Calendar No. 225

116TH CONGRESS
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S. 2543

[Report No. 116–120]

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 SENATE OF THE UNITED STATES

SEPTEMBER 25, 2019

Mr. GRASSLEY, from the Committee on Finance, reported the following original bill; which was read twice and placed on the calendar

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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 ''Prescription Drug Pricing Reduction Act of 2019''.

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

TITLE I—MEDICARE

Subtitle A—Part B

SEC. 101. IMPROVING MANUFACTURERS' REPORTING OF AVERAGE SALES PRICES TO SET ACCURATE PAYMENT RATES.

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

(1) by striking ''PRICE.—For requirements'' and inserting ''PRICE.—

''(1) IN GENERAL.—For requirements''; and

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

''(2) MANUFACTURERS THAT DO NOT HAVE A REBATE AGREEMENT.—

''(A) IN GENERAL.—For calendar quarters beginning with the first calendar quarter after the date of the enactment of this paragraph, the following provisions shall apply with respect to a manufacturer of an applicable drug or biological (as defined in subparagraph (B)) that has not entered into and does not have in effect a rebate agreement described in subsection (b) of section 1927 in the same manner and to the same extent as such provisions apply with re-

spect to a manufacturer that has entered into and has in effect such a rebate agreement:

"(i) Section 1927(b)(3)(A)(iii).

"(ii) Subparagraphs (B) and (C) (other than the rebate agreement suspension described in such subparagraph (C)) of section 1927(b)(3).

"(B) APPLICABLE DRUG OR BIOLOGICAL DEFINED.—For purposes of subparagraph (A), the term 'applicable drug or biological' means a drug or biological described in subparagraph (C), (E), or (G) of section 1842(o)(1) or in section 1881(b)(14)(B) that is payable under this part. For purposes of applying this paragraph, a drug or biological described in the previous sentence includes an item, service, supply, or product that is payable under this part as a drug or biological.".

(b) CONFORMING AMENDMENTS.—

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

(A) in paragraph (2)(A), by inserting "or subsection (f)(2), as applicable" after "under section 1927(b)(3)(A)(iii)"; and

(B) in each of paragraphs (3) and (6)(A), in the matter preceding subparagraph (A) and clause (i), respectively, by inserting ''or subsection (f)(2), as applicable,'' after ''under section 1927(b)(3)(A)(iii)''.

(2) TITLE XIX.—Section 1927(b)(3) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)) is amended—

(A) in subparagraph (A), in the flush matter following clause (iv), by inserting ''or section 1847A(f)(2)'' after ''Information reported under this subparagraph''; and

(B) in subparagraph (D), in the matter preceding clause (i), by striking ''or wholesalers under this paragraph or under'' and inserting ''or wholesalers under this paragraph, under section 1847A(f)(2), or under''.

(3) TECHNICAL CORRECTION.—Section 1927(b)(3)(A)(iii) of such Act (42 U.S.C. 1396r–8(b)(3)(A)(iii)) is amended by striking ''section 1881(b)(13)(A)(ii)'' and inserting ''section 1881(b)(14)(B)''.

SEC. 102. 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, 2021, 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 biological 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. 103. 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, 2020, 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. 104. 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, 2020, 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, 2019, the 5-year period beginning on January 1, 2020; 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. 105. IMPROVEMENTS TO MEDICARE SITE-OF-SERVICE TRANSPARENCY.

Section 1834(t) of the Social Security Act (42 U.S.C. 1395m(t)) is amended—

(1) in paragraph (1)—

(A) in the heading, by striking ''IN GENERAL'' and inserting ''SITE PAYMENT'';

(B) in the matter preceding subparagraph (A)—

(i) by striking ''or to'' and inserting '', to'';

(ii) by inserting '', or to a physician for services furnished in a physician's office'' after ''surgical center''; and

(iii) by inserting ''(or 2021 with respect to a physician for services furnished in a physician's office)'' after ''2018''; and

(C) in subparagraph (A)—

(i) by striking ''and the'' and inserting '', the''; and

(ii) by inserting '', and the physician fee schedule under section 1848 (with re-

spect to the practice expense component of such payment amount)'' after ''such section'';

(2) by redesignating paragraphs (2) through (4) and paragraphs (3) through (5), respectively; and

(3) by inserting after paragraph (1) the following new paragraph:

''(2) PHYSICIAN PAYMENT.—Beginning in 2021, the Secretary may expand the information included on the Internet website described in paragraph (1) to include—

''(A) the amount paid to a physician under section 1848 for an item or service for the settings described in paragraph (1); and

''(B) the estimated amount of beneficiary liability applicable to the item or service.''.

SEC. 106. MEDICARE PART B REBATE BY MANUFACTURERS FOR DRUGS OR BIOLOGICALS WITH PRICES INCREASING FASTER THAN INFLATION.

(a) IN GENERAL.—Section 1847A of the Social Security Act (42 U.S.C. 1395w–3a) is amended by adding at the end the following new subsection:

"(h) REBATE BY MANUFACTURERS FOR DRUGS OR BIOLOGICALS WITH PRICES INCREASING FASTER THAN INFLATION.—

"(1) REQUIREMENTS.—

"(A) SECRETARIAL PROVISION OF INFORMATION.—Not later than 6 months after the end of each rebate period (as defined in paragraph (2)(A)) beginning on or after January 1, 2021, the Secretary shall, for each rebatable drug (as defined in paragraph (2)(B)), report to each manufacturer of such rebatable drug the following for such rebate period:

"(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 rebatable drug and rebate period.

