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117TH CONGRESS
1ST SESSION

H. R. 5260

To amend titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices in the Medicare and Medicaid programs, to improve transparency related to pharmaceutical prices and transactions, to lower patients' out-of-pocket costs, and to ensure accountability to taxpayers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 14, 2021

Mr. PETERS (for himself, Mr. SCHRADER, Miss RICE of New York, Mrs. MURPHY of Florida, and Mr. CORREA) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices in the Medicare and Medicaid programs, to improve transparency related to pharmaceutical prices and transactions, to lower patients' out-of-pocket costs, and to ensure accountability to taxpayers, and for other purposes.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Reduced Costs and Continued Cures Act''.

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

TITLE I—ESTABLISHMENT OF PART B PAYMENT RULES FOR NEGOTIATION-ELIGIBLE DRUGS AND BIOLOGICALS

SEC. 101. ESTABLISHMENT OF PART B PAYMENT RULES FOR NEGOTIATION-ELIGIBLE DRUGS AND BIOLOGICALS.

Section 1847A of the Social Security Act (42 U.S.C. 1395w–3a) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by striking ''Subject to paragraph (7)'' and inserting ''Subject to paragraphs (7) and (9)'';

(B) in subparagraph (B), by striking at the end ''or'';

(C) in subparagraph (C), by striking the period at the end and inserting ''; or''; and

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

''(D) in the case of a negotiation-eligible drug or biological, the maximum allowable cost determined under paragraph (9).''; and

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

"(9) RULES FOR NEGOTIATION-ELIGIBLE DRUGS AND BIOLOGICALS.—

"(A) NOTIFICATION OF MANUFACTURERS OF NEGOTIATION-ELIGIBLE DRUGS AND BIOLOGICALS.—

"(i) IN GENERAL.—Not later than 180 days after the date of the enactment of this paragraph, the Secretary shall notify each manufacturer of each negotiation-eligible drug or biological that is subject to negotiation for payment under this part.

"(ii) NEGOTIATION-ELIGIBLE DRUG OR BIOLOGICAL.—In this paragraph, the term 'negotiation-eligible drug or biological' means a single source drug or biological (as defined in subparagraph (C)) for which each of the following have expired:

"(I) The period of regulatory data protections or exclusivity granted for such drug or biological (including for new chemical entities, biologics, orphan drugs, pediatric formulations, and clinical trials).

"(II) Subject to the succeeding sentence, the period of any patents

issued for such drug or biological up to 1 year after the approval of such drug or biological. In the case of small molecule product that is a such a drug or biological, the period of any patents listed in the publication, Approved Drug Products With Therapeutic Equivalence Evaluations (referred to as the 'Orange Book').

''(B) NEGOTIATION.—

''(i) IN GENERAL.—The Secretary and the manufacturer of a negotiation-eligible drug or biological shall during the negotiation period negotiate a maximum allowable cost for such drug or biological. In the case that the Secretary and the manufacturer do not determine a maximum allowable cost for such drug or biological, the Secretary shall determine the maximum allowable cost for such drug or biological at an amount that is at least 65 percent and not more than 75 percent of the average sales price of such drug or biological.

''(ii) MAXIMUM ALLOWABLE COST.—In this subparagraph, the term 'maximum

allowable cost' means the amount agreed to by the Secretary and the manufacturer of a negotiation-eligible drug or biological for a unit of such drug or biological that is not less than 65 percent and not more than 75 percent of the lowest average sales price of such drug or biological for the preceding 1-year period.

''(C) SINGLE SOURCE DRUG OR BIOLOGICAL.—For purposes of this paragraph, the term 'single source drug or biological' means—

''(i) a drug or drug product that—

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

''(II) is not the listed drug for any drug that is approved under section 505(j) and is marketed pursuant to such approval; or

''(ii) a biological product that—

''(I) is licensed under section 351(a) of the Public Health Service Act, including any product deemed to be licensed under such section pursu-

ant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act and is marketed pursuant to section 351 of the Public Health Service Act; and

''(II) is not the reference product for any biological product that is licensed and is marketed pursuant to such section of such Act.''.

TITLE II—MEDICARE

Subtitle A—Part B

SEC. 201. INCLUSION OF VALUE OF COUPONS IN DETERMINATION OF AVERAGE SALES PRICE FOR DRUGS AND BIOLOGICALS UNDER MEDICARE PART B.

Section 1847A(c) of the Social Security Act (42 U.S.C. 1395w–3a(c)) is amended—

(1) in paragraph (3)—

(A) by striking ''DISCOUNTS.—In calculating'' and inserting ''DISCOUNTS TO PURCHASERS AND COUPONS PROVIDED TO PRIVATELY INSURED INDIVIDUALS.—

''(A) DISCOUNTS TO PURCHASERS.—In calculating''; and

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

''(B) COUPONS PROVIDED TO REDUCE COST-SHARING.—For calendar quarters beginning on or after July 1, 2024, in calculating the manufacturer's average sales price under this subsection, such price shall include the value (as defined in paragraph (6)(J)) of any coupons provided under a drug coupon program of a manufacturer (as those terms are defined in subparagraphs (K) and (L), respectively, of paragraph (6)).''; and

(2) in paragraph (6), by adding at the end the following new subparagraphs:

''(J) VALUE.—The term 'value' means, with respect to a coupon (as defined in subparagraph (K)), the difference, if any, between—

''(i) the amount of any reduction or elimination of cost-sharing or other out-of-pocket costs described in such subparagraph to a patient as a result of the use of such coupon; and

''(ii) any charge to the patient for the use of such coupon.

"(K) COUPON.—The term 'coupon' means any financial support that is provided to a patient, either directly to the patient or indirectly to the patient through a physician, prescriber, pharmacy, or other provider, under a drug coupon program of a manufacturer (as defined in subparagraph (L)) that is used to reduce or eliminate cost-sharing or other out-of-pocket costs of the patient, including costs related to a deductible, coinsurance, or copayment, with respect to a drug or biological, including a biosimilar biological product, of the manufacturer.

"(L) DRUG COUPON PROGRAM.—

"(i) IN GENERAL.—Subject to clause (ii), the term 'drug coupon program' means, with respect to a manufacturer, a program through which the manufacturer provides coupons to patients as described in subparagraph (K).

"(ii) EXCLUSIONS.—Such term does not include—

"(I) a patient assistance program operated by a manufacturer that provides free or discounted drugs or biologicals, including biosimilar bio-

logical products, (through in-kind donations) to patients of low income; or

''(II) a contribution by a manufacturer to a nonprofit or Foundation that provides free or discounted drugs or biologicals, including biosimilar biological products, (through in-kind donations) to patients of low income.''.

SEC. 202. PAYMENT FOR BIOSIMILAR BIOLOGICAL PRODUCTS DURING INITIAL PERIOD.

Section 1847A(c)(4) of the Social Security Act (42 U.S.C. 1395w–3a(c)(4)) is amended—

(1) in each of subparagraphs (A) and (B), by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively, and moving such subclauses 2 ems to the right;

(2) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii) and moving such clauses 2 ems to the right;

(3) by striking ''UNAVAILABLE.—In the case'' and inserting ''UNAVAILABLE.—

''(A) IN GENERAL.—Subject to subparagraph (B), in the case''; and

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

''(B) LIMITATION ON PAYMENT AMOUNT FOR BIOSIMILAR BIOLOGICAL PRODUCTS DURING INITIAL PERIOD.—In the case of a biosimilar biological product furnished on or after July 1, 2023, in lieu of applying subparagraph (A) during the initial period described in such subparagraph with respect to the biosimilar biological product, the amount payable under this section for the biosimilar biological product is the lesser of the following:

''(i) The amount determined under clause (ii) of such subparagraph for the biosimilar biological product.

''(ii) The amount determined under subsection (b)(1)(B) for the reference biological product.''.

SEC. 203. TEMPORARY INCREASE IN MEDICARE PART B PAYMENT FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

Section 1847A(b)(8) of the Social Security Act (42 U.S.C. 1395w–3a(b)(8)) is amended—

(1) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and indenting appropriately;

(2) by striking ''PRODUCT.—The amount'' and inserting the following: ''PRODUCT.—

''(A) IN GENERAL.—Subject to subparagraph (B), the amount''; and

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

''(B) TEMPORARY PAYMENT INCREASE FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

''(i) IN GENERAL.—Beginning January 1, 2023, in the case of a biosimilar biological product described in paragraph (1)(C) that is furnished during the applicable 5-year period for such product, the amount specified in this paragraph for such product is an amount equal to the lesser of the following:

''(I) The amount specified in subparagraph (A) for such product if clause (ii) of such subparagraph was applied by substituting '8 percent' for '6 percent'.

''(II) The amount determined under subsection (b)(1)(B) for the reference biological product.

"(ii) APPLICABLE 5-YEAR PERIOD.—For purposes of clause (i), the applicable 5-year period for a biosimilar biological product is—

"(I) in the case of such a product for which payment was made under this paragraph as of December 31, 2012, the 5-year period beginning on January 1, 2023; and

"(II) in the case of such a product that is not described in subclause (I), the 5-year period beginning on the first day of the first calendar quarter in which payment was made for such product under this paragraph.".

SEC. 204. 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, 2024, 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, 2024, 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, pro-

vide 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 2025, shall be the dollar amount specified under such subparagraph for 2024, increased by the percentage in-

crease 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) PROSPECTIVE PAYMENT AMOUNT BENCHMARK QUARTER.—The term 'prospective 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, 2024' 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, 2024.

''(C) EXEMPTION FOR SHORTAGES.—The Secretary may reduce or waive the rebate amount under paragraph (1)(B) with respect to a part B rebatable drug that is described as

currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act or in the case of other exigent circumstances, as determined by the Secretary.

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

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

''(ii) in the case such drug is determined (pursuant to such section 1192(c)) to no longer be a selected drug, for each applicable year beginning after the price applicability period with respect to such drug, clause (i) of paragraph (3)(C) shall be applied as if the term 'payment amount benchmark quarter' were defined under

paragraph (3)(D) as the calendar quarter beginning January 1 of the last year beginning during such price applicability period with respect to such selected drug and clause (ii) of paragraph (3)(C) shall be applied as if the term 'benchmark period CPI–U' were defined under paragraph (3)(E) as if the reference to 'July 2015' under such paragraph were a reference to the July of the year preceding such last year.

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

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

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

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

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

''(8) STUDY AND REPORT.—

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

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

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

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

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

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

prices for the benchmark period and the rebate period.''.

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

(1) in subsection (a)—

(A) in paragraph (1)—

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

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

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

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

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

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

''(9) In the case of a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) for which payment under this subsection is not packaged into a payment for a covered OPD service (as defined in subsection (t)(1)(B)) (or group of services) furnished on or after July 1, 2024, under the system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1834(x)(5), paragraph (1)(DD) of subsection (a), and the flush left matter following paragraph

(9) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1834(x)(5) and subsection (a) apply under such section and subsection.''; and

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

''(F) PART B REBATABLE DRUGS.—In the case of a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) for which payment under this part is not packaged into a payment for a service furnished on or after July 1, 2024, under the system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1834(x)(5), paragraph (1)(DD) of subsection (a), and the flush left matter following paragraph (9) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1834(x)(5) and subsection (a) apply under such section and subsection.''.

(c) CONFORMING AMENDMENTS.—

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

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

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

SEC. 205. ESTABLISHMENT OF MAXIMUM ADD-ON PAYMENT FOR DRUGS AND BIOLOGICALS.

(a) IN GENERAL.—Section 1847A of the Social Security Act (42 U.S.C. 1395w–3a) is amended—

(1) in subsection (b)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking ''paragraph (7)'' and inserting ''paragraphs (7) and (9)''; and

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

''(9) MAXIMUM ADD-ON PAYMENT AMOUNT.—

''(A) IN GENERAL.—In determining the payment amount under the provisions of subparagraph (A), (B), or (C) of paragraph (1) of this subsection, subsection (c)(4)(A)(ii), or subsection (d)(3)(C) for a drug or biological furnished on or after January 1, 2024, if the applicable add-on payment (as defined in subparagraph (B)) for each drug or biological on a claim for a date of service exceeds the maximum add-on payment amount specified under subparagraph (C) for the drug or biological, then the payment amount otherwise determined for the drug or biological under those provisions, as applicable, shall be reduced by the amount of such excess.

''(B) APPLICABLE ADD-ON PAYMENT DEFINED.—In this paragraph, the term 'applicable add-on payment' means the following amounts, determined without regard to the application of subparagraph (A):

"(i) In the case of a multiple source drug, an amount equal to the difference between—

"(I) the amount that would otherwise be applied under paragraph (1)(A); and

"(II) the amount that would be applied under such paragraph if '100 percent' were substituted for '106 percent'.

"(ii) In the case of a single source drug or biological, an amount equal to the difference between—

"(I) the amount that would otherwise be applied under paragraph (1)(B); and

"(II) the amount that would be applied under such paragraph if '100 percent' were substituted for '106 percent'.

"(iii) In the case of a biosimilar biological product, the amount otherwise determined under paragraph (8)(B).

"(iv) In the case of a drug or biological during the initial period described in

subsection (c)(4)(A), an amount equal to the difference between—

"(I) the amount that would otherwise be applied under subsection (c)(4)(A)(ii); and

"(II) the amount that would be applied under such subsection if '100 percent' were substituted, as applicable, for—

"(aa) '103 percent' in subclause (I) of such subsection; or

"(bb) any percent in excess of 100 percent applied under subclause (II) of such subsection.

"(v) In the case of a drug or biological to which subsection (d)(3)(C) applies, an amount equal to the difference between—

"(I) the amount that would otherwise be applied under such subsection; and

"(II) the amount that would be applied under such subsection if '100 percent' were substituted, as applicable, for—

''(aa) any percent in excess of 100 percent applied under clause (i) of such subsection; or

''(bb) '103 percent' in clause (ii) of such subsection.

''(C) MAXIMUM ADD-ON PAYMENT AMOUNT SPECIFIED.—For purposes of subparagraph (A), the maximum add-on payment amount specified in this subparagraph is—

''(i) for each of 2024 through 2031, $1,000; and

''(ii) for a subsequent year, the amount specified in this subparagraph for the preceding year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year.

Any amount determined under this subparagraph that is not a multiple of $10 shall be rounded to the nearest multiple of $10.''; and

(2) in subsection (c)(4)(A)(ii), by striking ''in the case'' and inserting ''subject to subsection (b)(9), in the case''.

(b) CONFORMING AMENDMENTS RELATING TO SEPARATELY PAYABLE DRUGS.—

(1) OPPS.—Section 1833(t)(14) of the Social Security Act (42 U.S.C. 1395l(t)(14)) is amended—

(A) in subparagraph (A)(iii)(II), by inserting ", subject to subparagraph (I)" after "are not available"; and

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

"(I) APPLICATION OF MAXIMUM ADD-ON PAYMENT FOR SEPARATELY PAYABLE DRUGS AND BIOLOGICALS.—In establishing the amount of payment under subparagraph (A) for a specified covered outpatient drug that is furnished as part of a covered OPD service (or group of services) on or after January 1, 2024, if such payment is determined based on the average price for the year established under section 1847A pursuant to clause (iii)(II) of such subparagraph, the provisions of subsection (b)(9) of section 1847A shall apply to the amount of payment so established in the same manner as such provisions apply to the amount of payment under section 1847A.".

(2) ASC.—Section 1833(i)(2)(D) of the Social Security Act (42 U.S.C. 1395l(i)(2)(D)) is amended—

(A) by moving clause (v) 6 ems to the left;

(B) by redesignating clause (vi) as clause (vii); and

(C) by inserting after clause (v) the following new clause:

''(vi) If there is a separate payment under the system described in clause (i) for a drug or biological furnished on or after January 1, 2024, the provisions of subsection (t)(14)(I) shall apply to the establishment of the amount of payment for the drug or biological under such system in the same manner in which such provisions apply to the establishment of the amount of payment under subsection (t)(14)(A).''.

SEC. 206. GAO STUDY AND REPORT ON AVERAGE SALES PRICE.

(a) STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States (in this section referred to as the ''Comptroller General'') shall conduct a study on spending for applicable drugs under part B of title XVIII of the Social Security Act.

(2) APPLICABLE DRUGS DEFINED.—In this section, the term ''applicable drugs'' means drugs and biologicals—

(A) for which reimbursement under such part B is based on the average sales price of the drug or biological; and

(B) that account for the largest percentage of total spending on drugs and biologicals under such part B (as determined by the Comptroller General, but in no case less that 25 drugs or biologicals).

(3) REQUIREMENTS.—The study under paragraph (1) shall include an analysis of the following:

(A) The extent to which each applicable drug is paid for—

(i) under such part B for Medicare beneficiaries; or

(ii) by private payers in the commercial market.

(B) Any change in Medicare spending or Medicare beneficiary cost-sharing that would occur if the average sales price of an applicable drug was based solely on payments by private payers in the commercial market.

(C) The extent to which drug manufacturers provide rebates, discounts, or other price concessions to private payers in the commercial market for applicable drugs, which the manufacturer includes in its average sales price calculation, for—

(i) formulary placement;

(ii) utilization management considerations; or

(iii) other purposes.

(D) Barriers to drug manufacturers providing such price concessions for applicable drugs.

(E) Other areas determined appropriate by the Comptroller General.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

SEC. 207. AUTHORITY TO USE ALTERNATIVE PAYMENT FOR DRUGS AND BIOLOGICALS TO PREVENT POTENTIAL DRUG SHORTAGES.

(a) IN GENERAL.—Section 1847A(e) of the Social Security Act (42 U.S.C. 1395w–3a(e)) is amended—

(1) by striking ''PAYMENT IN RESPONSE TO PUBLIC HEALTH EMERGENCY.—In the case'' and inserting ''PAYMENTS.—

''(1) IN RESPONSE TO PUBLIC HEALTH EMERGENCY.—In the case''; and

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

''(2) PREVENTING POTENTIAL DRUG SHORTAGES.—

''(A) IN GENERAL.—In the case of a drug or biological that the Secretary determines is described in subparagraph (B) for one or more quarters beginning on or after January 1, 2024, the Secretary may use wholesale acquisition cost (or other reasonable measure of a drug or biological price) instead of the manufacturer's average sales price for such quarters and for subsequent quarters until the end of the quarter in which such drug or biological is removed from the drug shortage list under section 506E of the Federal Food, Drug, and Cos-

metic Act, or in the case of a drug or biological described in subparagraph (B)(ii), the date on which the Secretary determines that the total manufacturing capacity or the total number of manufacturers of such drug or biological is sufficient to mitigate a potential shortage of the drug or biological.

''(B) DRUG OR BIOLOGICAL DESCRIBED.—For purposes of subparagraph (A), a drug or biological described in this subparagraph is a drug or biological—

''(i) that is listed on the drug shortage list maintained by the Food and Drug Administration pursuant to section 506E of the Federal Food, Drug, and Cosmetic Act, and with respect to which any manufacturer of such drug or biological notifies the Secretary of a permanent discontinuance or an interruption that is likely to lead to a meaningful disruption in the manufacturer's supply of that drug pursuant to section 506C(a) of such Act; or

''(ii) that—

''(I) is described in section 506C(a) of such Act;

"(II) was listed on the drug shortage list maintained by the Food and Drug Administration pursuant to section 506E of such Act within the preceding 5 years; and

"(III) for which the total manufacturing capacity of all manufacturers with an approved application for such drug or biological that is currently marketed or total number of manufacturers with an approved application for such drug or biological that is currently marketed declines during a 6-month period, as determined by the Secretary.

"(C) PROVISION OF ADDITIONAL INFORMATION.—For each quarter in which the amount of payment for a drug or biological described in subparagraph (B) pursuant to subparagraph (A) exceeds the amount of payment for the drug or biological otherwise applicable under this section, each manufacturer of such drug or biological shall provide to the Secretary information related to the potential cause or causes

of the shortage and the expected duration of the shortage with respect to such drug.''.

(b) TRACKING SHORTAGE DRUGS THROUGH CLAIMS.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish a mechanism (such as a modifier) for purposes of tracking utilization under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) of drugs and biologicals listed on the drug shortage list maintained by the Food and Drug Administration pursuant to section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e).

(c) HHS REPORT AND RECOMMENDATIONS.—

(1) IN GENERAL.—Not later than July 1, 2024, the Secretary shall submit to Congress a report on shortages of drugs within the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.). The report shall include—

(A) an analysis of—

(i) the effect of drug shortages on Medicare beneficiary access, quality, safety, and out-of-pocket costs;

(ii) the effect of drug shortages on health providers, including hospitals and physicians, across the Medicare program;

(iii) the current role of the Centers for Medicare & Medicaid Services (CMS) in addressing drug shortages, including CMS's working relationship and communication with other Federal agencies and stakeholders;

(iv) the role of all actors in the drug supply chain (including drug manufacturers, distributors, wholesalers, secondary wholesalers, group purchasing organizations, hospitals, and physicians) on drug shortages within the Medicare program; and

(v) payment structures and incentives under parts A, B, C, and D of the Medicare program and their effect, if any, on drug shortages; and

(B) relevant findings and recommendations to Congress.

(2) PUBLIC AVAILABILITY.—The report under this subsection shall be made available to the public.

(3) CONSULTATION.—The Secretary shall consult with the drug shortage task force authorized under section 506D(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356d(a)(1)(A))

in preparing the report under this subsection, as appropriate.

