pursuant to section 1860D–2(a)(2) is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for such coverage under the plan.

(D) PLAN DESIGN.—

(i) IN GENERAL.—The Secretary does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan.

(ii) USE OF CATEGORIES AND CLASSES IN FORMULARIES.—The Secretary may not find that the design of categories and classes within a formulary violates clause (i) if such categories and classes are consistent with guidelines (if any) for such categories and classes established by the United States Pharmacopeia.

(f) APPLICATION OF LIMITED RISK PLANS.—

(1) CONDITIONS FOR APPROVAL OF LIMITED RISK PLANS.—The Secretary may only approve a limited risk plan (as defined in paragraph (4)(A)) for a PDP region if the access requirements under section 1860D–3(a) would not be met for the region but for the approval of such a plan (or a fallback prescription drug plan under subsection (g)).

(2) RULES.—The following rules shall apply with respect to the approval of a limited risk plan in a PDP region:

(A) LIMITED EXERCISE OF AUTHORITY.—Only the minimum number of such plans may be approved in order to meet the access requirements under section 1860D–3(a).

(B) MAXIMIZING ASSUMPTION OF RISK.—The Secretary shall provide priority in approval for those plans bearing the highest level of risk (as computed by the Secretary), but the Secretary may take into account the level of the bids submitted by such plans.

(C) NO FULL UNDERWRITING FOR LIMITED RISK PLANS.—In no case may the Secretary approve a limited risk plan under which the modification of risk level provides for no (or a de minimis) level of financial risk.

(3) ACCEPTANCE OF ALL FULL RISK CONTRACTS.—There shall be no limit on the number of full risk plans that are approved under subsection (e).

(4) RISK-PLANS DEFINED.—For purposes of this subsection:

(A) LIMITED RISK PLAN.—The term "limited risk plan" means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in subparagraph (E) of subsection (b)(2) in its bid submitted for the

plan under such subsection. Such term does not include a fallback prescription drug plan.

(B) FULL RISK PLAN.—The term "full risk plan" means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

(g) GUARANTEEING ACCESS TO COVERAGE.—

(1) SOLICITATION OF BIDS.—

(A) IN GENERAL.—Separate from the bidding process under subsection (b), the Secretary shall provide for a process for the solicitation of bids from eligible fallback entities (as defined in paragraph (2)) for the offering in all fallback service areas (as defined in paragraph (3)) in one or more PDP regions of a fallback prescription drug plan (as defined in paragraph (4)) during the contract period specified in paragraph (5).

(B) ACCEPTANCE OF BIDS.—

(i) IN GENERAL.—Except as provided in this subparagraph, the provisions of subsection (e) shall apply with respect to the approval or disapproval of fallback prescription drug plans. The Secretary shall enter into contracts under this subsection with eligible fallback entities for the offering of fallback prescription drug plans so approved in fallback service areas.

(ii) LIMITATION OF 1 PLAN FOR ALL FALLBACK SERVICE AREAS IN A PDP REGION.—With respect to all fallback service areas in any PDP region for a contract period, the Secretary shall approve the offering of only 1 fallback prescription drug plan.

(iii) COMPETITIVE PROCEDURES.—Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))) shall be used to enter into a contract under this subsection. The provisions of subsection (d) of section 1874A shall apply to a contract under this section in the same manner as they apply to a contract under such section.

(iv) TIMING.—The Secretary shall approve a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans would otherwise be offered.

(V) NO NATIONAL FALLBACK PLAN.—The Secretary shall not enter into a contract with a single fallback entity for the offering of fallback plans throughout the United States.

(2) ELIGIBLE FALLBACK ENTITY.—For purposes of this section, the term "eligible fallback entity" means, with respect to all fallback service areas in a PDP region for a contract period, an entity that—

(A) meets the requirements to be a PDP sponsor (or would meet such requirements but for the fact that the entity is not a risk-bearing entity); and

(B) does not submit a bid under section 1860D–11(b) for any prescription drug plan for any PDP region for the first year of such contract period.

For purposes of subparagraph (B), an entity shall be treated as submitting a bid with respect to a prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

(3) FALLBACK SERVICE AREA.—For purposes of this subsection, the term "fallback service area" means, for a PDP region with respect to a year, any area within such region for which the Secretary determines before the beginning of the year that the access requirements of the first sentence of section 1860D–3(a) will not be met for part D eligible individuals residing in the area for the year.

(4) FALLBACK PRESCRIPTION DRUG PLAN.—For purposes of this part, the term "fallback prescription drug plan" means a prescription drug plan that—

(A) only offers the standard prescription drug coverage and access to negotiated prices described in section 1860D–2(a)(1)(A) and does not include any supplemental prescription drug coverage; and

(B) meets such other requirements as the Secretary may specify.

(5) PAYMENTS UNDER THE CONTRACT.—

(A) IN GENERAL.—A contract entered into under this subsection shall provide for—

(i) payment for the actual costs (taking into account negotiated price concessions described in section 1860D–2(d)(1)(B)) of covered part D drugs provided to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

(ii) payment of management fees that are tied to performance measures established by the Secretary for the management, administration, and delivery of the benefits under the contract.

(B) PERFORMANCE MEASURES.—The performance measures established by the Secretary pursuant to subparagraph (A)(ii) shall include at least measures for each of the following:

(i) COSTS.—The entity contains costs to the Medicare Prescription Drug Account and to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

(ii) QUALITY PROGRAMS.—The entity provides such enrollees with quality programs that avoid adverse drug reactions and overutilization and reduce medical errors.

(iii) CUSTOMER SERVICE.—The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

(iv) BENEFIT ADMINISTRATION AND CLAIMS ADJUDICATION.—The entity provides efficient and effective benefit administration and claims adjudication.

(6) MONTHLY BENEFICIARY PREMIUM.—Except as provided in section 1860D–13(b) (relating to late enrollment penalty) and subject to section 1860D–14 (relating to low-income assistance), the monthly beneficiary premium to be charged under a fallback prescription drug plan offered in all fallback service areas in a PDP region shall be uniform and shall be equal to 25.5 percent of an amount equal to the Secretary's estimate of the average monthly per capita actuarial cost, including administrative expenses, under the fallback prescription drug plan of providing coverage in the region, as calculated by the Chief Actuary of the Centers for Medicare & Medicaid Services. In calculating such administrative expenses, the Chief Actuary shall use a factor that is based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

(7) GENERAL CONTRACT TERMS AND CONDITIONS.—

(A) IN GENERAL.—Except as may be appropriate to carry out this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans under this subsection shall be the same as the terms and conditions of contracts under this part for prescription drug plans.

(B) PERIOD OF CONTRACT.—

(i) IN GENERAL.—Subject to clause (ii), a contract approved for a fallback prescription drug plan for fallback service areas for a PDP region under this section shall be for a period of 3 years (except as may be renewed after a subsequent bidding process).

(ii) LIMITATION.—A fallback prescription drug plan may be offered under a contract in an area for a year only if that area is a fallback service area for that year.

(C) ENTITY NOT PERMITTED TO MARKET OR BRAND FALLBACK PRESCRIPTION DRUG PLANS.—An eligible fallback entity with a contract under this subsection may not engage in any marketing or branding of a fallback prescription drug plan.

(h) ANNUAL REPORT ON USE OF LIMITED RISK PLANS AND FALLBACK PLANS.—The Secretary shall submit to Congress an annual report that describes instances in which limited risk plans and fallback prescription drug plans were offered under subsections (f) and (g). The Secretary shall include in such report such recommendations as may be appropriate to limit the need for the provision of such plans and to maximize the assumption of financial risk under section subsection (f).

(i) NONINTERFERENCE.—In order to promote competition under this part and in carrying out this part, the Secretary*, except as provided under part E of title XI*—

(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and

(2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

(j) COORDINATION OF BENEFITS.—A PDP sponsor offering a prescription drug plan shall permit State Pharmaceutical Assistance Programs and Rx plans under sections 1860D–23 and 1860D–24 to coordinate benefits with the plan and, in connection with such co-

ordination with such a Program, not to impose fees that are unrelated to the cost of coordination.

REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION DRUG PLAN (PDP) SPONSORS

SEC. 1860D–12. (a) GENERAL REQUIREMENTS.—Each PDP sponsor of a prescription drug plan shall meet the following requirements:

(1) LICENSURE.—Subject to subsection (c), the sponsor is organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan.

(2) ASSUMPTION OF FINANCIAL RISK FOR UNSUBSIDIZED COVERAGE.—

(A) IN GENERAL.—Subject to subparagraph (B), to the extent that the entity is at risk the entity assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D–15(b).

(B) REINSURANCE PERMITTED.—The plan sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing such coverage.

(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the case of a PDP sponsor that is not described in paragraph (1) and for which a waiver has been approved under subsection (c), such sponsor shall meet solvency standards established by the Secretary under subsection (d).

(b) CONTRACT REQUIREMENTS.—

(1) IN GENERAL.—The Secretary shall not permit the enrollment under section 1860D–1 in a prescription drug plan offered by a PDP sponsor under this part, and the sponsor shall not be eligible for payments under section 1860D–14 or 1860D–15, unless the Secretary has entered into a contract under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover more than one prescription drug plan. Such contract shall provide that the sponsor agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(2) LIMITATION ON ENTITIES OFFERING FALLBACK PRESCRIPTION DRUG PLANS.—The Secretary shall not enter into a contract with a PDP sponsor for the offering of a prescription drug plan (other than a fallback prescription drug plan) in a PDP region for a year if the sponsor—

(A) submitted a bid under section 1860D–11(g) for such year (as the first year of a contract period under such section) to offer a fallback prescription drug plan in any PDP region;

(B) offers a fallback prescription drug plan in any PDP region during the year; or

(C) offered a fallback prescription drug plan in that PDP region during the previous year.

For purposes of this paragraph, an entity shall be treated as submitting a bid with respect to a prescription drug plan or of-

fering a fallback prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

(3) INCORPORATION OF CERTAIN MEDICARE ADVANTAGE CONTRACT REQUIREMENTS.—Except as otherwise provided, the following provisions of section 1857 shall apply to contracts under this section in the same manner as they apply to contracts under section 1857(a):

(A) MINIMUM ENROLLMENT.—Paragraphs (1) and (3) of section 1857(b), except that—

(i) the Secretary may increase the minimum number of enrollees required under such paragraph (1) as the Secretary determines appropriate; and

(ii) the requirement of such paragraph (1) shall be waived during the first contract year with respect to an organization in a region.

(B) CONTRACT PERIOD AND EFFECTIVENESS.—Section 1857(c), except that in applying paragraph (4)(B) of such section any reference to payment amounts under section 1853 shall be deemed payment amounts under section 1860D–15.

(C) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—Section 1857(d).

(D) ADDITIONAL CONTRACT TERMS.—Section 1857(e); except that section 1857(e)(2) shall apply as specified to PDP sponsors and payments under this part to an MA–PD plan shall be treated as expenditures made under part D. Notwithstanding any other provision of law, information provided to the Secretary under the application of section 1857(e)(1) to contracts under this section under the preceding sentence—

(i) may be used for the purposes of carrying out this part, improving public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services (as the Secretary determines appropriate); and

(ii) shall be made available to Congressional support agencies (in accordance with their obligations to support Congress as set out in their authorizing statutes) for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the program under this title.

(E) INTERMEDIATE SANCTIONS.—Section 1857(g) (other than paragraph (1)(F) of such section), except that in applying such section the reference in section 1857(g)(1)(B) to section 1854 is deemed a reference to this part.

(F) PROCEDURES FOR TERMINATION.—Section 1857(h).

(4) PROMPT PAYMENT OF CLEAN CLAIMS.—

(A) PROMPT PAYMENT.—

(i) IN GENERAL.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall pro-

vide that payment shall be issued, mailed, or otherwise transmitted with respect to all clean claims submitted by pharmacies (other than pharmacies that dispense drugs by mail order only or are located in, or contract with, a long-term care facility) under this part within the applicable number of calendar days after the date on which the claim is received.

(ii) CLEAN CLAIM DEFINED.—In this paragraph, the term "clean claim" means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.

(iii) DATE OF RECEIPT OF CLAIM.—In this paragraph, a claim is considered to have been received—

(I) with respect to claims submitted electronically, on the date on which the claim is transferred; and

(II) with respect to claims submitted otherwise, on the 5th day after the postmark date of the claim or the date specified in the time stamp of the transmission.

(B) APPLICABLE NUMBER OF CALENDAR DAYS DEFINED.—In this paragraph, the term "applicable number of calendar days" means—

(i) with respect to claims submitted electronically, 14 days; and

(ii) with respect to claims submitted otherwise, 30 days.

(C) INTEREST PAYMENT.—

(i) IN GENERAL.—Subject to clause (ii), if payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in subparagraph (B)) after a clean claim is received, the PDP sponsor shall pay interest to the pharmacy that submitted the claim at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which payment is made (as determined under subparagraph (D)(iv)). Interest amounts paid under this subparagraph shall not be counted against the administrative costs of a prescription drug plan or treated as allowable risk corridor costs under section 1860D–15(e).

(ii) AUTHORITY NOT TO CHARGE INTEREST.—The Secretary may provide that a PDP sponsor is not charged interest under clause (i) in the case where there are exigent circumstances, including natural disasters and other unique and unexpected events, that prevent the timely processing of claims.

(D) PROCEDURES INVOLVING CLAIMS.—

(i) CLAIM DEEMED TO BE CLEAN.—A claim is deemed to be a clean claim if the PDP sponsor involved does

not provide notice to the claimant of any deficiency in the claim—

(I) with respect to claims submitted electronically, within 10 days after the date on which the claim is received; and

(II) with respect to claims submitted otherwise, within 15 days after the date on which the claim is received.

(ii) CLAIM DETERMINED TO NOT BE A CLEAN CLAIM.—

(I) IN GENERAL.—If a PDP sponsor determines that a submitted claim is not a clean claim, the PDP sponsor shall, not later than the end of the period described in clause (i), notify the claimant of such determination. Such notification shall specify all defects or improprieties in the claim and shall list all additional information or documents necessary for the proper processing and payment of the claim.

(II) DETERMINATION AFTER SUBMISSION OF ADDITIONAL INFORMATION.—A claim is deemed to be a clean claim under this paragraph if the PDP sponsor involved does not provide notice to the claimant of any defect or impropriety in the claim within 10 days of the date on which additional information is received under subclause (I).

(iii) OBLIGATION TO PAY.—A claim submitted to a PDP sponsor that is not paid or contested by the sponsor within the applicable number of days (as defined in subparagraph (B)) after the date on which the claim is received shall be deemed to be a clean claim and shall be paid by the PDP sponsor in accordance with subparagraph (A).

(iv) DATE OF PAYMENT OF CLAIM.—Payment of a clean claim under such subparagraph is considered to have been made on the date on which—

(I) with respect to claims paid electronically, the payment is transferred; and

(II) with respect to claims paid otherwise, the payment is submitted to the United States Postal Service or common carrier for delivery.

(E) ELECTRONIC TRANSFER OF FUNDS.—A PDP sponsor shall pay all clean claims submitted electronically by electronic transfer of funds if the pharmacy so requests or has so requested previously. In the case where such payment is made electronically, remittance may be made by the PDP sponsor electronically as well.

(F) PROTECTING THE RIGHTS OF CLAIMANTS.—

(i) IN GENERAL.—Nothing in this paragraph shall be construed to prohibit or limit a claim or action not covered by the subject matter of this section that any individual or organization has against a provider or a PDP sponsor.

(ii) ANTI-RETALIATION.—Consistent with applicable Federal or State law, a PDP sponsor shall not retali-

ate against an individual or provider for exercising a right of action under this subparagraph.

(G) RULE OF CONSTRUCTION.—A determination under this paragraph that a claim submitted by a pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under this title, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination shall not relieve any party of civil or criminal liability with respect to the claim, nor does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

(5) SUBMISSION OF CLAIMS BY PHARMACIES LOCATED IN OR CONTRACTING WITH LONG-TERM CARE FACILITIES.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that a pharmacy located in, or having a contract with, a long-term care facility shall have not less than 30 days (but not more than 90 days) to submit claims to the sponsor for reimbursement under the plan.

(6) REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD.—If the PDP sponsor of a prescription drug plan uses a standard for reimbursement of pharmacies based on the cost of a drug, each contract entered into with such sponsor under this part with respect to the plan shall provide that the sponsor shall update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.

(7) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.—

(A) IN GENERAL.—Section 1862(o)(1) shall apply with respect to a PDP sponsor with a contract under this part, a pharmacy, and payments to such pharmacy under this part in the same manner as such section applies with respect to the Secretary, a provider of services or supplier, and payments to such provider of services or supplier under this title. A PDP sponsor shall notify the Secretary regarding the imposition of any payment suspension pursuant to the previous sentence, such as through the secure internet website portal (or other successor technology) established under section 1859(i).

(B) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as limiting the authority of a PDP sponsor to conduct postpayment review.

(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).

(c) WAIVER OF CERTAIN REQUIREMENTS TO EXPAND CHOICE.—

(1) AUTHORIZING WAIVER.—

(A) IN GENERAL.—In the case of an entity that seeks to offer a prescription drug plan in a State, the Secretary

shall waive the requirement of subsection (a)(1) that the entity be licensed in that State if the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for approval of the application described in paragraph (2) have been met.

(B) APPLICATION OF REGIONAL PLAN WAIVER RULE.—In addition to the waiver available under subparagraph (A), the provisions of section 1858(d) shall apply to PDP sponsors under this part in a manner similar to the manner in which such provisions apply to MA organizations under part C, except that no application shall be required under paragraph (1)(B) of such section in the case of a State that does not provide a licensing process for such a sponsor.

(2) GROUNDS FOR APPROVAL.—

(A) IN GENERAL.—The grounds for approval under this paragraph are—

(i) subject to subparagraph (B), the grounds for approval described in subparagraphs (B), (C), and (D) of section 1855(a)(2); and

(ii) the application by a State of any grounds other than those required under Federal law.

(B) SPECIAL RULES.—In applying subparagraph (A)(i)—

(i) the ground of approval described in section 1855(a)(2)(B) is deemed to have been met if the State does not have a licensing process in effect with respect to the PDP sponsor; and

(ii) for plan years beginning before January 1, 2008, if the State does have such a licensing process in effect, such ground for approval described in such section is deemed to have been met upon submission of an application described in such section.

(3) APPLICATION OF WAIVER PROCEDURES.—With respect to an application for a waiver (or a waiver granted) under paragraph (1)(A) of this subsection, the provisions of subparagraphs (E), (F), and (G) of section 1855(a)(2) shall apply, except that clauses (i) and (ii) of such subparagraph (E) shall not apply in the case of a State that does not have a licensing process described in paragraph (2)(B)(i) in effect.

(4) REFERENCES TO CERTAIN PROVISIONS.—In applying provisions of section 1855(a)(2) under paragraphs (2) and (3) of this subsection to prescription drug plans and PDP sponsors—

(A) any reference to a waiver application under section 1855 shall be treated as a reference to a waiver application under paragraph (1)(A) of this subsection; and

(B) any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d) of this section.

(d) SOLVENCY STANDARDS FOR NON-LICENSED ENTITIES.—

(1) ESTABLISHMENT AND PUBLICATION.—The Secretary, in consultation with the National Association of Insurance Commissioners, shall establish and publish, by not later than January 1, 2005, financial solvency and capital adequacy standards for entities described in paragraph (2).

(2) COMPLIANCE WITH STANDARDS.—A PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Secretary shall establish certification procedures for such sponsors with respect to such solvency standards in the manner described in section 1855(c)(2).

(e) LICENSURE DOES NOT SUBSTITUTE FOR OR CONSTITUTE CERTIFICATION.—The fact that a PDP sponsor is licensed in accordance with subsection (a)(1) or has a waiver application approved under subsection (c) does not deem the sponsor to meet other requirements imposed under this part for a sponsor.

(f) PERIODIC REVIEW AND REVISION OF STANDARDS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary may periodically review the standards established under this section and, based on such review, may revise such standards if the Secretary determines such revision to be appropriate.

(2) PROHIBITION OF MIDYEAR IMPLEMENTATION OF SIGNIFICANT NEW REGULATORY REQUIREMENTS.—The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

(g) PROHIBITION OF STATE IMPOSITION OF PREMIUM TAXES; RELATION TO STATE LAWS.—The provisions of sections 1854(g) and 1856(b)(3) shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C.

* * * * * * *

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

SEC. 1860D–14. (a) INCOME-RELATED SUBSIDIES FOR [INDIVIDUALS WITH INCOME UP TO 150 PERCENT OF POVERTY LINE] *CERTAIN INDIVIDUALS*.—

(1) [INDIVIDUALS WITH INCOME BELOW 135 PERCENT OF POVERTY LINE.—] *INDIVIDUALS WITH CERTAIN LOW INCOMES*.—In the case of a subsidy eligible individual (as defined in paragraph (3)) who is determined to have income that is below 135 percent *(or, with respect to a plan year beginning on or after January 1, 2022, 150 percent)* of the poverty line applicable to a family of the size involved and who meets the resources requirement described in paragraph (3)(D) or who is covered under this paragraph under paragraph (3)(B)(i), the individual is entitled under this section to the following:

(A) FULL PREMIUM SUBSIDY.—An income-related premium subsidy equal to 100 percent of the amount described in subsection (b)(1), but not to exceed the premium amount specified in subsection (b)(2)(B).

(B) ELIMINATION OF DEDUCTIBLE.—A reduction in the annual deductible applicable under section 1860D–2(b)(1) to $0.

(C) CONTINUATION OF COVERAGE ABOVE THE INITIAL COVERAGE LIMIT.—[The continuation] *For a year preceding*

2022, the continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b)) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced cost-sharing described in subparagraph (D).

(D) REDUCTION IN COST-SHARING BELOW OUT-OF-POCKET THRESHOLD.—

(i) INSTITUTIONALIZED INDIVIDUALS.—In the case of an individual who is a full-benefit dual eligible individual and who is an institutionalized individual or couple (as defined in section 1902(q)(1)(B)) or, effective on a date specified by the Secretary (but in no case earlier than January 1, 2012), who would be such an institutionalized individual or couple, if the full-benefit dual eligible individual were not receiving services under a home and community-based waiver authorized for a State under section 1115 or subsection (c) or (d) of section 1915 or under a State plan amendment under subsection (i) of such section or services provided through enrollment in a medicaid managed care organization with a contract under section 1903(m) or under section 1932, the elimination of any beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)).