"(ii) Information on the amount (if any) of the excess average sales price increase described in subparagraph (A)(ii) of such paragraph for such rebatable drug and rebate period.

"(iii) The rebate amount specified under such paragraph for such rebatable drug and rebate period.

"(B) MANUFACTURER REBATE.—

"(i) IN GENERAL.—Subject to clause (ii), for each rebate period beginning on or after January 1, 2021, the manufacturer of a rebatable drug shall, for such drug, not later than 30 days after the date of receipt from the Secretary of the information and rebate amount pursuant to subparagraph (A) for such rebate period, provide to the Secretary a rebate that is equal to the amount specified in paragraph (3) for such drug for such rebate period.

"(ii) EXEMPTION FOR SHORTAGES.—The Secretary may reduce or waive the rebate under this subparagraph with respect to a rebatable drug 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 .

"(C) REQUEST FOR RECONSIDERATION.—The Secretary shall establish procedures under which a manufacturer of a rebatable drug may request a reconsideration by the Secretary of the rebate amount specified under paragraph

(3) for such rebatable drug and rebate period, as reported to the manufacturer pursuant to subparagraph (A)(iii).

''(2) REBATE PERIOD AND REBATABLE DRUG DEFINED.—In this subsection:

''(A) REBATE PERIOD.—The term 'rebate period' means a calendar quarter beginning on or after January 1, 2021.

''(B) REBATABLE DRUG.—The term 'rebatable drug' means a single source drug or biological (other than a biosimilar biological product)—

''(i) described in section 1842(o)(1)(C) for which the payment amount is provided under this section; or

''(ii) for which payment is made separately under section 1833(i) or section 1833(t) and for which the payment amount is calculated based on the payment amount under this section.

''(3) REBATE AMOUNT.—

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

to paragraph (4), the amount equal to the product of—

"(i) subject to subparagraph (B), the total number of units of the billing and payment code for such rebatable drug furnished during the rebate period; and

"(ii) the amount (if any) by which—

"(I) the amount determined under subsection (b)(4) for such rebatable drug during the rebate period; exceeds

"(II) the inflation-adjusted base payment amount determined under subparagraph (C) of this paragraph for such rebatable drug during the rebate period.

"(B) EXCLUDED UNITS.—For purposes of subparagraph (A)(i), the total number of units of the billing and payment code for rebatable drugs furnished during a rebate period shall not include units with respect to which the manufacturer provides a discount under the program under section 340B of the Public Health Service Act or a rebate under section 1927.

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

"(i) the amount determined under subsection (b)(4) for such rebatable 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 rebate period exceeds the benchmark period CPI–U (as defined in subparagraph (E)).

"(D) PAYMENT AMOUNT BENCHMARK QUARTER.—The term 'payment amount benchmark quarter' means the calendar quarter beginning July 1, 2019.

"(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 2019.

"(F) REBATE PERIOD CPI–U.—The term 'rebate period CPI–U' means, with respect to a

rebate period, the consumer price index for all urban consumers (United States city average) for the last month of the calendar quarter that is two calendar quarters prior to the rebate period.

''(4) APPLICATION TO NEW DRUGS.—In the case of a rebatable drug first approved or licensed by the Food and Drug Administration after July 1, 2019, the following shall apply:

''(A) DURING INITIAL PERIOD.—For quarters during the initial period in which the payment amount for such drug is determined using the methodology described in subsection (c)(4)—

''(i) clause (ii)(I) of paragraph (3)(A) shall be applied as if the reference to 'the amount determined under subsection (b)(4),' were a reference to 'the wholesale acquisition cost applicable under subsection (c)(4)';

''(ii) clause (i) of paragraph (3)(C) shall be applied—

''(I) as if the reference to 'the amount determined under subsection (b)(4),' were a reference to 'the whole-

sale acquisition cost applicable under subsection (c)(4)'; and

"(II) as if the term 'payment amount benchmark quarter' were defined under paragraph (3)(D) as the first full calendar quarter after the day on which the drug was first marketed; and

"(iii) clause (ii) of paragraph (3)(C) shall be applied as if the term 'benchmark period CPI–U' were defined under paragraph (4)(E) as if the reference to 'July 2019' 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) AFTER INITIAL PERIOD.—For quarters beginning after such initial period—

"(i) 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 first full calendar quarter for which the Secretary is able to compute an average sales price for the rebatable drug; and

''(ii) clause (ii) of paragraph (3)(C) shall be applied as if the term 'benchmark period CPI–U' were defined under paragraph (4)(E) as if the reference to 'July 2019' under such paragraph were a reference to 'the first month of the first full calendar quarter for which the Secretary is able to compute an average sales price for the rebatable drug'.

''(5) 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.

''(6) ENFORCEMENT.—

''(A) CIVIL MONEY PENALTY.—

''(i) IN GENERAL.—The Secretary shall impose a civil money penalty on a manufacturer that fails to comply with the requirements under paragraph (1)(B) with respect to providing a rebate for a rebatable drug for a rebate period for each such failure in an amount equal to the sum of—

''(I) the rebate amount specified pursuant to paragraph (3) for such drug for such rebate period; and

''(II) 25 percent of such amount.