SEC. 208. CHANGE IN DEFINITION OF STRENGTH FOR THE PURPOSES OF DETERMINING INTERCHANGEABILITY OF BIOLOGICAL AND BIOSIMILAR PRODUCTS.

(a) Section 351(i) of the Public Health Service Act is amended by inserting the following after paragraph (4):

''(5) The term 'strength', in reference to a biological product intended for administration by injection, means the total content of drug substance in the dosage form without regard to the concentration of drug substance or total volume of the biological product.''.

(b) Section 351(k)(7)(C)(ii)(I) of the Public Health Service Act is amended by inserting ''concentration,'' after ''delivery device,''.

Subtitle B—Part D

SEC. 209. MEDICARE PART D MODERNIZATION REDESIGN.

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

(1) in paragraph (2)—

(A) in subparagraph (A), in the matter preceding clause (i), by inserting ''for a year

preceding 2024 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2024 and each subsequent year'' after ''paragraph (3)'';

(B) in subparagraph (C)—

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

(ii) in clause (ii)(III), by striking ''and each subsequent year'' and inserting '', 2021, 2022, and 2023''; and

(C) in subparagraph (D)—

(i) in clause (i)—

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

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

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

(2) in paragraph (3)(A)—

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

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

(3) in paragraph (4)—

(A) in subparagraph (A)—

(i) in clause (i)—

(I) by redesignating subclauses (I) and (II) as items (aa) and (bb), respectively, and indenting appropriately;

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

''(I) for a year preceding 2024, the greater of—'';

(III) by striking the period at the end of item (bb), as redesignated by

subclause (I), and inserting ''; and''; and

(IV) by adding at the end the following:

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

(ii) in clause (ii)—

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

(II) by adding at the end the following new sentence: ''The Secretary shall continue to calculate the dollar amounts specified in clause (i)(I)(aa), including with the adjustment under this clause, after 2023 for purposes of section 1860D–14(a)(1)(D)(iii).'';

(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, 2022, and 2023''; and

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

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

''(VII) for 2024, is equal to—

''(aa) $3,100 for beneficiaries determined to have income that is over 400 percent of the Federal poverty line applicable to a family of the size involved;

''(bb) $1,800 for beneficiaries determined to have income that is between 300 to 400 percent of the Federal poverty line applicable to a family of the size involved; or

''(cc) $1,200 for beneficiaries determined to have income that is below 300 percent of the Federal poverty line applicable to a family of the size involved; or

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

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

(C) in subparagraph (C)(i), by striking ''and for amounts'' and inserting ''and for a year preceding 2024 for amounts''; and

(D) in subparagraph (E), by striking ''In applying'' and inserting ''For each of 2011 through 2023, in applying''.

(b) DECREASING REINSURANCE PAYMENT AMOUNT.—Section 1860D–15(b) of the Social Security Act (42 U.S.C. 1395w–115(b)) is amended—

(1) in paragraph (1)—

(A) by striking ''equal to 80 percent'' and inserting ''equal to—

''(A) for a year preceding 2024, 80 percent'';

(B) in subparagraph (A), as added by paragraph (1), by striking the period at the end and inserting ''; and''; and

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

''(B) for 2024 and each subsequent year, the sum of—

''(i) an amount equal to the applicable percentage specified in paragraph (5)(A) of such allowable reinsurance costs attributable to that portion of gross 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) with respect to applicable drugs (as defined in section 1860D–14B(g)(2)); and

''(ii) an amount equal to the applicable percentage specified in paragraph (5)(B) of allowable reinsurance costs attributable to that portion of gross 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) with

respect to covered part D drugs that are not applicable drugs (as so defined).''; and

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

''(5) APPLICABLE PERCENTAGE SPECIFIED.—For purposes of paragraph (1)(B), the applicable percentage specified in this paragraph is—

''(A) with respect to applicable drugs (as defined in section 1860D–14B(g)(2))—

''(i) for 2024, 60 percent;

''(ii) for 2025, 40 percent; and

''(iii) for 2026 and each subsequent year, 20 percent; and

''(B) with respect to covered part D drugs that are not applicable drugs (as so defined)—

''(i) for 2024, 80 percent;

''(ii) for 2025, 60 percent; and

''(iii) for 2026 and each subsequent year, 40 percent.''.

(c) MANUFACTURER DISCOUNT PROGRAM DURING INITIAL AND CATASTROPHIC PHASES OF COVERAGE.—

(1) IN GENERAL.—Part D of title XVIII of the Social Security Act is amended by inserting after section 1860D–14A (42 U.S.C. 1495w–114) the following new section:

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

"(a) ESTABLISHMENT.—The Secretary shall establish a manufacturer discount program (in this section referred to as the 'program'). Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of the duties described in subsection (c). The Secretary shall establish a model agreement for use under the program by not later than January 1, 2023, in consultation with manufacturers, and allow for comment on such model agreement.

"(b) TERMS OF AGREEMENT.—

"(1) IN GENERAL.—

"(A) AGREEMENT.—An agreement under this section shall require the manufacturer to provide applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer that are dispensed on or after January 1, 2024.

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

''(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.

''(5) EFFECTIVE DATE OF AGREEMENT.—An agreement under this section shall take effect on a date determined appropriate by the Secretary, which may be at the start of a calendar quarter.

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

''(6) FUNDING.—For purposes of carrying out this section, 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 $4,000,000 for each of fiscal years 2021 through 2024, to remain available until expended.

''(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; and

''(C) has incurred costs for covered part D drugs in the year that are above the annual deductible specified in section 1860D–2(b)(1) for such year.

''(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(c) of the Federal Food, Drug, and Cosmetic Act or, in the case of a bio-

logic product, licensed under section 351 of the Public Health Service Act (including 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.—Except as provided in subparagraph (B), the term 'discounted price' means 90 percent of the negotiated price of the applicable drug of a manufacturer.

"(B) PHASE-IN FOR CERTAIN DRUGS DISPENSED FOR SUBSIDY ELIGIBLE INDIVIDUALS.—

"(i) IN GENERAL.—In the case of an applicable drug of a specified manufacturer (as defined in clause (ii)) that is dispensed for an applicable beneficiary who is a subsidy eligible individual (as defined in section 1860D–14(a)(3), the term 'discounted price' means the specified LIS percent (as defined in clause (iii)) of the negotiated price of the applicable drug of the manufacturer.

"(ii) SPECIFIED MANUFACTURER.—In this subparagraph, the term 'specified manufacturer' means a manufacturer of an applicable drug for which, in the calendar year 2 years prior to the current plan year (referred to in this clause as the 'applicable period'), the total reimbursement under

this title during the applicable period represented less than 1 percent of the total reimbursement under this title for all prescription drugs during such period.

''(iii) SPECIFIED LIS PERCENT.—In this subparagraph, the term 'specified LIS percent' means—

''(I) for 2024, 98 percent;

''(II) for 2025, 97 percent;

''(III) for 2026, 96 percent;

''(IV) for 2027, 95 percent;

''(V) for 2028, 94 percent;

''(VI) for 2029, 93 percent;

''(VII) for 2030, 92 percent;

''(VIII) for 2031, 91 percent; and

''(IX) for 2032 and each subsequent year, 90 percent.

''(C) 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.

''(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 1860D–2(d)(1)(B), 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).''.

(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 to applicable drugs dispensed on or after January 1, 2024, and, subject to paragraph (2), agreements under this section shall be terminated as of such date.

''(2) CONTINUED APPLICATION FOR APPLICABLE DRUGS DISPENSED PRIOR TO SUNSET.—The provisions of this section (including all responsibilities and duties) shall continue to apply after January 1, 2024, with respect to applicable drugs dispensed prior to such date.''.

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

(A) in subsection (b)(2)(C)(iii)—

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

''(I) the reinsurance''; and

(ii) by adding at the end the following:

''(II) for 2024 and each subsequent year, the manufacturer dis-

counts provided under section 1860D–14B 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 added by clause (i) of this subparagraph, by adding ''and'' at the end; and

(iii) by adding at the end the following:

''(ii) for 2024 and each subsequent year, the manufacturer discounts provided under section 1860D–14B;''.

(4) CLARIFICATION REGARDING EXCLUSION OF MANUFACTURER DISCOUNTS FROM TROOP.—Section 1860D–2(b)(4) of the Social Security Act (42 U.S.C. 1395w–102(b)(4)) is amended—

(A) in subparagraph (C), by inserting ''and subject to subparagraph (F)'' after ''subparagraph (E)''; and

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

''(F) CLARIFICATION REGARDING EXCLUSION OF MANUFACTURER DISCOUNTS.—In applying subparagraph (A), incurred costs shall not include any manufacturer discounts provided under section 1860D–14B.''.

(d) DETERMINATION OF ALLOWABLE REINSURANCE COSTS.—Section 1860D–15(b) of the Social Security Act (42 U.S.C. 1395w–115(b)) is amended—

(1) in paragraph (2)—

(A) by striking ''COSTS.—For purposes'' and inserting: ''COSTS.—

''(A) IN GENERAL.—Subject to subparagraph (B), for purposes''; and

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

''(B) INCLUSION OF MANUFACTURER DISCOUNTS ON APPLICABLE DRUGS.—For purposes of applying subparagraph (A), the term 'allowable reinsurance costs' shall include the portion of the negotiated price (as defined in section 1860D–14B(g)(6)) of an applicable drug (as defined in section 1860D–14B(g)(2)) that was paid by a manufacturer under the manufacturer discount program under section 1860D–14B.''; and

(2) in paragraph (3)—

(A) in the first sentence, by striking ''For purposes'' and inserting ''Subject to paragraph (2)(B), for purposes''; and

(B) in the second sentence, by inserting ''or, in the case of an applicable drug, by a manufacturer'' after ''by the individual or under the plan''.

(e) UPDATING RISK ADJUSTMENT METHODOLOGIES TO ACCOUNT FOR PART D MODERNIZATION REDESIGN.—Section 1860D–15(c) of the Social Security Act (42 U.S.C. 1395w–115(c)) is amended by adding at the end the following new paragraph:

''(3) UPDATING RISK ADJUSTMENT METHODOLOGIES TO ACCOUNT FOR PART D MODERNIZATION REDESIGN.—The Secretary shall update the risk adjustment methodologies used to adjust bid amounts pursuant to this subsection as appropriate to take into account changes in benefits under this part pursuant to the amendments made by section 2 of the Seniors Prescription Drug Relief Act.''.

(f) CONDITIONS FOR COVERAGE OF DRUGS UNDER THIS PART.—Section 1860D–43 of the Social Security Act (42 U.S.C. 1395w–153) is amended—

(1) in subsection (a)—

(A) in paragraph (2), by striking ''and'' at the end;

(B) in paragraph (3), by striking the period at the end and inserting a semicolon; and

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

''(4) participate in the manufacturer discount program under section 1860D–14B;

''(5) have entered into and have in effect an agreement described in subsection (b) of such section 1860D–14B with the Secretary; and

''(6) 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 1860D–14B.'';

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

''(b) EFFECTIVE DATE.—Paragraphs (1) through (3) of subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011, and before January 1, 2024, and paragraphs (4) through (6) of such subsection shall apply to covered part D drugs dispensed on or after January 1, 2024.''; and

(3) in subsection (c), by striking paragraph (2) and inserting the following:

''(2) the Secretary determines that in the period beginning on January 1, 2011, and ending on December 31, 2011 (with respect to paragraphs (1) through (3) of subsection (a)), or the period beginning on January 1, 2024, and ending December 31, 2024 (with respect to paragraphs (4) through (6) of such subsection), there were extenuating circumstances.''.

(g) CONFORMING AMENDMENTS.—

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

(A) in subsection (a)(2)(A)(i)(I), by striking '', or an increase in the initial'' and inserting ''or for a year preceding 2024 an increase in the initial'';

(B) in subsection (c)(1)(C)—

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

(ii) by inserting ''for a year preceding 2024 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2024 and each subsequent year''

after ''subsection (b)(3) for the year'' each place it appears; and

(C) in subsection (d)(1)(A), by striking ''or an initial'' and inserting ''or for a year preceding 2024 an initial''.

(2) Section 1860D–4(a)(4)(B)(i) of the Social Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is amended by striking ''the initial'' and inserting ''for a year preceding 2024, the initial''.

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

(A) in paragraph (1)—

(i) in subparagraph (C), by striking ''The continuation'' and inserting ''For a year preceding 2024, the continuation'';

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

(iii) in subparagraph (E), by striking ''The elimination'' and inserting ''For a year preceding 2024, the elimination''; and

(B) in paragraph (2)—

(i) in subparagraph (C), by striking ''The continuation'' and inserting ''For a

year preceding 2024, the continuation''; and

(ii) in subparagraph (E)—

(I) by inserting ''for a year preceding 2024,'' after ''subsection (c)''; and

(II) 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)(B)(4)(B)(i)'' and inserting ''section 1860D–2(b)(B)(4)(C)(i)''.

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

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

''(i) for years prior to 2024, any discount'';

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

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

''(ii) for 2024 and each subsequent year, any discount provided pursuant to section 1860D–14B.''.

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

(A) by inserting ''for a year before 2024'' after ''1860D–2(b)(3)''; and

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

(h) EFFECTIVE DATE.—The amendments made by this section shall apply to plan year 2024 and subsequent plan years.

SEC. 210. PUBLIC DISCLOSURE OF DRUG DISCOUNTS AND OTHER PHARMACY BENEFIT MANAGER (PBM) PROVISIONS.

(a) PUBLIC DISCLOSURE OF DRUG DISCOUNTS.—

(1) IN GENERAL.—Section 1150A of the Social Security Act (42 U.S.C. 1320b–23) is amended—

(A) in subsection (c), in the matter preceding paragraph (1), by striking ''this section'' and inserting ''subsection (b)(1)''; and

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

''(e) PUBLIC AVAILABILITY OF CERTAIN INFORMATION.—

''(1) IN GENERAL.—Subject to paragraphs (2) and (3), in order to allow patients and employers to compare PBMs' ability to negotiate rebates, discounts, and price concessions and the amount of such rebates, discounts, and price concessions that are passed through to plan sponsors, not later than July 1, 2025, the Secretary shall make available on the Internet website of the Department of Health and Human Services the information provided to the Secretary and described in paragraphs (2) and (3) of subsection (b) with respect to each PBM.

''(2) LAG IN DATA.—The information made available in a plan year under paragraph (1) shall not include information with respect to such plan year or the two preceding plan years.

''(3) CONFIDENTIALITY.—The Secretary shall ensure that such information is displayed in a manner that prevents the disclosure of information on rebates, discounts, and price concessions with respect to an individual drug or an individual PDP sponsor, MA organization, or qualified health benefits plan.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1)(A) shall take effect on January 1, 2025.

(b) PLAN AUDIT OF PHARMACY BENEFIT MANAGER DATA.—Section 1860D–2(d)(3) of the Social Security Act (42 U.S.C. 1395w–102(d)(3)) is amended—

(1) by striking ''AUDITS.—To protect'' and inserting the following: ''AUDITS.—

''(A) AUDITS OF PLANS BY THE SECRETARY.—To protect''; and

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

''(B) AUDITS OF PHARMACY BENEFIT MANAGERS BY PDP SPONSORS AND MA ORGANIZATIONS.—

''(i) IN GENERAL.—Beginning January 1, 2025, in order to ensure that—

''(I) contracting terms between a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan and its contracted or owned pharmacy benefit manager are met; and

''(II) the PDP sponsor and MA organization can account for the cost of each covered part D drug net of all direct and indirect remuneration,

the PDP sponsor or MA organization shall conduct financial audits.

''(ii) INDEPENDENT THIRD PARTY.—An audit described in clause (i) shall—

''(I) be conducted by an independent third party; and

''(II) account and reconcile flows of funds that determine the net cost of covered part D drugs, including direct and indirect remuneration from drug manufacturers and pharmacies or provided to pharmacies.

''(iii) REBATE AGREEMENTS.—A PDP sponsor and an MA organization shall require pharmacy benefit managers to make rebate contracts with drug manufacturers made on their behalf available under audits described in clause (i).

''(iv) CONFIDENTIALITY AGREEMENTS.—Audits described in clause (i) shall be subject to confidentiality agreements to prevent, except as required under clause (vii), the redisclosure of data transmitted under the audit.

"(v) FREQUENCY.—A financial audit under clause (i) shall be conducted periodically (but in no case less frequently than once every 2 years).

"(vi) TIMEFRAME FOR PBM TO PROVIDE INFORMATION.—A PDP sponsor and an MA organization shall require that a pharmacy benefit manager that is being audited under clause (i) provide (as part of their contracting agreement) the requested information to the independent third party conducting the audit within 45 days of the date of the request.

"(vii) SUBMISSION OF AUDIT REPORTS TO THE SECRETARY.—

"(I) IN GENERAL.—A PDP sponsor and an MA organization shall submit to the Secretary the final report on any audit conducted under clause (i) within 30 days of the PDP sponsor or MA organization receiving the report from the independent third party conducting the audit.

"(II) REVIEW.—The Secretary shall review final reports submitted

under clause (i) to determine the extent to which the goals specified in subclauses (I) and (II) of subparagraph (B)(i) are met.

''(III) CONFIDENTIALITY.—Notwithstanding any other provision of law, information disclosed in a report submitted under clause (i) related to the net cost of a covered part D drug is confidential and shall not be disclosed by the Secretary or a Medicare contractor.

''(viii) NOTICE OF NONCOMPLIANCE.—A PDP sponsor and an MA organization shall notify the Secretary if any pharmacy benefit manager is not complying with requests for access to information required under an audit under clause (i).

''(ix) CIVIL MONETARY PENALTIES.—

''(I) IN GENERAL.—Subject to subclause (II), if the Secretary determines that a PDP sponsor or an MA organization has failed to conduct an audit under clause (i), the Secretary

may impose a civil monetary penalty of not more than $10,000 for each day of such noncompliance.

''(II) PROCEDURE.—The provisions of section 1128A, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section, shall apply to civil monetary penalties under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A.''.

(c) DISCLOSURE TO PHARMACY OF POST-POINT-OF-SALE PHARMACY PRICE CONCESSIONS AND INCENTIVE PAYMENTS.—Section 1860D–2(d)(2) of the Social Security Act (42 U.S.C. 1395w–102(d)(2)) is amended—

(1) by striking ''DISCLOSURE.—A PDP sponsor'' and inserting the following: ''DISCLOSURE.—

''(A) TO THE SECRETARY.—A PDP sponsor''; and

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

''(B) TO PHARMACIES.—

''(i) IN GENERAL.—For plan year 2025 and subsequent plan years, a PDP

sponsor offering a prescription drug plan and an MA organization offering an MA–PD plan shall report any pharmacy price concession or incentive payment that occurs with respect to a pharmacy after payment for covered part D drugs at the point-of-sale, including by an intermediary organization with which a PDP sponsor or MA organization has contracted, to the pharmacy.

''(ii) TIMING.—The reporting of price concessions and incentive payments to a pharmacy under clause (i) shall be made on a periodic basis (but in no case less frequently than annually).

''(iii) CLAIM LEVEL.—The reporting of price concessions and incentive payments to a pharmacy under clause (i) shall be at the claim level or approximated at the claim level if the price concession or incentive payment was applied at a level other than at the claim level.''.

(d) DISCLOSURE OF P&T COMMITTEE CONFLICTS OF INTEREST.—

(1) IN GENERAL.—Section 1860D–4(b)(3)(A) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)(A)) is amended by adding at the end the following new clause:

"(iii) DISCLOSURE OF CONFLICTS OF INTEREST.—With respect to plan year 2025 and subsequent plan years, a PDP sponsor of a prescription drug plan and an MA organization offering an MA–PD plan shall, as part of its bid submission under section 1860D–11(b), provide the Secretary with a completed statement of financial conflicts of interest, including with manufacturers, from each member of any pharmacy and therapeutic committee used by the sponsor or organization pursuant to this paragraph.".

(2) INCLUSION IN BID.—Section 1860D–11(b)(2) of the Social Security Act (42 U.S.C. 1395w–111(b)(2)) is amended—

(A) by redesignating subparagraph (F) as subparagraph (G); and

(B) by inserting after subparagraph (E) the following new subparagraph:

''(F) P&T COMMITTEE CONFLICTS OF INTEREST.—The information required to be disclosed under section 1860D–4(b)(3)(A)(iii).''.

(e) INFORMATION ON DIRECT AND INDIRECT REMUNERATION REQUIRED TO BE INCLUDED IN BID.—Section 1860D–11(b) of the Social Security Act (42 U.S.C. 1395w–111(b)) is amended—

(1) in paragraph (1), by adding at the end the following new sentence: ''With respect to actual amounts of direct and indirect remuneration submitted pursuant to clause (v) of paragraph (2), such amounts shall be consistent with data reported to the Secretary in a prior year.''; and

(2) in paragraph (2)(C)—

(A) in clause (iii), by striking ''and'' at the end;

(B) in clause (iv), by striking the period at the end and inserting the following: '', and, with respect to plan year 2025 and subsequent plan years, actual and projected administrative expenses assumed in the bid, categorized by the type of such expense, including actual and projected price concessions retained by a pharmacy benefit manager; and''; and

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

"(v) with respect to plan year 2025 and subsequent plan years, actual and projected direct and indirect remuneration, categorized as received from each of the following:

"(I) A pharmacy.

"(II) A manufacturer.

"(III) A pharmacy benefit manager.

"(IV) Other entities, as determined by the Secretary.".