(ii) LOWEST INCOME DUAL ELIGIBLE INDIVIDUALS.—In the case of an individual not described in clause (i) who is a full-benefit dual eligible individual and whose income does not exceed 100 percent of the poverty line applicable to a family of the size involved, the substitution for the beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)) of a copayment amount ❚that does not exceed $1 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i)) and $3 for any other drug, or, if less, the copayment amount applicable to an individual under clause (iii).❚ *that does not exceed—*

(I) for plan years before plan year 2021—

(aa) for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i)), $1 or, if less, the copayment amount applicable to an individual under clause (iii); and

(bb) for any other drug, $3 or, if less, the copayment amount applicable to an individual under clause (iii); and

(II) for plan year 2021—

(aa) for a generic drug, $0; and

(bb) for any other drug, the dollar amount applied under this clause (after application of

paragraph (4)(A)) for plan year 2020 for a drug described in subclause (I)(bb); and

(III) for a subsequent year, the dollar amount applied under this clause for the previous year for the drug, increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

(iii) OTHER INDIVIDUALS.—In the case of an individual not described in clause (i) or (ii), the substitution for the beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)) of a copayment amount that ❚does not exceed the copayment amount specified under❚ *does not exceed—*

(I)for plan years beginning before plan year 2021, the copayment amount specified under section ❚1860D–2(b)(4)(A)(i)(I)❚ *1860D–2(b)(4)(A)(i)(I)(aa)* for the drug and year involved❚.❚*; and*

(II) for plan year 2021 and each subsequent plan year, the copayment amount applied under clause (ii) for the drug and year involved.

(E) ELIMINATION OF COST-SHARING ABOVE ANNUAL OUT-OF-POCKET THRESHOLD.—❚The elimination❚ *For a year preceding 2022, the elimination* of any cost-sharing imposed under section 1860D–2(b)(4)(A).

(F) ROUNDING.—Any amount established under clause (ii) of subparagraph (D), including as applied under clause (iii) of such subparagraph or paragraph (2)(D), that is based on an increase of $3, that is not a multiple of 5 cents or 10 cents, respectively, shall be rounded to the nearest multiple of 5 cents or 10 cents, respectively.

(2) ❚OTHER INDIVIDUALS WITH INCOME BELOW 150 PERCENT OF POVERTY LINE.—❚ *OTHER LOW-INCOME INDIVIDUALS.*—In the case of a subsidy eligible individual who is not described in paragraph (1), the individual is entitled under this section to the following:

(A) SLIDING SCALE PREMIUM SUBSIDY.—An income-related premium subsidy determined on a linear sliding scale ranging from 100 percent of the amount described in paragraph (1)(A) for individuals with incomes at or below 135 percent *(or, with respect to a plan year beginning on or after January 1, 2022, 150 percent)* of such level to 0 percent of such amount for individuals with incomes at 150 percent *(or, with respect to a plan year beginning on or after January 1, 2022, 200 percent)* of such level.

(B) REDUCTION OF DEDUCTIBLE.—A reduction in the annual deductible applicable under section 1860D–2(b)(1) to $50.

(C) CONTINUATION OF COVERAGE ABOVE THE INITIAL COVERAGE LIMIT.—❚The continuation❚ *For a year preceding 2022, the continuation* of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b)) for ex-

penditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced coinsurance described in subparagraph (D).

(D) REDUCTION IN COST-SHARING BELOW OUT-OF-POCKET THRESHOLD.—The substitution for the beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts above the deductible under subparagraph (B) through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)) [of coinsurance of] *of*—

(i) for plan years before plan year 2021, coinsurance of "15 percent" instead of coinsurance of "25 percent" in section 1860D–2(b)(2)[.]*; and*

(ii) for plan year 2021 and each subsequent plan year, a copayment amount that does not exceed the copayment amount applied under paragraph (1)(D)(ii) for the drug and year involved.

(E) REDUCTION OF COST-SHARING ABOVE ANNUAL OUT-OF-POCKET THRESHOLD.—Subject to [subsection (c), the substitution for] *subsection (c)*—

(i) for plan years before plan year 2021, the substitution for the cost-sharing imposed under section 1860D–2(b)(4)(A) of a copayment or coinsurance not to exceed the copayment or coinsurance amount specified under section [1860D–2(b)(4)(A)(i)(I)] *1860D–2(b)(4)(A)(i)(I)(aa)* for the drug and year involved[.]*; and*

(ii) for plan year 2021, the elimination of any cost-sharing imposed under section 1860D–2(b)(4)(A).

(3) DETERMINATION OF ELIGIBILITY.—

(A) SUBSIDY ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this part, subject to subparagraph (F), the term "subsidy eligible individual" means a part D eligible individual who—

(i) is enrolled in a prescription drug plan or MA–PD plan;

(ii) has income below 150 percent *(or, with respect to a plan year beginning on or after January 1, 2022, 200 percent)* of the poverty line applicable to a family of the size involved; and

(iii) *in the case of a plan year beginning before January 1, 2022,* meets the resources requirement described in subparagraph (D) or (E).

(B) DETERMINATIONS.—

(i) IN GENERAL.—The determination of whether a part D eligible individual residing in a State is a subsidy eligible individual and whether the individual is described in paragraph (1) shall be determined under the State plan under title XIX for the State under section 1935(a) or by the Commissioner of Social Security. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.

(ii) EFFECTIVE PERIOD.—Determinations under this subparagraph shall be effective beginning with the month in which the individual applies for a determination that the individual is a subsidy eligible individual and shall remain in effect for a period specified by the Secretary, but not to exceed 1 year.

(iii) REDETERMINATIONS AND APPEALS THROUGH MEDICAID.—Redeterminations and appeals, with respect to eligibility determinations under clause (i) made under a State plan under title XIX, shall be made in accordance with the frequency of, and manner in which, redeterminations and appeals of eligibility are made under such plan for purposes of medical assistance under such title.

(iv) REDETERMINATIONS AND APPEALS THROUGH COMMISSIONER.—With respect to eligibility determinations under clause (i) made by the Commissioner of Social Security—

(I) redeterminations shall be made at such time or times as may be provided by the Commissioner;

(II) the Commissioner shall establish procedures for appeals of such determinations that are similar to the procedures described in the third sentence of section 1631(c)(1)(A); and

(III) judicial review of the final decision of the Commissioner made after a hearing shall be available to the same extent, and with the same limitations, as provided in subsections (g) and (h) of section 205.

(v) TREATMENT OF MEDICAID BENEFICIARIES.—Subject to subparagraph (F), the Secretary—

(I) shall provide that part D eligible individuals who are full-benefit dual eligible individuals (as defined in section 1935(c)(6)) or who are recipients of supplemental security income benefits under title XVI shall be treated as subsidy eligible individuals described in paragraph (1); **[**and**]**

(II) may provide that part D eligible individuals not described in subclause (I) who are determined for purposes of the State plan under title XIX to be eligible for medical assistance under clause (i), (iii), or (iv) of section 1902(a)(10)(E) are treated as being determined to be subsidy eligible individuals described in paragraph (1)**[**.**]***;*

(III) with respect to plan years beginning on or after January 1, 2021, shall provide that any part D eligible individual who is enrolled for medical assistance under the State Medicaid plan of a territory (as defined in section 1935(f)) under title XIX (or a waiver of such a plan) shall be treated as a subsidy eligible individual described in paragraph (1); and

(IV) with respect to plan years beginning on or after January 1, 2022, shall, notwithstanding the preceding clauses of this subparagraph, provide

that any part D eligible individual not described in subclause (I), (II), or (III) who is enrolled, as of the day before the date on which such individual attains the age of 65, for medical assistance under a State plan under title XIX (or a waiver of such plan) pursuant to clause (i)(VIII) or (ii)(XX) of section 1902(a)(10)(A), and who has income below 200 percent of the poverty line applicable to a family of the size involved, shall be treated as a subsidy eligible individual described in paragraph (1) for a limited period of time, as specified by the Secretary.

Insofar as the Secretary determines that the eligibility requirements under the State plan for medical assistance referred to in subclause (II) are substantially the same as the requirements for being treated as a subsidy eligible individual described in paragraph (1), the Secretary shall provide for the treatment described in such subclause.

(vi) SPECIAL RULE FOR WIDOWS AND WIDOWERS.—Notwithstanding the preceding provisions of this subparagraph, in the case of an individual whose spouse dies during the effective period for a determination or redetermination that has been made under this subparagraph, such effective period shall be extended through the date that is 1 year after the date on which the determination or redetermination would (but for the application of this clause) otherwise cease to be effective.

(C) INCOME DETERMINATIONS.—For purposes of applying this section—

(i) in the case of a part D eligible individual who is not treated as a subsidy eligible individual under subparagraph (B)(v), income shall be determined in the manner described in section 1905(p)(1)(B), without regard to the application of section 1902(r)(2) and ❚except that support and maintenance furnished in kind shall not be counted as income; and❚ *except that—*

(I) support and maintenance furnished in kind shall not be counted as income; and

(II) for plan years beginning on or after January 1, 2022, any distribution or withdrawal from an eligible retirement plan (as defined in subparagraph (B) of section 402(c)(8) of the Internal Revenue Code of 1986, but excluding any defined benefit plan described in clause (iv) or (v) of such subparagraph and any qualified trust (as defined in subparagraph (A) of such section) which is part of such a defined benefit plan) shall be counted as income; and

(ii) the term "poverty line" has the meaning given such term in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)), including any revision required by such section.

Nothing in clause (i) shall be construed to affect the application of section 1902(r)(2) for the determination of eligibility for medical assistance under title XIX.

(D) RESOURCE STANDARD APPLIED TO FULL LOW-INCOME SUBSIDY TO BE BASED ON THREE TIMES SSI RESOURCE STANDARD.—The resources requirement of this subparagraph is that an individual's resources (as determined under section 1613 for purposes of the supplemental security income program subject to the life insurance policy exclusion provided under subparagraph (G)) do not exceed—

(i) for 2006 three times the maximum amount of resources that an individual may have and obtain benefits under that program; and

(ii) for a subsequent year the resource limitation established under this clause for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any resource limitation established under clause (ii) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(E) ALTERNATIVE RESOURCE STANDARD.—

(i) IN GENERAL.—The resources requirement of this subparagraph is that an individual's resources (as determined under section 1613 for purposes of the supplemental security income program subject to the life insurance policy exclusion provided under subparagraph (G)) do not exceed—

(I) for 2006, $10,000 (or $20,000 in the case of the combined value of the individual's assets or resources and the assets or resources of the individual's spouse); and

(II) for a subsequent year the dollar amounts specified in this subclause (or subclause (I)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any dollar amount established under subclause (II) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(ii) USE OF SIMPLIFIED APPLICATION FORM AND PROCESS.—The Secretary, jointly with the Commissioner of Social Security, shall—

(I) develop a model, simplified application form and process consistent with clause (iii) for the determination and verification of a part D eligible individual's assets or resources under this subparagraph; and

(II) provide such form to States.

(iii) DOCUMENTATION AND SAFEGUARDS.—Under such process—

(I) the application form shall consist of an attestation under penalty of perjury regarding the level of assets or resources (or combined assets and re-

sources in the case of a married part D eligible individual) and valuations of general classes of assets or resources;

(II) such form shall be accompanied by copies of recent statements (if any) from financial institutions in support of the application; and

(III) matters attested to in the application shall be subject to appropriate methods of verification.

(iv) METHODOLOGY FLEXIBILITY.—The Secretary may permit a State in making eligibility determinations for premium and cost-sharing subsidies under this section to use the same asset or resource methodologies that are used with respect to eligibility for medical assistance for medicare cost-sharing described in section 1905(p) so long as the Secretary determines that the use of such methodologies will not result in any significant differences in the number of individuals determined to be subsidy eligible individuals.

(F) TREATMENT OF TERRITORIAL RESIDENTS.—In the case of a part D eligible individual who is not a resident of the 50 States or the District of Columbia, the individual is not eligible to be a subsidy eligible individual under this section but may be eligible for financial assistance with prescription drug expenses under section 1935(e). *The previous sentence shall not apply with respect to eligibility determinations for premium and cost-sharing subsidies under this section made on or after January 1, 2021.*

(G) LIFE INSURANCE POLICY EXCLUSION.—In determining the resources of an individual (and the eligible spouse of the individual, if any) under section 1613 for purposes of subparagraphs (D) and (E) no part of the value of any life insurance policy shall be taken into account.

(4) INDEXING DOLLAR AMOUNTS.—

(A) COPAYMENT FOR LOWEST INCOME DUAL ELIGIBLE INDIVIDUALS.—The dollar amounts applied under paragraph (1)(D)(ii)—

(i) for 2007 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year; or

(ii) for a subsequent year *(before 2021)* shall be the dollar amounts specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any amount established under clause (i) or (ii), that is based on an increase of $1 or $3, that is not a multiple of 5 cents or 10 cents, respectively, shall be rounded to the nearest multiple of 5 cents or 10 cents, respectively.

(B) REDUCED DEDUCTIBLE.—The dollar amount applied under paragraph (2)(B)—

(i) for 2007 shall be the dollar amount specified in such paragraph increased by the annual percentage

increase described in section 1860D–2(b)(6) for 2007; or

(ii) for a subsequent year shall be the dollar amount specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase described in section 1860D–2(b)(6) for the year involved.

Any amount established under clause (i) or (ii) that is not a multiple of $1 shall be rounded to the nearest multiple of $1.

(5) WAIVER OF DE MINIMIS PREMIUMS.—The Secretary shall, under procedures established by the Secretary, permit a prescription drug plan or an MA–PD plan to waive the monthly beneficiary premium for a subsidy eligible individual if the amount of such premium is de minimis. If such premium is waived under the plan, the Secretary shall not reassign subsidy eligible individuals enrolled in the plan to other plans based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark premium amount.

(b) PREMIUM SUBSIDY AMOUNT.—

(1) IN GENERAL.—The premium subsidy amount described in this subsection for a subsidy eligible individual residing in a PDP region and enrolled in a prescription drug plan or MA–PD plan is the low-income benchmark premium amount (as defined in paragraph (2)) for the PDP region in which the individual resides or, if greater, the amount specified in paragraph (3).

(2) LOW-INCOME BENCHMARK PREMIUM AMOUNT DEFINED.—

(A) IN GENERAL.—For purposes of this subsection, the term "low-income benchmark premium amount" means, with respect to a PDP region in which—

(i) all prescription drug plans are offered by the same PDP sponsor, the weighted average of the amounts described in subparagraph (B)(i) for such plans; or

(ii) there are prescription drug plans offered by more than one PDP sponsor, the weighted average of amounts described in subparagraph (B) for prescription drug plans and MA–PD plans described in section 1851(a)(2)(A)(i) offered in such region.

(B) PREMIUM AMOUNTS DESCRIBED.—The premium amounts described in this subparagraph are, in the case of—

(i) a prescription drug plan that is a basic prescription drug plan, the monthly beneficiary premium for such plan;

(ii) a prescription drug plan that provides alternative prescription drug coverage the actuarial value of which is greater than that of standard prescription drug coverage, the portion of the monthly beneficiary premium that is attributable to basic prescription drug coverage; and

(iii) an MA–PD plan, the portion of the MA monthly prescription drug beneficiary premium that is attributable to basic prescription drug benefits (described in

section 1852(a)(6)(B)(ii)) and determined before the application of the monthly rebate computed under section 1854(b)(1)(C)(i) for that plan and year involved and, in the case of a qualifying plan, before the application of the increase under section 1853(o) for that plan and year involved.

The premium amounts described in this subparagraph do not include any amounts attributable to late enrollment penalties under section 1860D–13(b).

(3) ACCESS TO 0 PREMIUM PLAN.—In no case shall the premium subsidy amount under this subsection for a PDP region be less than the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the region.

(c) ADMINISTRATION OF SUBSIDY PROGRAM.—

(1) IN GENERAL.—The Secretary shall provide a process whereby, in the case of a part D eligible individual who is determined to be a subsidy eligible individual and who is enrolled in a prescription drug plan or is enrolled in an MA–PD plan—

(A) the Secretary provides for a notification of the PDP sponsor or the MA organization offering the plan involved that the individual is eligible for a subsidy and the amount of the subsidy under subsection (a);

(B) the sponsor or organization involved reduces the premiums or cost-sharing otherwise imposed by the amount of the applicable subsidy and submits to the Secretary information on the amount of such reduction;

(C) the Secretary periodically and on a timely basis reimburses the sponsor or organization for the amount of such reductions; and

(D) the Secretary ensures the confidentiality of individually identifiable information.

In applying subparagraph (C), the Secretary shall compute reductions based upon imposition under subsections (a)(1)(D) and (a)(2)(E) of unreduced copayment amounts applied under such subsections.

(2) USE OF CAPITATED FORM OF PAYMENT.—The reimbursement under this section with respect to cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved.

(d) FACILITATION OF REASSIGNMENTS.—Beginning not later than January 1, 2011, the Secretary shall, in the case of a subsidy eligible individual who is enrolled in one prescription drug plan and is subsequently reassigned by the Secretary to a new prescription drug plan, provide the individual, within 30 days of such reassignment, with—

(1) information on formulary differences between the individual's former plan and the plan to which the individual is reassigned with respect to the individual's drug regimens; and

(2) a description of the individual's right to request a coverage determination, exception, or reconsideration under section 1860D–4(g), bring an appeal under section 1860D–4(h), or resolve a grievance under section 1860D–4(f).

(e) RELATION TO MEDICAID PROGRAM.—For special provisions under the medicaid program relating to medicare prescription drug benefits, see section 1935.

MEDICARE COVERAGE GAP DISCOUNT PROGRAM

SEC. 1860D–14A. (a) ESTABLISHMENT.—[The Secretary] *Subject to subsection (h), the Secretary* shall establish a Medicare coverage gap discount program (in this section referred to as the "program") by not later than January 1, 2011. 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)(1). The Secretary shall establish a model agreement for use under the program by not later than 180 days after the date of the enactment of this section, 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.

(B) PROVISION OF DISCOUNTED PRICES AT THE POINT-OF-SALE.—Except as provided in subsection (c)(1)(A)(iii), such discounted prices 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 2011.—In order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2011, and ending on December 31, 2011, the manufacturer shall enter into such agreement not later than not later than 30 days after the date of the establishment of a model agreement under subsection (a).

(ii) 2012 AND SUBSEQUENT YEARS.—In order for an agreement with a manufacturer to be in effect under this section with respect to plan year 2012 or a subsequent plan year, the manufacturer shall enter into such agreement (or such agreement shall be renewed under paragraph (4)(A)) not later than January 30 of the preceding year.

(2) PROVISION OF APPROPRIATE DATA.—Each manufacturer with an agreement in effect under this section shall collect and have available appropriate data, as determined by the Secretary, to ensure that it can demonstrate to the Secretary compliance with the requirements under the program.

(3) COMPLIANCE WITH REQUIREMENTS FOR ADMINISTRATION OF PROGRAM.—Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under subsection (d)(3), as applicable, for purposes of administering the program, including any determination under clause (i) of subsection (c)(1)(A) or procedures established under such subsection (c)(1)(A).

(4) LENGTH OF AGREEMENT.—

(A) IN GENERAL.—An agreement under this section shall be effective for an initial period of not less than 18 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 AND SPECIAL RULE FOR SUPPLEMENTAL BENEFITS.—

(1) DUTIES DESCRIBED.—The duties described in this subsection are the following:

(A) ADMINISTRATION OF PROGRAM.—Administering the program, including—

(i) the determination of the amount of the discounted price of an applicable drug of a manufacturer;

(ii) except as provided in clause (iii), 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;

(iii) in the case where, during the period beginning on January 1, 2011, and ending on December 31, 2011, it is not practicable to provide such discounted prices at the point-of-sale (as described in clause (ii)), the es-

tablishment of procedures to provide such discounted prices as soon as practicable after the point-of-sale;

(iv) 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;

(v) 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;

(vi) the establishment of procedures to implement the special rule for supplemental benefits under paragraph (2); and

(vii) providing a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the third party with a contract under subsection (d)(3).

(B) MONITORING COMPLIANCE.—

(i) IN GENERAL.—The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under this section.

(ii) 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).

(C) 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.

(2) SPECIAL RULE FOR SUPPLEMENTAL BENEFITS.—For plan year 2011 and each subsequent plan year, in the case where an applicable beneficiary has supplemental benefits with respect to applicable drugs under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in, the applicable beneficiary shall not be provided a discounted price for an applicable drug under this section until after such supplemental benefits have been applied with respect to the applicable drug.

(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)(1).

(2) LIMITATION.—

(A) IN GENERAL.—Subject to subparagraph (B), in providing for such implementation, the Secretary shall not receive or distribute any funds of a manufacturer under the program.

(B) EXCEPTION.—The limitation under subparagraph (A) shall not apply to the Secretary with respect to drugs dispensed during the period beginning on January 1, 2011, and ending on December 31, 2011, but only if the Secretary determines that the exception to such limitation under this subparagraph is necessary in order for the Secretary to begin implementation of this section and provide applicable beneficiaries timely access to discounted prices during such period.

(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.—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 shall 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 commensurate with 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;

(C) is not entitled to an income-related subsidy under section 1860D–14(a); and

(D) who—

(i) has reached or exceeded the initial coverage limit under section 1860D–2(b)(3) during the year; and

(ii) has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B).

(2) APPLICABLE DRUG.—The term "applicable drug" means, with respect to an applicable beneficiary, a covered part D drug—

(A) approved under a new drug application under section 505(b) 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 (other than, with respect to a plan year before 2019, a product licensed under subsection (k) of such section 351); and

(B)(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.

(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 50 percent (or, with respect to a plan year after plan year 2018, 30 percent) of the negotiated price of the applicable drug of a manufacturer.

(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.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall at or above the initial coverage limit under section 1860D–2(b)(3) and below the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) for the year, the manufacturer of the applicable drug shall provide the discounted price under this section on only the portion of the negotiated price of the applicable drug that falls at or above such initial coverage limit and below such annual out-of-pocket threshold.

(5) MANUFACTURER.—The term "manufacturer" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. 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 (as in effect on the date of enactment of this section), except that 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).

(h) SUNSET OF PROGRAM.—

(1) IN GENERAL.—The program shall not apply with respect to applicable drugs dispensed on or after January 1, 2022, and, subject to paragraph (2), agreements under this section shall be terminated as of such date.