''(ii) APPLICATION.—The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(B) NO PAYMENT FOR MANUFACTURERS WHO FAIL TO PAY PENALTY.—If the manufacturer of a rebatable drug fails to pay a civil money penalty under subparagraph (A) with respect to the failure to provide a rebate for a rebatable drug for a rebate period by a date specified by the Secretary after the imposition of such penalty, no payment shall be available under this part for such rebatable drug for calendar quarters beginning on or after such date until the Secretary determines the manufacturer has paid the penalty due under such subparagraph.''.

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

(1) in paragraph (4), by striking ''and'' at the end;

(2) in paragraph (5), by striking the period at the end and inserting ''; and''; and

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

''(6) determination of the rebate amount for a rebatable drug under paragraph (3) of subsection (h), including with respect to a new drug pursuant to paragraph (4) of such subsection, including—

''(A) a decision by the Secretary with respect to a request for reconsideration under paragraph (1)(C); and

''(B) the determination of—

''(i) the total number of units of the billing and payment code under paragraph (3)(A)(i); and

''(ii) the inflation-adjusted payment amount under paragraph (3)(C).''.

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

SEC. 107. REQUIRING MANUFACTURERS OF CERTAIN SINGLE-DOSE CONTAINER OR SINGLE-USE PACKAGE DRUGS PAYABLE UNDER PART B OF THE MEDICARE PROGRAM TO PROVIDE REFUNDS WITH RESPECT TO DISCARDED AMOUNTS OF SUCH DRUGS.

Section 1847A of the Social Security Act (42 U.S.C. 1395–3a), as amended by section 106, is amended by adding at the end the following new subsection:

''(i) REFUND FOR CERTAIN DISCARDED SINGLE-DOSE CONTAINER OR SINGLE-USE PACKAGE DRUGS.—

''(1) SECRETARIAL PROVISION OF INFORMATION.—

''(A) IN GENERAL.—For each calendar quarter beginning on or after July 1, 2021, the Secretary shall, with respect to a refundable single-dose container or single-use package drug (as defined in paragraph (8)), report to each manufacturer (as defined in subsection (c)(6)(A)) of such refundable single-dose container or single-use package drug the following for the calendar quarter:

''(i) Subject to subparagraph (C), information on the total number of units of the billing and payment code of such drug, if any, that were discarded during such

quarter, as determined using a mechanism such as the JW modifier used as of the date of enactment of this subsection (or any such successor modifier that includes such data as determined appropriate by the Secretary).

''(ii) The refund amount that the manufacturer is liable for pursuant to paragraph (3).

''(B) DETERMINATION OF DISCARDED AMOUNTS.—For purposes of subparagraph (A)(i), with respect to a refundable single-dose container or single-use package drug furnished during a quarter, the amount of such drug that was discarded shall be determined based on the amount of such drug that was unused and discarded for each drug on the date of service.

''(C) EXCLUSION OF UNITS OF PACKAGED DRUGS.—The total number of units of the billing and payment code of a refundable single-dose container or single-use package drug of a manufacturer furnished during a calendar quarter for purposes of subparagraph (A)(i), and the determination of the estimated total allowed charges for the drug in the quarter for purposes

of paragraph (3)(A)(ii), shall not include such units that are packaged into the payment amount for an item or service and are not separately payable.

''(2) MANUFACTURER REQUIREMENT.—For each calendar quarter beginning on or after July 1, 2021, the manufacturer of a refundable single-dose container or single-use package drug shall, for such drug, provide to the Secretary a refund that is equal to the amount specified in paragraph (3) for such drug for such quarter.

''(3) REFUND AMOUNT.—

''(A) IN GENERAL.—The amount of the refund specified in this paragraph is, with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after July 1, 2021, an amount equal to the estimated amount (if any) by which—

''(i) the product of—

''(I) the total number of units of the billing and payment code for such drug that were discarded during such

quarter (as determined under paragraph (1)); and

''(II)(aa) in the case of a refundable single-dose container or single-use package drug that is a single source drug or biological, the amount determined for such drug under subsection (b)(4); or

''(bb) in the case of a refundable single-dose container or single-use package drug that is a biosimilar biological product, the average sales price determined under subsection (b)(8)(A); exceeds

''(ii) an amount equal to the applicable percentage (as defined in subparagraph (B)) of the estimated total allowed charges for such drug during the quarter.

''(B) APPLICABLE PERCENTAGE DEFINED.—

''(i) IN GENERAL.—For purposes of subparagraph (A)(ii), the term 'applicable percentage' means—

''(I) subject to subclause (II), 10 percent; and

''(II) in the case of a refundable single-dose container or single-use package drug described in subclause (I) of clause (iii) and, if applicable, a refundable single-dose container or single-use package drug described in subclause (II) of such clause, a percentage specified by the Secretary pursuant to clause (ii).