SEC. 211. PUBLIC DISCLOSURE OF DIRECT AND INDIRECT REMUNERATION REVIEW AND AUDIT RESULTS.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152) is amended by adding at the end the following new subsection:

"(e) PUBLIC DISCLOSURE OF DIRECT AND INDIRECT REMUNERATION REVIEW AND FINANCIAL AUDIT RESULTS.—

"(1) DIR REVIEW RESULTS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), in 2023 and each subse-

quent year, the Secretary shall make available to the public on the Internet website of the Centers for Medicare & Medicaid Services information on discrepancies related to summary and detailed DIR reports submitted by PDP sponsors pursuant to section 1860D–15 across all prescription drug plans based on the most recent data available. Information made available under this subparagraph shall include the following:

"(i) The number of potential errors identified by the Secretary for PDP sponsors to review.

"(ii) The extent to which PDP sponsors resubmitted DIR reports to make changes for previous contract years.

"(iii) The extent to which resubmitted DIR reports resulted in an increase or decrease in DIR in a previous contract year.

"(B) EXCLUSION OF CERTAIN SUBMISSIONS IN CALCULATION.—The Secretary shall exclude any information in DIR reports submitted with respect to PACE programs under section 1894 (pursuant to section 1860D–21(f)) and qualified retiree prescription drug plans (as

defined in section 1860D–22(a)(2)) from the information that is made available to the public under subparagraph (A).

''(2) FINANCIAL AUDIT RESULTS.—In 2023 and each subsequent year, the Secretary shall make available to the public on the Internet website of the Centers for Medicare & Medicaid Services the results of DIR audits required under section 1860D–12(b)(3)(C). Information made available under this paragraph shall include the following:

''(A) With respect to the year, the number of PDP sponsors that received each of the following:

''(i) A notice of observations or findings that required the sponsor to make DIR report corrections.

''(ii) An unqualified audit opinion that renders the audit closed.

''(iii) A qualified audit opinion that requires the sponsor to submit a corrective action plan to the Secretary.

''(iv) An adverse opinion, with a description of the types of actions that the Secretary takes when issuing an adverse opinion.

''(B) With respect to a preceding year:

''(i) The number of PDP sponsors that reopened a previously closed reconciliation as a result of an audit, including as a result of DIR changes.

''(ii) The extent to which the Secretary recouped an overpayment or made an underpayment as a result of a reopening of a previously closed reconciliation.

''(3) DEFINITION OF DIR.—For purposes of this subsection, the term 'DIR' means direct and indirect remuneration as defined in section 423.308 of title 42, Code of Federal Regulations, or any successor regulation.''.

SEC. 212. IMPROVEMENTS TO PROVISION OF PARTS A AND B CLAIMS DATA TO PRESCRIPTION DRUG PLANS.

(a) DATA USE.—

(1) IN GENERAL.—Paragraph (6) of section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)), as added by section 50354 of division E of the Bipartisan Budget Act of 2018 (Public Law 115–123), relating to providing prescription drug plans with parts A and B claims data to pro-

mote the appropriate use of medications and improve health outcomes, is amended—

(A) in subparagraph (B)—

(i) by redesignating clauses (i), (ii), and (iii) as subclauses (I), (II), and (III), respectively, and moving such subclauses 2 ems to the right;

(ii) by striking ''PURPOSES.—A PDP sponsor'' and inserting ''PURPOSES.—

''(i) IN GENERAL.—A PDP sponsor.''; and

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

''(ii) CLARIFICATION.—The limitation on data use under subparagraph (C)(i) shall not apply to the extent that the PDP sponsor is using the data provided to carry out any of the purposes described in clause (i).''; and

(B) in subparagraph (C)(i), by striking ''To inform'' and inserting ''Subject to subparagraph (B)(ii), to inform''.

(2) EFFECTIVE DATE.—The amendments made by this subsection shall apply to plan years beginning on or after January 1, 2025.

(b) MANNER OF PROVISION.—Subparagraph (D) of such paragraph (6) is amended—

(1) by striking ''DESCRIBED.—The data described in this clause'' and inserting ''DESCRIBED.—

''(i) IN GENERAL.—The data described in this subparagraph''; and

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

''(ii) MANNER OF PROVISION.—

''(I) IN GENERAL.—Such data may be provided pursuant to this paragraph in the same manner as data under the Part D Enhanced Medication Therapy Management model tested under section 1115A, through Application Programming Interface, or in another manner as determined by the Secretary.

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

(c) TECHNICAL CORRECTION.—Such paragraph (6) is redesignated as paragraph (7).

SEC. 213. 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, 2025, and end-

ing on December 31, 2025, there were extenuating circumstances.

"(3) APPLICABLE YEAR.—For purposes of this section the term 'applicable year' means a year beginning with 2025.

"(b) AGREEMENTS.—

"(1) TERMS OF AGREEMENT.—An agreement described in this subsection, with respect to a manufacturer of a part D rebatable drug, is an agreement under which the following shall apply:

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

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

"(ii) Information on the amount (if any) of the excess average manufacturer price increase described in subsection

(c)(1)(B) for each dosage form and strength with respect to such drug and year.

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

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

''(2) LENGTH OF AGREEMENT.—

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

year unless terminated under subparagraph (B).

"(B) TERMINATION.—

"(i) BY SECRETARY.—The Secretary may provide for termination of an agreement under this section for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

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

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

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

"(C) EFFECTIVENESS OF TERMINATION.—Any termination under this paragraph shall not affect rebates due under the agreement under this section before the effective date of its termination.

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

"(c) REBATE AMOUNT.—

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

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

''(B) the amount (if any) by which—

''(i) the annual manufacturer price (as determined in paragraph (2)) paid for such dosage form and strength with respect to such part D rebatable drug for the year; exceeds

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

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

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

"(B) the ratio of—

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

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

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

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

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

"(4) DETERMINATION OF BENCHMARK YEAR MANUFACTURER PRICE.—The benchmark year manufacturer price determined under this paragraph for

a dosage form and strength, with respect to a part D rebatable drug and an applicable year, is the sum of the products of—

"(A) the average manufacturer price (as defined in subsection (h)(6)) of such dosage form and strength, as calculated for a unit of such drug, with respect to each of the calendar quarters of the payment amount benchmark year (as defined in subsection (h)(3)); and

"(B) the ratio of—

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

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

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

"(A) SUBSEQUENTLY APPROVED DRUGS.—In the case of a part D rebatable drug first approved or licensed by the Food and Drug Administration after January 1, 2016, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term 'payment amount bench-

mark year' were defined under subsection (h)(3) as the first calendar year beginning after the day on which the drug was first marketed by any manufacturer and subparagraph (B) of paragraph (3) shall be applied as if the term 'benchmark period CPI–U' were defined under subsection (h)(4) as if the reference to 'January 2016' under such subsection were a reference to 'January of the first year beginning after the date on which the drug was first marketed by any manufacturer'.

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

"(C) TREATMENT OF NEW FORMULATIONS.—

"(i) IN GENERAL.—In the case of a part D rebatable drug that is a line extension of a part D rebatable drug that is an oral solid dosage form, the Secretary shall

establish a formula for determining the amount specified in this subsection with respect to such part D rebatable drug and an applicable year with consideration of the original part D rebatable drug.

''(ii) LINE EXTENSION DEFINED.—In this subparagraph, the term 'line extension' means, with respect to a part D rebatable drug, a new formulation of the drug (as determined by the Secretary), such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation.

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

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

E of title XI, the rebate under subsection (b)(1)(B) shall be waived; and

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

"(d) REBATE DEPOSITS.—Amounts paid as rebates under subsection (c) shall be deposited into the Medicare Prescription Drug Account in the Federal Supplementary

Medical Insurance Trust Fund established under section 1841.

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

''(f) CIVIL MONEY PENALTY.—In the case of a manufacturer of a part D rebatable drug with an agreement in effect under this section who has failed to comply with the terms of the agreement under subsection (b)(1)(B) with respect to such drug for an applicable year, the 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 2026, shall be the dollar amount specified under such subparagraph for 2025, increased by the percentage increase in the consumer price index for all urban consumers (United States city aver-

age) for the 12-month period beginning with January of 2025; and

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

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

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

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

"(4) BENCHMARK PERIOD CPI–U.—The term 'benchmark period CPI–U' means the consumer

price index for all urban consumers (United States city average) for January 2016.

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

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

(b) CONFORMING AMENDMENTS.—

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

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

section 1834(x)'' and inserting '', section 1834(x), or section 1860D–14B''.

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

SEC. 214. PROHIBITING BRANDING ON PART D BENEFIT CARDS.

(a) IN GENERAL.—Section 1851(j)(2)(B) of the Social Security Act (42 U.S.C. 1395w–21(j)(2)(B)) is amended by striking ''co-branded network provider'' and inserting ''co-branded, co-owned, or affiliated network provider, pharmacy, or pharmacy benefit manager''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to plan years beginning on or after January 1, 2025.

SEC. 215. REQUIRING PRESCRIPTION DRUG PLANS AND MA–PD PLANS TO REPORT POTENTIAL FRAUD, WASTE, AND ABUSE TO THE SECRETARY OF HHS.

Section 1860D–4 of the Social Security Act (42 U.S.C. 1395w–104), as amended by section 225, is

amended by adding at the end the following new subsection:

''(p) REPORTING POTENTIAL FRAUD, WASTE, AND ABUSE.—Beginning January 1, 2024, the PDP sponsor of a prescription drug plan shall report to the Secretary, as specified by the Secretary—

''(1) any substantiated or suspicious activities (as defined by the Secretary) with respect to the program under this part as it relates to fraud, waste, and abuse; and

''(2) any steps made by the PDP sponsor after identifying such activities to take corrective actions.''.

SEC. 216. 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)), as amended by section 226, is amended 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 estab-

lished 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, 2026, 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).''.

SEC. 217. ADDITION OF NEW MEASURES BASED ON ACCESS TO BIOSIMILAR BIOLOGICAL PRODUCTS TO THE 5-STAR RATING SYSTEM UNDER MEDICARE ADVANTAGE.

(a) IN GENERAL.—Section 1853(o)(4) of the Social Security Act (42 U.S.C. 1395w–23(o)(4)) is amended by adding at the end the following new subparagraph:

''(E) ADDITION OF NEW MEASURES BASED ON ACCESS TO BIOSIMILAR BIOLOGICAL PRODUCTS.—

''(i) IN GENERAL.—For 2028 and subsequent years, the Secretary shall add a new set of measures to the 5-star rating system based on access to biosimilar biological products covered under part B and, in the case of MA–PD plans, such products that are covered part D drugs. Such measures shall assess the impact a plan's benefit structure may have on enrollees' utilization of or ability to access biosimilar biological products, including in comparison to the reference biological product, and shall include measures, as applicable, with respect to the following:

''(I) COVERAGE.—Assessing whether a biosimilar biological prod-

uct is on the plan formulary in lieu of or in addition to the reference biological product.

''(II) PREFERENCING.—Assessing tier placement or cost-sharing for a biosimilar biological product relative to the reference biological product.

''(III) UTILIZATION MANAGEMENT TOOLS.—Assessing whether and how utilization management tools are used with respect to a biosimilar biological product relative to the reference biological product.

''(IV) UTILIZATION.—Assessing the percentage of enrollees prescribed the biosimilar biological product and the percentage of enrollees prescribed the reference biological product when the reference biological product is also on the plan formulary.

''(ii) DEFINITIONS.—In this subparagraph, the terms 'biosimilar biological product' and 'reference biological product' have the meaning given those terms in section 1847A(c)(6).

''(iii) PROTECTING PATIENT INTERESTS.—In developing such measures, the Secretary shall ensure that each measure developed to address coverage, preferencing, or utilization management is constructed such that patients retain access to appropriate therapeutic options without undue administrative burden.''.

(b) CLARIFICATION REGARDING APPLICATION TO PRESCRIPTION DRUG PLANS.—To the extent the Secretary of Health and Human Services applies the 5-star rating system under section 1853(o)(4) of the Social Security Act (42 U.S.C. 1395w–23(o)(4)), or a similar system, to prescription drug plans under part D of title XVIII of such Act, the provisions of subparagraph (E) of such section, as added by subsection (a) of this section, shall apply under the system with respect to such plans in the same manner as such provisions apply to the 5-star rating system under such section 1853(o)(4).

SEC. 218. HHS STUDY AND REPORT ON THE INFLUENCE OF PHARMACEUTICAL MANUFACTURER THIRD-PARTY REIMBURSEMENT HUBS ON HEALTH CARE PROVIDERS WHO PRESCRIBE THEIR DRUGS AND BIOLOGICALS.

(a) STUDY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall conduct a study on the influence of pharmaceutical manufacturer distribution models that provide third-party reimbursement hub services on health care providers who prescribe the manufacturer's drugs and biologicals, including for Medicare part D beneficiaries.

(2) REQUIREMENTS.—The study under paragraph (1) shall include an analysis of the following:

(A) The influence of pharmaceutical manufacturer distribution models that provide third-party reimbursement hub services to health care providers who prescribe the manufacturer's drugs and biologicals, including—

(i) the operations of pharmaceutical manufacturer distribution models that provide reimbursement hub services for health care providers who prescribe the manufacturer's products;

(ii) Federal laws affecting these pharmaceutical manufacturer distribution models; and

(iii) whether hub services could improperly incentivize health care providers

to deem a drug or biological as medically necessary under section 423.578 of title 42, Code of Federal Regulations.

(B) Other areas determined appropriate by the Secretary.

(b) REPORT.—Not later than January 1, 2024, the Secretary shall submit to Congress a report on the study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

(c) CONSULTATION.—In conducting the study under subsection (a) and preparing the report under subsection (b), the Secretary shall consult with the Attorney General.

SEC. 219. ESTABLISHING A MONTHLY CAP ON BENEFICIARY INCURRED COSTS FOR INSULIN PRODUCTS AND SUPPLIES UNDER A PRESCRIPTION DRUG PLAN OR MA–PD PLAN.

(a) IN GENERAL.—Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102), as amended by sections 121 and 133, is further amended—

(1) in subsection (b)(2)—

(A) in subparagraph (A), by striking ''and (E)'' and inserting ''(E), and (F)'';

(B) in subparagraph (B), by striking ''and (D)'' and inserting ''(D), and (F)''; and

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

''(F) CAP ON INCURRED COSTS FOR INSULIN PRODUCTS AND SUPPLIES.—

''(i) IN GENERAL.—The coverage provides benefits, for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold described in paragraph (4)(B) and with respect to a month (beginning with January of 2022), with cost sharing that is equal to $0 for a specified covered part D drug (as defined in clause (iii)) furnished to an individual who has incurred costs during such month with respect to specified covered part D drugs equal to—

''(I) for months occurring in 2022, $50; or

''(II) for months occurring in a subsequent year, the amount applicable under this clause for months occurring in the year preceding such subsequent year, increased by the annual percentage increase specified in paragraph (6) for such subsequent

year and rounded to the nearest dollar.

''(ii) APPLICATION.—The provisions of clauses (i) through (iii) of paragraph (4)(C) shall apply with respect to the determination of the incurred costs for specified covered part D drugs for purposes of clause (i) in the same manner as such provisions apply with respect to the determination of incurred costs for covered part D drugs for purposes of paragraph (4)(A).

''(iii) SPECIFIED COVERED PART D DRUG.—For purposes of this subparagraph, the term 'specified covered part D drug' means a covered part D drug that is—

''(I) insulin; or

''(II) a medical supply associated with the injection of insulin (as defined in regulations of the Secretary promulgated pursuant to subsection (e)(1)(B)).''; and

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

''(5) SAME PROTECTION WITH RESPECT TO EXPENDITURES FOR INSULIN AND CERTAIN MEDICAL SUPPLIES.—The coverage provides the coverage required under subsection (b)(2)(F).''.

(b) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—Section 1860D–14(a)(1)(D) of the Social Security Act (42 U.S.C. 1395w–114(a)(1)(D)), as amended by section 121, is further amended—

(A) in clause (ii), by striking ''section 1860D–2(b)(2)'' and inserting ''section 1860D–2(b)(2)(A)''; and

(B) in clause (iii), by striking ''section 1860D–2(b)(2)'' and inserting ''section 1860D–2(b)(2)(A)''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply with respect to plan year 2022 and each subsequent plan year.

SEC. 220. MONTHLY OUT-OF-POCKET COST SHARING MAXIMUM FOR ENROLLEES WHO INCUR A SIGNIFICANT PORTION OF COSTS TOWARDS ANNUAL OUT-OF-POCKET THRESHOLD.

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

(1) in paragraph (2)—

(A) in subparagraph (A), by striking ''and (D)'' and inserting '', (D), and (E)''; and

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

''(E) MONTHLY OUT-OF-POCKET COST SHARING MAXIMUM FOR ENROLLEES WHO INCUR A SIGNIFICANT PORTION OF COSTS TOWARDS ANNUAL OUT-OF-POCKET THRESHOLD.—

''(i) ESTABLISHMENT OF PROCESS.—

''(I) IN GENERAL.—For plan years beginning on or after January 1, 2024, the Secretary shall, through notice and comment rulemaking, establish a process under which each PDP sponsor offering a prescription drug plan and each MA organization offering an MA–PD plan shall each plan year automatically enroll applicable enrollees in the option to have their monthly out-of-pocket cost-sharing under the plan capped and paid in monthly installments in accordance with this subparagraph (referred to in

this subparagraph as the 'monthly out-of-pocket cost sharing maximum option').

''(II) OPT OUT.—The process established under this clause shall permit an applicable enrollee, prior to the beginning of the plan year or at any point during the plan year, to opt out of enrollment in the monthly out-of-pocket cost sharing maximum option and pay any out-of-pocket cost-sharing otherwise applicable for any covered part D drug in full at the time of the dispensing of such drug (or at the time of such opt out in the case of costs incurred during such enrollment that have not yet been billed to the enrollee).

''(ii) DEFINITIONS.—

''(I) APPLICABLE ENROLLEE.—In this subparagraph, the term 'applicable enrollee' means any enrollee in a prescription drug plan or an MA–PD plan, including an enrollee who is a subsidy eligible individual (as defined

in paragraph (3) of section 1860D–14(a)), who incurs or is likely to incur a significant percentage of costs for covered part D drugs.

"(II) SIGNIFICANT PERCENTAGE.—For purposes of subclause (I), the Secretary shall, in the rulemaking under clause (i), define the term 'significant percentage' with respect to a percentage of the annual out-of-pocket threshold specified in paragraph (4)(B) but in no case shall the 'significant percentage' be less than 50 percent or more than 100 percent of the annual out-of-pocket threshold.

"(iii) DETERMINATION OF MONTHLY OUT-OF-POCKET COST SHARING MAXIMUM.—For each month in a plan year in which an applicable enrollee is enrolled in the monthly out-of-pocket cost sharing maximum option, the PDP sponsor or MA organization shall determine a monthly out-of-pocket cost sharing maximum (as defined in clause (v)) for such enrollee.

"(iv) BENEFICIARY MONTHLY PAYMENTS.—With respect to an applicable enrollee who is enrolled in the monthly out-of-pocket cost sharing maximum option, for each month described in clause (iii), the PDP sponsor or MA organization shall bill such enrollee an amount (not to exceed the monthly out-of-pocket cost sharing maximum) for the out-of-pocket costs of such enrollee in such month.

"(v) MONTHLY OUT-OF-POCKET COST SHARING MAXIMUM DEFINED.—In this subparagraph, the term 'monthly out-of-pocket cost sharing maximum' means, with respect to an enrollee—

"(I) for the first month in which this subparagraph applies, an amount determined by calculating—

"(aa) the annual out-of-pocket threshold specified in paragraph (4)(B) minus the incurred costs of the enrollee as described in paragraph (4)(C); divided by

"(bb) the number of months remaining in the plan year; and

"(II) for a subsequent month, an amount determined by calculating—

"(aa) the sum of any remaining out-of-pocket costs owed by the enrollee from a previous month that have not yet been billed to the enrollee and any additional costs incurred by the enrollee; divided by

"(bb) the number of months remaining in the plan year.

"(vi) ADDITIONAL REQUIREMENTS.—The following requirements shall apply with respect to the monthly out-of-pocket cost sharing maximum option under this subparagraph:

"(I) SECRETARIAL RESPONSIBILITIES.—The Secretary shall provide information to part D eligible individuals on the monthly out-of-pocket cost sharing maximum option through educational materials, including through

the notices provided under section 1804(a).

''(II) PDP SPONSOR AND MA ORGANIZATION RESPONSIBILITIES.—Each PDP sponsor offering a prescription drug plan or MA organization offering an MA–PD plan—

''(aa) shall not limit the application of the monthly out-of-pocket cost sharing maximum option to certain covered part D drugs;

''(bb) shall, prior to the plan year, notify prospective enrollees of such option, including the availability of the opt out under clause (i)(II);

''(cc) shall include information on such option in enrollee educational materials, including the availability of the opt out under clause (i)(II);

''(dd) shall have in place a mechanism to notify a pharmacy during the plan year when an en-

rollee incurs out-of-pocket costs with respect to covered part D drugs that make it likely the enrollee is an applicable enrollee;

''(ee) shall provide that a pharmacy, after receiving a notification described in item (dd) with respect to an enrollee, informs the enrollee of such notification;

''(ff) shall ensure that the application of this subparagraph has no effect on the amount paid to pharmacies (or the timing of such payments) with respect to covered part D drugs dispensed to the enrollee; and

''(gg) shall have in place a financial reconciliation process to correct inaccuracies in payments made by an enrollee under this subparagraph with respect to covered part D drugs during the plan year.