(2) CONTINUED APPLICATION FOR APPLICABLE DRUGS DISPENSED PRIOR TO SUNSET.—The provisions of this section (including all responsibilities and duties) shall continue to apply after January 1, 2022, with respect to applicable drugs dispensed prior to such date.

SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN DRUGS WITH PRICES INCREASING FASTER THAN INFLATION.

(a) IN GENERAL.—

(1) IN GENERAL.—Subject to the provisions of this section, in order for coverage to be available under this part for a part D rebatable drug (as defined in subsection (h)(1)) of a manufacturer (as defined in section 1927(k)(5)) dispensed during an applicable year, the manufacturer must have entered into and have in effect an agreement described in subsection (b).

(2) AUTHORIZING COVERAGE FOR DRUGS NOT COVERED UNDER AGREEMENTS.—Paragraph (1) shall not apply to the dispensing of a covered part D drug if—

(A) the Secretary has made a determination that the availability of the drug is essential to the health of beneficiaries under this part; or

(B) the Secretary determines that in the period beginning on January 1, 2022, and ending on December 31, 2022, there were extenuating circumstances.

(3) APPLICABLE YEAR.—For purposes of this section the term "applicable year" means a year beginning with 2022.

(b) AGREEMENTS.—

(1) TERMS OF AGREEMENT.—An agreement described in this subsection, with respect to a 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 vio-

lation 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 calendar quarter of the payment amount benchmark year (as defined in subsection (h)(3)); and

(B) the ratio of—

(i) the total number of units of such dosage form and strength dispensed during such calendar quarter of the payment amount benchmark year; to

(ii) the total number of units of such dosage form and strength dispensed during the payment amount benchmark year.

(5) SPECIAL TREATMENT OF CERTAIN DRUGS AND EXEMPTION.—

(A) SUBSEQUENTLY APPROVED DRUGS.—In the case of a part D rebatable drug first approved or licensed by the Food and Drug Administration after January 1, 2016, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term "payment amount benchmark year" were defined under subsection (h)(3) as the first calendar year beginning after the day on which the drug was first marketed by any manufacturer and subparagraph (B) of paragraph (3) shall be applied as if the term "benchmark period CPI–U" were defined under subsection (h)(4) as if the reference to "January 2016" under such subsection were a reference to "January of the first year beginning after the date on which the drug was first marketed by any manufacturer".

(B) EXEMPTION FOR SHORTAGES.—The Secretary may reduce or waive the rebate under paragraph (1) with respect to a part D rebatable drug that is described as currently in shortage on the shortage list in effect under section 506E of

the Federal Food, Drug, and Cosmetic Act or in the case of other exigent circumstances, as determined by the Secretary.

(C) TREATMENT OF NEW FORMULATIONS.—

(i) IN GENERAL.—In the case of a part D rebatable drug that is a line extension of a part D rebatable drug that is an oral solid dosage form, the Secretary shall establish a formula for determining the amount specified in this subsection with respect to such part D rebatable drug and an applicable year with consideration of the original part D rebatable drug.

(ii) LINE EXTENSION DEFINED.—In this subparagraph, the term "line 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)) and is determined (pursuant to such section 1192(c)) to no longer be a selected drug, for each applicable year beginning after the price applicability period with respect to such drug, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term "payment amount benchmark year" were defined under subsection (h)(3) as the last year beginning during such price applicability period with respect to such selected drug and subparagraph (B) of paragraph (3) shall be applied as if the term "benchmark period CPI–U" were defined under subsection (h)(4) as if the reference to "January 2016" under such subsection were a reference to January of the last year beginning during such price applicability period with respect to such drug.

(d) REBATE DEPOSITS.—Amounts paid as rebates under subsection (c) shall be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

(e) INFORMATION.—For purposes of carrying out this section, the Secretary shall use information submitted by manufacturers under section 1927(b)(3).

(f) CIVIL MONEY PENALTY.—In the case of a manufacturer of a part D rebatable drug with an agreement in effect under this section who has failed to comply with the terms of the agreement under subsection (b)(1)(B) with respect to such drug for an applicable year, the Secretary may impose a civil money penalty on such manufacturer in an amount equal to 125 percent of the amount specified in subsection (c) for such drug for such year. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(g) JUDICIAL REVIEW.—There shall be no judicial review of the following:

(1) The determination of units under this section.

(2) The determination of whether a drug is a part D rebatable drug under this section.

(3) The calculation of the rebate amount under this section.

(h) DEFINITIONS.—In this section:

(1) PART D REBATABLE DRUG DEFINED.—

(A) IN GENERAL.—The term "part D rebatable drug" means a drug or biological that would (without application of this section) be a covered part D drug, except such term shall, with respect to an applicable year, not include such a drug or biological if the average annual total cost under this part for such year per individual who uses such a drug or biological, as determined by the Secretary, is less than, subject to subparagraph (B), $100, as determined by the Secretary using the most recent data available or, if data is not available, as estimated by the Secretary.

(B) INCREASE.—The dollar amount applied under subparagraph (A)—

(i) for 2023, shall be the dollar amount specified under such subparagraph for 2022, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period beginning with January of 2022; and

(ii) for a subsequent year, shall be the dollar amount specified in this subparagraph for the previous year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period beginning with January of the previous year.

Any dollar amount specified under this subparagraph that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(2) UNIT DEFINED.—The term "unit" means, with respect to a part D rebatable drug, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the part D rebatable drug that is dispensed to individuals under this part.

(3) PAYMENT AMOUNT BENCHMARK YEAR.—The term "payment amount benchmark year" means the year beginning January 1, 2016.

(4) BENCHMARK PERIOD CPI–U.—The term "benchmark period CPI–U" means the consumer price index for all urban consumers (United States city average) for January 2016.

(5) APPLICABLE YEAR CPI–U.—The term "applicable year CPI–U" means, with respect to an applicable year, the consumer price index for all urban consumers (United States city average) for January of such year.

(6) AVERAGE MANUFACTURER PRICE.—The term "average manufacturer price" has the meaning, with respect to a part D rebatable drug of a manufacturer, given such term in section 1927(k)(1), with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927.

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, 2021, in consultation with manufacturers, and allow for comment on such model agreement.

(b) TERMS OF AGREEMENT.—

(1) IN GENERAL.—

(A) AGREEMENT.—An agreement under this section shall require the manufacturer to provide applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer that are dispensed on or after January 1, 2022.

(B) PROVISION OF DISCOUNTED PRICES AT THE POINT-OF-SALE.—The discounted prices described in subparagraph (A) shall be provided to the applicable beneficiary at the pharmacy or by the mail order service at the point-of-sale of an applicable drug.

(C) TIMING OF AGREEMENT.—

(i) SPECIAL RULE FOR 2022.—In order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2022, and ending on December 31, 2022, the manufacturer shall enter into such agreement not later than 30 days after the date of the establishment of a model agreement under subsection (a).

(ii) 2023 AND SUBSEQUENT YEARS.—In order for an agreement with a manufacturer to be in effect under this section with respect to plan year 2023 or a subsequent plan year, the manufacturer shall enter into such agreement (or such agreement shall be renewed under paragraph (4)(A)) not later than January 30 of the preceding year.

(2) PROVISION OF APPROPRIATE DATA.—Each manufacturer with an agreement in effect under this section shall collect and have available appropriate data, as determined by the Secretary, to ensure that it can demonstrate to the Secretary compliance with the requirements under the program.

(3) COMPLIANCE WITH REQUIREMENTS FOR ADMINISTRATION OF PROGRAM.—Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under subsection (d)(3), as applicable, for purposes of administering the program, including any determination under subparagraph (A) of subsection (c)(1) or procedures established under such subsection (c)(1).

(4) LENGTH OF AGREEMENT.—

(A) IN GENERAL.—An agreement under this section shall be effective for an initial period of not less than 12 months and shall be automatically renewed for a period of not less than 1 year unless terminated under subparagraph (B).

(B) TERMINATION.—

(i) BY THE SECRETARY.—The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

(ii) BY A MANUFACTURER.—A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

(I) if the termination occurs before January 30 of a plan year, as of the day after the end of the plan year; and

(II) if the termination occurs on or after January 30 of a plan year, as of the day after the end of the succeeding plan year.

(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect discounts for applicable drugs of the manufacturer that are due under the agreement before the effective date of its termination.

(iv) NOTICE TO THIRD PARTY.—The Secretary shall provide notice of such termination to a third party with a contract under subsection (d)(3) within not less than 30 days before the effective date of such termination.

(c) DUTIES DESCRIBED.—The duties described in this subsection are the following:

(1) ADMINISTRATION OF PROGRAM.—Administering the program, including—

(A) the determination of the amount of the discounted price of an applicable drug of a manufacturer;

(B) the establishment of procedures under which discounted prices are provided to applicable beneficiaries at pharmacies or by mail order service at the point-of-sale of an applicable drug;

(C) the establishment of procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

(i) the negotiated price of the applicable drug; and

(ii) the discounted price of the applicable drug;

(D) the establishment of procedures to ensure that the discounted price for an 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 for covered part D drugs in the year that are equal to or exceed the annual deductible specified in section 1860D–2(b)(1) for such year.

(2) APPLICABLE DRUG.—The term "applicable drug", with respect to an applicable beneficiary—

(A) means a covered part D drug—

(i) approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act; and

(ii)(I) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

(II) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available

under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

(III) is provided through an exception or appeal; and

(B) does not include a selected drug (as defined in section 1192(c)) during a price applicability period (as defined in section 1191(b)(2)) with respect to such drug.

(3) APPLICABLE NUMBER OF CALENDAR DAYS.—The term "applicable number of calendar days" means—

(A) with respect to claims for reimbursement submitted electronically, 14 days; and

(B) with respect to claims for reimbursement submitted otherwise, 30 days.

(4) DISCOUNTED PRICE.—

(A) IN GENERAL.—The term "discounted price" means, with respect to an applicable drug of a manufacturer furnished during a year to an applicable beneficiary—

(i) who has not incurred costs 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 in the year that are equal to or exceed such threshold for the year, 70 percent of the negotiated price of such drug.

(B) CLARIFICATION.—Nothing in this section shall be construed as affecting the responsibility of an applicable beneficiary for payment of a dispensing fee for an applicable drug.

(C) SPECIAL CASE FOR CERTAIN CLAIMS.—

(i) CLAIMS SPANNING DEDUCTIBLE.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall at or above the annual deductible specified in section 1860D–2(b)(1) for the year, the manufacturer of the applicable drug shall provide the discounted price under this section on only the portion of the negotiated price of the applicable drug that falls at or above such annual deductible.

(ii) CLAIMS SPANNING OUT-OF-POCKET THRESHOLD.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall entirely below or entirely above the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year, the manufacturer of the applicable drug shall provide the discounted price—

(I) in accordance with subparagraph (A)(i) on the portion of the negotiated price of the applicable drug that falls below such threshold; and

(II) in accordance with subparagraph (A)(ii) on the portion of such price of such drug that falls at or above such threshold.

(5) MANUFACTURER.—The term "manufacturer" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription

drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. 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).

SUBSIDIES FOR PART D ELIGIBLE INDIVIDUALS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

SEC. 1860D–15. (a) SUBSIDY PAYMENT.—In order to reduce premium levels applicable to qualified prescription drug coverage for part D eligible individuals consistent with an overall subsidy level of 74.5 percent for basic prescription drug coverage, to reduce adverse selection among prescription drug plans and MA–PD plans, and to promote the participation of PDP sponsors under this part and MA organizations under part C, the Secretary shall provide for payment to a PDP sponsor that offers a prescription drug plan and an MA organization that offers an MA–PD plan of the following subsidies in accordance with this section:

(1) DIRECT SUBSIDY.—A direct subsidy for each part D eligible individual enrolled in a prescription drug plan or MA–PD plan for a month equal to—

(A) the amount of the plan's standardized bid amount (as defined in section 1860D–13(a)(5)), adjusted under subsection (c)(1), reduced by

(B) the base beneficiary premium (as computed under paragraph (2) of section 1860D–13(a) and as adjusted under paragraph (1)(B) of such section).

(2) SUBSIDY THROUGH REINSURANCE.—The reinsurance payment amount (as defined in subsection (b)).

This section constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this section.

(b) REINSURANCE PAYMENT AMOUNT.—

(1) IN GENERAL.—The reinsurance payment amount under this subsection for a part D eligible individual enrolled in a prescription drug plan or MA–PD plan for a coverage year is an amount equal to 80 percent *(or, with respect to a coverage year after 2021, 20 percent)* of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B).

(2) ALLOWABLE REINSURANCE COSTS.—For purposes of this section, the term "allowable reinsurance costs" means, with respect to gross covered prescription drug costs under a prescription drug plan offered by a PDP sponsor or an MA–PD plan

offered by an MA organization, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization or by (or on behalf of) an enrollee under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were standard prescription drug coverage.

(3) GROSS COVERED PRESCRIPTION DRUG COSTS.—For purposes of this section, the term "gross covered prescription drug costs" means, with respect to a part D eligible individual enrolled in a prescription drug plan or MA–PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

(4) COVERAGE YEAR DEFINED.—For purposes of this section, the term "coverage year" means a calendar year in which covered part D drugs are dispensed if the claim for such drugs (and payment on such claim) is made not later than such period after the end of such year as the Secretary specifies.

(c) ADJUSTMENTS RELATING TO BIDS.—

(1) HEALTH STATUS RISK ADJUSTMENT.—

(A) ESTABLISHMENT OF RISK ADJUSTORS.—The Secretary shall establish an appropriate methodology for adjusting the standardized bid amount under subsection (a)(1)(A) to take into account variation in costs for basic prescription drug coverage among prescription drug plans and MA–PD plans based on the differences in actuarial risk of different enrollees being served. Any such risk adjustment shall be designed in a manner so as not to result in a change in the aggregate amounts payable to such plans under subsection (a)(1) and through that portion of the monthly beneficiary prescription drug premiums described in subsection (a)(1)(B) and MA monthly prescription drug beneficiary premiums.

(B) CONSIDERATIONS.—In establishing the methodology under subparagraph (A), the Secretary may take into account the similar methodologies used under section 1853(a)(3) to adjust payments to MA organizations for benefits under the original medicare fee-for-service program option.

(C) DATA COLLECTION.—In order to carry out this paragraph, the Secretary shall require—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to part A and part B data and such other information as the Secretary determines necessary; and

(ii) MA organizations that offer MA–PD plans to submit data regarding drug claims that can be linked at the individual level to other data that such organi-

zations are required to submit to the Secretary and such other information as the Secretary determines necessary.

(D) PUBLICATION.—At the time of publication of risk adjustment factors under section 1853(b)(1)(B)(i)(II), the Secretary shall publish the risk adjusters established under this paragraph for the succeeding year.

(2) GEOGRAPHIC ADJUSTMENT.—

(A) IN GENERAL.—Subject to subparagraph (B), for purposes of section 1860D–13(a)(1)(B)(iii), the Secretary shall establish an appropriate methodology for adjusting the national average monthly bid amount (computed under section 1860D–13(a)(4)) to take into account differences in prices for covered part D drugs among PDP regions.

(B) DE MINIMIS RULE.—If the Secretary determines that the price variations described in subparagraph (A) among PDP regions are de minimis, the Secretary shall not provide for adjustment under this paragraph.

(C) BUDGET NEUTRAL ADJUSTMENT.—Any adjustment under this paragraph shall be applied in a manner so as to not result in a change in the aggregate payments made under this part that would have been made if the Secretary had not applied such adjustment.

(d) PAYMENT METHODS.—

(1) IN GENERAL.—Payments under this section shall be based on such a method as the Secretary determines. The Secretary may establish a payment method by which interim payments of amounts under this section are made during a year based on the Secretary's best estimate of amounts that will be payable after obtaining all of the information.

(2) REQUIREMENT FOR PROVISION OF INFORMATION.—

(A) REQUIREMENT.—Payments under this section to a PDP sponsor or MA organization are conditioned upon the furnishing to the Secretary, in a form and manner specified by the Secretary, of such information as may be required to carry out this section.

(B) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to subparagraph (A) may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section.

(3) SOURCE OF PAYMENTS.—Payments under this section shall be made from the Medicare Prescription Drug Account.

(4) APPLICATION OF ENROLLEE ADJUSTMENT.—The provisions of section 1853(a)(2) shall apply to payments to PDP sponsors under this section in the same manner as they apply to payments to MA organizations under section 1853(a).

(e) PORTION OF TOTAL PAYMENTS TO A SPONSOR OR ORGANIZATION SUBJECT TO RISK (APPLICATION OF RISK CORRIDORS).—

(1) COMPUTATION OF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS.—

(A) IN GENERAL.—For purposes of this subsection, the term "adjusted allowable risk corridor costs" means, for a plan for a coverage year (as defined in subsection (b)(4))—

(i) the allowable risk corridor costs (as defined in subparagraph (B)) for the plan for the year, reduced by

(ii) the sum of (I) the total reinsurance payments made under subsection (b) to the sponsor of the plan for the year, and (II) the total subsidy payments made under section 1860D–14 to the sponsor of the plan for the year.

(B) ALLOWABLE RISK CORRIDOR COSTS.—For purposes of this subsection, the term "allowable risk corridor costs" means, with respect to a prescription drug plan offered by a PDP sponsor or an MA–PD plan offered by an MA organization, the part of costs (not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year) incurred by the sponsor or organization under the plan that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were basic prescription drug coverage taking into account the adjustment under section 1860D–11(c)(2). In computing allowable costs under this paragraph, the Secretary shall compute such costs based upon imposition under paragraphs (1)(D) and (2)(E) of section 1860D–14(a) of the maximum amount of copayments permitted under such paragraphs.

(2) ADJUSTMENT OF PAYMENT.—

(A) NO ADJUSTMENT IF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS WITHIN RISK CORRIDOR.—If the adjusted allowable risk corridor costs (as defined in paragraph (1)) for the plan for the year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (3)(A)(i)), but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (3)(A)(iii)) for the plan for the year, then no payment adjustment shall be made under this subsection.

(B) INCREASE IN PAYMENT IF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS ABOVE UPPER LIMIT OF RISK CORRIDOR.—

(i) COSTS BETWEEN FIRST AND SECOND THRESHOLD UPPER LIMITS.—If the adjusted allowable risk corridor costs for the plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between such adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

(ii) COSTS ABOVE SECOND THRESHOLD UPPER LIMITS.—If the adjusted allowable risk corridor costs for the plan for the year are greater than the second threshold upper limit of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to the sum of—

(I) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

(II) 80 percent of the difference between such adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) CONDITIONS FOR APPLICATION OF HIGHER PERCENTAGE FOR 2006 AND 2007.—The conditions described in this clause are met for 2006 or 2007 if the Secretary determines with respect to such year that—

(I) at least 60 percent of prescription drug plans and MA–PD plans to which this subsection applies have adjusted allowable risk corridor costs for the plan for the year that are more than the first threshold upper limit of the risk corridor for the plan for the year; and

(II) such plans represent at least 60 percent of part D eligible individuals enrolled in any prescription drug plan or MA–PD plan.

(C) REDUCTION IN PAYMENT IF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS BELOW LOWER LIMIT OF RISK CORRIDOR.—

(i) COSTS BETWEEN FIRST AND SECOND THRESHOLD LOWER LIMITS.—If the adjusted allowable risk corridor costs for the plan for the year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and such adjusted allowable risk corridor costs.

(ii) COSTS BELOW SECOND THRESHOLD LOWER LIMIT.—If the adjusted allowable risk corridor costs for the plan for the year are less the second threshold lower limit of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to the sum of—

(I) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(II) 80 percent of the difference between the second threshold upper limit of the risk corridor and such adjusted allowable risk corridor costs.

(3) ESTABLISHMENT OF RISK CORRIDORS.—

(A) IN GENERAL.—For each plan year the Secretary shall establish a risk corridor for each prescription drug plan and each MA–PD plan. The risk corridor for a plan for a year shall be equal to a range as follows:

(i) FIRST THRESHOLD LOWER LIMIT.—The first threshold lower limit of such corridor shall be equal to—

(I) the target amount described in subparagraph (B) for the plan; minus

(II) an amount equal to the first threshold risk percentage for the plan (as determined under subparagraph (C)(i)) of such target amount.

(ii) SECOND THRESHOLD LOWER LIMIT.—The second threshold lower limit of such corridor shall be equal to—

(I) the target amount described in subparagraph (B) for the plan; minus

(II) an amount equal to the second threshold risk percentage for the plan (as determined under subparagraph (C)(ii)) of such target amount.

(iii) FIRST THRESHOLD UPPER LIMIT.—The first threshold upper limit of such corridor shall be equal to the sum of—

(I) such target amount; and

(II) the amount described in clause (i)(II).

(iv) SECOND THRESHOLD UPPER LIMIT.—The second threshold upper limit of such corridor shall be equal to the sum of—

(I) such target amount; and

(II) the amount described in clause (ii)(II).

(B) TARGET AMOUNT DESCRIBED.—The target amount described in this paragraph is, with respect to a prescription drug plan or an MA–PD plan in a year, the total amount of payments paid to the PDP sponsor or MA–PD organization for the plan for the year, taking into account amounts paid by the Secretary and enrollees, based upon the standardized bid amount (as defined in section 1860D–13(a)(5) and as risk adjusted under subsection (c)(1)), reduced by the total amount of administrative expenses for the year assumed in such standardized bid.

(C) FIRST AND SECOND THRESHOLD RISK PERCENTAGE DEFINED.—

(i) FIRST THRESHOLD RISK PERCENTAGE.—Subject to clause (iii), for purposes of this section, the first threshold risk percentage is—

(I) for 2006 and 2007, and 2.5 percent;

(II) for 2008 through 2011, 5 percent; and

(III) for 2012 and subsequent years, a percentage established by the Secretary, but in no case less than 5 percent.

(ii) SECOND THRESHOLD RISK PERCENTAGE.—Subject to clause (iii), for purposes of this section, the second threshold risk percentage is—

(I) for 2006 and 2007, 5 percent;

(II) for 2008 through 2011, 10 percent; and

(III) for 2012 and subsequent years, a percentage established by the Secretary that is greater than the percent established for the year under clause (i)(III), but in no case less than 10 percent.

(iii) REDUCTION OF RISK PERCENTAGE TO ENSURE 2 PLANS IN AN AREA.—Pursuant to section 1860D–11(b)(2)(E)(ii), a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (2).

(4) PLANS AT RISK FOR ENTIRE AMOUNT OF SUPPLEMENTAL PRESCRIPTION DRUG COVERAGE.—A PDP sponsor and MA organization that offers a plan that provides supplemental prescription drug benefits shall be at full financial risk for the provision of such supplemental benefits.