''(ii) TREATMENT OF DRUGS THAT REQUIRE FILTRATION OR OTHER UNIQUE CIRCUMSTANCES.—The Secretary, through notice and comment rulemaking—

''(I) in the case of a refundable single-dose container or single-use package drug described in subclause (I) of clause (iii), shall increase the applicable percentage otherwise applicable under clause (i)(I) as determined appropriate by the Secretary; and

''(II) in the case of a refundable single-dose container or single-use package drug described in subclause (II) of clause (iii), may increase the

applicable percentage otherwise applicable under clause (i)(I) as determined appropriate by the Secretary.

''(iii) DRUG DESCRIBED.—For purposes of clause (ii), a refundable single-dose container or single-use package drug described in this clause is either of the following:

''(I) A refundable single-dose container or single-use package drug for which preparation instructions required and approved by the Commissioner of the Food and Drug Administration include filtration during the drug preparation process, prior to dilution and administration, and require that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process.

''(II) Any other refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product.

''(4) FREQUENCY.—Amounts required to be refunded pursuant to paragraph (2) shall be paid in regular intervals (as determined appropriate by the Secretary).

''(5) REFUND DEPOSITS.—Amounts paid as refunds pursuant to paragraph (2) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

''(6) ENFORCEMENT.—

''(A) AUDITS.—

''(i) MANUFACTURER AUDITS.—Each manufacturer of a refundable single-dose container or single-use package drug that is required to provide a refund under this subsection shall be subject to periodic audit with respect to such drug and such refunds by the Secretary.

''(ii) PROVIDER AUDITS.—The Secretary shall conduct periodic audits of claims submitted under this part with respect to refundable single-dose container or single-use package drugs in accordance with the authority under section 1833(e) to ensure compliance with the requirements applicable under this subsection.

"(B) CIVIL MONEY PENALTY.—

"(i) IN GENERAL.—The Secretary shall impose a civil money penalty on a manufacturer of a refundable single-dose container or single-use package drug who has failed to comply with the requirement under paragraph (2) for such drug for a calendar quarter in an amount equal to the sum of—

"(I) the amount that the manufacturer would have paid under such paragraph with respect to such drug for such quarter; and

"(II) 25 percent of such amount.

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

"(7) IMPLEMENTATION.—The Secretary shall implement this subsection through notice and comment rulemaking.

''(8) DEFINITION OF REFUNDABLE SINGLE-DOSE CONTAINER OR SINGLE-USE PACKAGE DRUG.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), in this subsection, the term 'refundable single-dose container or single-use package drug' means a single source drug or biological (as defined in section 1847A(c)(6)(D)) or a biosimilar biological product (as defined in section 1847A(c)(6)(H)) for which payment is established under this part and that is furnished from a single-dose container or single-use package.

''(B) EXCLUSIONS.—The term 'refundable single-dose container or single-use package drug' does not include a drug or biological that is either a radiopharmaceutical or an imaging agent.''.

SEC. 108. CLARIFICATION OF MEDICARE AVERAGE SALES PRICE PAYMENT METHODOLOGY.

(a) IN GENERAL.—Section 1847A(c) of the Social Security Act (42 U.S.C. 1395w–3a(c)), as amended by section 102, is amended—

(1) in paragraph (3)(A), in the first sentence—

(A) by striking ''and rebates'' and inserting ''rebates''; and

(B) by inserting ‘‘, and fees (other than bona fide service fees)’’ before the period at the end; and

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

‘‘(M) BONA FIDE SERVICE FEE.—The term ‘bona fide service fee’ means a fee paid by a manufacturer to an entity that—

‘‘(i) represents fair market value for a bona fide, itemized service that—

‘‘(I) is actually performed on behalf of the manufacturer; and

‘‘(II) the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement;

‘‘(ii) is not passed on, in whole or in part, to a client or customer of the entity, whether or not the entity takes title to the drug or biological;

‘‘(iii) is a fixed payment and not based on a percentage of sales; and

‘‘(iv) is not determined in a manner that takes into account the volume or value

of any referrals or business otherwise generated between the parties.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to drugs and biologicals furnished on or after the first day of the first calendar quarter that begins on or after the date that is 180 days after the date of the enactment of this Act.

SEC. 109. 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, 2021, if the ap-

plicable 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 2021 through 2028, $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, 2021, 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, 2021, 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. 110. TREATMENT OF DRUG ADMINISTRATION SERVICES FURNISHED BY CERTAIN EXCEPTED OFF-CAMPUS OUTPATIENT DEPARTMENTS OF A PROVIDER.

Section 1833(t)(16) of the Social Security Act (42 U.S.C. 1395l(t)(16)) is amended by adding at the end the following new subparagraph:

''(G) SPECIAL PAYMENT RULE FOR DRUG ADMINISTRATION SERVICES FURNISHED BY AN EXCEPTED DEPARTMENT OF A PROVIDER.—

''(i) IN GENERAL.—In the case of a covered OPD service that is a drug administration service (as defined by the Secretary) furnished by a department of a provider described in clause (ii) or (iv) of paragraph (21)(B), the payment amount for such service furnished on or after January 1, 2021, shall be the same payment amount (as determined in paragraph

(21)(C)) that would apply if the drug administration service was furnished by an off-campus outpatient department of a provider (as defined in paragraph (21)(B)).

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

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

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

SEC. 111. 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 manu-

facturer 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. 112. 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, 2021, 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 Cosmetic 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 manufactur-

ers 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, 2021, 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.