"(III) FAILURE TO PAY AMOUNT BILLED UNDER MONTHLY OUT-OF-POCKET COST SHARING MAXIMUM OPTION.—If an applicable enrollee fails to pay the amount billed for a month as required under this subparagraph, the applicable enrollee's enrollment in the monthly out-of-pocket cost sharing maximum option shall be terminated and the enrollee shall pay the cost-sharing otherwise applicable for any covered part D drugs subsequently dispensed to the enrollee up to the annual out-of-pocket threshold specified in paragraph (4)(B).

"(IV) CLARIFICATION REGARDING PAST DUE AMOUNTS.—Nothing in this subparagraph shall be construed as prohibiting a PDP sponsor or an MA organization from billing an enrollee for an amount owed under this subparagraph.

"(V) TREATMENT OF UNSETTLED BALANCES.—Any unsettled balances with respect to amounts owed

under this subparagraph shall be treated as plan losses and the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids.''; and

(2) in paragraph (4)—

(A) in subparagraph (C), by striking ''and subject to subparagraph (F)'' and inserting ''and subject to subparagraphs (F) and (G)''; and

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

''(G) INCLUSION OF COSTS PAID UNDER MONTHLY OUT-OF-POCKET COST SHARING MAXIMUM OPTION.—In applying subparagraph (A), with respect to an applicable enrollee who is enrolled in the monthly out-of-pocket cost sharing maximum option described in clause (i)(I) of paragraph (2)(E), costs shall be treated as incurred if such costs are paid by a PDP sponsor or an MA organization under the process provided under such paragraph.''.

(b) APPLICATION TO ALTERNATIVE PRESCRIPTION DRUG COVERAGE.—Section 1860D–2(c) of the Social Se-

curity Act (42 U.S.C. 1395w–102(c)) is amended by adding at the end the following new paragraph:

''(4) SAME MONTHLY OUT-OF-POCKET COST SHARING MAXIMUM.—For plan years beginning on or after January 1, 2024, the monthly out-of-pocket cost sharing maximum for applicable enrollees under the process provided under subsection (b)(2)(E) shall apply to such coverage.''.

Subtitle C—Miscellaneous

SEC. 221. DRUG MANUFACTURER PRICE TRANSPARENCY.

Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1128K the following new section:

''SEC. 1128L. DRUG MANUFACTURER PRICE TRANSPARENCY.

''(a) IN GENERAL.—

''(1) DETERMINATIONS.—Beginning July 1, 2025, the Secretary shall make determinations as to whether a drug is an applicable drug as described in subsection (b).

''(2) REQUIRED JUSTIFICATION.—If the Secretary determines under paragraph (1) that an applicable drug is described in subsection (b), the manufacturer of the applicable drug shall submit to the Secretary the justification described in subsection (c)

in accordance with the timing described in subsection (d).

''(b) APPLICABLE DRUG DESCRIBED.—

''(1) IN GENERAL.—An applicable drug is described in this subsection if it meets any of the following at the time of the determination:

''(A) LARGE INCREASE.—The drug (per dose)—

''(i) has a wholesale acquisition cost of at least $10; and

''(ii) had an increase in the wholesale acquisition cost, with respect to determinations made—

''(I) during 2023, of at least 100 percent since the date of the enactment of this section;

''(II) during 2024, of at least 100 percent in the preceding 12 months or of at least 150 percent in the preceding 24 months;

''(III) during 2025, of at least 100 percent in the preceding 12 months or of at least 200 percent in the preceding 36 months;

"(IV) during 2026, of at least 100 percent in the preceding 12 months or of at least 250 percent in the preceding 48 months; or

"(V) on or after January 1, 2027, of at least 100 percent in the preceding 12 months or of at least 300 percent in the preceding 60 months.

"(B) HIGH SPENDING WITH INCREASE.—The drug—

"(i) was in the top 50th percentile of net spending under title XVIII or XIX (to the extent data is available) during any 12-month period in the preceding 60 months; and

"(ii) per dose, had an increase in the wholesale acquisition cost, with respect to determinations made—

"(I) during 2023, of at least 15 percent since the date of the enactment of this section;

"(II) during 2024, of at least 15 percent in the preceding 12 months or

of at least 20 percent in the preceding 24 months;

"(III) during 2025, of at least 15 percent in the preceding 12 months or of at least 30 percent in the preceding 36 months;

"(IV) during 2026, of at least 15 percent in the preceding 12 months or of at least 40 percent in the preceding 48 months; or

"(V) on or after January 1, 2027, of at least 15 percent in the preceding 12 months or of at least 50 percent in the preceding 60 months.

"(C) HIGH LAUNCH PRICE FOR NEW DRUGS.—In the case of a drug that is marketed for the first time on or after January 1, 2023, and for which the manufacturer has established the first wholesale acquisition cost on or after such date, such wholesale acquisition cost for a year's supply or a course of treatment for such drug exceeds the gross spending for covered part D drugs at which the annual out-of-pocket threshold under section 1860D–2(b)(4)(B) would be met for the year.

"(2) SPECIAL RULES.—

"(A) AUTHORITY OF SECRETARY TO SUBSTITUTE PERCENTAGES WITHIN A DE MINIMIS RANGE.—For purposes of applying paragraph (1), the Secretary may substitute for each percentage described in subparagraph (A) or (B) of such paragraph (other than the percentile described subparagraph (B)(i) of such paragraph) a percentage within a de minimis range specified by the Secretary below the percentage so described.

"(B) DRUGS WITH HIGH LAUNCH PRICES ANNUALLY REPORT UNTIL A THERAPEUTIC EQUIVALENT IS AVAILABLE.—In the case of a drug that the Secretary determines is an applicable drug described in subparagraph (C) of paragraph (1), such drug shall remain described in such subparagraph (C) (and the manufacturer of such drug shall annually report the justification under subsection (c)(2)) until the Secretary determines that there is a therapeutic equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations, or any successor regulation) for such drug.

''(3) DOSE.—For purposes of applying paragraph (1), the Secretary shall establish a definition of the term 'dose'.

''(c) JUSTIFICATION DESCRIBED.—

''(1) INCREASE IN WAC.—In the case of a drug that the Secretary determines is an applicable drug described in subparagraph (A) or (B) of subsection (b)(1), the justification described in this subsection is all relevant, truthful, and nonmisleading information and supporting documentation necessary to justify the increase in the wholesale acquisition cost of the applicable drug of the manufacturer, as determined appropriate by the Secretary and which may include the following:

''(A) The individual factors that have contributed to the increase in the wholesale acquisition cost.

''(B) An explanation of the role of each factor in contributing to such increase.

''(C) Total expenditures of the manufacturer on—

''(i) materials and manufacturing for such drug;

''(ii) acquiring patents and licensing for each drug of the manufacturer; and

"(iii) costs to purchase or acquire the drug from another company, if applicable.

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

"(E) The total expenditures of the manufacturer on research and development for such drug.

"(F) The total revenue and net profit generated from the applicable drug for each calendar year since drug approval.

"(G) The total expenditures of the manufacturer that are associated with marketing and advertising for the applicable drug.

"(H) Additional information specific to the manufacturer of the applicable drug, such as—

"(i) the total revenue and net profit of the manufacturer for the period of such increase, as determined by the Secretary;

"(ii) metrics used to determine executive compensation; and

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

"(I) drug research and development; or

"(II) clinical trials on drugs that failed to receive approval by the Food and Drug Administration.

"(2) HIGH LAUNCH PRICE.—In the case of a drug that the Secretary determines is an applicable drug described in subparagraph (C) of subsection (b)(1), the justification described in this subsection is all relevant, truthful, and nonmisleading information and supporting documentation necessary to justify the wholesale acquisition cost of the applicable drug of the manufacturer, as determined by the Secretary and which may include the items described in subparagraph (C) through (H) of paragraph (1).

"(d) TIMING.—

"(1) NOTIFICATION.—Not later than 60 days after the date on which the Secretary makes the determination that a drug is an applicable drug under subsection (b), the Secretary shall notify the manufacturer of the applicable drug of such determination.

"(2) SUBMISSION OF JUSTIFICATION.—Not later than 180 days after the date on which a manufacturer receives a notification under paragraph (1),

the manufacturer shall submit to the Secretary the justification required under subsection (a).

"(3) POSTING ON INTERNET WEBSITE.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 30 days after receiving the justification under paragraph (2), the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services the justification, together with a summary of such justification that is written and formatted using language that is easily understandable by beneficiaries under titles XVIII and XIX.

"(B) EXCLUSION OF PROPRIETARY INFORMATION.—The Secretary shall exclude proprietary information, such as trade secrets and intellectual property, submitted by the manufacturer in the justification under paragraph (2) from the posting described in subparagraph (A).

"(e) EXCEPTION TO REQUIREMENT FOR SUBMISSION.—In the case of a drug that the Secretary determines is an applicable drug described in subparagraph (A) or (B) of subsection (b)(1), the requirement to submit a justification under subsection (a) shall not apply where the manufacturer, after receiving the notification under sub-

section (d)(1) with respect to the applicable drug of the manufacturer, reduces the wholesale acquisition cost of a drug so that it no longer is described in such subparagraph (A) or (B) for at least a 4-month period, as determined by the Secretary.

''(f) PENALTIES.—

''(1) FAILURE TO SUBMIT TIMELY JUSTIFICATION.—If the Secretary determines that a manufacturer has failed to submit a justification as required under this section, including in accordance with the timing and form required, with respect to an applicable drug, the Secretary shall apply a civil monetary penalty in an amount of $10,000 for each day the manufacturer has failed to submit such justification as so required.

''(2) FALSE INFORMATION.—Any manufacturer that submits a justification under this section and knowingly provides false information in such justification is subject to a civil monetary penalty in an amount not to exceed $100,000 for each item of false information.

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

provisions apply to a penalty or proceeding under section 1128A(a). Civil monetary penalties imposed under this subsection are in addition to other penalties as may be prescribed by law.

''(g) DEFINITIONS.—In this section:

''(1) DRUG.—The term 'drug' means a drug, as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act, that is intended for human use and subject to section 503(b)(1) of such Act, including a product licensed under section 351 of the Public Health Service Act.

''(2) MANUFACTURER.—The term 'manufacturer' has the meaning given that term in section 1847A(c)(6)(A).

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

SEC. 222. STRENGTHENING AND EXPANDING PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS.

Section 1150A of the Social Security Act (42 U.S.C. 1320b–23), as amended by section 223, is amended—

(1) in subsection (a)—

(A) in paragraph (1), by striking ''or'' at then end;

(B) in paragraph (2), by striking the comma at the end and inserting ''; or''; and

(C) by inserting after paragraph (2) the following new paragraph:

''(3) a State plan under title XIX, including a managed care entity (as defined in section 1932(a)(1)(B)),'';

(2) in subsection (b)—

(A) in paragraph (2)—

(i) by striking ''(excluding bona fide'' and all that follows through ''patient education programs))''; and

(ii) by striking ''aggregate amount of'' and inserting ''aggregate amount and percentage of'';

(B) in paragraph (3), by striking ''aggregate amount of'' and inserting ''aggregate amount and percentage (defined as a share of gross drug costs) of''; and

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

''(4) The aggregate amount of bona fide service fees (which include distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services

agreements and patient care programs (such as medication compliance programs and patient education programs)) the PBM received from—

''(A) PDP sponsors;

''(B) qualified health benefit plans;

''(C) managed care entities (as defined in section 1932(a)(1)(b)); and

''(D) drug manufacturers.'';

(3) in subsection (c), by adding at the end the following new paragraphs:

''(5) To States to carry out their administration and oversight of the State plan under title XIX.

''(6) To the Federal Trade Commission to carry out section 5(a) of the Federal Trade Commission Act (15 U.S.C. 45a) and any other relevant consumer protection or antitrust authorities enforced by such Commission, including reviewing proposed mergers in the prescription drug sector.

''(7) To assist the Department of Justice to carry out its antitrust authorities, including reviewing proposed mergers in the prescription drug sector.''; and

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

''(f) ANNUAL OIG EVALUATION AND REPORT.—

''(1) ANALYSIS.—The Inspector General of the Department of Health and Human Services shall conduct an annual evaluation of the information provided to the Secretary under this section. Such evaluation shall include an analysis of—

''(A) PBM rebates;

''(B) administrative fees;

''(C) the difference between what plans pay PBMs and what PBMs pay pharmacies;

''(D) generic dispensing rates; and

''(E) other areas determined appropriate by the Inspector General.

''(2) REPORT.—Not later than July 1, 2023, and annually thereafter, the Inspector General of the Department of Health and Human Services shall submit to Congress a report containing the results of the evaluation conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Inspector General determines appropriate. Such report shall not disclose the identity of a specific PBM, plan, or price charged for a drug.''.

SEC. 223. PRESCRIPTION DRUG PRICING DASHBOARDS.

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

"SEC. 1150C. PRESCRIPTION DRUG PRICING DASHBOARDS.

"(a) IN GENERAL.—Beginning not later than January 1, 2023, the Secretary shall establish, and annually update, internet website-based dashboards, through which beneficiaries, clinicians, researchers, and the public can review information on spending for, and utilization of, prescription drugs and biologicals (and related supplies and mechanisms of delivery) covered under each of parts B and D of title XVIII and under a State program under title XIX, including information on trends of such spending and utilization over time.

"(b) MEDICARE PART B DRUG AND BIOLOGICAL DASHBOARD.—

"(1) IN GENERAL.—The dashboard established under subsection (a) for part B of title XVIII shall provide the information described in paragraph (2).

"(2) INFORMATION DESCRIBED.—The information described in this paragraph is the following information with respect to drug or biologicals covered under such part B:

"(A) The brand name and, if applicable, the generic names of the drug or biological.

"(B) Consumer-friendly information on the uses and clinical indications of the drug or biological.

''(C) The manufacturer or labeler of the drug or biological.

''(D) To the extent feasible, the following information:

''(i) Average total spending per dosage unit of the drug or biological in the most recent 2 calendar years for which data is available.

''(ii) The percentage change in average spending on the drug or biological per dosage unit between the most recent calendar year for which data is available and—

''(I) the preceding calendar year; and

''(II) the preceding 5 and 10 calendar years.

''(iii) The annual growth rate in average spending per dosage unit of the drug or biological in the most recent 5 or 10 calendar years for which data is available.

''(iv) Total spending for the drug or biological for the most recent calendar year for which data is available.

''(v) The number of beneficiaries receiving the drug or biological in the most recent calendar year for which data is available.

''(vi) Average spending on the drug per beneficiary for the most recent calendar year for which data is available.

''(E) The average sales price of the drug or biological (as determined under section 1847A) for the most recent quarter.

''(F) Consumer-friendly information about the coinsurance amount for the drug or biological for beneficiaries for the most recent quarter. Such information shall not include coinsurance amounts for qualified medicare beneficiaries (as defined in section 1905(p)(1)).

''(G) For the most recent calendar year for which data is available—

''(i) the 15 drugs and biologicals with the highest total spending under such part; and

''(ii) any drug or biological for which the average annual per beneficiary spending exceeds the gross spending for covered part D drugs at which the annual out-of-

pocket threshold under section 1860D–2(b)(4)(B) would be met for the year.

''(H) Other information (not otherwise prohibited in law from being disclosed) that the Secretary determines would provide beneficiaries, clinicians, researchers, and the public with helpful information about drug and biological spending and utilization (including trends of such spending and utilization).

''(c) MEDICARE COVERED PART D DRUG DASHBOARD.—

''(1) IN GENERAL.—The dashboard established under subsection (a) for part D of title XVIII shall provide the information described in paragraph (2).

''(2) INFORMATION DESCRIBED.—The information described in this paragraph is the following information with respect to covered part D drugs under such part D:

''(A) The information described in subparagraphs (A) through (D) of subsection (b)(2).

''(B) Information on average annual beneficiary out-of-pocket costs below and above the annual out-of-pocket threshold under section 1860D–2(b)(4)(B) for the current plan year.

Such information shall not include out-of-pocket costs for subsidy eligible individuals under section 1860D–14.

''(C) Information on how to access resources as described in sections 1860D–1(c) and 1851(d).

''(D) For the most recent calendar year for which data is available—

''(i) the 15 covered part D drugs with the highest total spending under such part; and

''(ii) any covered part D drug for which the average annual per beneficiary spending exceeds the gross spending for covered part D drugs at which the annual out-of-pocket threshold under section 1860D–2(b)(4)(B) would be met for the year.

''(E) Other information (not otherwise prohibited in law from being disclosed) that the Secretary determines would provide beneficiaries, clinicians, researchers, and the public with helpful information about covered part D drug spending and utilization (including trends of such spending and utilization).

"(d) MEDICAID COVERED OUTPATIENT DRUG DASHBOARD.—

"(1) IN GENERAL.—The dashboard established under subsection (a) for title XIX shall provide the information described in paragraph (2).

"(2) INFORMATION DESCRIBED.—The information described in this paragraph is the following information with respect to covered outpatient drugs under such title:

"(A) The information described in subparagraphs (A) through (D) of subsection (b)(2).

"(B) For the most recent calendar year for which data is available, the 15 covered outpatient drugs with the highest total spending under such title.

"(C) Other information (not otherwise prohibited in law from being disclosed) that the Secretary determines would provide beneficiaries, clinicians, researchers, and the public with helpful information about covered outpatient drug spending and utilization (including trends of such spending and utilization).

''(e) DATA FILES.—The Secretary shall make available the underlying data for each dashboard established under subsection (a) in a machine-readable format.''.

SEC. 224. IMPROVING COORDINATION BETWEEN THE FOOD AND DRUG ADMINISTRATION AND THE CENTERS FOR MEDICARE & MEDICAID SERVICES.

(a) IN GENERAL.—

(1) PUBLIC MEETING.—

(A) IN GENERAL.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall convene a public meeting for the purposes of discussing and providing input on improvements to coordination between the Food and Drug Administration and the Centers for Medicare & Medicaid Services in preparing for the availability of novel medical products described in subsection (c) on the market in the United States.

(B) ATTENDEES.—The public meeting shall include—

(i) representatives of relevant Federal agencies, including representatives from each of the medical product centers within

the Food and Drug Administration and representatives from the coding, coverage, and payment offices within the Centers for Medicare & Medicaid Services;

(ii) stakeholders with expertise in the research and development of novel medical products, including manufacturers of such products;

(iii) representatives of commercial health insurance payers;

(iv) stakeholders with expertise in the administration and use of novel medical products, including physicians; and

(v) stakeholders representing patients and with expertise in the utilization of patient experience data in medical product development.

(C) TOPICS.—The public meeting shall include a discussion of—

(i) the status of the drug and medical device development pipeline related to the availability of novel medical products;

(ii) the anticipated expertise necessary to review the safety and effectiveness of such products at the Food and Drug Ad-

ministration and current gaps in such expertise, if any;

(iii) the expertise necessary to make coding, coverage, and payment decisions with respect to such products within the Centers for Medicare & Medicaid Services, and current gaps in such expertise, if any;

(iv) trends in the differences in the data necessary to determine the safety and effectiveness of a novel medical product and the data necessary to determine whether a novel medical product meets the reasonable and necessary requirements for coverage and payment under title XVIII of the Social Security Act pursuant to section 1862(a)(1)(A) of such Act (42 U.S.C. 1395y(a)(1)(A));

(v) the availability of information for sponsors of such novel medical products to meet each of those requirements; and

(vi) the coordination of information related to significant clinical improvement over existing therapies for patients between the Food and Drug Administration and the

Centers for Medicare & Medicaid Services with respect to novel medical products.

(D) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—No information discussed as a part of the public meeting under this paragraph shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code.

(2) IMPROVING TRANSPARENCY OF CRITERIA FOR MEDICARE COVERAGE.—

(A) DRAFT GUIDANCE.—Not later than 18 months after the public meeting under paragraph (1), the Secretary shall update the final guidance titled ''National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development'' to address any opportunities to improve the availability and coordination of information as described in clauses (iv) through (vi) of paragraph (1)(C).

(B) FINAL GUIDANCE.—Not later than 12 months after issuing draft guidance under subparagraph (A), the Secretary shall finalize the

updated guidance to address any such opportunities.

(b) REPORT ON CODING, COVERAGE, AND PAYMENT PROCESSES UNDER MEDICARE FOR NOVEL MEDICAL PRODUCTS.—Not later than 12 months after the date of the enactment of this Act, the Secretary shall publish a report on the Internet website of the Department of Health and Human Services regarding processes under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) with respect to the coding, coverage, and payment of novel medical products described in subsection (c). Such report shall include the following:

(1) A description of challenges in the coding, coverage, and payment processes under the Medicare program for novel medical products.

(2) Recommendations to—

(A) incorporate patient experience data (such as the impact of a disease or condition on the lives of patients and patient treatment preferences) into the coverage and payment processes within the Centers for Medicare & Medicaid Services;

(B) decrease the length of time to make national and local coverage determinations

under the Medicare program (as those terms are defined in subparagraph (A) and (B), respectively, of section 1862(l)(6) of the Social Security Act (42 U.S.C. 1395y(l)(6)));

(C) streamline the coverage process under the Medicare program and incorporate input from relevant stakeholders into such coverage determinations; and

(D) identify potential mechanisms to incorporate novel payment designs similar to those in development in commercial insurance plans and State plans under title XIX of such Act (42 U.S.C. 1396 et seq.) into the Medicare program.

(c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For purposes of this section, a novel medical product described in this subsection is a medical product, including a drug, biological (including gene and cell therapy), or medical device, that has been designated as a breakthrough therapy under section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)), a breakthrough device under section 515B of such Act (21 U.S.C. 360e–3), or a regenerative advanced therapy under section 506(g) of such Act (21 U.S.C. 356(g)).