(5) NO EFFECT ON MONTHLY PREMIUM.—No adjustment in payments made by reason of this subsection shall affect the monthly beneficiary premium or the MA monthly prescription drug beneficiary premium.

(f) DISCLOSURE OF INFORMATION.—

(1) IN GENERAL.—Each contract under this part and under part C shall provide that—

(A) the PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall provide the Secretary with such information as the Secretary determines is necessary to carry out this section; and

(B) the Secretary shall have the right in accordance with section 1857(d)(2)(B) (as applied under section 1860D–12(b)(3)(C)) to inspect and audit any books and records of a PDP sponsor or MA organization that pertain to the information regarding costs provided to the Secretary under subparagraph (A).

(2) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to the provisions of this section may be used—

(A) by officers, employees, and contractors of the Department of Health and Human Services for the purposes of, and to the extent necessary in—

(i) carrying out this section; and

(ii) conducting oversight, evaluation, and enforcement under this title; and

(B) by the Attorney General and the Comptroller General of the United States for the purposes of, and to the extent necessary in, carrying out health oversight activities.

(g) PAYMENT FOR FALLBACK PRESCRIPTION DRUG PLANS.—In lieu of the amounts otherwise payable under this section to a PDP

sponsor offering a fallback prescription drug plan (as defined in section 1860D–3(c)(4)), the amount payable shall be the amounts determined under the contract for such plan pursuant to section 1860D–11(g)(5).

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Subpart 3—Application to Medicare Advantage Program and Treatment of Employer-Sponsored Programs and Other Prescription Drug Plans

APPLICATION TO MEDICARE ADVANTAGE PROGRAM AND RELATED MANAGED CARE PROGRAMS

SEC. 1860D–21. (a) SPECIAL RULES RELATING TO OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—

(1) IN GENERAL.—An MA organization on and after January 1, 2006—

(A) may not offer an MA plan described in section 1851(a)(2)(A) in an area unless either that plan (or another MA plan offered by the organization in that same service area) includes required prescription drug coverage (as defined in paragraph (2)); and

(B) may not offer prescription drug coverage (other than that required under parts A and B) to an enrollee—

(i) under an MSA plan; or

(ii) under another MA plan unless such drug coverage under such other plan provides qualified prescription drug coverage and unless the requirements of this section with respect to such coverage are met.

(2) QUALIFYING COVERAGE.—For purposes of paragraph (1)(A), the term "required coverage" means with respect to an MA–PD plan—

(A) basic prescription drug coverage; or

(B) qualified prescription drug coverage that provides supplemental prescription drug coverage, so long as there is no MA monthly supplemental beneficiary premium applied under the plan (due to the application of a credit against such premium of a rebate under section 1854(b)(1)(C)).

(b) APPLICATION OF DEFAULT ENROLLMENT RULES.—

(1) SEAMLESS CONTINUATION.—In applying section 1851(c)(3)(A)(ii), an individual who is enrolled in a health benefits plan shall not be considered to have been deemed to make an election into an MA–PD plan unless such health benefits plan provides any prescription drug coverage.

(2) MA CONTINUATION.—In applying section 1851(c)(3)(B), an individual who is enrolled in an MA plan shall not be considered to have been deemed to make an election into an MA–PD plan unless—

(A) for purposes of the election as of January 1, 2006, the MA plan provided as of December 31, 2005, any prescription drug coverage; or

(B) for periods after January 1, 2006, such MA plan is an MA–PD plan.

(3) DISCONTINUANCE OF MA–PD ELECTION DURING FIRST YEAR OF ELIGIBILITY.—In applying the second sentence of section 1851(e)(4) in the case of an individual who is electing to discontinue enrollment in an MA–PD plan, the individual shall be permitted to enroll in a prescription drug plan under part D at the time of the election of coverage under the original medicare fee-for-service program.

(4) RULES REGARDING ENROLLEES IN MA PLANS NOT PROVIDING QUALIFIED PRESCRIPTION DRUG COVERAGE.—In the case of an individual who is enrolled in an MA plan (other than an MSA plan) that does not provide qualified prescription drug coverage, if the organization offering such coverage discontinues the offering with respect to the individual of all MA plans that do not provide such coverage—

(i) the individual is deemed to have elected the original medicare fee-for-service program option, unless the individual affirmatively elects to enroll in an MA–PD plan; and

(ii) in the case of such a deemed election, the disenrollment shall be treated as an involuntary termination of the MA plan described in subparagraph (B)(ii) of section 1882(s)(3) for purposes of applying such section.

The information disclosed under section 1852(c)(1) for individuals who are enrolled in such an MA plan shall include information regarding such rules.

(c) APPLICATION OF PART D RULES FOR PRESCRIPTION DRUG COVERAGE.—With respect to the offering of qualified prescription drug coverage by an MA organization under this part on and after January 1, 2006—

(1) IN GENERAL.—Except as otherwise provided, the provisions of this part shall apply under part C with respect to prescription drug coverage provided under MA–PD plans in lieu of the other provisions of part C that would apply to such coverage under such plans.

(2) WAIVER.—The Secretary shall waive the provisions referred to in paragraph (1) to the extent the Secretary determines that such provisions duplicate, or are in conflict with, provisions otherwise applicable to the organization or plan under part C or as may be necessary in order to improve coordination of this part with the benefits under this part.

(3) TREATMENT OF MA OWNED AND OPERATED PHARMACIES.—The Secretary may waive the requirement of section 1860D–4(b)(1)(C) in the case of an MA–PD plan that provides access (other than mail order) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization, if the Secretary determines that the organization's pharmacy network is sufficient to provide comparable access for enrollees under the plan.

(d) SPECIAL RULES FOR PRIVATE FEE-FOR-SERVICE PLANS THAT OFFER PRESCRIPTION DRUG COVERAGE.—With respect to an MA plan described in section 1851(a)(2)(C) that offers qualified prescription drug coverage, on and after January 1, 2006, the following rules apply:

(1) REQUIREMENTS REGARDING NEGOTIATED PRICES.—Subsections (a)(1) and (d)(1) of section 1860D–2 and section 1860D–4(b)(2)(A) shall not be construed to require the plan to provide negotiated prices (described in subsection (d)(1)(B) of such section), but shall apply to the extent the plan does so.

(2) MODIFICATION OF PHARMACY ACCESS STANDARD AND DISCLOSURE REQUIREMENT.—If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost-sharing, and without regard to whether they are participating pharmacies in a network or have entered into contracts or agreements with pharmacies to provide drugs to enrollees covered by the plan, subsections (b)(1)(C) and (k) of section 1860D–4 shall not apply to the plan.

(3) DRUG UTILIZATION MANAGEMENT PROGRAM AND MEDICATION THERAPY MANAGEMENT PROGRAM NOT REQUIRED.—The requirements of subparagraphs (A) and (C) of section 1860D–4(c)(1) shall not apply to the plan.

(4) APPLICATION OF REINSURANCE.—The Secretary shall determine the amount of reinsurance payments under section 1860D–15(b) using a methodology that—

(A) bases such amount on the Secretary's estimate of the amount of such payments that would be payable if the plan were an MA–PD plan described in section 1851(a)(2)(A)(i) and the previous provisions of this subsection did not apply; and

(B) takes into account the average reinsurance payments made under section 1860D–15(b) for populations of similar risk under MA–PD plans described in such section.

(5) EXEMPTION FROM RISK CORRIDOR PROVISIONS.—The provisions of section 1860D–15(e) shall not apply.

(6) EXEMPTION FROM NEGOTIATIONS.—Subsections (d) and (e)(2)(C) of section 1860D–11 shall not apply and the provisions of section 1854(a)(5)(B) prohibiting the review, approval, or disapproval of amounts described in such section shall apply to the proposed bid and terms and conditions described in section 1860D–11(d).

(7) TREATMENT OF INCURRED COSTS WITHOUT REGARD TO FORMULARY.—The exclusion of costs incurred for covered part D drugs which are not included (or treated as being included) in a plan's formulary under [section 1860D–2(b)(4)(B)(i)] *section 1860D–2(b)(4)(C)(i)* shall not apply insofar as the plan does not utilize a formulary.

(e) APPLICATION TO REASONABLE COST REIMBURSEMENT CONTRACTORS.—

(1) IN GENERAL.—Subject to paragraphs (2) and (3) and rules established by the Secretary, in the case of an organization that is providing benefits under a reasonable cost reimbursement contract under section 1876(h) and that elects to provide qualified prescription drug coverage to a part D eligible individual who is enrolled under such a contract, the provisions of this part (and related provisions of part C) shall apply to the provision of such coverage to such enrollee in the same manner as such provisions apply to the provision of such coverage under an MA–PD local plan described in section 1851(a)(2)(A)(i) and coverage under such a contract that so pro-

vides qualified prescription drug coverage shall be deemed to be an MA–PD local plan.

(2) LIMITATION ON ENROLLMENT.—In applying paragraph (1), the organization may not enroll part D eligible individuals who are not enrolled under the reasonable cost reimbursement contract involved.

(3) BIDS NOT INCLUDED IN DETERMINING NATIONAL AVERAGE MONTHLY BID AMOUNT.—The bid of an organization offering prescription drug coverage under this subsection shall not be taken into account in computing the national average monthly bid amount and low-income benchmark premium amount under this part.

(f) APPLICATION TO PACE.—

(1) IN GENERAL.—Subject to paragraphs (2) and (3) and rules established by the Secretary, in the case of a PACE program under section 1894 that elects to provide qualified prescription drug coverage to a part D eligible individual who is enrolled under such program, the provisions of this part (and related provisions of part C) shall apply to the provision of such coverage to such enrollee in a manner that is similar to the manner in which such provisions apply to the provision of such coverage under an MA–PD local plan described in section 1851(a)(2)(A)(ii) and a PACE program that so provides such coverage may be deemed to be an MA–PD local plan.

(2) LIMITATION ON ENROLLMENT.—In applying paragraph (1), the organization may not enroll part D eligible individuals who are not enrolled under the PACE program involved.

(3) BIDS NOT INCLUDED IN DETERMINING STANDARDIZED BID AMOUNT.—The bid of an organization offering prescription drug coverage under this subsection is not be taken into account in computing any average benchmark bid amount and low-income benchmark premium amount under this part.

SPECIAL RULES FOR EMPLOYER-SPONSORED PROGRAMS

SEC. 1860D–22. (a) SUBSIDY PAYMENT.—

(1) IN GENERAL.—The Secretary shall provide in accordance with this subsection for payment to the sponsor of a qualified retiree prescription drug plan (as defined in paragraph (2)) of a special subsidy payment equal to the amount specified in paragraph (3) for each qualified covered retiree under the plan (as defined in paragraph (4)). This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this section.

(2) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN DEFINED.—For purposes of this subsection, the term "qualified retiree prescription drug plan" means employment-based retiree health coverage (as defined in subsection (c)(1)) if, with respect to a part D eligible individual who is a participant or beneficiary under such coverage, the following requirements are met:

(A) ATTESTATION OF ACTUARIAL EQUIVALENCE TO STANDARD COVERAGE.—The sponsor of the plan provides the Secretary, annually or at such other time as the Secretary may require, with an attestation that the actuarial value of prescription drug coverage under the plan (as deter-

mined using the processes and methods described in section 1860D–11(c)) is at least equal to the actuarial value of standard prescription drug coverage, not taking into account [the value of any discount] *the value of—*

(i) for years prior to 2022, any discount or coverage provided during the gap in prescription drug coverage that occurs between the initial coverage limit under section 1860D–2(b)(3) during the year and the out-of-pocket threshold specified in section 1860D–2(b)(4)(B)[.]*; and*

(ii) for 2022 and each subsequent year, any discount provided pursuant to section 1860D–14C.

(B) AUDITS.—The sponsor of the plan, or an administrator of the plan designated by the sponsor, shall maintain (and afford the Secretary access to) such records as the Secretary may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription drug coverage and the accuracy of payments made under this section. The provisions of section 1860D–2(d)(3) shall apply to such information under this section (including such actuarial value and attestation) in a manner similar to the manner in which they apply to financial records of PDP sponsors and MA organizations.

(C) PROVISION OF DISCLOSURE REGARDING PRESCRIPTION DRUG COVERAGE.—The sponsor of the plan shall provide for disclosure of information regarding prescription drug coverage in accordance with section 1860D–13(b)(6)(B).

(3) EMPLOYER AND UNION SPECIAL SUBSIDY AMOUNTS.—

(A) IN GENERAL.—For purposes of this subsection, the special subsidy payment amount under this paragraph for a qualifying covered retiree for a coverage year enrolled with the sponsor of a qualified retiree prescription drug plan is, for the portion of the retiree's gross covered retiree plan-related prescription drug costs (as defined in subparagraph (C)(ii)) for such year that exceeds the cost threshold amount specified in subparagraph (B) and does not exceed the cost limit under such subparagraph, an amount equal to 28 percent of the allowable retiree costs (as defined in subparagraph (C)(i)) attributable to such gross covered prescription drug costs.

(B) COST THRESHOLD AND COST LIMIT APPLICABLE.—

(i) IN GENERAL.—Subject to clause (ii)—

(I) the cost threshold under this subparagraph is equal to $250 for plan years that end in 2006; and

(II) the cost limit under this subparagraph is equal to $5,000 for plan years that end in 2006.

(ii) INDEXING.—The cost threshold and cost limit amounts specified in subclauses (I) and (II) of clause (i) for a plan year that ends after 2006 shall be adjusted in the same manner as the annual deductible and the annual out-of-pocket threshold, respectively, are annually adjusted under paragraphs (1) and (4)(B) of section 1860D–2(b).

(C) DEFINITIONS.—For purposes of this paragraph:

(i) ALLOWABLE RETIREE COSTS.—The term "allowable retiree costs" means, with respect to gross covered prescription drug costs under a qualified retiree prescription drug plan by a plan sponsor, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or by or on behalf of a qualifying covered retiree under the plan.

(ii) GROSS COVERED RETIREE PLAN-RELATED PRESCRIPTION DRUG COSTS.—For purposes of this section, the term "gross covered retiree plan-related prescription drug costs" means, with respect to a qualifying covered retiree enrolled in a qualified retiree prescription drug plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year. Such costs shall be determined whether they are paid by the retiree or under the plan.

(iii) COVERAGE YEAR.—The term "coverage year" has the meaning given such term in section 1860D–15(b)(4).

(4) QUALIFYING COVERED RETIREE DEFINED.—For purposes of this subsection, the term "qualifying covered retiree" means a part D eligible individual who is not enrolled in a prescription drug plan or an MA–PD plan but is covered under a qualified retiree prescription drug plan.

(5) PAYMENT METHODS, INCLUDING PROVISION OF NECESSARY INFORMATION.—The provisions of section 1860D–15(d) (including paragraph (2), relating to requirement for provision of information) shall apply to payments under this subsection in a manner similar to the manner in which they apply to payment under section 1860D–15(b).

(6) CONSTRUCTION.—Nothing in this subsection shall be construed as—

(A) precluding a part D eligible individual who is covered under employment-based retiree health coverage from enrolling in a prescription drug plan or in an MA–PD plan;

(B) precluding such employment-based retiree health coverage or an employer or other person from paying all or any portion of any premium required for coverage under a prescription drug plan or MA–PD plan on behalf of such an individual;

(C) preventing such employment-based retiree health coverage from providing coverage—

(i) that is better than standard prescription drug coverage to retirees who are covered under a qualified retiree prescription drug plan; or

(ii) that is supplemental to the benefits provided under a prescription drug plan or an MA–PD plan, including benefits to retirees who are not covered under a qualified retiree prescription drug plan but who are enrolled in such a prescription drug plan or MA–PD plan; or

(D) preventing employers to provide for flexibility in benefit design and pharmacy access provisions, without regard

to the requirements for basic prescription drug coverage, so long as the actuarial equivalence requirement of paragraph (2)(A) is met.

(b) APPLICATION OF MA WAIVER AUTHORITY.—The provisions of section 1857(i) shall apply with respect to prescription drug plans in relation to employment-based retiree health coverage in a manner similar to the manner in which they apply to an MA plan in relation to employers, including authorizing the establishment of separate premium amounts for enrollees in a prescription drug plan by reason of such coverage and limitations on enrollment to part D eligible individuals enrolled under such coverage.

(c) DEFINITIONS.—For purposes of this section:

(1) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term "employment-based retiree health coverage" means health insurance or other coverage of health care costs (whether provided by voluntary insurance coverage or pursuant to statutory or contractual obligation) for part D eligible individuals (or for such individuals and their spouses and dependents) under a group health plan based on their status as retired participants in such plan.

(2) SPONSOR.—The term "sponsor" means a plan sponsor, as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974, in relation to a group health plan, except that, in the case of a plan maintained jointly by one employer and an employee organization and with respect to which the employer is the primary source of financing, such term means such employer.

(3) GROUP HEALTH PLAN.—The term "group health plan" includes such a plan as defined in section 607(1) of the Employee Retirement Income Security Act of 1974 and also includes the following:

(A) FEDERAL AND STATE GOVERNMENTAL PLANS.—Such a plan established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision thereof, or by any agency or instrumentality of any of the foregoing, including a health benefits plan offered under chapter 89 of title 5, United States Code.

(B) COLLECTIVELY BARGAINED PLANS.—Such a plan established or maintained under or pursuant to one or more collective bargaining agreements.

(C) CHURCH PLANS.—Such a plan established and maintained for its employees (or their beneficiaries) by a church or by a convention or association of churches which is exempt from tax under section 501 of the Internal Revenue Code of 1986.

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Subpart 4—Medicare Prescription Drug Discount Card and Transitional Assistance Program

MEDICARE PRESCRIPTION DRUG DISCOUNT CARD AND TRANSITIONAL ASSISTANCE PROGRAM

SEC. 1860D–31. (a) ESTABLISHMENT OF PROGRAM.—

(1) IN GENERAL.—The Secretary shall establish a program under this section—

(A) to endorse prescription drug discount card programs that meet the requirements of this section in order to provide access to prescription drug discounts through prescription drug card sponsors for discount card eligible individuals throughout the United States; and

(B) to provide for transitional assistance for transitional assistance eligible individuals enrolled in such endorsed programs.

(2) PERIOD OF OPERATION.—

(A) IMPLEMENTATION DEADLINE.—The Secretary shall implement the program under this section so that discount cards and transitional assistance are first available by not later than 6 months after the date of the enactment of this section.

(B) EXPEDITING IMPLEMENTATION.—The Secretary shall promulgate regulations to carry out the program under this section which may be effective and final immediately on an interim basis as of the date of publication of the interim final regulation. If the Secretary provides for an interim final regulation, the Secretary shall provide for a period of public comments on such regulation after the date of publication. The Secretary may change or revise such regulation after completion of the period of public comment.

(C) TERMINATION AND TRANSITION.—

(i) IN GENERAL.—Subject to clause (ii)—

(I) the program under this section shall not apply to covered discount card drugs dispensed after December 31, 2005; and

(II) transitional assistance shall be available after such date to the extent the assistance relates to drugs dispensed on or before such date.

(ii) TRANSITION.—In the case of an individual who is enrolled in an endorsed discount card program as of December 31, 2005, during the individual's transition period (if any) under clause (iii), in accordance with transition rules specified by the Secretary—

(I) such endorsed program may continue to apply to covered discount card drugs dispensed to the individual under the program during such transition period;

(II) no annual enrollment fee shall be applicable during the transition period;

(III) during such period the individual may not change the endorsed program plan in which the individual is enrolled; and

(IV) the balance of any transitional assistance remaining on January 1, 2006, shall remain available for drugs dispensed during the individual's transition period.

(iii) TRANSITION PERIOD.—The transition period under this clause for an individual is the period begin-

ning on January 1, 2006, and ending in the case of an individual who—

(I) is enrolled in a prescription drug plan or an MA–PD plan before the last date of the initial enrollment period under section 1860D–1(b)(2)(A), on the effective date of the individual's coverage under such part; or

(II) is not so enrolled, on the last day of such initial period.

(3) VOLUNTARY NATURE OF PROGRAM.—Nothing in this section shall be construed as requiring a discount card eligible individual to enroll in an endorsed discount card program under this section.

(4) GLOSSARY AND DEFINITIONS OF TERMS.—For purposes of this section:

(A) COVERED DISCOUNT CARD DRUG.—The term "covered discount card drug" has the meaning given the term "covered part D drug" in section 1860D–2(e).

(B) DISCOUNT CARD ELIGIBLE INDIVIDUAL.—The term "discount card eligible individual" is defined in subsection (b)(1)(A).

(C) ENDORSED DISCOUNT CARD PROGRAM; ENDORSED PROGRAM.—The terms "endorsed discount card program" and "endorsed program" mean a prescription drug discount card program that is endorsed (and for which the sponsor has a contract with the Secretary) under this section.

(D) NEGOTIATED PRICE.—Negotiated prices are described in subsection (e)(1)(A)(ii).

(E) PRESCRIPTION DRUG CARD SPONSOR; SPONSOR.—The terms "prescription drug card sponsor" and "sponsor" are defined in subsection (h)(1)(A).

(F) STATE.—The term "State" has the meaning given such term for purposes of title XIX.

(G) TRANSITIONAL ASSISTANCE ELIGIBLE INDIVIDUAL.—The term "transitional assistance eligible individual" is defined in subsection (b)(2).

(b) ELIGIBILITY FOR DISCOUNT CARD AND FOR TRANSITIONAL ASSISTANCE.—For purposes of this section:

(1) DISCOUNT CARD ELIGIBLE INDIVIDUAL.—

(A) IN GENERAL.—The term "discount card eligible individual" means an individual who—

(i) is entitled to benefits, or enrolled, under part A or enrolled under part B; and

(ii) subject to paragraph (4), is not an individual described in subparagraph (B).

(B) INDIVIDUAL DESCRIBED.—An individual described in this subparagraph is an individual described in subparagraph (A)(i) who is enrolled under title XIX (or under a waiver under section 1115 of the requirements of such title) and is entitled to any medical assistance for outpatient prescribed drugs described in section 1905(a)(12).

(2) TRANSITIONAL ASSISTANCE ELIGIBLE INDIVIDUAL.—

(A) IN GENERAL.—Subject to subparagraph (B), the term "transitional assistance eligible individual" means a discount card eligible individual who resides in one of the 50

States or the District of Columbia and whose income (as determined under subsection (f)(1)(B)) is not more than 135 percent of the poverty line (as defined in section 673(2) of the Community Services Block Grant Act, 42 U.S.C. 9902(2), including any revision required by such section) applicable to the family size involved (as determined under subsection (f)(1)(B)).