Subtitle B—Part D

SEC. 121. 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 2022 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2022 and each subsequent year'' after ''paragraph (3)'';

(B) in subparagraph (C)—

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

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

(C) in subparagraph (D)—

(i) in clause (i)—

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

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

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

(2) in paragraph (3)(A)—

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

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

(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 2022, the greater of—'';

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

(IV) by adding at the end the following:

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

(ii) in clause (ii)—

(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 2021 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''; and

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

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

''(VII) for 2022, is equal to $3,100; or

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

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

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

(D) in subparagraph (E), by striking ''In applying'' and inserting ''For each of 2011 through 2021, 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 2022, 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 a 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 2022, 60 percent;

''(ii) for 2023, 40 percent; and

''(iii) for 2024 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 2022, 80 percent;

''(ii) for 2023, 60 percent; and

''(iii) for 2024 and each subsequent year, 40 percent.''.

(c) MANUFACTURER CATASTROPHIC DISCOUNT PROGRAM.—

(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 CATASTROPHIC DISCOUNT PROGRAM.

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

''(b) TERMS OF AGREEMENT.—

''(1) IN GENERAL.—

''(A) AGREEMENT.—An agreement under this section shall require the manufacturer to

provide applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer that are dispensed on or after January 1, 2022.

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

''(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 2020 through 2023, 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 equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B).

"(2) APPLICABLE DRUG.—The term 'applicable drug' means, with respect to an applicable beneficiary, a covered part D drug—

"(A) approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (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.—The term 'discounted price' means 80 percent of the negotiated price of the applicable drug of a manufacturer.

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

"(C) SPECIAL CASE FOR CERTAIN CLAIMS.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall at or above the

annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) for the year, the manufacturer of the applicable drug shall provide the discounted price under this section on only the portion of the negotiated price of the applicable drug that falls at or above such annual out-of-pocket threshold.

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

''(6) NEGOTIATED PRICE.—The term 'negotiated price' has the meaning given such term in section 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, 2022, and, subject to paragraph (2), agreements under this section shall be terminated as of such date.

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

(3) INCLUSION OF ACTUARIAL VALUE OF MANUFACTURER DISCOUNTS IN BIDS.—Section 1860D–11

of the Social Security Act (42 U.S.C. 1395w–111) is amended—

(A) in subsection (b)(2)(C)(iii)—

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

''(I) the reinsurance''; and

(ii) by adding at the end the following:

''(II) for 2022 and each subsequent year, the manufacturer discounts provided under section 1860D–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 2022 and each subsequent year, the 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–14(g)(2)) that was paid by a manufacturer under the manufacturer catastrophic 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 model 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 121 of the Prescription Drug Pricing Reduction Act of 2019.''.

(f) CONFORMING AMENDMENTS.—

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

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

(B) in subsection (c)(1)(C)—

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

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

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

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

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

(A) in paragraph (1)—

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

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

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

(B) in paragraph (2)—

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

(ii) in subparagraph (E)—

(I) by inserting ''for a year preceding 2022,'' 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 2022, any discount'';

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

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

''(ii) for 2022 and each subsequent year, any discount provided pursuant to section 1860D–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 2022'' after ''1860D–2(b)(3)''; and

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

(7) Section 1860D–43(a)(1) of the Social Security Act (42 U.S.C. 1395w–153(a)(1)) is amended to read as follows:

''(1) participate in—

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

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

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

SEC. 122. PROVIDING THE MEDICARE PAYMENT ADVISORY COMMISSION AND MEDICAID AND CHIP PAYMENT AND ACCESS COMMISSION WITH ACCESS TO CERTAIN DRUG PAYMENT INFORMATION, INCLUDING CERTAIN REBATE INFORMATION.

(a) ACCESS TO CERTAIN PART D PAYMENT DATA.—Section 1860D–15(f) of the Social Security Act (42 U.S.C. 1395w–115(f)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (A)(ii), by striking ''and'' at the end;

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

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

"(C) by the Executive Director of the Medicare Payment Advisory Commission for purposes of monitoring, making recommendations, and analysis of the program under this title and by the Executive Director of the Medicaid and CHIP Payment and Access Commission for purposes of monitoring, making recommendations, and analysis of the Medicaid program established under title XIX and the Children's Health Insurance Program established under title XXI."; and

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

"(3) ADDITIONAL RESTRICTIONS ON DISCLOSURE OF INFORMATION.—The Executive Directors described in paragraph (2)(C) shall not disclose any of the following information disclosed to such Executive Directors or obtained by such Executive Directors pursuant to such paragraph, with respect to a prescription drug plan offered by a PDP sponsor or an MA–PD plan offered by an MA organization:

"(A) The specific amounts or the identity of the source of any rebates, price concessions, or other forms of direct or indirect remunera-

tion under such prescription drug plan or such MA–PD plan.

"(B) Information submitted with the bid submitted under section 1860D–11 by such PDP sponsor or section 1854 by such MA organization.

"(C) In the case of such information from prescription drug event records, in a form that would not be permitted under section 423.505(m) of title 42, Code of Federal Regulations, or any successor regulation, if made by the Centers for Medicare & Medicaid Services.".