SEC. 225. PATIENT CONSULTATION IN MEDICARE NATIONAL AND LOCAL COVERAGE DETERMINATIONS IN ORDER TO MITIGATE BARRIERS TO INCLUSION OF SUCH PERSPECTIVES.

Section 1862(l) of the Social Security Act (42 U.S.C. 1395y(l)) is amended by adding at the end the following new paragraph:

''(7) PATIENT CONSULTATION IN NATIONAL AND LOCAL COVERAGE DETERMINATIONS.—The Secretary may consult with patients and organizations representing patients in making national and local coverage determinations.''.

SEC. 226. GAO STUDY ON INCREASES TO MEDICARE AND MEDICAID SPENDING DUE TO COPAYMENT COUPONS AND OTHER PATIENT ASSISTANCE PROGRAMS.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on the impact of copayment coupons and other patient assistance programs on prescription drug pricing and expenditures within the Medicare and Medicaid programs. The study shall assess the following:

(1) The extent to which copayment coupons and other patient assistance programs contribute to inflated prescription drug prices under such programs.

(2) The impact copayment coupons and other patient assistance programs have in the Medicare Part D program established under part D of title XVIII of the Social Security Act (42 U.S.C. 1395w–101 et seq.) on utilization of higher-cost brand drugs and lower utilization of generic drugs in that program.

(3) The extent to which manufacturers report or obtain tax benefits, including deductions of business expenses and charitable contributions, for any of the following:

(A) Offering copayment coupons or other patient assistance programs.

(B) Sponsoring manufacturer patient assistance programs.

(C) Paying for sponsorships at outreach and advocacy events organized by patient assistance programs.

(4) The efficacy of oversight conducted to ensure that independent charity patient assistance programs adhere to guidance from the Office of the Inspector General of the Department of Health and Human Services on avoiding waste, fraud, and abuse.

(b) DEFINITIONS.—In this section:

(1) INDEPENDENT CHARITY PATIENT ASSISTANCE PROGRAM.—The term ''independent charity patient assistance program'' means any organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of such Code and which is not a private foundation (as defined in section 509(a) of such Code) that offers patient assistance.

(2) MANUFACTURER.—The term ''manufacturer'' has the meaning given that term in section 1927(k)(5) of the Social Security Act (42 U.S.C. 1396r–8(k)(5)).

(3) MANUFACTURER PATIENT ASSISTANCE PROGRAM.—The term ''manufacturer patient assistance program'' means an organization, including a private foundation (as so defined), that is sponsored by, or receives funding from, a manufacturer and that offers patient assistance. Such term does not include an independent charity patient assistance program.

(4) PATIENT ASSISTANCE.—The term ''patient assistance'' means assistance provided to offset the cost of drugs for individuals. Such term includes free products, coupons, rebates, copay or discount cards, and other means of providing assistance to individ-

uals related to drug costs, as determined by the Secretary of Health and Human Services.

(c) REPORT.—Not later than 24 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report describing the findings of the study required under subsection (a).

SEC. 227. MEDPAC REPORT ON SHIFTING COVERAGE OF CERTAIN MEDICARE PART B DRUGS TO MEDICARE PART D.

(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the ''Commission'') shall conduct a study on shifting coverage of certain drugs and biologicals for which payment is currently made under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.) to part D of such title (42 U.S.C. 1395w–21 et seq.). Such study shall include an analysis of—

(1) differences in program structures and payment methods for drugs and biologicals covered under such parts B and D, including effects of such a shift on program spending, beneficiary cost-sharing liability, and utilization management techniques for such drugs and biologicals; and

(2) the feasibility and policy implications of shifting coverage of drugs and biologicals for which

payment is currently made under such part B to such part D.

(b) REPORT.—

(1) IN GENERAL.—Not later than June 30, 2024, the Commission shall submit to Congress a report containing the results of the study conducted under subsection (a).

(2) CONTENTS.—The report under paragraph (1) shall include information, and recommendations as the Commission deems appropriate, regarding—

(A) formulary design under such part D;

(B) the ability of the benefit structure under such part D to control total spending on drugs and biologicals for which payment is currently made under such part B;

(C) changes to the bid process under such part D, if any, that may be necessary to integrate coverage of such drugs and biologicals into such part D; and

(D) any other changes to the program that Congress should consider in determining whether to shift coverage of such drugs and biologicals from such part B to such part D.

SEC. 228. TAKING STEPS TO FULFILL TREATY OBLIGATIONS TO TRIBAL COMMUNITIES.

(a) GAO STUDY.—The Comptroller General shall conduct a study regarding access to, and the cost of, prescription drugs among Indians. The study shall include—

(1) a review of what Indian health programs pay for prescription drugs on reservations and in urban centers relative to other consumers;

(2) recommendations to align the value of prescription drug discounts available under the Medicaid drug rebate program established under section 1927 of the Social Security Act (42 U.S.C. 1396r–8) with prescription drug discounts available to Tribal communities through the purchased/referred care program of the Indian Health Service for physician administered drugs; and

(3) an examination of how Tribal communities and urban Indian organizations utilize the Medicare part D program established under title XVIII of the Social Security Act (42 U.S.C. 1395w–101 et seq.) and recommendations to improve enrollment among Indians in that program.

(b) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report containing the results of the study conducted under subsection (a), together with

recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

(c) DEFINITIONS.—In this section:

(1) COMPTROLLER GENERAL.—The term ''Comptroller General'' means the Comptroller General of the United States.

(2) INDIAN; INDIAN HEALTH PROGRAM; INDIAN TRIBE.—The terms ''Indian'', ''Indian health program'', and ''Indian tribe'' have the meanings given those terms in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

TITLE III—MEDICAID

SEC. 301. MEDICAID PHARMACY AND THERAPEUTICS COMMITTEE IMPROVEMENTS.

(a) IN GENERAL.—Subparagraph (A) of section 1927(d)(4) of the Social Security Act (42 U.S.C. 1396r–8(d)(4)) is amended to read as follows:

''(A)(i) The formulary is developed and reviewed by a pharmacy and therapeutics committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State.

''(ii) Subject to clause (vi), the State establishes and implements a conflict of interest pol-

icy for the pharmacy and therapeutics committee that—

"(I) is publicly accessible;

"(II) requires all committee members to complete, on at least an annual basis, a disclosure of relationships, associations, and financial dealings that may affect their independence of judgement in committee matters; and

"(III) contains clear processes, such as recusal from voting or discussion, for those members who report a conflict of interest, along with appropriate processes to address any instance where a member fails to report a conflict of interest.

"(iii) The membership of the pharmacy and therapeutics committee—

"(I) includes at least 1 actively practicing physician and at least 1 actively practicing pharmacist, each of whom—

"(aa) is independent and free of conflict with respect to manufacturers and Medicaid participating plans or subcontractors, including pharmacy benefit managers; and

''(bb) has expertise in the care of 1 or more Medicaid-specific populations such as elderly or disabled individuals, children with complex medical needs, or low-income individuals with chronic illnesses; and

''(II) is made publicly available.

''(iv) At the option of the State, the State's drug use review board established under subsection (g)(3) may serve as the pharmacy and therapeutics committee provided the State ensures that such board meets the requirements of clauses (ii) and (iii).

''(v) The State reviews and has final approval of the formulary established by the pharmacy and therapeutics committee.

''(vi) If the Secretary determines it appropriate or necessary based on the findings and recommendations of the Comptroller General of the United States in the report submitted to Congress under section 303 of the Reduced Costs and Continued Cures Act, the Secretary shall issue guidance that States must follow for establishing conflict of interest policies for the pharmacy and therapeutics committee in ac-

cordance with the requirements of clause (ii), including appropriate standards and requirements for identifying, addressing, and reporting on conflicts of interest.''.

(b) APPLICATION TO MEDICAID MANAGED CARE ORGANIZATIONS.—Clause (xiii) of section 1903(m)(2)(A) of the Social Security Act (42 U.S.C. 1396b(m)(2)(A)) is amended—

(1) by striking ''and (III)'' and inserting ''(III)'';

(2) by striking the period at the end and inserting '', and (IV) any formulary used by the entity for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the entity is developed and reviewed by a pharmacy and therapeutics committee that meets the requirements of clauses (ii) and (iii) of section 1927(d)(4)(A).''; and

(3) by moving the left margin 2 ems to the left.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 1 year after the date of enactment of this Act.

SEC. 302. IMPROVING REPORTING REQUIREMENTS AND DEVELOPING STANDARDS FOR THE USE OF DRUG USE REVIEW BOARDS IN STATE MEDICAID PROGRAMS.

(a) IN GENERAL.—Section 1927(g)(3) of the Social Security Act (42 U.S.C. 1396r–8(g)(3)) is amended—

(1) by amending subparagraph (B) to read as follows:

"(B) MEMBERSHIP.—

"(i) IN GENERAL.—The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

"(I) The clinically appropriate prescribing of covered outpatient drugs.

"(II) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

"(III) Drug use review, evaluation, and intervention.

"(IV) Medical quality assurance.

"(ii) MEMBERSHIP REQUIREMENTS.—The membership of the DUR Board shall—

"(I) be made up of at least ⅓ but no more than 51 percent members who are licensed and actively practicing physicians and at least ⅓ members who are licensed and actively practicing pharmacists;

"(II) include at least 1 licensed and actively practicing physician and at least 1 licensed and actively practicing pharmacist, each of whom—

"(aa) is independent and free of any conflict, including with respect to manufacturers, medicaid managed care entities, or pharmacy benefit managers; and

"(bb) has expertise in the care of 1 or more categories of individuals who are likely to be eligible for benefits under this title, including elderly or disabled individuals, children with complex medical needs, or low-income individuals with chronic illnesses; and

''(III) be made publicly available.

''(iii) CONFLICT OF INTEREST POLICY.—The State shall establish and implement a conflict of interest policy for the DUR Board that—

''(I) is publicly accessible;

''(II) requires all board members to complete, on at least an annual basis, a disclosure of relationships, associations, and financial dealings that may affect their independence of judgement in board matters; and

''(III) contains clear processes, such as recusal from voting or discussion, for those members who report a conflict of interest, along with appropriate processes to address any instance where a member fails to report a conflict of interest.''; and

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

''(E) DUR BOARD MEMBERSHIP REPORTS.—

''(i) DUR BOARD REPORTS.—Each State shall require the DUR Board to pre-

pare and submit to the State an annual report on the DUR Board membership. Each such report shall include any conflicts of interest with respect to members of the DUR Board that the DUR Board recorded or was aware of during the period that is the subject of the report, and the process applied to address such conflicts of interest, in addition to any other information required by the State.

''(ii) INCLUSION OF DUR BOARD MEMBERSHIP INFORMATION IN STATE REPORTS.—Each annual State report to the Secretary required under subparagraph (D) shall include—

''(I) the number of individuals serving on the State's DUR Board;

''(II) the names and professions of the individuals serving on such DUR Board;

''(III) any conflicts of interest or recusals with respect to members of such DUR Board reported by the DUR Board or that the State was

aware of during the period that is the subject of the report; and

''(IV) whether the State has elected for such DUR Board to serve as the committee responsible for developing a State formulary under subsection (d)(4)(A).''.

(b) MANAGED CARE REQUIREMENTS.—Section 1932(i) of the Social Security Act (42 U.S.C. 1396u–2(i)) is amended—

(1) by striking ''section 483.3(s)(4)'' and inserting ''section 438.3(s)(4)'';

(2) by striking ''483.3(s)(5)'' and inserting ''438.3(s)(5)''; and

(3) by adding at the end the following: ''Such a managed care entity shall not be considered to be in compliance with the requirement of such section 438.3(s)(5) that the entity provide a detailed description of its drug utilization review activities unless the entity includes a description of the prospective drug review activities described in paragraph (2)(A) of section 1927(g) and the activities listed in paragraph (3)(C) of section 1927(g), makes the underlying drug utilization review data available to the

State and the Secretary, and provides such other information as deemed appropriate by the Secretary.''.

(c) DEVELOPMENT OF NATIONAL STANDARDS FOR MEDICAID DRUG USE REVIEW.—The Secretary of Health and Human Services may promulgate regulations or guidance establishing national standards for Medicaid drug use review programs under section 1927(g) of the Social Security Act (42 U.S.C. 1396r–8) and drug utilization review activities and requirements under section 1932(i) of such Act (42 U.S.C. 1396u–2(i)), for the purpose of aligning review criteria for prospective and retrospective drug use review across all State Medicaid programs.

(d) CMS GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance—

(1) outlining steps that States must take to come into compliance with statutory and regulatory requirements for prospective and retrospective drug use review under section 1927(g) of the Social Security Act (42 U.S.C. 1396r–8(g)) and drug utilization review activities and requirements under section 1932(i) of such Act (42 U.S.C. 1396u–2(i)) (including with respect to requirements that were in effect before the date of enactment of this Act); and

(2) describing the actions that the Secretary will take to enforce such requirements.

(e) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 1 year after the date of enactment of this Act.

SEC. 303. GAO REPORT ON CONFLICTS OF INTEREST IN STATE MEDICAID PROGRAM DRUG USE REVIEW BOARDS AND PHARMACY AND THERAPEUTICS (P&T) COMMITTEES.

(a) INVESTIGATION.—The Comptroller General of the United States shall conduct an investigation of potential or existing conflicts of interest among members of State Medicaid program State drug use review boards (in this section referred to as ''DUR Boards'') and pharmacy and therapeutics committees (in this section referred to as ''P&T Committees'').

(b) REPORT.—Not later than 24 months after the date of enactment of this Act, the Comptroller General shall submit to Congress a report on the investigation conducted under subsection (a) that includes the following:

(1) A description outlining how DUR Boards and P&T Committees operate in States, including details with respect to—

(A) the structure and operation of DUR Boards and statewide P&T Committees;

(B) States that operate separate P&T Committees for their fee-for-service Medicaid program and their Medicaid managed care organizations or other Medicaid managed care arrangements (collectively referred to in this section as ''Medicaid MCOs)''; and

(C) States that allow Medicaid MCOs to have their own P&T Committees and the extent to which pharmacy benefit managers administer or participate in such P&T Committees.

(2) A description outlining the differences between DUR Boards established in accordance with section 1927(g)(3) of the Social Security Act (42 U.S.C. 1396r(g)(3)) and P&T Committees.

(3) A description outlining the tools P&T Committees may use to determine Medicaid drug coverage and utilization management policies.

(4) An analysis of whether and how States or P&T Committees establish participation and independence requirements for DUR Boards and P&T Committees, including with respect to entities with connections with drug manufacturers, State Medicaid programs, managed care organizations, and other entities or individuals in the pharmaceutical industry.

(5) A description outlining how States, DUR Boards, or P&T Committees define conflicts of interest.

(6) A description of how DUR Boards and P&T Committees address conflicts of interest, including who is responsible for implementing such policies.

(7) A description of the tools, if any, States use to ensure that there are no conflicts of interest on DUR Boards and P&T Committees.

(8) An analysis of the effectiveness of tools States use to ensure that there are no conflicts of interest on DUR Boards and P&T Committees and, if applicable, recommendations as to how such tools could be improved.

(9) A review of strategies States may use to guard against conflicts of interest on DUR Boards and P&T Committees and to ensure compliance with the requirements of titles XI and XIX of the Social Security Act (42 U.S.C. 1301 et seq., 1396 et seq.) and access to effective, clinically appropriate, and medically necessary drug treatments for Medicaid beneficiaries, including recommendations for such legislative and administrative actions as the Comptroller General determines appropriate.

SEC. 304. ENSURING THE ACCURACY OF MANUFACTURER PRICE AND DRUG PRODUCT INFORMATION UNDER THE MEDICAID DRUG REBATE PROGRAM.

(a) AUDIT OF MANUFACTURER PRICE AND DRUG PRODUCT INFORMATION.—

(1) IN GENERAL.—Subparagraph (B) of section 1927(b)(3) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)) is amended to read as follows:

"(B) AUDITS AND SURVEYS OF MANUFACTURER PRICE AND DRUG PRODUCT INFORMATION.—

"(i) AUDITS.—The Secretary shall conduct ongoing audits of the price and drug product information reported by manufacturers under subparagraph (A) for the most recently ended rebate period to ensure the accuracy and timeliness of such information. In conducting such audits, the Secretary may employ evaluations, surveys, statistical sampling, predictive analytics, and other relevant tools and methods.

"(ii) VERIFICATIONS SURVEYS OF AVERAGE MANUFACTURER PRICE AND MANUFACTURER'S AVERAGE SALES PRICE.—In addition to the audits required under

clause (i), the Secretary may survey wholesalers and manufacturers (including manufacturers that directly distribute their covered outpatient drugs (in this subparagraph referred to as 'direct sellers')), when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) to make payment reported under subparagraph (A).

''(iii) PENALTIES.—In addition to other penalties as may be prescribed by law, including under subparagraph (C) of this paragraph, the Secretary may impose a civil monetary penalty in an amount not to exceed $185,000 on an annual basis on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with an audit or survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with

respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(iv) REPORTS.—

"(I) REPORT TO CONGRESS.—The Secretary shall, not later than 18 months after date of enactment of this subparagraph, submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate regarding additional regulatory or statutory changes that may be required in order to ensure accurate and timely reporting and oversight of manufacturer price and drug product information, including whether changes should be made to reasonable assumption requirements to ensure such assumptions are reasonable and accurate or whether another methodology for ensuring accurate and timely

reporting of price and drug product information should be considered to ensure the integrity of the drug rebate program under this section.

''(II) ANNUAL REPORTS.—The Secretary shall, on at least an annual basis, submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate summarizing the results of the audits and surveys conducted under this subparagraph during the period that is the subject of the report.

''(III) CONTENT.—Each report submitted under subclause (II) shall, with respect to the period that is the subject of the report, include summaries of—

''(aa) error rates in the price, drug product, and other relevant information supplied by manufacturers under subparagraph (A);

"(bb) the timeliness with which manufacturers, wholesalers, and direct sellers provide information required under subparagraph (A) or under clause (i) or (ii) of this subparagraph;

"(cc) the number of manufacturers, wholesalers, and direct sellers and drug products audited under this subparagraph;

"(dd) the types of price and drug product information reviewed under the audits conducted under this subparagraph;

"(ee) the tools and methodologies employed in such audits;

"(ff) the findings of such audits, including which manufacturers, if any, were penalized under this subparagraph; and

"(gg) such other relevant information as the Secretary shall deem appropriate.

"(IV) PROTECTION OF INFORMATION.—In preparing a report required under subclause (II), the Secretary shall redact such proprietary information as the Secretary determines appropriate to prevent disclosure of, and to safeguard, such information.

"(v) APPROPRIATIONS.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary $2,000,000 for fiscal year 2023 and each fiscal year thereafter to carry out this subparagraph.".

(2) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the first day of the first fiscal quarter that begins after the date of enactment of this Act.

(b) INCREASED PENALTIES FOR NONCOMPLIANCE WITH REPORTING REQUIREMENTS.—

(1) INCREASED PENALTY FOR LATE REPORTING OF INFORMATION.—Section 1927(b)(3)(C)(i) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(C)(i)) is amended by striking "increased by $10,000 for each day in which such information has not been provided and such amount shall be paid to the

Treasury'' and inserting '', for each covered outpatient drug with respect to which such information is not provided, $50,000 for the first day that such information is not provided on a timely basis and $19,000 for each subsequent day that such information is not provided''.

(2) INCREASED PENALTY FOR KNOWINGLY REPORTING FALSE INFORMATION.—Section 1927(b)(3)(C)(ii) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(C)(ii)) is amended by striking ''$100,000'' and inserting ''$500,000''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the first day of the first fiscal quarter that begins after the date of enactment of this Act.

SEC. 305. T–MSIS DRUG DATA ANALYTICS REPORTS.

(a) IN GENERAL.—Not later than May 1 of each calendar year beginning with calendar year 2024, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall publish on the Internet website of the Centers for Medicare & Medicaid Services that is accessible to the public a report of the most recently available data on provider prescribing patterns under the Medicaid program.

(b) CONTENT OF REPORT.—

(1) REQUIRED CONTENT.—Each report required under subsection (a) for a calendar year shall include the following information with respect to each State (and, to the extent available, with respect to Puerto Rico, the United States Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa):

(A) A comparison of covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act (42 U.S.C. 1396r–8(k)(2))) prescribing patterns under the State Medicaid plan or waiver of such plan (including drugs prescribed on a fee-for-service basis and drugs prescribed under managed care arrangements under such plan or waiver)—

(i) across all forms or models of reimbursement used under the plan or waiver;

(ii) within specialties and subspecialties, as defined by the Secretary;

(iii) by episodes of care for—

(I) each chronic disease category, as defined by the Secretary, that is represented in the 10 conditions that accounted for the greatest share of total spending under the plan or waiv-

er during the year that is the subject of the report;

(II) procedural groupings; and

(III) rare disease diagnosis codes;

(iv) by patient demographic characteristics, including race (to the extent that the Secretary determines that there is sufficient data available with respect to such characteristic in a majority of States), gender, and age;

(v) by patient high-utilizer or risk status; and

(vi) by high and low resource settings by facility and place of service categories, as determined by the Secretary.

(B) In the case of medical assistance for covered outpatient drugs (as so defined) provided under a State Medicaid plan or waiver of such plan in a managed care setting, an analysis of the differences in managed care prescribing patterns when a covered outpatient drug is prescribed in a managed care setting as compared to when the drug is prescribed in a fee-for-service setting.