(B) EXCLUSION OF INDIVIDUALS WITH CERTAIN PRESCRIPTION DRUG COVERAGE.—Such term does not include an individual who has coverage of, or assistance for, covered discount card drugs under any of the following:

(i) A group health plan or health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act), other than coverage under a plan under part C and other than coverage consisting only of excepted benefits (as defined in such section).

(ii) Chapter 55 of title 10, United States Code (relating to medical and dental care for members of the uniformed services).

(iii) A plan under chapter 89 of title 5, United States Code (relating to the Federal employees' health benefits program).

(3) SPECIAL TRANSITIONAL ASSISTANCE ELIGIBLE INDIVIDUAL.—The term "special transitional assistance eligible individual" means a transitional assistance eligible individual whose income (as determined under subsection (f)(1)(B)) is not more than 100 percent of the poverty line (as defined in section 673(2) of the Community Services Block Grant Act, 42 U.S.C. 9902(2), including any revision required by such section) applicable to the family size involved (as determined under subsection (f)(1)(B)).

(4) TREATMENT OF MEDICAID MEDICALLY NEEDY.—For purposes of this section, the Secretary shall provide for appropriate rules for the treatment of medically needy individuals described in section 1902(a)(10)(C) as discount card eligible individuals and as transitional assistance eligible individuals.

(c) ENROLLMENT AND ENROLLMENT FEES.—

(1) ENROLLMENT PROCESS.—The Secretary shall establish a process through which a discount card eligible individual is enrolled and disenrolled in an endorsed discount card program under this section consistent with the following:

(A) CONTINUOUS OPEN ENROLLMENT.—Subject to the succeeding provisions of this paragraph and subsection (h)(9), a discount card eligible individual who is not enrolled in an endorsed discount card program and is residing in a State may enroll in any such endorsed program—

(i) that serves residents of the State; and

(ii) at any time beginning on the initial enrollment date, specified by the Secretary, and before January 1, 2006.

(B) USE OF STANDARD ENROLLMENT FORM.—An enrollment in an endorsed program shall only be effected through completion of a standard enrollment form specified by the Secretary. Each sponsor of an endorsed program shall transmit to the Secretary (in a form and man-

ner specified by the Secretary) information on individuals who complete such enrollment forms and, to the extent provided under subsection (f), information regarding certification as a transitional assistance eligible individual.

(C) ENROLLMENT ONLY IN ONE PROGRAM.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), a discount card eligible individual may be enrolled in only one endorsed discount card program under this section.

(ii) CHANGE IN ENDORSED PROGRAM PERMITTED FOR 2005.—The Secretary shall establish a process, similar to (and coordinated with) the process for annual, coordinated elections under section 1851(e)(3) during 2004, under which an individual enrolled in an endorsed discount card program may change the endorsed program in which the individual is enrolled for 2005.

(iii) ADDITIONAL EXCEPTIONS.—The Secretary shall permit an individual to change the endorsed discount card program in which the individual is enrolled in the case of an individual who changes residence to be outside the service area of such program and in such other exceptional cases as the Secretary may provide (taking into account the circumstances for special election periods under section 1851(e)(4)). Under the previous sentence, the Secretary may consider a change in residential setting (such as placement in a nursing facility) or enrollment in or disenrollment from a plan under part C through which the individual was enrolled in an endorsed program to be an exceptional circumstance.

(D) DISENROLLMENT.—

(i) VOLUNTARY.—An individual may voluntarily disenroll from an endorsed discount card program at any time. In the case of such a voluntary disenrollment, the individual may not enroll in another endorsed program, except under such exceptional circumstances as the Secretary may recognize under subparagraph (C)(iii) or during the annual coordinated enrollment period provided under subparagraph (C)(ii).

(ii) INVOLUNTARY.—An individual who is enrolled in an endorsed discount card program and not a transitional assistance eligible individual may be disenrolled by the sponsor of the program if the individual fails to pay any annual enrollment fee required under the program.

(E) APPLICATION TO CERTAIN ENROLLEES.—In the case of a discount card eligible individual who is enrolled in a plan described in section 1851(a)(2)(A) or under a reasonable cost reimbursement contract under section 1876(h) that is offered by an organization that also is a prescription discount card sponsor that offers an endorsed discount card program under which the individual may be enrolled and that has made an election to apply the special rules

under subsection (h)(9)(B) for such an endorsed program, the individual may only enroll in such an endorsed discount card program offered by that sponsor.

(2) ENROLLMENT FEES.—

(A) IN GENERAL.—Subject to the succeeding provisions of this paragraph, a prescription drug card sponsor may charge an annual enrollment fee for each discount card eligible individual enrolled in an endorsed discount card program offered by such sponsor. The annual enrollment fee for either 2004 or 2005 shall not be prorated for portions of a year. There shall be no annual enrollment fee for a year after 2005.

(B) AMOUNT.—No annual enrollment fee charged under subparagraph (A) may exceed $30.

(C) UNIFORM ENROLLMENT FEE.—A prescription drug card sponsor shall ensure that the annual enrollment fee (if any) for an endorsed discount card program is the same for all discount card eligible individuals enrolled in the program and residing in the State.

(D) COLLECTION.—The annual enrollment fee (if any) charged for enrollment in an endorsed program shall be collected by the sponsor of the program.

(E) PAYMENT OF FEE FOR TRANSITIONAL ASSISTANCE ELIGIBLE INDIVIDUALS.—Under subsection (g)(1)(A), the annual enrollment fee (if any) otherwise charged under this paragraph with respect to a transitional assistance eligible individual shall be paid by the Secretary on behalf of such individual.

(F) OPTIONAL PAYMENT OF FEE BY STATE.—

(i) IN GENERAL.—The Secretary shall establish an arrangement under which a State may provide for payment of some or all of the enrollment fee for some or all enrollees who are not transitional assistance eligible individuals in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the enrollment fee shall be paid directly by the State to the sponsor.

(ii) NO FEDERAL MATCHING AVAILABLE UNDER MEDICAID OR SCHIP.—Expenditures made by a State for enrollment fees described in clause (i) shall not be treated as State expenditures for purposes of Federal matching payments under title XIX or XXI.

(G) RULES IN CASE OF CHANGES IN PROGRAM ENROLLMENT DURING A YEAR.—The Secretary shall provide special rules in the case of payment of an annual enrollment fee for a discount card eligible individual who changes the endorsed program in which the individual is enrolled during a year.

(3) ISSUANCE OF DISCOUNT CARD.—Each prescription drug card sponsor of an endorsed discount card program shall issue, in a standard format specified by the Secretary, to each discount card eligible individual enrolled in such program a card that establishes proof of enrollment and that can be used in a

coordinated manner to identify the sponsor, program, and individual for purposes of the program under this section.

(4) PERIOD OF ACCESS.—In the case of a discount card eligible individual who enrolls in an endorsed program, access to negotiated prices and transitional assistance, if any, under such endorsed program shall take effect on such date as the Secretary shall specify.

(d) PROVISION OF INFORMATION ON ENROLLMENT AND PROGRAM FEATURES.—

(1) SECRETARIAL RESPONSIBILITIES.—

(A) IN GENERAL.—The Secretary shall provide for activities under this subsection to broadly disseminate information to discount card eligible individuals (and prospective eligible individuals) regarding—

(i) enrollment in endorsed discount card programs; and

(ii) the features of the program under this section, including the availability of transitional assistance.

(B) PROMOTION OF INFORMED CHOICE.—In order to promote informed choice among endorsed prescription drug discount card programs, the Secretary shall provide for the dissemination of information which—

(i) compares the annual enrollment fee and other features of such programs, which may include comparative prices for covered discount card drugs; and

(ii) includes educational materials on the variability of discounts on prices of covered discount card drugs under an endorsed program.

The dissemination of information under clause (i) shall, to the extent practicable, be coordinated with the dissemination of educational information on other medicare options.

(C) SPECIAL RULE FOR INITIAL ENROLLMENT DATE UNDER THE PROGRAM.—To the extent practicable, the Secretary shall ensure, through the activities described in subparagraphs (A) and (B), that discount card eligible individuals are provided with such information at least 30 days prior to the initial enrollment date specified under subsection (c)(1)(A)(ii).

(D) USE OF MEDICARE TOLL-FREE NUMBER.—The Secretary shall provide through the toll-free telephone number 1–800–MEDICARE for the receipt and response to inquiries and complaints concerning the program under this section and endorsed programs.

(2) PRESCRIPTION DRUG CARD SPONSOR RESPONSIBILITIES.—

(A) IN GENERAL.—Each prescription drug card sponsor that offers an endorsed discount card program shall make available to discount card eligible individuals (through the Internet and otherwise) information that the Secretary identifies as being necessary to promote informed choice among endorsed discount card programs by such individuals, including information on enrollment fees and negotiated prices for covered discount card drugs charged to such individuals.

(B) RESPONSE TO ENROLLEE QUESTIONS.—Each sponsor offering an endorsed discount card program shall have a

mechanism (including a toll-free telephone number) for providing upon request specific information (such as negotiated prices and the amount of transitional assistance remaining available through the program) to discount card eligible individuals enrolled in the program. The sponsor shall inform transitional assistance eligible individuals enrolled in the program of the availability of such toll-free telephone number to provide information on the amount of available transitional assistance.

(C) INFORMATION ON BALANCE OF TRANSITIONAL ASSISTANCE AVAILABLE AT POINT-OF-SALE.—Each sponsor offering an endorsed discount card program shall have a mechanism so that information on the amount of transitional assistance remaining under subsection (g)(1)(B) is available (electronically or by telephone) at the point-of-sale of covered discount card drugs.

(3) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—

(A) IN GENERAL.—A prescription drug card sponsor offering an endorsed discount card program shall provide that each pharmacy that dispenses a covered discount card drug shall inform a discount card eligible individual enrolled in the program of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered discount card drug under the program that is therapeutically equivalent and bioequivalent and available at such pharmacy.

(B) TIMING OF NOTICE.—

(i) IN GENERAL.—Subject to clause (ii), the information under subparagraph (A) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

(ii) WAIVER.—The Secretary may waive clause (i) in such circumstances as the Secretary may specify.

(e) DISCOUNT CARD FEATURES.—

(1) SAVINGS TO ENROLLEES THROUGH NEGOTIATED PRICES.—

(A) ACCESS TO NEGOTIATED PRICES.—

(i) IN GENERAL.—Each prescription drug card sponsor that offers an endorsed discount card program shall provide each discount card eligible individual enrolled in the program with access to negotiated prices.

(ii) NEGOTIATED PRICES.—For purposes of this section, negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered discount card drugs, and include any dispensing fees for such drugs.

(B) ENSURING PHARMACY ACCESS.—Each prescription drug card sponsor offering an endorsed discount card program shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than solely by mail order) drugs directly to enrollees to ensure convenient access to covered discount card drugs at negotiated prices (consistent with rules established by the Sec-

retary). The Secretary shall establish convenient access rules under this clause that are no less favorable to enrollees than the standards for convenient access to pharmacies included in the statement of work of solicitation (#MDA906–03–R–0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

(C) PROHIBITION ON CHARGES FOR REQUIRED SERVICES.—

(i) IN GENERAL.—Subject to clause (ii), a prescription drug card sponsor (and any pharmacy contracting with such sponsor for the provision of covered discount card drugs to individuals enrolled in such sponsor's endorsed discount card program) may not charge an enrollee any amount for any items and services required to be provided by the sponsor under this section.

(ii) CONSTRUCTION.—Nothing in clause (i) shall be construed to prevent—

(I) the sponsor from charging the annual enrollment fee (except in the case of a transitional assistance eligible individual); and

(II) the pharmacy dispensing the covered discount card drug, from imposing a charge (consistent with the negotiated price) for the covered discount card drug dispensed, reduced by the amount of any transitional assistance made available.

(D) INAPPLICABILITY OF MEDICAID BEST PRICE RULES.—The prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under this section shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

(2) REDUCTION OF MEDICATION ERRORS AND ADVERSE DRUG INTERACTIONS.—Each endorsed discount card program shall implement a system to reduce the likelihood of medication errors and adverse drug interactions and to improve medication use.

(f) ELIGIBILITY PROCEDURES FOR ENDORSED PROGRAMS AND TRANSITIONAL ASSISTANCE.—

(1) DETERMINATIONS.—

(A) PROCEDURES.—The determination of whether an individual is a discount card eligible individual or a transitional assistance eligible individual or a special transitional assistance eligible individual (as defined in subsection (b)) shall be determined under procedures specified by the Secretary consistent with this subsection.

(B) INCOME AND FAMILY SIZE DETERMINATIONS.—For purposes of this section, the Secretary shall define the terms "income" and "family size" and shall specify the methods and period for which they are determined. If under such methods income or family size is determined based on the income or family size for prior periods of time, the Secretary shall permit (whether through a process of reconsideration or otherwise) an individual whose income or family

size has changed to elect to have eligibility for transitional assistance determined based on income or family size for a more recent period.

(2) USE OF SELF-CERTIFICATION FOR TRANSITIONAL ASSISTANCE.—

(A) IN GENERAL.—Under the procedures specified under paragraph (1)(A) an individual who wishes to be treated as a transitional assistance eligible individual or a special transitional assistance eligible individual under this section (or another qualified person on such individual's behalf) shall certify on the enrollment form under subsection (c)(1)(B) (or similar form specified by the Secretary), through a simplified means specified by the Secretary and under penalty of perjury or similar sanction for false statements, as to the amount of the individual's income, family size, and individual's prescription drug coverage (if any) insofar as they relate to eligibility to be a transitional assistance eligible individual or a special transitional assistance eligible individual. Such certification shall be deemed as consent to verification of respective eligibility under paragraph (3). A certification under this paragraph may be provided before, on, or after the time of enrollment under an endorsed program.

(B) TREATMENT OF SELF-CERTIFICATION.—The Secretary shall treat a certification under subparagraph (A) that is verified under paragraph (3) as a determination that the individual involved is a transitional assistance eligible individual or special transitional assistance eligible individual (as the case may be) for the entire period of the enrollment of the individual in any endorsed program.

(3) VERIFICATION.—

(A) IN GENERAL.—The Secretary shall establish methods (which may include the use of sampling and the use of information described in subparagraph (B)) to verify eligibility for individuals who seek to enroll in an endorsed program and for individuals who provide a certification under paragraph (2).

(B) INFORMATION DESCRIBED.—The information described in this subparagraph is as follows:

(i) MEDICAID-RELATED INFORMATION.—Information on eligibility under title XIX and provided to the Secretary under arrangements between the Secretary and States in order to verify the eligibility of individuals who seek to enroll in an endorsed program and of individuals who provide certification under paragraph (2).

(ii) SOCIAL SECURITY INFORMATION.—Financial information made available to the Secretary under arrangements between the Secretary and the Commissioner of Social Security in order to verify the eligibility of individuals who provide such certification.

(iii) INFORMATION FROM SECRETARY OF THE TREASURY.—Financial information made available to the Secretary under section 6103(l)(19) of the Internal Revenue Code of 1986 in order to verify the eligibility of individuals who provide such certification.

(C) VERIFICATION IN CASES OF MEDICAID ENROLLEES.—

(i) IN GENERAL.—Nothing in this section shall be construed as preventing the Secretary from finding that a discount card eligible individual meets the income requirements under subsection (b)(2)(A) if the individual is within a category of discount card eligible individuals who are enrolled under title XIX (such as qualified medicare beneficiaries (QMBs), specified low-income medicare beneficiaries (SLMBs), and certain qualified individuals (QI–1s)).

(ii) AVAILABILITY OF INFORMATION FOR VERIFICATION PURPOSES.—As a condition of provision of Federal financial participation to a State that is one of the 50 States or the District of Columbia under title XIX, for purposes of carrying out this section, the State shall provide the information it submits to the Secretary relating to such title in a manner specified by the Secretary that permits the Secretary to identify individuals who are described in subsection (b)(1)(B) or are transitional assistance eligible individuals or special transitional assistance eligible individuals.

(4) RECONSIDERATION.—

(A) IN GENERAL.—The Secretary shall establish a process under which a discount card eligible individual, who is determined through the certification and verification methods under paragraphs (2) and (3) not to be a transitional assistance eligible individual or a special transitional assistance eligible individual, may request a reconsideration of the determination.

(B) CONTRACT AUTHORITY.—The Secretary may enter into a contract to perform the reconsiderations requested under subparagraph (A).

(C) COMMUNICATION OF RESULTS.—Under the process under subparagraph (A) the results of such reconsideration shall be communicated to the individual and the prescription drug card sponsor involved.

(g) TRANSITIONAL ASSISTANCE.—

(1) PROVISION OF TRANSITIONAL ASSISTANCE.—An individual who is a transitional assistance eligible individual (as determined under this section) and who is enrolled with an endorsed program is entitled—

(A) to have payment made of any annual enrollment fee charged under subsection (c)(2) for enrollment under the program; and

(B) to have payment made, up to the amount specified in paragraph (2), under such endorsed program of 90 percent (or 95 percent in the case of a special transitional assistance eligible individual) of the costs incurred for covered discount card drugs obtained through the program taking into account the negotiated price (if any) for the drug under the program.

(2) LIMITATION ON DOLLAR AMOUNT.—

(A) IN GENERAL.—Subject to subparagraph (B), the amount specified in this paragraph for a transitional assistance eligible individual—

(i) for costs incurred during 2004, is $600; or

(ii) for costs incurred during 2005, is—

(I) $600, plus

(II) except as provided in subparagraph (E), the amount by which the amount available under this paragraph for 2004 for that individual exceeds the amount of payment made under paragraph (1)(B) for that individual for costs incurred during 2004.

(B) PRORATION.—

(i) IN GENERAL.—In the case of an individual not described in clause (ii) with respect to a year, the Secretary may prorate the amount specified in subparagraph (A) for the balance of the year involved in a manner specified by the Secretary.

(ii) INDIVIDUAL DESCRIBED.—An individual described in this clause is a transitional assistance eligible individual who—

(I) with respect to 2004, enrolls in an endorsed program, and provides a certification under subsection (f)(2), before the initial implementation date of the program under this section; and

(II) with respect to 2005, is enrolled in an endorsed program, and has provided such a certification, before February 1, 2005.

(C) ACCOUNTING FOR AVAILABLE BALANCES IN CASES OF CHANGES IN PROGRAM ENROLLMENT.—In the case of a transitional assistance eligible individual who changes the endorsed discount card program in which the individual is enrolled under this section, the Secretary shall provide a process under which the Secretary provides to the sponsor of the endorsed program in which the individual enrolls information concerning the balance of amounts available on behalf of the individual under this paragraph.

(D) LIMITATION ON USE OF FUNDS.—Pursuant to subsection (a)(2)(C), no assistance shall be provided under paragraph (1)(B) with respect to covered discount card drugs dispensed after December 31, 2005.

(E) NO ROLLOVER PERMITTED IN CASE OF VOLUNTARY DISENROLLMENT.—Except in such exceptional cases as the Secretary may provide, in the case of a transitional assistance eligible individual who voluntarily disenrolls from an endorsed plan, the provisions of subclause (II) of subparagraph (A)(ii) shall not apply.

(3) PAYMENT.—The Secretary shall provide a method for the reimbursement of prescription drug card sponsors for assistance provided under this subsection.

(4) COVERAGE OF COINSURANCE.—

(A) WAIVER PERMITTED BY PHARMACY.—Nothing in this section shall be construed as precluding a pharmacy from reducing or waiving the application of coinsurance imposed under paragraph (1)(B) in accordance with section 1128B(b)(3)(G).

(B) OPTIONAL PAYMENT OF COINSURANCE BY STATE.—

(i) IN GENERAL.—The Secretary shall establish an arrangement under which a State may provide for

payment of some or all of the coinsurance under paragraph (1)(B) for some or all enrollees in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the coinsurance shall be paid directly by the State to the pharmacy involved.

(ii) NO FEDERAL MATCHING AVAILABLE UNDER MEDICAID OR SCHIP.—Expenditures made by a State for coinsurance described in clause (i) shall not be treated as State expenditures for purposes of Federal matching payments under title XIX or XXI.

(iii) NOT TREATED AS MEDICARE COST-SHARING.—Coinsurance described in paragraph (1)(B) shall not be treated as coinsurance under this title for purposes of section 1905(p)(3)(B).

(C) TREATMENT OF COINSURANCE.—The amount of any coinsurance imposed under paragraph (1)(B), whether paid or waived under this paragraph, shall not be taken into account in applying the limitation in dollar amount under paragraph (2).

(5) ENSURING ACCESS TO TRANSITIONAL ASSISTANCE FOR QUALIFIED RESIDENTS OF LONG-TERM CARE FACILITIES AND AMERICAN INDIANS.—

(A) RESIDENTS OF LONG-TERM CARE FACILITIES.—The Secretary shall establish procedures and may waive requirements of this section as necessary to negotiate arrangements with sponsors to provide arrangements with pharmacies that support long-term care facilities in order to ensure access to transitional assistance for transitional assistance eligible individuals who reside in long-term care facilities.

(B) AMERICAN INDIANS.—The Secretary shall establish procedures and may waive requirements of this section to ensure that, for purposes of providing transitional assistance, pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 4 of the Indian Health Care Improvement Act) have the opportunity to participate in the pharmacy networks of at least two endorsed programs in each of the 50 States and the District of Columbia where such a pharmacy operates.

(6) NO IMPACT ON BENEFITS UNDER OTHER PROGRAMS.—The availability of negotiated prices or transitional assistance under this section shall not be treated as benefits or otherwise taken into account in determining an individual's eligibility for, or the amount of benefits under, any other Federal program.

(7) DISREGARD FOR PURPOSES OF PART C.—Nonuniformity of benefits resulting from the implementation of this section (including the provision or nonprovision of transitional assistance and the payment or waiver of any enrollment fee under this section) shall not be taken into account in applying section 1854(f).

(h) QUALIFICATION OF PRESCRIPTION DRUG CARD SPONSORS AND ENDORSEMENT OF DISCOUNT CARD PROGRAMS; BENEFICIARY PROTECTIONS.—

(1) PRESCRIPTION DRUG CARD SPONSOR AND QUALIFICATIONS.—

(A) PRESCRIPTION DRUG CARD SPONSOR AND SPONSOR DEFINED.—For purposes of this section, the terms "prescription drug card sponsor" and "sponsor" mean any nongovernmental entity that the Secretary determines to be appropriate to offer an endorsed discount card program under this section, which may include—

(i) a pharmaceutical benefit management company;

(ii) a wholesale or retail pharmacy delivery system;

(iii) an insurer (including an insurer that offers medicare supplemental policies under section 1882);

(iv) an organization offering a plan under part C; or

(v) any combination of the entities described in clauses (i) through (iv).