(b) ACCESS TO CERTAIN REBATE AND PAYMENT DATA UNDER MEDICARE AND MEDICAID.—Section 1927(b)(3)(D) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)) is amended—

(1) in the matter before clause (i), by striking "subsection (a)(6)(A)(ii)" and inserting "subsection (a)(6)(A)";

(2) in clause (v), by striking "and" at the end;

(3) in clause (vi), by striking the period at the end and inserting ", and";

(4) by inserting after clause (vi) the following new clause:

"(vii) to permit the Executive Director of the Medicare Payment Advisory Commission and the Executive Director of the Medicaid and CHIP Payment and Access Commission to review the information provided.";

(5) in the matter at the end, by striking "1860D–4(c)(2)(E)" and inserting "1860D–4(c)(2)(G)"; and

(6) by adding at the end the following new sentence: "Any information disclosed to the Executive Director of the Medicare Payment Advisory Commission or the Executive Director of the Medicaid and CHIP Payment and Access Commission pursuant to this subparagraph shall not be disclosed by either such Executive Director in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler.".

SEC. 123. 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, 2022, 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, 2022.

(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, 2022, 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 con-

tracted 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 2022 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 2022 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 2022 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 2022 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. 124. 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 2020 and each subsequent 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 2020 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. 125. INCREASING THE USE OF REAL-TIME BENEFIT TOOLS TO LOWER BENEFICIARY COSTS.

(a) REQUIRING PRESCRIPTION DRUG PLAN SPONSORS AND MEDICARE ADVANTAGE ORGANIZATIONS TO IN-

CLUDE REAL-TIME BENEFIT INFORMATION UNDER MEDICARE PART D.—Section 1860D–4 of the Social Security Act (42 U.S.C. 1395w–104) is amended—

(1) by redesignating subsection (m) (relating to program integrity transparency measures), as added by section 6063(c) of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Public Law 115–271), as subsection (n); and

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

''(o) REAL-TIME BENEFIT INFORMATION.—

''(1) IN GENERAL.—After the Secretary has adopted a standard under paragraph (3) for electronic real-time benefit tools, and at a time determined appropriate by the Secretary, a PDP sponsor of a prescription drug plan shall implement one or more of such tools that meet the requirements described in paragraph (2).

''(2) REQUIREMENTS.—For purposes of paragraph (1), the requirements described in this paragraph, with respect to an electronic real-time benefit tool, are that the tool is capable of—

''(A) integrating with electronic prescribing and electronic health record systems of pre-

scribing health care professionals for the transmission of eligibility and formulary and benefit information in real time to such professionals; and

''(B) with respect to a covered part D drug, transmitting such information specific to an individual enrolled in a prescription drug plan, including the following:

''(i) A list of any clinically-appropriate alternatives to such drug included in the formulary of such plan.

''(ii) Cost-sharing information and the negotiated price for such drug and such alternatives at—

''(I) multiple pharmacy options, including the individual's preferred pharmacy and, as applicable, other retail pharmacies and a mail order pharmacy; and

''(II) the formulary status of such drug and such alternatives and any prior authorization or other utilization management requirements applicable to such drug and such alter-

natives included in the formulary of such plan.

"(3) STANDARDS.—In order to be treated (for purposes of this subsection) as an electronic real-time benefit tool described in paragraph (1), such tool shall comply with technical standards adopted by the Secretary in consultation with the National Coordinator for Health Information Technology, the National Council for Prescription Drug Programs, other standard setting organizations determined appropriate by the Secretary, and stakeholders including PDP sponsors, Medicare Advantage organizations, health care professionals, and health information technology software vendors.

"(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to prohibit the application of paragraph (b)(7) of section 423.160 of title 42, Code of Federal Regulations, as is to be added to such section pursuant to the final rule published in the Federal Register on May 23, 2019, and titled 'Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses' (84 Fed. Reg. 23832 through 23884).".

(b) REQUIRING QUALIFIED ELECTRONIC HEALTH RECORDS TO INCLUDE REAL-TIME BENEFIT TOOLS.—

Section 3000(13) of the Public Health Service Act (42 U.S.C. 300jj(13)) is amended—

(1) in subparagraph (A), by striking ''and'' at the end;

(2) in subparagraph (B), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(C) includes, or is capable of including, a real-time benefit tool that conveys patient-specific real-time cost and coverage information with respect to prescription drugs that, with respect to any health information technology certified for electronic prescribing, the technology shall be capable of incorporating the information described in clauses (i) and (ii) of paragraph (2)(B) of section 1860D–4(o) of the Social Security Act at a time specified by the Secretary but not before the Secretary adopts a standard for such tools as described in paragraph (1) of such section.''.

(c) INCLUSION OF USE OF REAL-TIME ELECTRONIC INFORMATION IN SHARED DECISION-MAKING UNDER MIPS.—Section 1848(q)(2)(B)(iii)(IV) of the Social Security Act (42 U.S.C. 1395w–4(q)(2)(B)(iii)(IV)) is amended by adding at the end the following new sentence:

''This subcategory shall include as an activity option, beginning with the performance period starting on January 1, 2021, use of a real-time benefit tool as described in 1860D–4(o).''.

SEC. 126. 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 promote 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, 2022.