(2) ADDITIONAL CONTENT.—A report required under subsection (a) for a calendar year may include State-specific information about prescription utilization management tools under State Medicaid plans or waivers of such plans, including—

(A) a description of prescription utilization management tools under State programs to provide long-term services and supports under a State Medicaid plan or a waiver of such plan;

(B) a comparison of prescription utilization management tools applicable to populations covered under a State Medicaid plan waiver under section 1115 of the Social Security Act (42 U.S.C. 1315) and the models applicable to populations that are not covered under the waiver;

(C) a comparison of the prescription utilization management tools employed by different Medicaid managed care organizations, pharmacy benefit managers, and related entities within the State;

(D) a comparison of the prescription utilization management tools applicable to each enrollment category under a State Medicaid plan or waiver; and

(E) a comparison of the prescription utilization management tools applicable under the State Medicaid plan or waiver by patient high-utilizer or risk status.

(3) ADDITIONAL ANALYSIS.—To the extent practicable, the Secretary shall include in each report published under subsection (a)—

(A) analyses of national, State, and local patterns of Medicaid population-based prescribing behaviors; and

(B) recommendations for administrative or legislative action to improve the effectiveness of, and reduce costs for, covered outpatient drugs under Medicaid while ensuring timely beneficiary access to medically necessary covered outpatient drugs.

(c) USE OF T–MSIS DATA.—Each report required under subsection (a) shall—

(1) be prepared using data and definitions from the Transformed Medicaid Statistical Information System (''T–MSIS'') data set (or a successor data set) that is not more than 24 months old on the date that the report is published; and

(2) as appropriate, include a description with respect to each State of the quality and complete-

ness of the data, as well as any necessary caveats describing the limitations of the data reported to the Secretary by the State that are sufficient to communicate the appropriate uses for the information.

(d) PREPARATION OF REPORT.—Each report required under subsection (a) shall be prepared by the Administrator for the Centers for Medicare & Medicaid Services.

(e) APPROPRIATION.—For fiscal year 2023 and each fiscal year thereafter, there is appropriated to the Secretary $2,000,000 to carry out this section.

SEC. 306. RISK-SHARING VALUE-BASED PAYMENT AGREEMENTS FOR COVERED OUTPATIENT DRUGS UNDER MEDICAID.

(a) IN GENERAL.—Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended by adding at the end the following new subsection:

''(l) STATE OPTION TO PAY FOR COVERED OUTPATIENT DRUGS THROUGH RISK-SHARING VALUE-BASED AGREEMENTS.—

''(1) IN GENERAL.—Beginning January 1, 2025, a State shall have the option to pay (whether on a fee-for-service or managed care basis) for covered outpatient drugs that are potentially curative treatments intended for one-time use that are ad-

ministered to individuals under this title by entering into a risk-sharing value-based payment agreement with the manufacturer of the drug in accordance with the requirements of this subsection.

''(2) SECRETARIAL APPROVAL.—

''(A) IN GENERAL.—A State shall submit a request to the Secretary to enter into a risk-sharing value based payment agreement, and the Secretary shall not approve a proposed risk-sharing value-based payment agreement between a State and a manufacturer for payment for a covered outpatient drug of the manufacturer unless the following requirements are met:

''(i) MANUFACTURER IS PARTY TO REBATE AGREEMENT AND IN COMPLIANCE WITH REQUIREMENTS.—The manufacturer has a rebate agreement in effect as required under subsections (a) and (b) of this section and is in compliance with all applicable requirements under this title.

''(ii) NO INCREASE TO PROJECTED NET FEDERAL SPENDING.—

''(I) IN GENERAL.—The Chief Actuary certifies that the projected payments for each covered outpatient

drug under such proposed agreement would not result in greater estimated Federal spending under this title than the net Federal spending that would result in the absence of the agreement.

''(II) NET FEDERAL SPENDING DEFINED.—For purposes of this subsection, the term 'net Federal spending' means the amount of Federal payments the Chief Actuary estimates would be made under this title for administering a covered outpatient drug to an individual eligible for medical assistance under a State plan or a waiver of such plan, reduced by the amount of all rebates the Chief Actuary estimates would be paid with respect to the administering of such drug, including all rebates under this title and any supplemental or other additional rebates, in the absence of such an agreement.

''(III) INFORMATION.—The Chief Actuary shall make the certifications

required under this clause based on the most recently available and reliable drug pricing and product information. The State and manufacturer shall provide the Secretary and the Chief Actuary with all necessary information required to make the estimates needed for such certifications.

''(iii) LAUNCH AND LIST PRICE JUSTIFICATIONS.—The manufacturer submits all relevant information and supporting documentation necessary for pricing decisions as deemed appropriate by the Secretary, which shall be truthful and nonmisleading, including manufacturer information and supporting documentation for launch price or list price increases, and any applicable justification required under section 1128L.

''(iv) CONFIDENTIALITY OF INFORMATION; PENALTIES.—The provisions of subparagraphs (C) and (D) of subsection (b)(3) shall apply to a manufacturer that fails to submit the information and documentation required under clauses (ii) and

(iii) on a timely basis, or that knowingly provides false or misleading information, in the same manner as such provisions apply to a manufacturer with a rebate agreement under this section.

''(B) CONSIDERATION OF STATE REQUEST FOR APPROVAL.—

''(i) IN GENERAL.—The Secretary shall treat a State request for approval of a risk-sharing value-based payment agreement in the same manner that the Secretary treats a State plan amendment, and subpart B of part 430 of title 42, Code of Federal Regulations, including, subject to clause (ii), the timing requirements of section 430.16 of such title (as in effect on the date of enactment of this subsection), shall apply to a request for approval of a risk-sharing value-based payment agreement in the same manner as such subpart applies to a State plan amendment.

''(ii) TIMING.—The Secretary shall consult with the Commissioner of Food and Drugs as required under subparagraph (C) and make a determination on

whether to approve a request from a State for approval of a proposed risk-sharing value-based payment agreement (or request additional information necessary to allow the Secretary to make a determination with respect to such request for approval) within the time period, to the extent practicable, specified in section 430.16 of title 42, Code of Federal Regulations (as in effect on the date of enactment of this subsection), but in no case shall the Secretary take more than 180 days after the receipt of such request for approval or response to such request for additional information to make such a determination (or request additional information).

''(C) CONSULTATION WITH THE COMMISSIONER OF FOOD AND DRUGS.—In considering whether to approve a risk-sharing value-based payment agreement, the Secretary, to the extent necessary, shall consult with the Commissioner of Food and Drugs to determine whether the relevant clinical parameters specified in such agreement are appropriate.

"(3) INSTALLMENT-BASED PAYMENT STRUCTURE.—

"(A) IN GENERAL.—A risk-sharing value-based payment agreement shall provide for a payment structure under which, for every installment year of the agreement (subject to subparagraph (B)), the State shall pay the total installment year amount in equal installments to be paid at regular intervals over a period of time that shall be specified in the agreement.

"(B) REQUIREMENTS FOR INSTALLMENT PAYMENTS.—

"(i) TIMING OF FIRST PAYMENT.—The State shall make the first of the installment payments described in subparagraph (A) for an installment year not later than 30 days after the end of such year.

"(ii) LENGTH OF INSTALLMENT PERIOD.—The period of time over which the State shall make the installment payments described in subparagraph (A) for an installment year shall not be longer than 5 years.

"(iii) NONPAYMENT OR REDUCED PAYMENT OF INSTALLMENTS FOLLOWING

A FAILURE TO MEET CLINICAL PARAMETER.—If, prior to the payment date (as specified in the agreement) of any installment payment described in subparagraph (A) or any other alternative date or time frame (as otherwise specified in the agreement), the covered outpatient drug which is subject to the agreement fails to meet a relevant clinical parameter of the agreement, the agreement shall provide that—

"(I) the installment payment shall not be made; or

"(II) the installment payment shall be reduced by a percentage specified in the agreement that is based on the outcome achieved by the drug relative to the relevant clinical parameter.

"(4) NOTICE OF INTENT.—

"(A) IN GENERAL.—Subject to subparagraph (B), a manufacturer of a covered outpatient drug shall not be eligible to enter into a risk-sharing value-based payment agreement under this subsection with respect to such drug unless the manufacturer notifies the Secretary

that the manufacturer is interested in entering into such an agreement with respect to such drug. The decision to submit and timing of a request to enter into a proposed risk-sharing value-based payment agreement shall remain solely within the discretion of the State and shall only be effective upon Secretarial approval as required under this subsection.

''(B) TREATMENT OF SUBSEQUENTLY APPROVED DRUGS.—

''(i) IN GENERAL.—In the case of a manufacturer of a covered outpatient drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act after the date of enactment of this subsection, not more than 90 days after meeting with the Food and Drug Administration following phase II clinical trials for such drug (or, in the case of a drug described in clause (ii), not later than March 31, 2025), the manufacturer must notify the Secretary of the manufacturer's intent to enter into a risk-sharing value-based payment agreement under this sub-

section with respect to such drug. If no such meeting has occurred, the Secretary may use discretion as to whether a potentially curative treatment intended for one-time use may qualify for a risk-sharing value-based payment agreement under this section. A manufacturer notification of interest shall not have any influence on a decision for approval by the Food and Drug Administration.

''(ii) APPLICATION TO CERTAIN SUBSEQUENTLY APPROVED DRUGS.—A drug described in this clause is a covered outpatient drug of a manufacturer—

''(I) that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act after the date of enactment of this subsection; and

''(II) with respect to which, as of January 1, 2025, more than 90 days have passed after the manufacturer's meeting with the Food and Drug Ad-

ministration following phase II clinical trials for such drug.

''(iii) PARALLEL APPROVAL.—The Secretary, in coordination with the Administrator of the Centers for Medicare & Medicaid Services and the Commissioner of Food and Drugs, shall, to the extent practicable, approve a State's request to enter into a proposed risk-sharing value-based payment agreement that otherwise meets the requirements of this subsection at the time that such a drug is approved by the Food and Drug Administration to help provide that no State that wishes to enter into such an agreement is required to pay for the drug in full at one time if the State is seeking to pay over a period of time as outlined in the proposed agreement.

''(iv) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be applied or construed to modify or affect the timeframes or factors involved in the Secretary's determination of whether to approve or license a drug under section 505 of the Federal Food, Drug, and Cosmetic

Act or section 351 of the Public Health Service Act.

''(5) SPECIAL PAYMENT RULES.—

''(A) IN GENERAL.—Except as otherwise provided in this paragraph, with respect to an individual who is administered a unit of a covered outpatient drug that is purchased under a State plan by a State Medicaid agency under a risk-sharing value-based payment agreement in an installment year, the State shall remain liable to the manufacturer of such drug for payment for such unit without regard to whether the individual remains enrolled in the State plan under this title (or a waiver of such plan) for each installment year for which the State is to make installment payments for covered outpatient drugs purchased under the agreement in such year.

''(B) DEATH.—In the case of an individual described in subparagraph (A) who dies during the period described in such subparagraph, the State plan shall not be liable for any remaining payment for the unit of the covered outpatient drug administered to the individual which is

owed under the agreement described in such subparagraph.

''(C) WITHDRAWAL OF APPROVAL.—In the case of a covered outpatient drug that is the subject of a risk-sharing value-based agreement between a State and a manufacturer under this subsection, including a drug approved in accordance with section 506(c) of the Federal Food, Drug, and Cosmetic Act, and such drug is the subject of an application that has been withdrawn by the Secretary, the State plan shall not be liable for any remaining payment that is owed under the agreement.

''(D) ALTERNATIVE ARRANGEMENT UNDER AGREEMENT.—Subject to approval by the Secretary, the terms of a proposed risk-sharing value-based payment agreement submitted for approval by a State may provide that subparagraph (A) shall not apply.

''(E) GUIDANCE.—Not later than January 1, 2025, the Secretary shall issue guidance to States establishing a process for States to notify the Secretary when an individual who is administered a unit of a covered outpatient drug that is purchased by a State plan under a risk-

sharing value-based payment agreement ceases to be enrolled under the State plan under this title (or a waiver of such plan) or dies before the end of the installment period applicable to such unit under the agreement.

''(6) TREATMENT OF PAYMENTS UNDER RISK-SHARING VALUE-BASED AGREEMENTS FOR PURPOSES OF AVERAGE MANUFACTURER PRICE; BEST PRICE.—The Secretary shall treat any payments made to the manufacturer of a covered outpatient drug under a risk-sharing value-based payment agreement under this subsection during a rebate period in the same manner that the Secretary treats payments made under a State supplemental rebate agreement under sections 447.504(c)(19) and 447.505(c)(7) of title 42, Code of Federal Regulations (or any successor regulations) for purposes of determining average manufacturer price and best price under this section with respect to the covered outpatient drug and a rebate period and for purposes of offsets required under subsection (b)(1)(B).

''(7) ASSESSMENTS AND REPORT TO CONGRESS.—

''(A) ASSESSMENTS.—

"(i) IN GENERAL.—Not later than 180 days after the end of each assessment period of any risk-sharing value-based payment agreement for a State approved under this subsection, the Secretary shall conduct an evaluation of such agreement which shall include an evaluation by the Chief Actuary to determine whether program spending under the risk-sharing value-based payment agreement aligned with the projections for the agreement made under paragraph (2)(A)(ii), including an assessment of whether actual Federal spending under this title under the agreement was less or more than net Federal spending would have been in the absence of the agreement.

"(ii) ASSESSMENT PERIOD.—For purposes of clause (i)—

"(I) the first assessment period for a risk-sharing value-based payment agreement shall be the period of time over which payments are scheduled to be made under the agreement for the first 10 individuals who are

administered covered outpatient drugs under the agreement except that such period shall not exceed the 5-year period after the date on which the Secretary approves the agreement; and

''(II) each subsequent assessment period for a risk-sharing value-based payment agreement shall be the 5-year period following the end of the previous assessment period.

''(B) RESULTS OF ASSESSMENTS.—

''(i) TERMINATION OPTION.—If the Secretary determines as a result of the assessment by the Chief Actuary under subparagraph (A) that the actual Federal spending under this title for any covered outpatient drug that was the subject of the State's risk-sharing value-based payment agreement was greater than the net Federal spending that would have resulted in the absence of the agreement, the Secretary may terminate approval of such agreement and shall immediately conduct an assessment under this paragraph of any other ongoing risk-sharing value-based

payment agreement to which the same manufacturer is a party.

''(ii) REPAYMENT REQUIRED.—

''(I) IN GENERAL.—If the Secretary determines as a result of the assessment by the Chief Actuary under subparagraph (A) that the Federal spending under the risk-sharing value-based agreement for a covered outpatient drug that was subject to such agreement was greater than the net Federal spending that would have resulted in the absence of the agreement, the manufacturer shall repay the difference to the State and Federal governments in a timely manner as determined by the Secretary.

''(II) TERMINATION FOR FAILURE TO PAY.—The failure of a manufacturer to make repayments required under subclause (I) in a timely manner shall result in immediate termination of all risk-sharing value-based agreements to which the manufacturer is a party.

"(III) ADDITIONAL PENALTIES.—In the case of a manufacturer that fails to make repayments required under subclause (I), the Secretary may treat such manufacturer in the same manner as a manufacturer that fails to pay required rebates under this section, and the Secretary may—

"(aa) suspend or terminate the manufacturer's rebate agreement under this section; and

"(bb) pursue any other remedy that would be available if the manufacturer had failed to pay required rebates under this section.

"(C) REPORT TO CONGRESS.—Not later than 5 years after the first risk-sharing value-based payment agreement is approved under this subsection, the Secretary shall submit to Congress and make available to the public a report that includes—

"(i) an assessment of the impact of risk-sharing value-based payment agree-

ments on access for individuals who are eligible for benefits under a State plan or waiver under this title to medically necessary covered outpatient drugs and related treatments;

''(ii) an analysis of the impact of such agreements on overall State and Federal spending under this title;

''(iii) an assessment of the impact of such agreements on drug prices, including launch price and price increases; and

''(iv) such recommendations to Congress as the Secretary deems appropriate.

''(8) GUIDANCE AND REGULATIONS.—

''(A) IN GENERAL.—Not later than January 1, 2025, the Secretary shall issue guidance to States seeking to enter into risk-sharing value-based payment agreements under this subsection that includes a model template for such agreements. The Secretary may issue any additional guidance or promulgate regulations as necessary to implement and enforce the provisions of this subsection.

''(B) MODEL AGREEMENTS.—

"(i) IN GENERAL.—If a State expresses an interest in pursuing a risk-sharing value-based payment agreement under this subsection with a manufacturer for the purchase of a covered outpatient drug, the Secretary may share with such State any risk-sharing value-based agreement between a State and the manufacturer for the purchase of such drug that has been approved under this subsection. While such shared agreement may serve as a template for a State that wishes to propose, the use of a previously approved agreement shall not affect the submission and approval process for approval of a proposed risk-sharing value-based payment agreement under this subsection, including the requirements under paragraph (2)(A).

"(ii) CONFIDENTIALITY.—In the case of a risk-sharing value-based payment agreement that is disclosed to a State by the Secretary under this subparagraph and that is only in effect with respect to a single State, the confidentiality of information

provisions described in subsection (b)(3)(D) shall apply to such information.

''(C) OIG CONSULTATION.—

''(i) IN GENERAL.—The Secretary shall consult with the Office of the Inspector General of the Department of Health and Human Services to determine whether there are potential program integrity concerns with agreement approvals or templates and address accordingly.

''(ii) OIG POLICY UPDATES AS NECESSARY.—The Inspector General of the Department of Health and Human Services shall review and update, as necessary, any policies or guidelines of the Office of the Inspector General of the Department of Human Services (including policies related to the enforcement of section 1128B) to accommodate the use of risk-sharing value-based payment agreements in accordance with this section.

''(9) RULES OF CONSTRUCTION.—

''(A) MODIFICATIONS.—Nothing in this subsection or any regulations promulgated under this subsection shall prohibit a State

from requesting a modification from the Secretary to the terms of a risk-sharing value-based payment agreement. A modification that is expected to result in any increase to projected net State or Federal spending under the agreement shall be subject to recertification by the Chief Actuary as described in paragraph (2)(A)(ii) before the modification may be approved.

''(B) REBATE AGREEMENTS.—Nothing in this subsection shall be construed as requiring a State to enter into a risk-sharing value-based payment agreement or as limiting or superseding the ability of a State to enter into a supplemental rebate agreement for a covered outpatient drug.

''(C) FFP FOR PAYMENTS UNDER RISK-SHARING VALUE-BASED PAYMENT AGREEMENTS.—Federal financial participation shall be available under this title for any payment made by a State to a manufacturer for a covered outpatient drug under a risk-sharing value-based payment agreement in accordance with this subsection, except that no Federal financial participation shall be available for any

payment made by a State to a manufacturer under such an agreement on and after the effective date of a disapproval of such agreement by the Secretary.

''(D) CONTINUED APPLICATION OF OTHER PROVISIONS.—Except as expressly provided in this subsection, nothing in this subsection or in any regulations promulgated under this subsection shall affect the application of any other provision of this Act.

''(10) APPROPRIATIONS.—For fiscal year 2023 and each fiscal year thereafter, there are appropriated to the Secretary $5,000,000 for the purpose of carrying out this subsection.

''(11) DEFINITIONS.—In this subsection:

''(A) CHIEF ACTUARY.—The term 'Chief Actuary' means the Chief Actuary of the Centers for Medicare & Medicaid Services.

''(B) INSTALLMENT YEAR.—The term 'installment year' means, with respect to a risk-sharing value-based payment agreement, a 12-month period during which a covered outpatient drug is administered under the agreement.

''(C) POTENTIALLY CURATIVE TREATMENT INTENDED FOR ONE-TIME USE.—The term 'po-

tentially curative treatment intended for one-time use' means a treatment that consists of the administration of a covered outpatient drug that—

"(i) is a form of gene therapy for a rare disease, as defined by the Commissioner of Food and Drugs, designated under section 526 of the Federal Food, Drug, and Cosmetics Act, and approved under section 505 of such Act or licensed under subsection (a) or (k) of section 351 of the Public Health Service Act to treat a serious or life-threatening disease or condition;

"(ii) if administered in accordance with the labeling of such drug, is expected to result in either—

"(I) the cure of such disease or condition; or

"(II) a reduction in the symptoms of such disease or condition to the extent that such disease or condition is not expected to lead to early mortality; and

"(iii) is expected to achieve a result described in clause (ii), which may be achieved over an extended period of time, after not more than 3 administrations.

"(D) RELEVANT CLINICAL PARAMETER.—The term 'relevant clinical parameter' means, with respect to a covered outpatient drug that is the subject of a risk-sharing value-based payment agreement—

"(i) a clinical endpoint specified in the drug's labeling or supported by one or more of the compendia described in section 1861(t)(2)(B)(ii)(I) that—

"(I) is able to be measured or evaluated on an annual basis for each year of the agreement on an independent basis by a provider or other entity; and

"(II) is required to be achieved (based on observed metrics in patient populations) under the terms of the agreement; or

"(ii) a surrogate endpoint (as defined in section 507(e)(9) of the Federal Food, Drug, and Cosmetic Act), including those

developed by patient-focused drug development tools, that—

"(I) is able to be measured or evaluated on an annual basis for each year of the agreement on an independent basis by a provider or other entity; and

"(II) has been qualified by the Food and Drug Administration.