(B) ADMINISTRATIVE QUALIFICATIONS.—Each endorsed discount card program shall be operated directly, or through arrangements with an affiliated organization (or organizations), by one or more entities that have demonstrated experience and expertise in operating such a program or a similar program and that meets such business stability and integrity requirements as the Secretary may specify.

(C) ACCOUNTING FOR TRANSITIONAL ASSISTANCE.—The sponsor of an endorsed discount card program shall have arrangements satisfactory to the Secretary to account for the assistance provided under subsection (g) on behalf of transitional assistance eligible individuals.

(2) APPLICATIONS FOR PROGRAM ENDORSEMENT.—

(A) SUBMISSION.—Each prescription drug card sponsor that seeks endorsement of a prescription drug discount card program under this section shall submit to the Secretary, at such time and in such manner as the Secretary may specify, an application containing such information as the Secretary may require.

(B) APPROVAL; COMPLIANCE WITH APPLICABLE REQUIREMENTS.—The Secretary shall review the application submitted under subparagraph (A) and shall determine whether to endorse the prescription drug discount card program. The Secretary may not endorse such a program unless—

(i) the program and prescription drug card sponsor offering the program comply with the applicable requirements under this section; and

(ii) the sponsor has entered into a contract with the Secretary to carry out such requirements.

(C) TERMINATION OF ENDORSEMENT AND CONTRACTS.—An endorsement of an endorsed program and a contract under subparagraph (B) shall be for the duration of the program under this section (including any transition applicable under subsection (a)(2)(C)(ii)), except that the Secretary may, with notice and for cause (as defined by the Secretary), terminate such endorsement and contract.

(D) ENSURING CHOICE OF PROGRAMS.—

(i) IN GENERAL.—The Secretary shall ensure that there is available to each discount card eligible individual a choice of at least 2 endorsed programs (each offered by a different sponsor).

(ii) LIMITATION ON NUMBER.—The Secretary may limit (but not below 2) the number of sponsors in a State that are awarded contracts under this paragraph.

(3) SERVICE AREA ENCOMPASSING ENTIRE STATES.—Except as provided in paragraph (9), if a prescription drug card sponsor that offers an endorsed program enrolls in the program individuals residing in any part of a State, the sponsor must permit any discount card eligible individual residing in any portion of the State to enroll in the program.

(4) SAVINGS TO MEDICARE BENEFICIARIES.—Each prescription drug card sponsor that offers an endorsed discount card program shall pass on to discount card eligible individuals enrolled in the program negotiated prices on covered discount card drugs, including discounts negotiated with pharmacies and manufacturers, to the extent disclosed under subsection (i)(1).

(5) GRIEVANCE MECHANISM.—Each prescription drug card sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor carries out the endorsed discount card program) and enrollees in endorsed discount card programs of the sponsor under this section in a manner similar to that required under section 1852(f).

(6) CONFIDENTIALITY OF ENROLLEE RECORDS.—

(A) IN GENERAL.—For purposes of the program under this section, the operations of an endorsed program are covered functions and a prescription drug card sponsor is a covered entity for purposes of applying part C of title XI and all regulatory provisions promulgated thereunder, including regulations (relating to privacy) adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(B) WAIVER AUTHORITY.—In order to promote participation of sponsors in the program under this section, the Secretary may waive such relevant portions of regulations relating to privacy referred to in subparagraph (A), for such appropriate, limited period of time, as the Secretary specifies.

(7) LIMITATION ON PROVISION AND MARKETING OF PRODUCTS AND SERVICES.—The sponsor of an endorsed discount card program—

(A) may provide under the program—

(i) a product or service only if the product or service is directly related to a covered discount card drug; or

(ii) a discount price for nonprescription drugs; and

(B) may, to the extent otherwise permitted under paragraph (6) (relating to application of HIPAA requirements), market a product or service under the program only if the product or service is directly related to—

(i) a covered discount card drug; or

(ii) a drug described in subparagraph (A)(ii) and the marketing consists of information on the discounted price made available for the drug involved.

(8) ADDITIONAL PROTECTIONS.—Each endorsed discount card program shall meet such additional requirements as the Secretary identifies to protect and promote the interest of discount card eligible individuals, including requirements that ensure that discount card eligible individuals enrolled in endorsed discount card programs are not charged more than the lower of the price based on negotiated prices or the usual and customary price.

(9) SPECIAL RULES FOR CERTAIN ORGANIZATIONS.—

(A) IN GENERAL.—In the case of an organization that is offering a plan under part C or enrollment under a reasonable cost reimbursement contract under section 1876(h) that is seeking to be a prescription drug card sponsor under this section, the organization may elect to apply the special rules under subparagraph (B) with respect to enrollees in any plan described in section 1851(a)(2)(A) that it offers or under such contract and an endorsed discount card program it offers, but only if it limits enrollment under such program to individuals enrolled in such plan or under such contract.

(B) SPECIAL RULES.—The special rules under this subparagraph are as follows:

(i) LIMITATION ON ENROLLMENT.—The sponsor limits enrollment under this section under the endorsed discount card program to discount card eligible individuals who are enrolled in the part C plan involved or under the reasonable cost reimbursement contract involved and is not required nor permitted to enroll other individuals under such program.

(ii) PHARMACY ACCESS.—Pharmacy access requirements under subsection (e)(1)(B) are deemed to be met if the access is made available through a pharmacy network (and not only through mail order) and the network used by the sponsor is approved by the Secretary.

(iii) SPONSOR REQUIREMENTS.—The Secretary may waive the application of such requirements for a sponsor as the Secretary determines to be duplicative or to conflict with a requirement of the organization under part C or section 1876 (as the case may be) or to be necessary in order to improve coordination of this section with the benefits under such part or section.

(i) DISCLOSURE AND OVERSIGHT.—

(1) DISCLOSURE.—Each prescription drug card sponsor offering an endorsed discount card program shall disclose to the Secretary (in a manner specified by the Secretary) information relating to program performance, use of prescription drugs by discount card eligible individuals enrolled in the program, the extent to which negotiated price concessions described in subsection (e)(1)(A)(ii) made available to the entity by a manufacturer are passed through to enrollees through pharmacies or

otherwise, and such other information as the Secretary may specify. The provisions of section 1927(b)(3)(D) shall apply to drug pricing data reported under the previous sentence (other than data in aggregate form).

(2) OVERSIGHT; AUDIT AND INSPECTION AUTHORITY.—The Secretary shall provide appropriate oversight to ensure compliance of endorsed discount card programs and their sponsors with the requirements of this section. The Secretary shall have the right to audit and inspect any books and records of a prescription discount card sponsor (and of any affiliated organization referred to in subsection (h)(1)(B)) that pertain to the endorsed discount card program under this section, including amounts payable to the sponsor under this section.

(3) SANCTIONS FOR ABUSIVE PRACTICES.—The Secretary may implement intermediate sanctions or may revoke the endorsement of a program offered by a sponsor under this section if the Secretary determines that the sponsor or the program no longer meets the applicable requirements of this section or that the sponsor has engaged in false or misleading marketing practices. The Secretary may impose a civil money penalty in an amount not to exceed $10,000 for conduct that a party knows or should know is a violation of this section. The provisions of section 1128A (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(j) TREATMENT OF TERRITORIES.—

(1) IN GENERAL.—The Secretary may waive any provision of this section (including subsection (h)(2)(D)) in the case of a resident of a State (other than the 50 States and the District of Columbia) insofar as the Secretary determines it is necessary to secure access to negotiated prices for discount card eligible individuals (or, at the option of the Secretary, individuals described in subsection (b)(1)(A)(i)).

(2) TRANSITIONAL ASSISTANCE.—

(A) IN GENERAL.—In the case of a State, other than the 50 States and the District of Columbia, if the State establishes a plan described in subparagraph (B) (for providing transitional assistance with respect to the provision of prescription drugs to some or all individuals residing in the State who are described in subparagraph (B)(i)), the Secretary shall pay to the State for the entire period of the operation of this section an amount equal to the amount allotted to the State under subparagraph (C).

(B) PLAN.—The plan described in this subparagraph is a plan that—

(i) provides transitional assistance with respect to the provision of covered discount card drugs to some or all individuals who are entitled to benefits under part A or enrolled under part B, who reside in the State, and who have income below 135 percent of the poverty line; and

(ii) assures that amounts received by the State under this paragraph are used only for such assistance.

(C) ALLOTMENT LIMIT.—The amount described in this subparagraph for a State is equal to $35,000,000 multiplied by the ratio (as estimated by the Secretary) of—

(i) the number of individuals who are entitled to benefits under part A or enrolled under part B and who reside in the State (as determined by the Secretary as of July 1, 2003), to

(ii) the sum of such numbers for all States to which this paragraph applies.

(D) CONTINUED AVAILABILITY OF FUNDS.—Amounts made available to a State under this paragraph which are not used under this paragraph shall be added to the amount available to that State for purposes of carrying out section 1935(e). *The previous sentence shall not apply with respect to amounts made available to a State under this paragraph on or after January 1, 2021.*

(k) FUNDING.—

(1) ESTABLISHMENT OF TRANSITIONAL ASSISTANCE ACCOUNT.—

(A) IN GENERAL.—There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1841 an account to be known as the "Transitional Assistance Account" (in this subsection referred to as the "Account").

(B) FUNDS.—The Account shall consist of such gifts and bequests as may be made as provided in section 201(i)(1), accrued interest on balances in the Account, and such amounts as may be deposited in, or appropriated to, the Account as provided in this subsection.

(C) SEPARATE FROM REST OF TRUST FUND.—Funds provided under this subsection to the Account shall be kept separate from all other funds within the Federal Supplementary Medical Insurance Trust Fund, but shall be invested, and such investments redeemed, in the same manner as all other funds and investments within such Trust Fund.

(2) PAYMENTS FROM ACCOUNT.—

(A) IN GENERAL.—The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments for transitional assistance provided under subsections (g) and (j)(2).

(B) TREATMENT IN RELATION TO PART B PREMIUM.—Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1839.

(3) APPROPRIATIONS TO COVER BENEFITS.—There are appropriated to the Account in a fiscal year, out of any moneys in the Treasury not otherwise appropriated, an amount equal to the payments made from the Account in the year.

(4) FOR ADMINISTRATIVE EXPENSES.—There are authorized to be appropriated to the Secretary such sums as may be necessary to carry out the Secretary's responsibilities under this section.

(5) TRANSFER OF ANY REMAINING BALANCE TO MEDICARE PRESCRIPTION DRUG ACCOUNT.—Any balance remaining in the Account after the Secretary determines that funds in the Account are no longer necessary to carry out the program under this section shall be transferred and deposited into the Medicare Prescription Drug Account under section 1860D–16.

(6) CONSTRUCTION.—Nothing in this section shall be construed as authorizing the Secretary to provide for payment (other than payment of an enrollment fee on behalf of a transitional assistance eligible individual under subsection (g)(1)(A)) to a sponsor for administrative expenses incurred by the sponsor in carrying out this section (including in administering the transitional assistance provisions of subsections (f) and (g)).

Subpart 5—Definitions and Miscellaneous Provisions

DEFINITIONS; TREATMENT OF REFERENCES TO PROVISIONS IN PART C

SEC. 1860D–41. (a) DEFINITIONS.—For purposes of this part:

(1) BASIC PRESCRIPTION DRUG COVERAGE.—The term "basic prescription drug coverage" is defined in section 1860D–2(a)(3).

(2) COVERED PART D DRUG.—The term "covered part D drug" is defined in section 1860D–2(e).

(3) CREDITABLE PRESCRIPTION DRUG COVERAGE.—The term "creditable prescription drug coverage" has the meaning given such term in section 1860D–13(b)(4).

(4) PART D ELIGIBLE INDIVIDUAL.—The term "part D eligible individual" has the meaning given such term in section 1860D–1(a)(4)(A).

(5) FALLBACK PRESCRIPTION DRUG PLAN.—The term "fallback prescription drug plan" has the meaning given such term in section 1860D–11(g)(4).

(6) INITIAL COVERAGE LIMIT.—The term "initial coverage limit" means such limit as established under section 1860D–2(b)(3) *for a year before 2022*, or, in the case of coverage that is not standard prescription drug coverage, the comparable limit (if any) established under the coverage *for such year*.

(7) INSURANCE RISK.—The term "insurance risk" means, with respect to a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitution.

(8) MA PLAN.—The term "MA plan" has the meaning given such term in section 1860D–1(a)(4)(B).

(9) MA–PD PLAN.—The term "MA–PD plan" has the meaning given such term in section 1860D–1(a)(4)(C).

(10) MEDICARE PRESCRIPTION DRUG ACCOUNT.—The term "Medicare Prescription Drug Account" means the Account created under section 1860D–16(a).

(11) PDP APPROVED BID.—The term "PDP approved bid" has the meaning given such term in section 1860D–13(a)(6).

(12) PDP REGION.—The term "PDP region" means such a region as provided under section 1860D–11(a)(2).

(13) PDP SPONSOR.—The term "PDP sponsor" means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part for such a sponsor.

(14) PRESCRIPTION DRUG PLAN.—The term "prescription drug plan" means prescription drug coverage that is offered—

(A) under a policy, contract, or plan that has been approved under section 1860D–11(e); and

(B) by a PDP sponsor pursuant to, and in accordance with, a contract between the Secretary and the sponsor under section 1860D–12(b).

(15) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term "qualified prescription drug coverage" is defined in section 1860D–2(a)(1).

(16) STANDARD PRESCRIPTION DRUG COVERAGE.—The term "standard prescription drug coverage" is defined in section 1860D–2(b).

(17) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—The term "State Pharmaceutical Assistance Program" has the meaning given such term in section 1860D–23(b).

(18) SUBSIDY ELIGIBLE INDIVIDUAL.—The term "subsidy eligible individual" has the meaning given such term in section 1860D–14(a)(3)(A).

(b) APPLICATION OF PART C PROVISIONS UNDER THIS PART.—For purposes of applying provisions of part C under this part with respect to a prescription drug plan and a PDP sponsor, unless otherwise provided in this part such provisions shall be applied as if—

(1) any reference to an MA plan included a reference to a prescription drug plan;

(2) any reference to an MA organization or a provider-sponsored organization included a reference to a PDP sponsor;

(3) any reference to a contract under section 1857 included a reference to a contract under section 1860D–12(b);

(4) any reference to part C included a reference to this part; and

(5) any reference to an election period under section 1851 were a reference to an enrollment period under section 1860D–1.

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CONDITION FOR COVERAGE OF DRUGS UNDER THIS PART

SEC. 1860D–43. (a) IN GENERAL.—In order for coverage to be available under this part for covered part D drugs (as defined in section 1860D–2(e)) of a manufacturer, the manufacturer must—

[(1) participate in the Medicare coverage gap discount program under section 1860D–14A;

[(2) have entered into and have in effect an agreement described in subsection (b) of such section with the Secretary; and

[(3) have entered into and have in effect, under terms and conditions specified by the Secretary, a contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of such section.**]**

(1) participate in—

(A) for 2011 through 2021, the Medicare coverage gap discount program under section 1860D–14A; and

(B) for 2022 and each subsequent year, the manufacturer discount program under section 1860D–14C;

(2) have entered into and have in effect—

(A) for 2011 through 2021, an agreement described in subsection (b) of section 1860D–14A with the Secretary; and

(B) for 2022 and each subsequent year, an agreement described in subsection (b) of section 1860D–14C with the Secretary; and

(3) have entered into and have in effect, under terms and conditions specified by the Secretary—

(A) for 2011 through 2021, a contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of section 1860D–14A; and

(B) for 2022 and each subsequent year, a contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of section 1860D–14C.

[(b) EFFECTIVE DATE.—Subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011.]

(b) EFFECTIVE DATE.—Paragraphs (1)(A), (2)(A), and (3)(A) of subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011, and before January 1, 2022, and paragraphs (1)(B), (2)(B), and (3)(B) of such subsection shall apply to covered part D drugs dispensed under this part on or after January 1, 2022.

(c) AUTHORIZING COVERAGE FOR DRUGS NOT COVERED UNDER AGREEMENTS.—Subsection (a) shall not apply to the dispensing of a covered part D drug if—

(1) the Secretary has made a determination that the availability of the drug is essential to the health of beneficiaries under this part; or

(2) the Secretary determines that in the period beginning on January 1, 2011, and December 31, 2011, there were extenuating circumstances.

(d) DEFINITION OF MANUFACTURER.—In this section, the term "manufacturer" has the meaning given such term in section 1860D–14A(g)(5).

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TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

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SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION DRUG BENEFIT

SEC. 1935. (a) REQUIREMENTS RELATING TO MEDICARE PRESCRIPTION DRUG LOW-INCOME SUBSIDIES MEDICARE TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE, AND MEDICARE COST-SHARING.—As a condition of its State plan under this title under section 1902(a)(66) and receipt of any Federal financial assistance under section 1903(a) subject to subsection (e), a State shall do the following:

(1) INFORMATION FOR TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE VERIFICATION.—The State shall provide the Secretary with information to carry out section 1860D–31(f)(3)(B)(i).

(2) ELIGIBILITY DETERMINATIONS FOR LOW-INCOME SUBSIDIES.—The State shall—

(A) make determinations of eligibility for premium and cost-sharing subsidies under and in accordance with section 1860D–14;

(B) inform the Secretary of such determinations in cases in which such eligibility is established; and

(C) otherwise provide the Secretary with such information as may be required to carry out part D, other than subpart 4, of title XVIII (including section 1860D–14).

(3) SCREENING FOR ELIGIBILITY, AND ENROLLMENT OF, BENEFICIARIES FOR MEDICARE COST-SHARING.—As part of making an eligibility determination required under paragraph (2) for an individual, the State shall make a determination of the individual's eligibility for medical assistance for any medicare cost-sharing described in section 1905(p)(3) and, if the individual is eligible for any such medicare cost-sharing, offer enrollment to the individual under the State plan (or under a waiver of such plan).

(4) CONSIDERATION OF DATA TRANSMITTED BY THE SOCIAL SECURITY ADMINISTRATION FOR PURPOSES OF MEDICARE SAVINGS PROGRAM.—The State shall accept data transmitted under section 1144(c)(3) and act on such data in the same manner and in accordance with the same deadlines as if the data constituted an initiation of an application for benefits under the Medicare Savings Program (as defined for purposes of such section) that had been submitted directly by the applicant. The date of the individual's application for the low income subsidy program from which the data have been derived shall constitute the date of filing of such application for benefits under the Medicare Savings Program.

(b) REGULAR FEDERAL SUBSIDY OF ADMINISTRATIVE COSTS.—The amounts expended by a State in carrying out subsection (a) are expenditures reimbursable under the appropriate paragraph of section 1903(a).

(c) FEDERAL ASSUMPTION OF MEDICAID PRESCRIPTION DRUG COSTS FOR DUALLY ELIGIBLE INDIVIDUALS.—

(1) PHASED-DOWN STATE CONTRIBUTION.—

(A) IN GENERAL.—Each of the 50 States and the District of Columbia for each month beginning with January 2006 shall provide for payment under this subsection to the Secretary of the product of—

(i) the amount computed under paragraph (2)(A) for the State and month;

(ii) the total number of full-benefit dual eligible individuals (as defined in paragraph (6)) for such State and month; and

(iii) the factor for the month specified in paragraph (5).

(B) FORM AND MANNER OF PAYMENT.—Payment under subparagraph (A) shall be made in a manner specified by the Secretary that is similar to the manner in which State

payments are made under an agreement entered into under section 1843, except that all such payments shall be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

(C) COMPLIANCE.—If a State fails to pay to the Secretary an amount required under subparagraph (A), interest shall accrue on such amount at the rate provided under section 1903(d)(5). The amount so owed and applicable interest shall be immediately offset against amounts otherwise payable to the State under section 1903(a), in accordance with the Federal Claims Collection Act of 1996 and applicable regulations.

(D) DATA MATCH.—The Secretary shall perform such periodic data matches as may be necessary to identify and compute the number of full-benefit dual eligible individuals for purposes of computing the amount under subparagraph (A).

(2) AMOUNT.—

(A) IN GENERAL.—The amount computed under this paragraph for a State described in paragraph (1) and for a month in a year is equal to—

(i) 1/12 of the product of—

(I) the base year State medicaid per capita expenditures for covered part D drugs for full-benefit dual eligible individuals (as computed under paragraph (3)); and

(II) a proportion equal to 100 percent minus the Federal medical assistance percentage (as defined in section 1905(b)) applicable to the State for the fiscal year in which the month occurs; and

(ii) increased for each year (beginning with 2004 up to and including the year involved) by the applicable growth factor specified in paragraph (4) for that year.

(B) NOTICE.—The Secretary shall notify each State described in paragraph (1) not later than October 15 before the beginning of each year (beginning with 2006) of the amount computed under subparagraph (A) for the State for that year.

(3) BASE YEAR STATE MEDICAID PER CAPITA EXPENDITURES FOR COVERED PART D DRUGS FOR FULL-BENEFIT DUAL ELIGIBLE INDIVIDUALS.—

(A) IN GENERAL.—For purposes of paragraph (2)(A), the "base year State medicaid per capita expenditures for covered part D drugs for full-benefit dual eligible individuals" for a State is equal to the weighted average (as weighted under subparagraph (C)) of—

(i) the gross per capita medicaid expenditures for prescription drugs for 2003, determined under subparagraph (B); and

(ii) the estimated actuarial value of prescription drug benefits provided under a capitated managed care plan per full-benefit dual eligible individual for 2003, as determined using such data as the Secretary determines appropriate.

(B) GROSS PER CAPITA MEDICAID EXPENDITURES FOR PRESCRIPTION DRUGS.—

(i) IN GENERAL.—The gross per capita medicaid expenditures for prescription drugs for 2003 under this subparagraph is equal to the expenditures, including dispensing fees, for the State under this title during 2003 for covered outpatient drugs, determined per full-benefit-dual-eligible-individual for such individuals not receiving medical assistance for such drugs through a medicaid managed care plan.