(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. 127. PERMANENTLY AUTHORIZE A SUCCESSFUL PILOT ON RETROACTIVE MEDICARE PART D COVERAGE FOR LOW-INCOME BENEFICIARIES.

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

(1) by redesignating subsection (e) as subsection (f); and

(2) by inserting after subsection (d) the following new subsection:

''(e) LIMITED INCOME NEWLY ELIGIBLE TRANSITION (LI NET) PROGRAM.—

''(1) IN GENERAL.—By not later than 2022, the Secretary shall establish a program to provide transitional coverage for covered part D drugs for LI NET eligible individuals in accordance with this subsection.

''(2) LI NET ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this subsection, the term 'LI NET eligible individual' means a part D eligible individual who—

''(A) meets the requirements of clauses (ii) and (iii) of subsection (a)(3)(A); and

''(B) has not yet enrolled in a prescription drug plan or an MA-PD plan, or, who has so enrolled, but with respect to whom coverage under such plan has not yet taken effect.

''(3) TRANSITIONAL COVERAGE DEFINED.—For purposes of this subsection, the term 'transitional coverage' means the following with respect to a LI NET eligible individual:

''(A) ALL LI NET ELIGIBLE INDIVIDUALS.—Immediate access to covered part D drugs at the point of sale during the period that begins on the first day of the month such individual is determined to meet the requirements of clauses (ii) and (iii) of subsection

(a)(3)(A) and ends on the date that coverage under a prescription drug plan or an MA–PD plan takes effect with respect to such individual.

''(B) FULL-BENEFIT DUAL ELIGIBLES AND SSI RECIPIENTS.—In the case of a LI NET eligible individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)) or recipient of supplemental security income benefits under title XVI, retroactive coverage (in the form of reimbursement of the amounts that would have been paid under this part had such individual been enrolled in a prescription drug plan or an MA–PD plan) of covered part D drugs purchased by such individual during the period that—

''(i) begins on the date that is the later of the date that—

''(I) such individual was first eligible for a low income subsidy under this part; or

''(II) is 36 months prior to the date such individual enrolls in a prescription drug plan or an MA–PD plan; and

''(ii) ends on the date that coverage under such plan takes effect.

''(4) PROGRAM ADMINISTRATION.—

''(A) SINGLE POINT OF CONTACT.—The Secretary shall, to the extent feasible, administer the program under this subsection through a contract with a single program administrator who will provide for a single point of contact for LI NET eligible individuals.

''(B) BENEFIT DESIGN.—The Secretary shall ensure that the transitional coverage provided to LI NET eligible individuals under this subsection—

''(i) provides access to all covered part D drugs under an open formulary;

''(ii) permits all pharmacies determined by the Secretary to be in good standing to process claims under the program;

''(iii) is consistent with such requirements as the Secretary considers necessary to improve patient safety and ensure appropriate dispensing of medication; and

''(iv) meets such other requirements as the Secretary may establish.

''(5) RELATIONSHIP TO OTHER PROVISIONS OF THIS TITLE; WAIVER AUTHORITY.—

''(A) IN GENERAL.—The following provisions shall not apply to the program under this subsection:

''(i) Paragraphs (1) and (3)(B) of section 1860D–4(a) (dissemination of general information; availability of information on changes in formulary through the internet).

''(ii) Subparagraphs (A) and (B) of section 1860D–4(b)(3) (development and revision by a pharmacy and therapeutic committee; formulary development).

''(iii) Paragraphs (1)(C) and (2) of section 1860D–4(c) (medication therapy management program).

''(B) WAIVER AUTHORITY.—The Secretary may waive such other requirements of title XI and this title as may be necessary to carry out the purposes of the program established under this subsection.''.

SEC. 128. MEDICARE PART D REBATE BY MANUFACTURERS FOR CERTAIN DRUGS WITH PRICES INCREASING FASTER THAN INFLATION.

(a) IN GENERAL.—Subpart 2 of part D of title XVIII of the Social Security Act is amended by inserting after section 1860D–14B, as added by section 121, the following new section:

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

''(a) REQUIREMENTS.—

''(1) SECRETARIAL PROVISION OF INFORMATION.—

''(A) IN GENERAL.—Subject to subparagraph (B), not later than 6 months after the end of each rebate period (as defined in paragraph (4)(A)) beginning on or after January 1, 2022, the Secretary shall, for each rebatable covered part D drug (as defined in paragraph (4)(B)), report to each manufacturer (as defined in paragraph (4)(C)) of such rebatable covered part D drug the following for the rebate period:

''(i) Information on the total number of units (as defined in paragraph (4)(D)) of each dosage form and strength de-

scribed in paragraph (1)(A) of subsection (b) for such rebatable covered part D drug and rebate period.

''(ii) Information on the amount (if any) of the excess price described in paragraph (1)(B) of such subsection for such rebatable covered part D drug and rebate period.

''(iii) The rebate amount specified under such subsection for such rebatable covered part D drug and rebate period.

''(iv) Other information determined appropriate by the Secretary.

''(B) TRANSITION RULE FOR INFORMATION IN 2022.—Notwithstanding subparagraph (A), the Secretary may, for each rebatable covered part D drug, delay the timeframe for reporting the information and rebate amount described in clauses (i), (ii), (iii), and (iv) of such subparagraph for rebate periods in 2022 until not later than December 31, 2023.