"(E) RISK-SHARING VALUE-BASED PAYMENT AGREEMENT.—The term 'risk-sharing value-based payment agreement' means an agreement between a State plan and a manufacturer—

"(i) for the purchase of a covered outpatient drug of the manufacturer that is a potentially curative treatment intended for one-time use;

"(ii) under which payment for such drug shall be made pursuant to an installment-based payment structure that meets the requirements of paragraph (3);

"(iii) which conditions payment on the achievement of at least 2 relevant clinical

parameters (as defined in subparagraph (C));

''(iv) which provides that—

''(I) the State plan will directly reimburse the manufacturer for the drug; or

''(II) a third party will reimburse the manufacture in a manner approved by the Secretary; and

''(v) is approved by the Secretary in accordance with paragraph (2).

''(F) TOTAL INSTALLMENT YEAR AMOUNT.—The term 'total installment year amount' means, with respect to a risk-sharing value-based payment agreement for the purchase of a covered outpatient drug and an installment year, an amount equal to the product of—

''(i) the unit price of the drug charged under the agreement; and

''(ii) the number of units of such drug administered under the agreement during such installment year.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 1903(i)(10)(A) of the Social Security Act (42 U.S.C. 1396b(i)(10)(A)) is amended by striking ''or unless section 1927(a)(3) applies'' and inserting '', section 1927(a)(3) applies with respect to such drugs, or such drugs are the subject of a risk-sharing value-based payment agreement under section 1927(l)''.

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

(A) in paragraph (1)(A), by inserting ''(except for drugs for which payment is made by a State under a risk-sharing value-based payment agreement under subsection (l))'' after ''under the State plan for such period''; and

(B) in paragraph (3)—

(i) in subparagraph (C)(i), by inserting ''or subsection (l)(2)(A)'' after ''subparagraph (A)''; and

(ii) in subparagraph (D), in the matter preceding clause (i), by inserting '', under subsection (l)(2)(A),'' after ''under this paragraph''.

SEC. 307. MODIFICATION OF MAXIMUM REBATE AMOUNT UNDER MEDICAID DRUG REBATE PROGRAM.

(a) IN GENERAL.—Subparagraph (D) of section 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)) is amended to read as follows:

''(D) MAXIMUM REBATE AMOUNT.—

''(i) IN GENERAL.—Except as provided in clause (ii), in no case shall the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator multiple source drug for a rebate period exceed—

''(I) for rebate periods beginning after December 31, 2009, and before September 30, 2025, 100 percent of the average manufacturer price of the drug; and

''(II) for rebate periods beginning on or after October 1, 2025, 125 percent of the average manufacturer price of the drug.

''(ii) NO MAXIMUM AMOUNT FOR DRUGS IF AMP INCREASES OUTPACE INFLATION.—

"(I) IN GENERAL.—If the average manufacturer price with respect to each dosage form and strength of a single source drug or an innovator multiple source drug increases on or after October 1, 2024, and such increased average manufacturer price exceeds the inflation-adjusted average manufacturer price determined with respect to such drug under subclause (II) for the rebate period, clause (i) shall not apply and there shall be no limitation on the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph for the rebate period with respect to each dosage form and strength of the single source drug or innovator multiple source drug.

"(II) INFLATION-ADJUSTED AVERAGE MANUFACTURER PRICE DEFINED.—In this clause, the term 'inflation-adjusted average manufacturer price' means, with respect to a single source drug or an innovator multiple source drug and a rebate period, the

average manufacturer price for each dosage form and strength of the drug for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the 1st day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.''.

(b) TREATMENT OF SUBSEQUENTLY APPROVED DRUGS.—Section 1927(c)(2)(B) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)(B)) is amended by inserting ''and clause (ii)(II) of subparagraph (D)'' after ''clause (ii)(II) of subparagraph (A)''.

(c) TECHNICAL AMENDMENTS.—Section 1927(c)(3)(C)(ii)(IV) of the Social Security Act (42 U.S.C. 1396r–9(c)(3)(C)(ii)(IV)) is amended—

(1) by striking ''subparagraph (A)'' and inserting ''paragraph (3)(A)''; and

(2) by striking ''this subparagraph'' and inserting ''paragraph (3)(C)''.

TITLE IV—ADDRESSING INTERMEDIARIES AND DRUG COMPETITION

SEC. 401. HEALTH PLAN OVERSIGHT OF PHARMACY BENEFIT MANAGER SERVICES.

Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.) is amended by adding at the end the following:

''SEC. 2729A. HEALTH PLAN OVERSIGHT OF PHARMACY BENEFIT MANAGER SERVICES.

''(a) IN GENERAL.—A group health plan or health insurance issuer offering group or individual health insurance coverage or an entity or subsidiary providing pharmacy benefits management services shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or coverage, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan or coverage from making the reports described in subsection (b).

''(b) REPORTS TO GROUP PLAN SPONSORS.—

"(1) IN GENERAL.—Beginning with the first plan year that begins after the date of enactment of this section, not less frequently than once every six months, a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the self-funded group health plan and at the request of any other group health plan a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format. Each such report shall include, with respect to the applicable group health plan or health insurance coverage—

"(A) information collected from drug manufacturers by such issuer or entity on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the enrollees in such plan or coverage;

"(B) a list of each covered drug dispensed during the reporting period, including, with respect to each such drug during the reporting period—

"(i) the brand name, chemical entity, and National Drug Code;

''(ii) the number of enrollees for whom the drug was filled during the plan year, the total number of prescription fills for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, including whether the dispensing channel was by retail, mail order, or specialty pharmacy;

''(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dose;

''(iv) the total out-of-pocket spending by enrollees on such drug, including enrollee spending through copayments, coinsurance, and deductibles; and

''(v) for any drug for which gross spending of the group health plan or health insurance coverage exceeded $10,000 during the reporting period—

''(I) a list of all other available drugs in the same therapeutic category or class, including brand name drugs and biological products and ge-

neric drugs or biosimilar biological products that are in the same therapeutic category or class; and

''(II) the rationale for preferred formulary placement of a particular drug or drugs in that therapeutic category or class;

''(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic category or class of drugs, during the reporting period—

''(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;

''(ii) the number of enrollees who filled a prescription for a drug in that category or class;

''(iii) if applicable to that category or class, a description of the formulary tiers and utilization mechanisms (such as prior authorization or step therapy) employed for drugs in that category or class;

"(iv) the total out-of-pocket spending by enrollees, including enrollee spending through copayments, coinsurance, and deductibles; and

"(v) for each therapeutic category or class under which three or more drugs are marketed and available—

"(I) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration—

"(aa) to be paid by drug manufacturers for claims incurred during the reporting period; or

"(bb) that is related to utilization of drugs, in such therapeutic category or class;

"(II) the total net spending by the health plan or health insurance coverage on that category or class of drugs; and

"(III) the net price per dosage unit or course of treatment incurred by the health plan or health insurance

coverage and its enrollees, after manufacturer rebates, fees, and other remuneration for drugs dispensed within such therapeutic category or class during the reporting period;

''(D) total gross spending on prescription drugs by the plan or coverage during the reporting period, before rebates and other manufacturer fees or remuneration;

''(E) total amount received, or expected to be received, by the health plan or health insurance coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party related to utilization of drug or drug spending under that health plan or health insurance coverage during the reporting period;

''(F) the total net spending on prescription drugs by the health plan or health insurance coverage during the reporting period; and

''(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm who referred the group health

plan's or health insurance issuer's business to the pharmacy benefit manager.

"(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (or successor regulations), and shall restrict the use and disclosure of such information according to such privacy regulations.

"(3) DISCLOSURE AND REDISCLOSURE.—

"(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

"(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an

entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1).

''(c) ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall enforce this section.

''(2) FAILURE TO PROVIDE TIMELY INFORMATION.—A health insurance issuer or an entity providing pharmacy benefit management services that violates subsection (a) or fails to provide information required under subsection (b) or a drug manufacturer that fails to provide information under subsection (b)(1)(A), in a timely manner shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

''(3) FALSE INFORMATION.—A health insurance issuer, entity providing pharmacy benefit management services, or drug manufacturer that knowingly provides false information under this section shall be subject to a civil money penalty in an amount not

to exceed $100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.

''(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

''(5) SAFE HARBOR.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with this section.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit entities providing pharmacy benefits management services from retaining bona fide service fees, provided that such fees are transparent to group health plans and health insurance issuers and are not linked directly to the price or formulary placement or position of a drug.

''(e) DEFINITIONS.—In this section—

''(1) the term 'similarly situated pharmacy' means, with respect to a particular pharmacy, another pharmacy that is approximately the same size (as measured by the number of prescription drugs dispensed), and that serves patients in the same geographical area, whether through physical locations or mail order;

''(2) the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act; and

''(3) the term 'bona fide service fees' means fees paid by a manufacturer, customer, or client (other than a group health plan or health insurance issuer) of an entity providing pharmacy benefit management services, to an entity providing pharmacy benefit management services, that represent fair market value for bona fide, itemized services actually performed on behalf of the manufacturer, customer, or client would otherwise perform or contract for in the absence of the service arrangement, without prior consent for any specific arrangements.''.

SEC. 402. STUDY OF PHARMACEUTICAL SUPPLY CHAIN INTERMEDIARIES AND MERGER ACTIVITY.

(a) INITIAL REPORT.—Not later than 1 year after the date of enactment of this Act, the Commission shall

submit to the appropriate committees of Congress a report that—

(1) addresses at minimum—

(A) whether pharmacy benefit managers—

(i) charge payers a higher price than the reimbursement rate at which the pharmacy benefit managers reimburse competing pharmacies;

(ii) steer patients for anticompetitive purposes to any pharmacies, including retail, mail-order, or any other type of pharmacy, in which the pharmacy benefit manager has an ownership interest;

(iii) audit or review proprietary data, including acquisition costs, patient information, or dispensing information, of competing pharmacies that can be used for anticompetitive purposes; or

(iv) use formulary designs to increase the market share of higher cost prescription drugs and depress the market share of lower cost prescription drugs (each net of rebates and discounts);

(B) how companies and payers assess the benefits, costs, and risks of contracting with

intermediaries, including pharmacy services administrative organizations, and whether more information about the roles of intermediaries should be available to consumers and payers; and

(C) whether there are any specific legal or regulatory obstacles the Commission currently faces in ensuring a competitive and transparent marketplace in the pharmaceutical supply chain, including the pharmacy benefit manager marketplace and pharmacy services administrative organizations; and

(2) provides—

(A) observations or conclusions drawn from the November 2017 roundtable entitled ''Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics'', and any similar efforts;

(B) specific actions the Commission intends to take as a result of the November 2017 roundtable, and any similar efforts, including a detailed description of relevant forthcoming actions, additional research or roundtable discussions, consumer education efforts, or enforcement actions; and

(C) policy or legislative recommendations to—

(i) improve transparency and competition in the pharmaceutical supply chain;

(ii) prevent and deter anticompetitive behavior in the pharmaceutical supply chain; and

(iii) best ensure that consumers benefit from any cost savings or efficiencies that may result from mergers and consolidations.

(b) INTERIM REPORT.—Not later than 180 days after the date of enactment of this Act, the Commission shall submit to the appropriate committees of Congress an interim report on the progress of the report required by subsection (a), along with preliminary findings and conclusions based on information collected to that date.

(c) DEFINITIONS.—In this section:

(1) APPROPRIATE COMMITTEES OF CONGRESS.—The term ''appropriate committees of Congress'' means—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on the Judiciary of the Senate; and

(C) the Committee on the Judiciary of the House of Representatives.

(2) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

SEC. 403. REQUIREMENT THAT DIRECT-TO-CONSUMER ADVERTISEMENTS FOR PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS INCLUDE TRUTHFUL AND NON-MISLEADING PRICING INFORMATION.

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

''SEC. 1150D. REQUIREMENT THAT DIRECT-TO-CONSUMER ADVERTISEMENTS FOR PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS INCLUDE TRUTHFUL AND NON-MISLEADING PRICING INFORMATION.

''(a) IN GENERAL.—The Secretary shall require that each direct-to-consumer advertisement for a prescription drug or biological product for which payment is available under title XVIII or XIX includes an appropriate disclosure of truthful and non-misleading pricing information with respect to the drug or product.

''(b) DETERMINATION BY CMS.—The Secretary, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall determine the components of

the requirement under subsection (a), such as the forms of advertising, the manner of disclosure, the price point listing, and the price information for disclosure.''.

SEC. 404. CHANGE CONDITIONS OF FIRST GENERIC EXCLUSIVITY TO SPUR ACCESS AND COMPETITION.

Clause (iv) of section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)) is amended—

(1) in subclause (I), after ''180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant'' by inserting ''or by an applicant whose application is approved pursuant to subclause (III)''; and

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

''(III) APPLICANT APPROVAL.—An application containing a certification described in paragraph (2)(A)(vii)(IV) that is for a drug for which a first applicant has submitted an application containing such a certification can be approved notwithstanding the eligibility of a first applicant for the 180-day exclusivity period described in subclause (II)(aa) if each of the following conditions is met:

''(aa) The approval of such an application could be made effective, but for the eligibility of a first applicant for 180-day exclusivity under this clause.

''(bb) At least 30 months have passed since the date of submission of an application for the drug by at least one first applicant.

''(cc) Approval of an application for the drug submitted by at least one first applicant is not precluded under clause (iii).

''(dd) No application for the drug submitted by any first applicant is approved at the time the conditions under items (aa), (bb), and (cc) are all met, regardless of whether such an application is subsequently approved.''.

SEC. 405. ENDING THE PRACTICE PREVENTING MARKET COMPETITION KNOWN AS "PAY-FOR-DELAY".

(a) CONGRESSIONAL FINDINGS AND DECLARATION OF PURPOSES.—

(1) FINDINGS.—Congress finds the following:

(A) In 1984, the Drug Price Competition and Patent Term Restoration Act (Public Law 98–417) (referred to in this Act as the ''1984

Act''), was enacted with the intent of facilitating the early entry of generic drugs while preserving incentives for innovation.

(B) Prescription drugs make up approximately 10 percent of the national health care spending.

(C) Initially, the 1984 Act was successful in facilitating generic competition to the benefit of consumers and health care payers, although 88 percent of all prescriptions dispensed in the United States are generic drugs, they account for only 28 percent of all expenditures.

(D) Generic drugs cost substantially less than brand name drugs, with discounts off the brand price averaging 80 to 85 percent.

(E) Federal dollars currently account for over 40 percent of the $325,000,000,000 spent on retail prescription drugs, and this share is expected to rise to 47 percent by 2025.

(F)(i) In recent years, the intent of the 1984 Act has been subverted by certain settlement agreements in which brand name companies transfer value to their potential generic competitors to settle claims that the generic

company is infringing the branded company's patents.

(ii) These ''reverse payment'' settlement agreements—

(I) allow a branded company to share its monopoly profits with the generic company as a way to protect the branded company's monopoly; and

(II) have unduly delayed the marketing of low-cost generic drugs contrary to free competition, the interests of consumers, and the principles underlying antitrust law.

(iii) Because of the price disparity between brand name and generic drugs, such agreements are more profitable for both the brand and generic manufacturers than competition and will become increasingly common unless prohibited.

(iv) These agreements result in consumers losing the benefits that the 1984 Act was intended to provide.

(G) In 2010, the Biologics Price Competition and Innovation Act (Public Law 111–148) (referred to in this Act as the ''BPCIA''), was

enacted with the intent of facilitating the early entry of biosimilar and interchangeable follow-on versions of branded biological products while preserving incentives for innovation.

(H) Biological drugs play an important role in treating many serious illnesses, from cancers to genetic disorders. They are also expensive, representing more than 40 percent of all prescription drug spending.

(I) Competition from biosimilar and interchangeable biological products promises to lower drug costs and increase patient access to biological medicines. But ''reverse payment'' settlement agreements also threaten to delay the entry of biosimilar and interchangeable biological products, which would undermine the goals of BPCIA.

(2) PURPOSES.—The purposes of this Act are—

(A) to enhance competition in the pharmaceutical market by stopping anticompetitive agreements between brand name and generic drug and biosimilar biological product manufacturers that limit, delay, or otherwise prevent

competition from generic drugs and biosimilar biological products; and

(B) to support the purpose and intent of antitrust law by prohibiting anticompetitive practices in the pharmaceutical industry that harm consumers.

(b) UNLAWFUL COMPENSATION FOR DELAY.—

(1) IN GENERAL.—The Federal Trade Commission Act (15 U.S.C. 44 et seq.) is amended by inserting after section 26 (15 U.S.C. 57c–2) the following:

"SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS AND BIOSIMILARS.

''(a) IN GENERAL.—

''(1) ENFORCEMENT PROCEEDING.—The Commission may initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling, on a final or interim basis, a patent claim, in connection with the sale of a drug product or biological product.

''(2) PRESUMPTION AND VIOLATION.—

''(A) IN GENERAL.—Subject to subparagraph (B), in such a proceeding, an agreement shall be presumed to have anticompetitive effects and shall be a violation of this section if—

"(i) an ANDA filer or a biosimilar biological product application filer receives anything of value, including an exclusive license; and

"(ii) the ANDA filer or biosimilar biological product application filer agrees to limit or forgo research, development, manufacturing, marketing, or sales of the ANDA product or biosimilar biological product, as applicable, for any period of time.

"(B) EXCEPTION.—Subparagraph (A) shall not apply if the parties to such agreement demonstrate by clear and convincing evidence that—

"(i) the value described in subparagraph (A)(i) is compensation solely for other goods or services that the ANDA filer or biosimilar biological product application filer has promised to provide; or

"(ii) the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

''(b) LIMITATIONS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall not presume—

''(1) that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity; or

''(2) that the agreement's provision for entry of the ANDA product or biosimilar biological product prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is procompetitive.

''(c) EXCLUSIONS.—Nothing in this section shall prohibit a resolution or settlement of a patent infringement claim in which the consideration that the ANDA filer or biosimilar biological product application filer, respectively, receives as part of the resolution or settlement includes only one or more of the following:

''(1) The right to market and secure final approval in the United States for the ANDA product or biosimilar biological product at a date, whether certain or contingent, prior to the expiration of—

''(A) any patent that is the basis for the patent infringement claim; or

''(B) any patent right or other statutory exclusivity that would prevent the marketing of

such ANDA product or biosimilar biological product.

''(2) A payment for reasonable litigation expenses not to exceed—

''(A) for calendar year 2021, $7,500,000; or

''(B) for calendar year 2022 and each subsequent calendar year, the amount determined for the preceding calendar year adjusted to reflect the percentage increase (if any) in the Producer Price Index for Legal Services published by the Bureau of Labor Statistics of the Department of Labor for the most recent calendar year.

''(3) A covenant not to sue on any claim that the ANDA product or biosimilar biological product infringes a United States patent.

''(d) ENFORCEMENT.—

''(1) ENFORCEMENT.—A violation of this section shall be treated as an unfair method of competition under section 5(a)(1).

''(2) JUDICIAL REVIEW.—

''(A) IN GENERAL.—Any party that is subject to a final order of the Commission, issued in an administrative adjudicative proceeding

under the authority of subsection (a)(1), may, within 30 days of the issuance of such order, petition for review of such order in—

"(i) the United States Court of Appeals for the District of Columbia Circuit;

"(ii) the United States Court of Appeals for the circuit in which the ultimate parent entity, as defined in section 801.1(a)(3) of title 16, Code of Federal Regulations, or any successor thereto, of the NDA holder or biological product license holder is incorporated as of the date that the NDA or biological product license application, as applicable, is filed with the Commissioner of Food and Drugs; or

"(iii) the United States Court of Appeals for the circuit in which the ultimate parent entity of the ANDA filer or biosimilar biological product application filer is incorporated as of the date that the ANDA or biosimilar biological product application is filed with the Commissioner of Food and Drugs.

"(B) TREATMENT OF FINDINGS.—In a proceeding for judicial review of a final order of

the Commission, the findings of the Commission as to the facts, if supported by evidence, shall be conclusive.

''(e) ANTITRUST LAWS.—Nothing in this section shall modify, impair, limit, or supersede the applicability of the antitrust laws as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), and of section 5 of this Act to the extent that section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit, or supersede the right of an ANDA filer or biosimilar biological product application filer to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition.

''(f) PENALTIES.—

''(1) FORFEITURE.—Each party that violates or assists in the violation of this section shall forfeit and pay to the United States a civil penalty sufficient to deter violations of this section, but in no event greater than 3 times the value received by the party that is reasonably attributable to the violation of this section. If no such value has been received by the NDA holder, the biological product license holder, the ANDA filer, or the biosimilar biological product application filer, the penalty to the NDA holder,

the biological product license holder, the ANDA filer, or the biosimilar biological product application filer shall be sufficient to deter violations, but in no event shall be greater than 3 times the value given to an ANDA filer or biosimilar biological product application filer reasonably attributable to the violation of this section. Such penalty shall accrue to the United States and may be recovered in a civil action brought by the Commission, in its own name by any of its attorneys designated by it for such purpose, in a district court of the United States against any party that violates this section. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

''(2) CEASE AND DESIST.—

''(A) IN GENERAL.—If the Commission has issued a cease and desist order with respect to a party in an administrative adjudicative proceeding under the authority of subsection (a)(1), an action brought pursuant to paragraph (1) may be commenced against such party at any time before the expiration of 1 year after such order becomes final pursuant to section 5(g).