(ii) DETERMINATION.—In determining the amount under clause (i), the Secretary shall—

(I) use data from the Medicaid Statistical Information System (MSIS) and other available data;

(II) exclude expenditures attributable to covered outpatient prescription drugs that are not covered part D drugs (as defined in section 1860D–2(e), including drugs described in subparagraph (K) of section 1927(d)(2)); and

(III) reduce such expenditures by the product of such portion and the adjustment factor (described in clause (iii)).

(iii) ADJUSTMENT FACTOR.—The adjustment factor described in this clause for a State is equal to the ratio for the State for 2003 of—

(I) aggregate payments under agreements under section 1927; to

(II) the gross expenditures under this title for covered outpatient drugs referred to in clause (i).

Such factor shall be determined based on information reported by the State in the medicaid financial management reports (form CMS–64) for the 4 quarters of calendar year 2003 and such other data as the Secretary may require.

(C) WEIGHTED AVERAGE.—The weighted average under subparagraph (A) shall be determined taking into account—

(i) with respect to subparagraph (A)(i), the average number of full-benefit dual eligible individuals in 2003 who are not described in clause (ii); and

(ii) with respect to subparagraph (A)(ii), the average number of full-benefit dual eligible individuals in such year who received in 2003 medical assistance for covered outpatient drugs through a medicaid managed care plan.

(4) APPLICABLE GROWTH FACTOR.—The applicable growth factor under this paragraph for—

(A) each of 2004, 2005, and 2006, is the average annual percent change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most recent National Health Expenditure projections for the years involved); and

(B) a succeeding year, is the annual percentage increase specified in section 1860D–2(b)(6) for the year.

(5) FACTOR.—The factor under this paragraph for a month—

(A) in 2006 is 90 percent;
(B) in 2007 is 88⅓ percent;
(C) in 2008 is 86⅔ percent;
(D) in 2009 is 85 percent;
(E) in 2010 is 83⅓ percent;
(F) in 2011 is 81⅔ percent;
(G) in 2012 is 80 percent;
(H) in 2013 is 78⅓ percent;
(I) in 2014 is 76⅔ percent; or
(J) after December 2014, is 75 percent.

(6) FULL-BENEFIT DUAL ELIGIBLE INDIVIDUAL DEFINED.—

(A) IN GENERAL.—For purposes of this section, the term "full-benefit dual eligible individual" means for a State for a month an individual who—

(i) has coverage for the month for covered part D drugs under a prescription drug plan under part D of title XVIII, or under an MA–PD plan under part C of such title; and

(ii) is determined eligible by the State for medical assistance for full benefits under this title for such month under section 1902(a)(10)(A) or 1902(a)(10)(C), by reason of section 1902(f), or under any other category of eligibility for medical assistance for full benefits under this title, as determined by the Secretary.

(B) TREATMENT OF MEDICALLY NEEDY AND OTHER INDIVIDUALS REQUIRED TO SPEND DOWN.—In applying subparagraph (A) in the case of an individual determined to be eligible by the State for medical assistance under section 1902(a)(10)(C) or by reason of section 1902(f), the individual shall be treated as meeting the requirement of subparagraph (A)(ii) for any month if such medical assistance is provided for in any part of the month.

(d) COORDINATION OF PRESCRIPTION DRUG BENEFITS.—

(1) MEDICARE AS PRIMARY PAYOR.—In the case of a part D eligible individual (as defined in section 1860D–1(a)(3)(A)) who is described in subsection (c)(6)(A)(ii), notwithstanding any other provision of this title, medical assistance is not available under this title for such drugs (or for any cost-sharing respecting such drugs), and the rules under this title relating to the provision of medical assistance for such drugs shall not apply. The provision of benefits with respect to such drugs shall not be considered as the provision of care or services under the plan under this title. No payment may be made under section 1903(a) for prescribed drugs for which medical assistance is not available pursuant to this paragraph.

(2) COVERAGE OF CERTAIN EXCLUDABLE DRUGS.—In the case of medical assistance under this title with respect to a covered outpatient drug (other than a covered part D drug) furnished to an individual who is enrolled in a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title, the State may elect to provide such medical assistance in the manner otherwise provided in the case of individuals who are not full-benefit dual eligible individuals or through an arrangement with such plan.

(e) TREATMENT OF TERRITORIES.—

(1) IN GENERAL.—In the case of a State, other than the 50 States and the District of Columbia—

(A) the previous provisions of this section shall not apply to residents of such State *before January 1, 2021*; and

(B) if the State establishes and submits to the Secretary a plan described in paragraph (2) (for providing medical assistance with respect to the provision of prescription drugs to part D eligible individuals), the amount otherwise determined under section 1108(f) (as increased under section 1108(g)) for the State shall be increased by the amount for the fiscal period specified in paragraph (3).

(2) PLAN.—The Secretary shall determine that a plan is described in this paragraph if the plan—

(A) provides medical assistance with respect to the provision of covered part D drugs (as defined in section 1860D–2(e)) to low-income part D eligible individuals;

(B) provides assurances that additional amounts received by the State that are attributable to the operation of this subsection shall be used only for such assistance and related administrative expenses and that no more than 10 percent of the amount specified in paragraph (3)(A) for the State for any fiscal period shall be used for such administrative expenses; and

(C) meets such other criteria as the Secretary may establish.

(3) INCREASED AMOUNT.—

(A) IN GENERAL.—The amount specified in this paragraph for a State for a year *(before 2021)* is equal to the product of—

(i) the aggregate amount specified in subparagraph (B); and

(ii) the ratio (as estimated by the Secretary) of—

(I) the number of individuals who are entitled to benefits under part A or enrolled under part B and who reside in the State (as determined by the Secretary based on the most recent available data before the beginning of the year); to

(II) the sum of such numbers for all States that submit a plan described in paragraph (2).

(B) AGGREGATE AMOUNT.—The aggregate amount specified in this subparagraph for—

(i) the last 3 quarters of fiscal year 2006, is equal to $28,125,000;

(ii) fiscal year 2007, is equal to $37,500,000; or

(iii) [a subsequent year] *each of fiscal years 2008 through 2020*, is equal to the aggregate amount specified in this subparagraph for the previous year increased by annual percentage increase specified in section 1860D–2(b)(6) for the year involved.

(4) REPORT.—The Secretary shall submit to Congress a report on the application of this subsection and may include in the report such recommendations as the Secretary deems appropriate.

(f) TERRITORY DEFINED.—In this section, the term "territory" means Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.

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PUBLIC HEALTH SERVICE ACT

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TITLE XXVII—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

PART A—INDIVIDUAL AND GROUP MARKET REFORMS

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Subpart II—Improving Coverage

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SEC. 2729A. FAIR PRICE DRUG NEGOTIATION PROGRAM AND APPLICATION OF MAXIMUM FAIR PRICES.

(a) IN GENERAL.—In the case of a group health plan or health insurance issuer offering 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 Drug 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 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;

(2) the plan or issuer shall apply any cost-sharing responsibilities under such plan or coverage, with respect to such selected drug, by substituting the maximum fair price negotiated under such part for such drug in lieu of the contracted rate under such plan or coverage for such selected drug; and

(3) the Secretary shall apply the provisions of such part to such plan, issuer, and coverage, and such individuals so enrolled in such plans.

(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall publicly disclose in a manner and in accordance with a process specified by the Secretary any election made under section 1197 of the Social Security Act by the plan or issuer to not participate in the Fair Drug Price Negotiation Program under part E of

title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under such plan or coverage before the beginning of the plan year for which such election was made.

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EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

TABLE OF CONTENTS

Sec. 1. Short title and table of contents.

TITLE I—PROTECTION OF EMPLOYEE BENEFIT RIGHTS

* * * * * * *

Subtitle B—Regulatory Provisions

* * * * * * *

PART 7—GROUP HEALTH PLAN REQUIREMENTS

* * * * * * *

Subpart B—Other Requirements

* * * * * * *

Sec. 716. Fair Price Drug Negotiation Program and application of maximum fair prices.

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TITLE I—PROTECTION OF EMPLOYEE BENEFIT RIGHTS

* * * * * * *

SUBTITLE B—REGULATORY PROVISIONS

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PART 7—GROUP HEALTH PLAN REQUIREMENTS

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SUBPART B—OTHER REQUIREMENTS

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SEC. 716. FAIR PRICE DRUG 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 Drug 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 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 pro-

visions apply to prescription drug plans and MA–PD plans, and to individuals enrolled under such prescription drug plans and MA–PD plans;

(2) the plan or issuer shall apply any cost-sharing responsibilities under such plan or coverage, with respect to such selected drug, by substituting the maximum fair price negotiated under such part for such drug in lieu of the contracted rate under such plan or coverage for such selected drug; and

(3) the Secretary shall apply the provisions of such part to such plan, issuer, and coverage, and such individuals so enrolled in such plans.

(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group health plan or a health insurance issuer offering group health insurance coverage shall publicly disclose in a manner and in accordance with a process specified by the Secretary any election made under section 1197 of the Social Security Act by the plan or issuer to not participate in the Fair Drug Price Negotiation Program under part E of title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under such plan or coverage before the beginning of the plan year for which such election was made.

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INTERNAL REVENUE CODE OF 1986

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Subtitle A—Income Taxes

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CHAPTER 1—NORMAL TAXES AND SURTAXES

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Subchapter B—COMPUTATION OF TAXABLE INCOME

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PART IX—ITEMS NOT DEDUCTIBLE

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SEC. 275. CERTAIN TAXES.

(a) GENERAL RULE.—No deduction shall be allowed for the following taxes:

(1) Federal income taxes, including—

(A) the tax imposed by section 3101 (relating to the tax on employees under the Federal Insurance Contributions Act);

(B) the taxes imposed by sections 3201 and 3211 (relating to the taxes on railroad employees and railroad employee representatives); and

(C) the tax withheld at source on wages under section 3402.

(2) Federal war profits and excess profits taxes.

(3) Estate, inheritance, legacy, succession, and gift taxes.

(4) Income, war profits, and excess profits taxes imposed by the authority of any foreign country or possession of the United States if the taxpayer chooses to take to any extent the benefits of section 901.

(5) Taxes on real property, to the extent that section 164(d) requires such taxes to be treated as imposed on another taxpayer.

(6) Taxes imposed by chapters 41, 42, 43, 44, 45, 46, and 54 *or by section 4192*.

Paragraph (1) shall not apply to any taxes to the extent such taxes are allowable as a deduction under section 164(f).

(b) CROSS REFERENCE.—For disallowance of certain other taxes, see section 164(c).

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Subtitle D—Miscellaneous Excise Taxes

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CHAPTER 32—MANUFACTURERS EXCISE TAXES

SUBCHAPTER A. INCOME TAXES.

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[SUBCHAPTER E. ALCOHOL, TOBACCO, AND CERTAIN OTHER EXCISE TAXES]

SUBCHAPTER E. OTHER MEDICAL PRODUCTS

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Subchapter E—[MEDICAL DEVICES] *OTHER MEDICAL PRODUCTS*

Sec. 4191. Medical devices.

Sec. 4192. Selected drugs during noncompliance periods.

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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).

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Subchapter G—EXEMPTIONS, REGISTRATION, ETC.

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SEC. 4221. CERTAIN TAX-FREE SALES.

(a) GENERAL RULE.—Under regulations prescribed by the Secretary, no tax shall be imposed under this chapter (other than under section 4121 or 4081) on the sale by the manufacturer (or under subchapter C of chapter 31 on the first retail sale) of an article—

(1) for use by the purchaser for further manufacture, or for resale by the purchaser to a second purchaser for use by such second purchaser in further manufacture,

(2) for export, or for resale by the purchaser to a second purchaser for export,

(3) for use by the purchaser as supplies for vessels or aircraft,

(4) to a State or local government for the exclusive use of a State or local government,

(5) to a nonprofit educational organization for its exclusive use, or

(6) to a qualified blood collector organization (as defined in section 7701(a)(49)) for such organization's exclusive use in the collection, storage, or transportation of blood,

but only if such exportation or use is to occur before any other use. Paragraphs (4), (5), and (6) shall not apply to the tax imposed by section 4064. In the case of taxes imposed by section 4051 or 4071, paragraphs (4) and (5) shall not apply on and after October 1, 2022. In the case of the tax imposed by section 4131, paragraphs (3), (4), and (5) shall not apply and paragraph (2) shall apply only if the use of the exported vaccine meets such requirements as the Secretary may by regulations prescribe. In the case of taxes imposed by subchapter C or D, paragraph (6) shall not apply. In the case of the tax imposed by section 4191 *or 4192*, paragraphs (3), (4), (5), and (6) shall not apply.

(b) PROOF OF RESALE FOR FURTHER MANUFACTURE; PROOF OF EXPORT.—Where an article has been sold free of tax under subsection (a)—

(1) for resale by the purchaser to a second purchaser for use by such second purchaser in further manufacture, or

(2) for export, or for resale by the purchaser to a second purchaser for export,

subsection (a) shall cease to apply in respect of such sale of such article unless, within the 6-month period which begins on the date of the sale by the manufacturer (or, if earlier, on the date of ship-

ment by the manufacturer), the manufacturer receives proof that the article has been exported or resold for use in further manufacture.

(c) MANUFACTURER RELIEVED FROM LIABILITY IN CERTAIN CASES.—In the case of any article sold free of tax under this section (other than a sale to which subsection (b) applies), and in the case of any article sold free of tax under section 4053(6), if the manufacturer in good faith accepts a certification by the purchaser that the article will be used in accordance with the applicable provisions of law, no tax shall thereafter be imposed under this chapter in respect of such sale by such manufacturer.

(d) DEFINITIONS.—For purposes of this section—

(1) MANUFACTURER.—The term "manufacturer" includes a producer or importer of an article, and, in the case of taxes imposed by subchapter C of chapter 31, includes the retailer with respect to the first retail sale.

(2) EXPORT.—The term "export" includes shipment to a possession of the United States; and the term "exported" includes shipped to a possession of the United States.

(3) SUPPLIES FOR VESSELS OR AIRCRAFT.—The term "supplies for vessels or aircraft" means fuel supplies, ships' stores, sea stores, or legitimate equipment on vessels of war of the United States or of any foreign nation, vessels employed in the fisheries or in the whaling business, or vessels actually engaged in foreign trade or trade between the Atlantic and Pacific ports of the United States or between the United States and any of its possessions. For purposes of the preceding sentence, the term "vessels" includes civil aircraft employed in foreign trade or trade between the United States and any of its possessions, and the term "vessels of war of the United States or of any foreign nation" includes aircraft owned by the United States or by any foreign nation and constituting a part of the armed forces thereof.

(4) STATE OR LOCAL GOVERNMENT.—The term "State or local government" means any State, any political subdivision thereof, or the District of Columbia.

(5) NONPROFIT EDUCATIONAL ORGANIZATION.—The term "nonprofit educational organization" means an educational organization described in section 170(b)(1)(A)(ii) which is exempt from income tax under section 501(a). The term also includes a school operated as an activity of an organization described in section 501(c)(3) which is exempt from income tax under section 501(a), if such school normally maintains a regular faculty and curriculum and normally has a regularly enrolled body of pupils or students in attendance at the place where its educational activities are regularly carried on.

(6) USE IN FURTHER MANUFACTURE.—An article shall be treated as sold for use in further manufacture if—

(A) such article is sold for use by the purchaser as material in the manufacture or production of, or as a component part of, another article taxable under this chapter to be manufactured or produced by him; or

(B) in the case of gasoline taxable under section 4081, such gasoline is sold for use by the purchaser, for nonfuel

purposes, as a material in the manufacture or production of another article to be manufactured or produced by him.

(7) QUALIFIED BUS.—

(A) IN GENERAL.—The term "qualified bus" means—

(i) an intercity or local bus, and

(ii) a school bus.

(B) INTERCITY OR LOCAL BUS.—The term "intercity or local bus" means any automobile bus which is used predominantly in furnishing (for compensation) passenger land transportation available to the general public if—

(i) such transportation is scheduled and along regular routes, or

(ii) the seating capacity of such bus is at least 20 adults (not including the driver).

(C) SCHOOL BUS.—The term "school bus" means any automobile bus substantially all the use of which is in transporting students and employees of schools. For purposes of the preceding sentence, the term "school" means an educational organization which normally maintains a regular faculty and curriculum and normally has a regularly enrolled body of pupils or students in attendance at the place where its educational activities are carried on.

(e) SPECIAL RULES.—

(1) RECIPROCITY REQUIRED IN CASE OF CIVIL AIRCRAFT.—In the case of articles sold for use as supplies for aircraft, the privileges granted under subsection (a)(3) in respect of civil aircraft employed in foreign trade or trade between the United States and any of its possessions, in respect of aircraft registered in a foreign country, shall be allowed only if the Secretary of the Treasury has been advised by the Secretary of Commerce that he has found that such foreign country allows, or will allow, substantially reciprocal privileges in respect of aircraft registered in the United States. If the Secretary of the Treasury is advised by the Secretary of Commerce that he has found that a foreign country has discontinued or will discontinue the allowance of such privileges, the privileges granted under subsection (a)(3) shall not apply thereafter in respect of civil aircraft registered in that foreign country and employed in foreign trade or trade between the United States and any of its possessions.

(2) TIRES.—

(A) TAX-FREE SALES.—Under regulations prescribed by the Secretary, no tax shall be imposed under section 4071 on the sale by the manufacturer of a tire if—

(i) such tire is sold for use by the purchaser for sale on or in connection with the sale of another article manufactured or produced by such purchaser; and

(ii) such other article is to be sold by such purchaser in a sale which either will satisfy the requirements of paragraph (2), (3), (4), or (5) of subsection (a) for a tax-free sale, or would satisfy such requirements but for the fact that such other article is not subject to tax under this chapter.

(B) PROOF.—Where a tire has been sold free of tax under this paragraph, this paragraph shall cease to apply unless,

within the 6-month period which begins on the date of the sale by him (or, if earlier, on the date of the shipment by him), the manufacturer of such tire receives proof that the other article referred to in clause (ii) of subparagraph (A) has been sold in a manner which satisfies the requirements of such clause (ii) (including in the case of a sale for export, proof of export of such other article).

(C) SUBSECTION (A)(1) DOES NOT APPLY.—Paragraph (1) of subsection (a) shall not apply with respect to the tax imposed under section 4071 on the sale of a tire.

(3) TIRES USED ON INTERCITY, LOCAL, AND SCHOOL BUSES.—Under regulations prescribed by the Secretary, the tax imposed by section 4071 shall not apply in the case of tires sold for use by the purchaser on or in connection with a qualified bus.

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Subtitle F—Procedure and Administration

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CHAPTER 65—ABATEMENTS, CREDITS, AND REFUNDS

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Subchapter B—RULES OF SPECIAL APPLICATION

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SEC. 6416. CERTAIN TAXES ON SALES AND SERVICES.

(a) CONDITION TO ALLOWANCE.—

(1) GENERAL RULE.—No credit or refund of any overpayment of tax imposed by chapter 31 (relating to retail excise taxes), or chapter 32 (manufacturers taxes), shall be allowed or made unless the person who paid the tax establishes, under regulations prescribed by the Secretary, that he—

(A) has not included the tax in the price of the article with respect to which it was imposed and has not collected the amount of the tax from the person who purchased such article;

(B) has repaid the amount of the tax to the ultimate purchaser of the article;

(C) in the case of an overpayment under subsection (b)(2) of this section—

(i) has repaid or agreed to repay the amount of the tax to the ultimate vendor of the article, or

(ii) has obtained the written consent of such ultimate vendor to the allowance of the credit or the making of the refund; or

(D) has filed with the Secretary the written consent of the person referred to in subparagraph (B) to the allowance of the credit or the making of the refund.

(2) EXCEPTIONS.—This subsection shall not apply to—

(A) the tax imposed by section 4041 (relating to tax on special fuels) on the use of any liquid, and

(B) an overpayment of tax under paragraph (1), (3)(A), (4), (5), or (6) of subsection (b) of this section.

(3) SPECIAL RULE.—For purposes of this subsection, in any case in which the Secretary determines that an article is not taxable, the term "ultimate purchaser" (when used in paragraph (1)(B) of this subsection) includes a wholesaler, jobber, distributor, or retailer who, on the 15th day after the date of such determination, holds such article for sale; but only if claim for credit or refund by reason of this paragraph is filed on or before the date for filing the return with respect to the taxes imposed under chapter 32 for the first period which begins more than 60 days after the date on such determination.

(4) REGISTERED ULTIMATE VENDOR OR CREDIT CARD ISSUER TO ADMINISTER CREDITS AND REFUNDS OF GASOLINE TAX.—

(A) IN GENERAL.—For purposes of this subsection, except as provided in subparagraph (B), if an ultimate vendor purchases any gasoline on which tax imposed by section 4081 has been paid and sells such gasoline to an ultimate purchaser described in subparagraph (C) or (D) of subsection (b)(2) (and such gasoline is for a use described in such subparagraph), such ultimate vendor shall be treated as the person (and the only person) who paid such tax, but only if such ultimate vendor is registered under section 4101.

(B) CREDIT CARD ISSUER.—For purposes of this subsection, if the purchase of gasoline described in subparagraph (A) (determined without regard to the registration status of the ultimate vendor) is made by means of a credit card issued to the ultimate purchaser, paragraph (1) shall not apply and the person extending the credit to the ultimate purchaser shall be treated as the person (and the only person) who paid the tax, but only if such person—

(i) is registered under section 4101,

(ii) has established, under regulations prescribed by the Secretary, that such person—

(I) has not collected the amount of the tax from the person who purchased such article, or

(II) has obtained the written consent from the ultimate purchaser to the allowance of the credit or refund, and

(iii) has so established that such person—

(I) has repaid or agreed to repay the amount of the tax to the ultimate vendor,

(II) has obtained the written consent of the ultimate vendor to the allowance of the credit or refund, or

(III) has otherwise made arrangements which directly or indirectly provides the ultimate vendor with reimbursement of such tax.

If clause (i), (ii), or (iii) is not met by such person extending the credit to the ultimate purchaser, then such person shall collect an amount equal to the tax from the ultimate

purchaser and only such ultimate purchaser may claim such credit or payment.

(C) TIMING OF CLAIMS.—The procedure and timing of any claim under subparagraph (A) or (B) shall be the same as for claims under section 6427(i)(4), except that the rules of section 6427(i)(3)(B) regarding electronic claims shall not apply unless the ultimate vendor or credit card issuer has certified to the Secretary for the most recent quarter of the taxable year that all ultimate purchasers of the vendor or credit card issuer are certified and entitled to a refund under subparagraph (C) or (D) of subsection (b)(2).