"(B) EXCEPTION.—In an action under subparagraph (A), the findings of the Commission as to the material facts in the administrative adjudicative proceeding with respect to the violation of this section by a party shall be conclusive unless—

"(i) the terms of such cease and desist order expressly provide that the Commission's findings shall not be conclusive; or

"(ii) the order became final by reason of section 5(g)(1), in which case such finding shall be conclusive if supported by evidence.

"(3) CIVIL PENALTY.—In determining the amount of the civil penalty described in this section, the court shall take into account—

"(A) the nature, circumstances, extent, and gravity of the violation;

"(B) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the NDA holder, the biological product license holder, the ANDA filer, or the biosimilar biological

product application filer, compensation received by the ANDA filer or biosimilar biological product application filer, and the amount of commerce affected; and

''(C) other matters that justice requires.

''(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

''(g) DEFINITIONS.—In this section:

''(1) AGREEMENT.—The term 'agreement' means anything that would constitute an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of this Act.

''(2) AGREEMENT RESOLVING OR SETTLING A PATENT INFRINGEMENT CLAIM.—The term 'agreement resolving or settling a patent infringement claim' includes any agreement that is entered into within 30 days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

''(3) ANDA.—The term 'ANDA' means an abbreviated new drug application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) or a new drug application filed under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)).

''(4) ANDA FILER.—The term 'ANDA filer' means a party that owns or controls an ANDA filed with the Food and Drug Administration or has the exclusive rights under such ANDA to distribute the ANDA product.

''(5) ANDA PRODUCT.—The term 'ANDA product' means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

''(6) BIOLOGICAL PRODUCT.—The term 'biological product' has the meaning given such term in section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)).

''(7) BIOLOGICAL PRODUCT LICENSE APPLICATION.—The term 'biological product license application' means an application under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

''(8) BIOLOGICAL PRODUCT LICENSE HOLDER.—The term 'biological product license holder' means—

''(A) the holder of an approved biological product license application for a biological product;

''(B) a person owning or controlling enforcement of any patents that claim the biological product that is the subject of such approved application; or

''(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

''(9) BIOSIMILAR BIOLOGICAL PRODUCT.—The term 'biosimilar biological product' means the product to be manufactured under the biosimilar biological product application that is the subject of the patent infringement claim.

''(10) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION.—The term 'biosimilar biological product ap-

plication' means an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) for licensure of a biological product as biosimilar to, or interchangeable with, a reference product.

''(11) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FILER.—The term 'biosimilar biological product application filer' means a party that owns or controls a biosimilar biological product application filed with the Food and Drug Administration or has the exclusive rights under such application to distribute the biosimilar biological product.

''(12) DRUG PRODUCT.—The term 'drug product' has the meaning given such term in section 314.3(b) of title 21, Code of Federal Regulations (or any successor regulation).

''(13) MARKET.—The term 'market' means the promotion, offering for sale, selling, or distribution of a drug product.

''(14) NDA.—The term 'NDA' means a new drug application filed under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

''(15) NDA HOLDER.—The term 'NDA holder' means—

"(A) the holder of an approved NDA application for a drug product;

"(B) a person owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the 'FDA Orange Book') in connection with the NDA; or

"(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

"(16) PARTY.—The term 'party' means any person, partnership, corporation, or other legal entity.

"(17) PATENT INFRINGEMENT.—The term 'patent infringement' means infringement of any patent or of any filed patent application, including any extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition, and extensions thereof.

''(18) PATENT INFRINGEMENT CLAIM.—The term 'patent infringement claim' means any allegation made to an ANDA filer or biosimilar biological product application filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product, or biosimilar biological product license application or biosimilar biological product, may infringe any patent held by, or exclusively licensed to, the NDA holder, biological product license holder, ANDA filer, or biosimilar biological product application filer of the drug product or biological product, as applicable.

''(19) STATUTORY EXCLUSIVITY.—The term 'statutory exclusivity' means those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year data exclusivity), section 527 (orphan drug exclusivity), or section 505A (pediatric exclusivity) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E), 360cc, 355a), or on the licensing of biological product applications under section 351(k)(7) (12-year exclusivity) or paragraph (2) or (3) of section 351(m) (pediatric exclusivity) of the Public Health Service Act (42 U.S.C. 262) or under section 527 of the Federal Food, Drug, and Cos-

metic Act (21 U.S.C. 360cc) (orphan drug exclusivity).''.

(2) EFFECTIVE DATE.—Section 27 of the Federal Trade Commission Act, as added by this section, shall apply to all agreements described in section 27(a)(1) of that Act entered into on or after the date of enactment of this Act.

(c) CERTIFICATION OF AGREEMENTS.—

(1) NOTICE OF ALL AGREEMENTS.—Section 1111(7) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by inserting '', or the owner of a patent for which a claim of infringement could reasonably be asserted against any person for making, using, offering to sell, selling, or importing into the United States a biological product that is the subject of a biosimilar biological product application'' before the period at the end.

(2) CERTIFICATION OF AGREEMENTS.—Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by adding at the end the following:

''(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any

agreement under subsection (a) or (b) that is required to be filed under subsection (c), within 30 days after such filing, shall execute and file with the Assistant Attorney General and the Commission a certification as follows: 'I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification—

"'(1) represent the complete, final, and exclusive agreement between the parties;

"'(2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and

"'(3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.'.".

(d) NOTIFICATION OF AGREEMENTS.—Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note), as

amended by section 4(b), is further amended by adding at the end the following:

''(e) RULE OF CONSTRUCTION.—

''(1) IN GENERAL.—An agreement that is required under subsection (a) or (b) shall include agreements resolving any outstanding disputes, including agreements resolving or settling a Patent Trial and Appeal Board proceeding.

''(2) DEFINITION.—For purposes of subparagraph (A), the term 'Patent Trial and Appeal Board proceeding' means a proceeding conducted by the Patent Trial and Appeal Board of the United States Patent and Trademark Office, including an inter partes review instituted under chapter 31 of title 35, United States Code, a post-grant review instituted under chapter 32 of that title (including a proceeding instituted pursuant to the transitional program for covered business method patents, as described in section 18 of the Leahy-Smith America Invents Act (35 U.S.C. 321 note)), and a derivation proceeding instituted under section 135 of that title.''.

(e) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))

is amended by inserting ''section 27 of the Federal Trade Commission Act or'' after ''that the agreement has violated''.

(f) COMMISSION LITIGATION AUTHORITY.—Section 16(a)(2) of the Federal Trade Commission Act (15 U.S.C. 56(a)(2)) is amended—

(1) in subparagraph (D), by striking ''or'' after the semicolon;

(2) in subparagraph (E), by inserting ''or'' after the semicolon; and

(3) inserting after subparagraph (E) the following:

''(F) under section 27,''.

(g) REPORT ON ADDITIONAL EXCLUSION.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Federal Trade Commission shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a recommendation, and the Commission's basis for such recommendation, regarding a potential amendment to include in section 27(c) of the Federal Trade Commission Act (as added by section 3 of this Act) an additional exclusion for consideration granted by an NDA holder to a ANDA filer or by a biological

product license holder to a biosimilar biological product application filer as part of the resolution or settlement, a release, waiver, or limitation of a claim for damages or other monetary relief.

(2) DEFINITIONS.—In this section, the terms ''ANDA filer'', ''biological product license holder'', ''biosimilar biological product application filer'', and ''NDA holder'' have the meanings given such terms in section 27(g) of the Federal Trade Commission Act (as added by section 3 of this Act).

(h) STATUTE OF LIMITATIONS.—The Federal Trade Commission shall commence any enforcement proceeding described in section 27 of the Federal Trade Commission Act, as added by section 3, except for an action described in section 27(f)(2) of the Federal Trade Commission Act, not later than 6 years after the date on which the parties to the agreement file the certification under section 1112(d) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (21 U.S.C. 355 note).

(i) SEVERABILITY.—If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the

provisions of such Act or amendments to any person or circumstance shall not be affected.

SEC. 406. EMPOWERING THE FTC TO PREVENT "PRODUCT HOPPING".

(a) IN GENERAL.—The Federal Trade Commission Act (15 U.S.C. 41 et seq.) is amended by inserting after section 26 (15 U.S.C. 57c–2) the following:

"SEC. 27. PRODUCT HOPPING.

''(a) DEFINITIONS.—In this section:

''(1) ABBREVIATED NEW DRUG APPLICATION.—The term 'abbreviated new drug application' means an application under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

''(2) BIOSIMILAR BIOLOGICAL PRODUCT.—The term 'biosimilar biological product' means a biological product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

''(3) BIOSIMILAR BIOLOGICAL PRODUCT LICENSE APPLICATION.—The term 'biosimilar biological product license application' means an application submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

''(4) FOLLOW-ON PRODUCT.—The term 'follow-on product'—

"(A) means a drug approved through an application or supplement to an application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or a biological product licensed through an application or supplement to an application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for a change, modification, or reformulation to the same manufacturer's previously approved drug or biological product that treats the same medical condition; and

"(B) excludes such an application or supplement to an application for a change, modification, or reformulation of a drug or biological product that is requested by the Secretary or necessary to comply with law, including sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c).

"(5) GENERIC DRUG.—The term 'generic drug' means a drug approved under an application submitted under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

''(6) LISTED DRUG.—The term 'listed drug' means a drug listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)).

''(7) MANUFACTURER.—The term 'manufacturer' means the holder, licensee, or assignee of—

''(A) an approved application for a drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)); or

''(B) a biological product license under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

''(8) REFERENCE PRODUCT.—The term 'reference product' has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

''(9) ULTIMATE PARENT ENTITY.—The term 'ultimate parent entity' has the meaning given the term in section 801.1 of title 16, Code of Federal Regulations, or any successor regulation.

''(b) PROHIBITION ON PRODUCT HOPPING.—

''(1) PRIMA FACIE.—Except as provided in paragraph (2), a manufacturer of a reference product or listed drug shall be considered to have engaged in an unfair method of competition in or af-

fecting commerce in violation of section 5(a) if the Commission demonstrates by a preponderance of the evidence in a proceeding initiated by the Commission under subsection (c)(1)(A), or in a suit brought under subparagraph (B) or (C) of subsection (c)(1), that, during the period beginning on the date on which the manufacturer of the reference product or listed drug first receives notice that an applicant has submitted to the Commissioner of Food and Drugs an abbreviated new drug application or biosimilar biological product license application and ending on the date that is 180 days after the date on which that generic drug or biosimilar biological product is first marketed, the manufacturer engaged in either of the following actions:

''(A) The manufacturer engaged in a hard switch, which shall be established by demonstrating that the manufacturer engaged in either of the following actions:

''(i) Upon the request of the manufacturer of the listed drug or reference product, the Commissioner of Food and Drugs withdrew the approval of the application for the listed drug or reference product or placed the listed drug or reference product

on the discontinued products list and the manufacturer marketed or sold a follow-on product.

''(ii) The manufacturer of the listed drug or reference product—

''(I)(aa) announced withdrawal of, discontinuance of the manufacture of, or intent to withdraw the application with respect to the drug or reference product in a manner that impedes competition from a generic drug or a biosimilar biological product, as established by objective circumstances; or

''(bb) destroyed the inventory of the listed drug or reference product in a manner that impedes competition from a generic drug or a biosimilar biological product, which may be established by objective circumstances; and

''(II) marketed or sold a follow-on product.

''(B) The manufacturer engaged in a soft switch, which shall be established by dem-

onstrating that the manufacturer engaged in both of the following actions:

"(i) The manufacturer took actions with respect to the listed drug or reference product other than those described in subparagraph (A) that unfairly disadvantage the listed drug or reference product relative to the follow-on product described in clause (ii) in a manner that impedes competition from a generic drug or a biosimilar biological product that is highly similar to, and has no clinically meaningful difference with respect to safety, purity, and potency from, the reference product, which may be established by objective circumstances.

"(ii) The manufacturer marketed or sold a follow-on product.

"(2) JUSTIFICATION.—

"(A) IN GENERAL.—Subject to paragraph (3), the actions described in paragraph (1) by a manufacturer of a listed drug or reference product shall not be considered to be an unfair method of competition in or affecting commerce if—

"(i) the manufacturer demonstrates to the Commission or a district court of the United States, as applicable, by a preponderance of the evidence in a proceeding initiated by the Commission under subsection (c)(1)(A), or in a suit brought under subparagraph (B) or (C) of subsection (c)(1), that—

"(I) the manufacturer would have taken the actions regardless of whether a generic drug that references the listed drug or biosimilar biological product that references the reference product had already entered the market; and

"(II)(aa) with respect to a hard switch under paragraph (1)(A), the manufacturer took the action for reasons relating to the safety risk to patients of the listed drug or reference product;

"(bb) with respect to an action described in item (aa) or (bb) of paragraph (1)(A)(ii)(I), there is a supply disruption that—

"(AA) is outside of the control of the manufacturer;

"(BB) prevents the production or distribution of the applicable listed drug or reference product; and

"(CC) cannot be remedied by reasonable efforts; or

"(cc) with respect to a soft switch under paragraph (1)(B), the manufacturer had legitimate pro-competitive reasons, apart from the financial effects of reduced competition, to take the action.

"(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) may be construed to limit the information that the Commission may otherwise obtain in any proceeding or action instituted with respect to a violation of this section.

"(3) RESPONSE.—With respect to a justification offered by a manufacturer under paragraph (2), the Commission may—

"(A) rebut any evidence presented by a manufacturer during that justification; or

''(B) establish by a preponderance of the evidence that, on balance, the pro-competitive benefits from the conduct described in subparagraph (A) or (B) of paragraph (1), as applicable, do not outweigh any anticompetitive effects of the conduct, even in consideration of the justification so offered.

''(c) ENFORCEMENT.—

''(1) IN GENERAL.—If the Commission has reason to believe that any manufacturer has violated, is violating, or is about to violate this section, the Commission may take any of the following actions:

''(A) Institute a proceeding—

''(i) that, except as provided in paragraph (2), complies with the requirements under section 5(b); and

''(ii) in which the Commission may impose on the manufacturer any penalty that the Commission may impose for a violation of section 5.

''(B) In the same manner and to the same extent as provided in section 13(b), bring suit in a district court of the United States to temporarily enjoin the action of the manufacturer.

"(C) Bring suit in a district court of the United States, in which the Commission may seek—

"(i) to permanently enjoin the action of the manufacturer;

"(ii) any of the remedies described in paragraph (3); and

"(iii) any other equitable remedy, including ancillary equitable relief.

"(2) JUDICIAL REVIEW.—

"(A) IN GENERAL.—Notwithstanding any provision of section 5, any manufacturer that is subject to a final order of the Commission that is issued in a proceeding instituted under paragraph (1)(A) may, not later than 30 days after the date on which the Commission issues the order, petition for review of the order in—

"(i) the United States Court of Appeals for the District of Columbia Circuit; or

"(ii) the court of appeals of the United States for the circuit in which the ultimate parent entity of the manufacturer is incorporated.

''(B) TREATMENT OF FINDINGS.—In a review of an order issued by the Commission conducted by a court of appeals of the United States under subparagraph (A), the factual findings of the Commission shall be conclusive if those facts are supported by the evidence.

''(3) EQUITABLE REMEDIES.—

''(A) DISGORGEMENT.—

''(i) IN GENERAL.—In a suit brought under paragraph (1)(C), the Commission may seek, and the court may order, disgorgement of any unjust enrichment that a person obtained as a result of the violation that gives rise to the suit.

''(ii) CALCULATION.—Any disgorgement that is ordered with respect to a person under clause (i) shall be offset by any amount of restitution ordered under subparagraph (B).

''(iii) LIMITATIONS PERIOD.—The Commission may seek disgorgement under this subparagraph not later than 5 years after the latest date on which the person from which the disgorgement is sought receives any unjust enrichment from the ef-

fects of the violation that gives rise to the suit in which the Commission seeks the disgorgement.

''(B) RESTITUTION.—

''(i) IN GENERAL.—In a suit brought under paragraph (1)(C), the Commission may seek, and the court may order, restitution with respect to the violation that gives rise to the suit.

''(ii) LIMITATIONS PERIOD.—The Commission may seek restitution under this subparagraph not later than 5 years after the latest date on which the person from which the restitution is sought receives any unjust enrichment from the effects of the violation that gives rise to the suit in which the Commission seeks the restitution.

''(4) RULES OF CONSTRUCTION.—Nothing in this subsection may be construed as—

''(A) requiring the Commission to bring a suit seeking a temporary injunction under paragraph (1)(B) before bringing a suit seeking a permanent injunction under paragraph (1)(C); or

''(B) affecting any other authority of the Commission under this Act to seek relief or obtain a remedy with respect to a violation of this Act.''.

(b) APPLICABILITY.—Section 27 of the Federal Trade Commission Act, as added by subsection (a), shall apply with respect to any—

(1) conduct that occurs on or after the date of enactment of this Act; and

(2) action or proceeding that is commenced on or after the date of enactment of this Act.

(c) ANTITRUST LAWS.—Nothing in this section, or the amendments made by this section, shall modify, impair, limit, or supersede the applicability of the antitrust laws as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), and of section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that it applies to unfair methods of competition.

(d) RULEMAKING.—The Federal Trade Commission may issue rules under section 553 of title 5, United States Code, to carry out section 27 of the Federal Trade Commission Act, as added by subsection (a), including by defining any terms used in such section 27 (other than terms that are defined in subsection (a) of such section 27).

SEC. 407. PROMOTING COMPETITION BY LIMITING PATENT THICKETS.

(a) IN GENERAL.—Section 271(e) of title 35, United States Code, is amended—

(1) in paragraph (2)(C), in the flush text following clause (ii), by adding at the end the following: ''With respect to a submission described in clause (ii), the act of infringement shall extend to any patent that claims the biological product, a method of using the biological product, or a method or product used to manufacture the biological product.''; and

(2) by adding at the end the following:

''(7)(A) Subject to subparagraphs (C), (D), and (E), if the sponsor of an approved application for a reference product, as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) (referred to in this paragraph as the 'reference product sponsor'), brings an action for infringement under this section against an applicant for approval of a biological product under section 351(k) of such Act that references that reference product (referred to in this paragraph as the 'subsection (k) applicant'), the reference product sponsor may assert in the action a total of not more than 20 patents of the type described in subparagraph (B), not more than 10 of which

shall have issued after the date specified in section 351(l)(7)(A) of such Act.

''(B) The patents described in this subparagraph are patents that satisfy each of the following requirements:

''(i) Patents that claim the biological product that is the subject of an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) (or a use of that product) or a method or product used in the manufacture of such biological product.

''(ii) Patents that are included on the list of patents described in section 351(l)(3)(A) of the Public Health Service Act (42 U.S.C. 262(l)(3)(A)), including as provided under section 351(l)(7) of such Act.

''(iii) Patents that—

''(I) have an actual filing date of more than 4 years after the date on which the reference product is approved; or

''(II) include a claim to a method in a manufacturing process that is not used by the reference product sponsor.

''(C) The court in which an action described in subparagraph (A) is brought may increase the number of patents limited under that subparagraph—

''(i) if the request to increase that number is made without undue delay; and

''(ii)(I) if the interest of justice so requires; or

''(II) for good cause shown, which—

''(aa) shall be established if the subsection (k) applicant fails to provide information required under section 351(l)(2)(A) of the Public Health Service Act (42 U.S.C. 262(l)(2)(A)) that would enable the reference product sponsor to form a reasonable belief with respect to whether a claim of infringement under this section could reasonably be asserted; and

''(bb) may be established—

''(AA) if there is a material change to the biological product (or process with respect to the biological product) of the subsection (k) applicant that is the subject of the application;

''(BB) if, with respect to a patent on the supplemental list described in section 351(l)(7)(A) of Public Health Service Act (42 U.S.C. 262(l)(7)(A)), the patent would have issued before the date specified in such section 351(l)(7)(A) but for the failure of the Office to issue the patent or a

delay in the issuance of the patent, as described in paragraph (1) of section 154(b) and subject to the limitations under paragraph (2) of such section 154(b); or

''(CC) for another reason that shows good cause, as determined appropriate by the court.

''(D) In determining whether good cause has been shown for the purposes of subparagraph (C)(ii)(II), a court may consider whether the reference product sponsor has provided a reasonable description of the identity and relevance of any information beyond the subsection (k) application that the court believes is necessary to enable the court to form a belief with respect to whether a claim of infringement under this section could reasonably be asserted.

''(E) The limitation imposed under subparagraph (A)—

''(i) shall apply only if the subsection (k) applicant completes all actions required under paragraphs (2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of section 351(l) of the Public Health Service Act (42 U.S.C. 262(l)); and

''(ii) shall not apply with respect to any patent that claims, with respect to a biological product, a

method for using that product in therapy, diagnosis, or prophylaxis, such as an indication or method of treatment or other condition of use.''.

(b) APPLICABILITY.—The amendments made by subsection (a) shall apply with respect to an application submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) on or after the date of enactment of this Act.

TITLE V—BENEFICIARY COST SHARING FAIRNESS

SEC. 501. REPEALING OF RULE BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.

The final rule of the Department of Health and Human Services titled ''Fraud And Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals And Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees; Additional Delayed Effective Date'' published on November 30, 2020 (85 Fed. Reg. 76666–76731), shall have no force or effect of law.

SEC. 502. DEFINING COST UNDER PRESCRIPTION DRUG PLANS UNDER PART D OF MEDICARE.

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

(1) in clause (i), by inserting ''of the net costs to the plan, inclusive of all direct and indirect remuneration, including rebates paid by manufacturers to the plan sponsor, either directly or through a pharmacy benefit manager or other third party'' before the semicolon; and

(2) in clause (ii), by inserting ''net'' before ''costs''.

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