(b) SPECIAL CASES IN WHICH TAX PAYMENTS CONSIDERED OVERPAYMENTS.—Under regulations prescribed by the Secretary, credit or refund (without interest) shall be allowed or made in respect of the overpayments determined under the following paragraphs:

(1) PRICE READJUSTMENTS.—

(A) IN GENERAL.—Except as provided in subparagraph (B) or (C), if the price of any article in respect of which a tax, based on such price, is imposed by chapter 31 or 32, is readjusted by reason of the return or repossession of the article or a covering or container, or by a bona fide discount, rebate, or allowance, including a readjustment for local advertising (but only to the extent provided in section 4216(e)(2) and (3)), the part of the tax proportionate to the part of the price repaid or credited to the purchaser shall be deemed to be an overpayment.

(B) FURTHER MANUFACTURE.—Subparagraph (A) shall not apply in the case of an article in respect of which tax was computed under section 4223(b)(2); but if the price for which such article was sold is readjusted by reason of the return or repossession of the article, the part of the tax proportionate to the part of such price repaid or credited to the purchaser shall be deemed to be an overpayment.

(C) ADJUSTMENT OF TIRE PRICE.—No credit or refund of any tax imposed by subsection (a) or (b) of section 4071 shall be allowed or made by reason of an adjustment of a tire pursuant to a warranty or guarantee.

(2) SPECIFIED USES AND RESALES.—The tax paid under chapter 32 (or under subsection (a) or (d) of section 4041 in respect of sales or under section 4051) in respect of any article shall be deemed to be an overpayment if such article was, by any person—

(A) exported;

(B) used or sold for use as supplies for vessels or aircraft;

(C) sold to a State or local government for the exclusive use of a State or local government;

(D) sold to a nonprofit educational organization for its exclusive use;

(E) sold to a qualified blood collector organization (as defined in section 7701(a)(49)) for such organization's exclusive use in the collection, storage, or transportation of blood;

(F) in the case of any tire taxable under section 4071(a), sold to any person for use as described in section 4221(e)(3); or

(G) in the case of gasoline, used or sold for use in the production of special fuels referred to in section 4041.

Subparagraphs (C), (D), and (E) shall not apply in the case of any tax paid under section 4064. In the case of the tax imposed by section 4131, subparagraphs (B), (C), (D), and (E) shall not apply and subparagraph (A) shall apply only if the use of the exported vaccine meets such requirements as the Secretary may by regulations prescribe. This paragraph shall not apply in the case of any tax imposed under section 4041(a)(1) or 4081 on diesel fuel or kerosene and any tax paid under section 4121. Subparagraphs (C) and (D) shall not apply in the case of any tax imposed on gasoline under section 4081 if the requirements of subsection (a)(4) are not met. In the case of taxes imposed by subchapter C or D of chapter 32, subparagraph (E) shall not apply. In the case of the tax imposed by section 4191 *or 4192*, subparagraphs (B), (C), (D), and (E) shall not apply.

(3) TAX-PAID ARTICLES USED FOR FURTHER MANUFACTURE, ETC..—If the tax imposed by chapter 32 has been paid with respect to the sale of any article (other than coal taxable under section 4121) by the manufacturer, producer, or importer thereof and such article is sold to a subsequent manufacturer or producer before being used, such tax shall be deemed to be an overpayment by such subsequent manufacturer or producer if—

(A) in the case of any article other than any fuel taxable under section 4081, such article is used by the subsequent manufacturer or producer as material in the manufacture or production of, or as a component part of—

(i) another article taxable under chapter 32, or

(ii) an automobile bus chassis or an automobile bus body,

manufactured or produced by him; or

(B) in the case of any fuel taxable under section 4081, such fuel is used by the subsequent manufacturer or producer, for nonfuel purposes, as a material in the manufacture or production of any other article manufactured or produced by him.

(4) TIRES.—If—

(A) the tax imposed by section 4071 has been paid with respect to the sale of any tire by the manufacturer, producer, or importer thereof, and

(B) such tire is sold by any person on or in connection with, or with the sale of, any other article, such tax shall be deemed to be an overpayment by such person if such other article is—

(i) an automobile bus chassis or an automobile bus body,

(ii) by such person exported, sold to a State or local government for the exclusive use of a State or local government, sold to a nonprofit educational organization for its exclusive use, or used or sold for use as supplies for vessels or aircraft, or

(iii) sold to a qualified blood collector organization for its exclusive use in connection with a vehicle the organization certifies will be primarily used in the collection, storage, or transportation of blood.

(5) RETURN OF CERTAIN INSTALLMENT ACCOUNTS.—If—

(A) tax was paid under section 4216(d)(1) in respect of any installment account,

(B) such account is, under the agreement under which the account was sold, returned to the person who sold such account, and

(C) the consideration is readjusted as provided in such agreement,

the part of the tax paid under section 4216(d)(1) allocable to the part of the consideration repaid or credited to the purchaser of such account shall be deemed to be an overpayment.

(6) TRUCK CHASSIS, BODIES, AND SEMITRAILERS USED FOR FURTHER MANUFACTURE.—If—

(A) the tax imposed by section 4051 has been paid with respect to the sale of any article, and

(B) before any other use, such article is by any person used as a component part of another article taxable under section 4051 manufactured or produced by him,

such tax shall be deemed to be an overpayment by such person. For purposes of the preceding sentence, an article shall be treated as having been used as a component part of another article if, had it not been broken or rendered useless in the manufacture or production of such other article, it would have been so used.

This subsection shall apply in respect of an article only if the exportation or use referred to in the applicable provision of this subsection occurs before any other use, or, in the case of a sale or resale, the use referred to in the applicable provision of this subsection is to occur before any other use.

(c) REFUND TO EXPORTER OR SHIPPER.—Under regulations prescribed by the Secretary the amount of any tax imposed by chapter 31, or chapter 32 erroneously or illegally collected in respect of any article exported to a foreign country or shipped to a possession of the United States may be refunded to the exporter or shipper thereof, if the person who paid such tax waives his claim to such amount.

(d) CREDIT ON RETURNS.—Any person entitled to a refund of tax imposed by chapter 31 or 32, paid to the Secretary may, instead of filing a claim for refund, take credit therefor against taxes imposed by such chapter due on any subsequent return. The preceding sentence shall not apply to the tax imposed by section 4081 in the case of refunds described in section 4081(e).

(e) ACCOUNTING PROCEDURES FOR LIKE ARTICLES.—Under regulations prescribed by the Secretary, if any person uses or resells like articles, then for purposes of this section the manufacturer, producer, or importer of any such article may be identified, and the amount of tax paid under chapter 32 in respect of such article may be determined—

(1) on a first-in-first-out basis,

(2) on a last-in-first-out basis, or

(3) in accordance with any other consistent method approved by the Secretary.

(f) MEANING OF TERMS.—For purposes of this section, any term used in this section has the same meaning as when used in chapter 31, 32, or 33, as the case may be.

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Subtitle K—Group Health Plan Requirements

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CHAPTER 100—GROUP HEALTH PLAN REQUIREMENTS

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Subchapter B—OTHER REQUIREMENTS

Sec. 9811. Standards relating to benefits for mothers and newborns.

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Sec. 9816. Fair Price Drug Negotiation Program and application of maximum fair prices.

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SEC. 9816. FAIR PRICE DRUG 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 Drug Negotiation Program under part E of title XI of such Act, with respect to a price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 1192(c) of such Act) with respect to such period with respect to which coverage is provided under such plan—

(1) the provisions of such part shall apply, as applicable—

(A) if coverage of such selected drug is provided under such plan if the drug is furnished or dispensed at a pharmacy or by a mail order service, to the plan, and to the individuals enrolled under such plan during such period, with respect to such selected drug, in the same manner as such provisions apply to prescription drug plans and MA–PD plans, and to individuals enrolled under such prescription drug plans and MA–PD plans during such period; and

(B) if coverage of such selected drug is provided under such plan if the drug is furnished or administered by a hospital, physician, or other provider of services or supplier, to the plan, to the individuals enrolled under such plan, and to hospitals, physicians, and other providers of services and suppliers during such period, with respect to such drug in the same manner as such provisions apply to the Secretary, to individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, and

to hospitals, physicians, and other providers and suppliers participating under title XVIII during such period;

(2) the plan shall apply any cost-sharing responsibilities under such plan, with respect to such selected drug, by substituting an amount not more than the maximum fair price negotiated under such part E of title XI for such drug in lieu of the drug price upon which the cost-sharing would have otherwise applied; and

(3) the Secretary shall apply the provisions of such part E to such plan and such individuals so enrolled in such plan.

(b) NOTIFICATION REGARDING NONPARTICIPATION IN FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group health plan shall publicly disclose in a manner and in accordance with a process specified by the Secretary any election made under section 1197 of the Social Security Act by the plan to not participate in the Fair Drug Price Negotiation Program under part E of title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under such plan before the beginning of the plan year for which such election was made.

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Subchapter C—GENERAL PROVISIONS

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SEC. 9831. GENERAL EXCEPTIONS.

(a) EXCEPTION FOR CERTAIN PLANS.—The requirements of this chapter shall not apply to—

(1) any governmental plan, and

(2) *other than with respect to section 9816,* any group health plan for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees.

(b) EXCEPTION FOR CERTAIN BENEFITS.—The requirements of this chapter shall not apply to any group health plan in relation to its provision of excepted benefits described in section 9832(c)(1).

(c) EXCEPTION FOR CERTAIN BENEFITS IF CERTAIN CONDITIONS MET.—

(1) LIMITED, EXCEPTED BENEFITS.—The requirements of this chapter shall not apply to any group health plan in relation to its provision of excepted benefits described in section 9832(c)(2) if the benefits—

(A) are provided under a separate policy, certificate, or contract of insurance; or

(B) are otherwise not an integral part of the plan.

(2) NONCOORDINATED, EXCEPTED BENEFITS.—The requirements of this chapter shall not apply to any group health plan in relation to its provision of excepted benefits described in section 9832(c)(3) if all of the following conditions are met:

(A) The benefits are provided under a separate policy, certificate, or contract of insurance.

(B) There is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor.

(C) Such benefits are paid with respect to an event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor.

(3) SUPPLEMENTAL EXCEPTED BENEFITS.—The requirements of this chapter shall not apply to any group health plan in relation to its provision of excepted benefits described in section 9832(c)(4) if the benefits are provided under a separate policy, certificate, or contract of insurance.

(d) EXCEPTION FOR QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—

(1) IN GENERAL.—For purposes of this title (except as provided in section 4980I(f)(4) and notwithstanding any other provision of this title), the term "group health plan" shall not include any qualified small employer health reimbursement arrangement.

(2) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENT.—For purposes of this subsection—

(A) IN GENERAL.—The term "qualified small employer health reimbursement arrangement" means an arrangement which—

(i) is described in subparagraph (B), and

(ii) is provided on the same terms to all eligible employees of the eligible employer.

(B) ARRANGEMENT DESCRIBED.—An arrangement is described in this subparagraph if—

(i) such arrangement is funded solely by an eligible employer and no salary reduction contributions may be made under such arrangement,

(ii) such arrangement provides, after the employee provides proof of coverage, for the payment of, or reimbursement of, an eligible employee for expenses for medical care (as defined in section 213(d)) incurred by the eligible employee or the eligible employee's family members (as determined under the terms of the arrangement), and

(iii) the amount of payments and reimbursements described in clause (ii) for any year do not exceed $4,950 ($10,000 in the case of an arrangement that also provides for payments or reimbursements for family members of the employee).

(C) CERTAIN VARIATION PERMITTED.—For purposes of subparagraph (A)(ii), an arrangement shall not fail to be treated as provided on the same terms to each eligible employee merely because the employee's permitted benefit under such arrangement varies in accordance with the variation in the price of an insurance policy in the relevant individual health insurance market based on—

(i) the age of the eligible employee (and, in the case of an arrangement which covers medical expenses of the eligible employee's family members, the age of such family members), or

(ii) the number of family members of the eligible employee the medical expenses of which are covered under such arrangement.

The variation permitted under the preceding sentence shall be determined by reference to the same insurance policy with respect to all eligible employees.

(D) RULES RELATING TO MAXIMUM DOLLAR LIMITATION.—

(i) AMOUNT PRORATED IN CERTAIN CASES.—In the case of an individual who is not covered by an arrangement for the entire year, the limitation under subparagraph (B)(iii) for such year shall be an amount which bears the same ratio to the amount which would (but for this clause) be in effect for such individual for such year under subparagraph (B)(iii) as the number of months for which such individual is covered by the arrangement for such year bears to 12.

(ii) INFLATION ADJUSTMENT.—In the case of any year beginning after 2016, each of the dollar amounts in subparagraph (B)(iii) shall be increased by an amount equal to—

(I) such dollar amount, multiplied by

(II) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which the taxable year begins, determined by substituting "calendar year 2015" for "calendar year 2016" in subparagraph (A)(ii) thereof.

If any dollar amount increased under the preceding sentence is not a multiple of $50, such dollar amount shall be rounded to the next lowest multiple of $50.

(3) OTHER DEFINITIONS.—For purposes of this subsection—

(A) ELIGIBLE EMPLOYEE.—The term "eligible employee" means any employee of an eligible employer, except that the terms of the arrangement may exclude from consideration employees described in any clause of section 105(h)(3)(B) (applied by substituting "90 days" for "3 years" in clause (i) thereof).

(B) ELIGIBLE EMPLOYER.—The term "eligible employer" means an employer that—

(i) is not an applicable large employer as defined in section 4980H(c)(2), and

(ii) does not offer a group health plan to any of its employees.

(C) PERMITTED BENEFIT.—The term "permitted benefit" means, with respect to any eligible employee, the maximum dollar amount of payments and reimbursements which may be made under the terms of the qualified small employer health reimbursement arrangement for the year with respect to such employee.

(4) NOTICE.—

(A) IN GENERAL.—An employer funding a qualified small employer health reimbursement arrangement for any year shall, not later than 90 days before the beginning of such year (or, in the case of an employee who is not eligible to participate in the arrangement as of the beginning of such year, the date on which such employee is first so eligible), provide a written notice to each eligible employee which includes the information described in subparagraph (B).

(B) CONTENTS OF NOTICE.—The notice required under subparagraph (A) shall include each of the following:

(i) A statement of the amount which would be such eligible employee's permitted benefit under the arrangement for the year.

(ii) A statement that the eligible employee should provide the information described in clause (i) to any health insurance exchange to which the employee applies for advance payment of the premium assistance tax credit.

(iii) A statement that if the employee is not covered under minimum essential coverage for any month the employee may be subject to tax under section 5000A for such month and reimbursements under the arrangement may be includible in gross income.

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VI. DISSENTING VIEWS

Our constituents deserve better than Speaker Pelosi's H.R. 3, the more appropriately titled Fewer Cures for Patients Act.

Democrats and Republicans support lowering drug prices, cracking down on overpriced drugs, giving patients more power to choose affordable medicines, and removing the incentives in federal health programs that reward bad actors for raising prices.

In fact, at Chairman Neal's invitation, both parties of this Committee were working together toward that important goal.[1] At least until Speaker Nancy Pelosi trashed the bipartisan work and forced through a secretly written, deeply controversial, and highly partisan drug bill to cure political illnesses rather than actual medical ones.

At the heart of H.R. 3 is a dangerous trade-off for the American people: lower drug prices in the short-term but fewer lifesaving cures and treatments in the long term.

Supporters of H.R. 3 have said they ". . . frankly think it's worth it."[2] Republicans know these artificial and short-term savings are not worth it—H.R. 3 presents a cruel and false choice.

With the average new medicine costing $2.6 billion and 15 years to gain approval here in the U.S.[3], it's nothing short of a denial of reality to believe there will be no substantial loss of cures as a result of H.R. 3's price controls. Even the non-partisan Congressional Budget Office concedes the point.[4]

Given the ravages of Alzheimer's, Parkinson's, cancer, diabetes, ALS, Glioblastoma, and so many other diseases for which families today are without hope, Republicans believe even one cure lost is one too many.

Those who live in foreign countries with price controls have access to fewer new drugs than those living in the United States. Innovation has also plummeted: One study found that in the 1980s, pharmaceutical R&D in the EU "exceeded U.S. R&D by about 24 percent, but by 2004, EU R&D trailed U.S. R&D by about 15 percent," resulting in fewer new drug and fewer jobs.[5]

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[1] "Committee Leaders Announce Call for Comments on Bipartisan Medicare Part D Drug Pricing Legislation," Committee on Ways and Means, Republicans. 23 May 2019. Accessed 28 Oct 2009. https://gop-waysandmeans.house.gov/committee-leaders-announce-call-for-comments-on-bipartisan-medicare-part-d-drug-pricing-legislation/

[2] Facher, Lev, "Democrats" new logic on drug pricing: Developing slightly fewer medicines is OK if it means lower prices," *STAT News,* 28 Oct 2019, Accessed 31 Oct 2019, https://www.statnews.com/2019/10/28/democrats-new-logic-drug-prices-biomedical-innovation/

[3] DiMasi, JA, et al. Innovation in the pharmaceutical industry: new estimates of R&D costs. J Health Economics. 2016;47:20–33.

[4] Congressional Budget Office, "Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare," 11 Oct 2019, Accessed 31 Oct 2019, https://www.cbo.gov/publication/55722

[5] Joseph H. Golec, John A. Vernon. "European Pharmaceutical Price Regulation, Firm Profitability, and R&D Spending." November 2006, https://www.nber.org/papers/w12676

If the U.S. had adopted the price control policies used abroad, the world would not have as many treatments; longevity in the U.S. and globally would decline.[6]

That's not the American culture of hope and innovation.

Just as harmful, H.R. 3 discourages researchers from being the first to market a new life-saving cure. Instead it rewards those who delay their breakthroughs—to be second or even third to a market. That makes no sense.

Critics have long said drug companies spend too much time on these "me too drugs;" yet in H.R. 3, Democrats are rewarding that behavior. Why lead the globe in finding a cure to ALS? Why put an end to cancer? Under H.R. 3, it's smarter for companies to develop another statin.

Congress should support policies that reward the researchers taking the biggest risks to cure the toughest diseases our families face.

Moreover, nonpartisan experts have raised concerns H.R. 3 could be unconstitutional, with potential violations of the Takings Clause of the Fifth Amendment, Congress's Taxing Power, the Excessive Fines Clause of the Eighth Amendment.[7]

That finding is, in part, because it's outrageous to categorize a price setting operation backed with the force of a backbreaking federal 95% excise tax on all sales of a drug if a manufacturer refuses to take a payment based on a foreign price as part of a "negotiation."

Republicans will not accept this potentially unconstitutional premise, nor the cruel Democrat "trade-off" of fewer cures.

It's not worth it to deny the hope of new medicines and cures from making their way to our loved ones. It's not worth it to tell those suffering with life-threatening illnesses they have to keep waiting because we may never find a treatment. Our scientists and creators need the time and resources to focus on what matters most: discovering new, life-saving cures. H.R. 3 denies them that priority.

Does this mean that drug companies should get off scot-free in this process? Absolutely not. But H.R. 3 doesn't go after bad actors, it goes instead after cures. This is dangerous.

It doesn't have to be this way. Americans can have lower drug prices and spur more life-saving cures.

Committee members have bipartisan policies that Democrats and Republicans have worked on together that could be signed into law today. We all agree that we must get the incentives right within Medicare to punish bad actors and reward lower prices. And it is possible to achieve this without jeopardizing innovation and new cures.

During the partisan markup of H.R. 3, Republicans offered 25 amendments.[8] All were rejected by Democrats. One was a full bi-

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[6] Darius N. Lakdawalla, Dana P. Goldman, Pierre-Carl Michaud, Neeraj Sood, Robert Lempert, Ze Cong, Han de Vries, and Italo Gutierrez. U.S. Pharmaceutical Policy in A Global Marketplace. DOI 10.1377/hlthaff.28.1.w138

[7] Florko, Nicholas, "Nonpartisan congressional report suggests Pelosi's drug pricing bill could be found unconstitutional," *STAT,* 25 Oct 2019, Accessed 31 Oct 2019, https://www.statnews.com/2019/10/25/report-pelosi-drug-pricing-bill-unconstitutional/

[8] Ways and Means Republicans, "Markup of Health and Worker and Family Support Legislation", 22 Oct 2019, Accessed 31 Oct 2019, https://gop-waysandmeans.house.gov/event/markup-of-health-and-worker-and-family-support-legislation/

partisan substitute with over 40 policies to lower drug costs that could go to the President's desk today.[9] The substitute achieves the President's and Congress's shared goals of coming together to lower out-of-pocket costs for Americans without crushing innovation in a few key ways.

First, the amendment cracks down on overpriced drugs by going after bad actors and prevents anti-competitive actions from drug creators by pulling back the curtain on the drug supply chain. Additionally, the policies contained in the amendment empower patients to choose the most affordable medicines for them by getting patients more accessible and useful information about how much treatments cost.

Second, the amendment reduces the incentives in Medicare that lead to higher prices. This is done by reforming the way Medicare pays for drugs, including smarter add-on payments and having the program pay for the quality or care, instead of simply writing a paycheck for the site of the service.

Third, the amendment modernizes the successful Medicare prescription drug program by lowering seniors' out-of-pocket spending in the initial benefit and capping seniors' annual drug spending at $3,100.

Fourth, the amendment includes more generous tax benefits for families with high medical costs and lowers the costs of life-saving medical devices.

Finally, and most importantly, the bipartisan substitute amendment preserves the hope for future cures by rejecting partisan price controls.

Unfortunately, this commonsense amendment was rejected, as Congressional Democrats continue to look for cures for political illnesses rather than real ones. H.R. 3's "dictate or destroy" power will only halt valuable research into new life-saving medicines and give foreign countries dangerous influence over America's health care system.

It would be a grave mistake for patients if H.R. 3 were to become law. For all these reasons and more, Ways and Means Republicans reject H.R. 3 as ordered reported by Committee Democrats.

REP. KEVIN BRADY,
Republican Leader, Committee on Ways and Means.

DEVIN NUNES,
Republican Leader, Health Subcommittee Committee on Ways and Means.

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[9] "Amendment to the Amendment in the Nature of a Substitute to H.R. 3 Offered by Rep. Brady of Texas," Accessed 31 Oct 2019, https://gop-waysandmeans.house.gov/wp-content/uploads/2019/10/V9-A2.-Brady-AINS-FCR-wm-ans_01_xml2.pdf