''(2) MANUFACTURER REBATE.—

''(A) IN GENERAL.—Subject to subparagraph (B), for each rebate period beginning on or after January 1, 2022, each manufacturer of

a rebatable covered part D drug shall, not later than 30 days after the date of receipt from the Secretary of the information and rebate amount pursuant to paragraph (1), provide to the Secretary a rebate that is equal to the amount specified in subsection (b) for such drug for such rebate period.

''(B) EXEMPTION FOR SHORTAGES.—The Secretary may reduce or waive the rebate under this paragraph with respect to a rebatable covered part D drug 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.

''(3) REQUEST FOR RECONSIDERATION.—The Secretary shall establish procedures under which a manufacturer of a rebatable covered part D drug may request a reconsideration by the Secretary of the rebate amount specified under subsection (b) for such drug and rebate period, as reported to the manufacturer pursuant to paragraph (1). Timing for a reconsideration shall be coordinated with the timing of reconciliation, as described in subsection (b)(6) and as determined appropriate by the Secretary.

''(4) DEFINITIONS.—In this section:

''(A) REBATE PERIOD.—

''(i) IN GENERAL.—Subject to clause (ii), the term 'rebate period' means, with respect to a year, each of the six month periods that begin on January 1 and July 1 of the year.

''(ii) INITIAL REBATE PERIOD FOR SUBSEQUENTLY APPROVED DRUGS.—In the case of a rebatable covered part D drug described in subsection (c), the initial rebate period for which a rebate amount is determined for such rebatable covered part D drug pursuant to such subsection shall be the period beginning with the first month after the last day of the six month period that begins on the day on which the drug was first marketed and ending on the last day of the first full rebate period under clause (i) that begins after the last day of such six month period.

''(B) REBATABLE COVERED PART D DRUG.—The term 'rebatable covered part D drug' means a covered part D drug approved under a new drug application under section

505(c) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351(a) of the Public Health Service Act.

''(C) MANUFACTURER.—The term 'manufacturer' has the meaning given such term in section 1860D—14A(g).

''(D) UNITS.—The term 'units' means, with respect to a rebatable covered part D drug, the lowest common quantity (such as the number of capsules or tablets, milligrams of molecules, or grams) of such drug dispensed to individuals under this part.

''(E) PRICE.—The term 'price' means, with respect to a rebatable covered part D drug, the wholesale acquisition cost (as defined in section 1847A(c)(6)(B)) for such drug.

''(b) REBATE AMOUNT.—

''(1) IN GENERAL.—Subject to subsection (e)(2), the amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a rebatable covered part D drug, is the amount equal to the product of—

''(A) the total number of units of such dosage form and strength for each rebatable covered part D drug during the rebate period; and

''(B) the amount (if any) by which—

''(i) the unit-weighted average price for such dosage form and strength of the drug determined under paragraph (2) for the rebate period; exceeds

''(ii) the inflation-adjusted price for such dosage form and strength determined under paragraph (3) for the rebate period.

''(2) DETERMINATION OF UNIT-WEIGHTED AVERAGE PRICE.—

''(A) IN GENERAL.—The unit-weighted average price determined under this paragraph for a rebate period, with respect to each dosage form and strength of a rebatable covered Part D drug, is the sum of the products of—

''(i) the weighted average price determined under subparagraph (B) with respect to each package size of such dosage form and strength dispensed during the rebate period; and

''(ii) the ratio of—

"(I) the total number of units of such package size dispensed during the rebate period; to

"(II) the total number of units of such dosage form and strength of such drug dispensed during such rebate period.

"(B) COMPUTATION OF WEIGHTED AVERAGE PRICE.—The weighted average price, with respect to each package size of such dosage form and strength of a rebatable covered part D drug dispensed during a rebate period, is the sum of the products of—

"(i) each price, as calculated for a unit of such drug, applicable to each package size of such dosage form and strength of such drug during the rebate period; and

"(ii) the ratio of—

"(I) the number of days for which each such price is applicable during the rebate period; to

"(II) the total number of days in such rebate period.

"(3) DETERMINATION OF INFLATION-ADJUSTED PRICE.—

"(A) IN GENERAL.—The inflation-adjusted price determined under this paragraph for a rebate period, with respect to each dosage form and strength of a rebatable covered part D drug, is—

"(i) the benchmark unit-weighted price determined under subparagraph (B) for the rebate period; increased by

"(ii) the percentage by which the rebate period CPI–U (as defined in paragraph (4)) for the rebate period exceeds the benchmark CPI–U (as defined in paragraph (5)).

"(B) DETERMINATION OF BENCHMARK UNIT-WEIGHTED PRICE.—The benchmark unit-weighted price determined under this subparagraph for a rebate period, with respect to each dosage form and strength of a rebatable covered part D drug, is the sum of the products of—

"(i) each price, as calculated for a unit of such drug, applicable to each package size of such dosage form and strength of such drug on July 1, 2019; and

"(ii) the ratio of—

''(I) the total number of units of such package size dispensed on July 1, 2019; to

''(II) the total number of units of such dosage form and strength dispensed on July 1, 2019.

''(4) BENCHMARK CPI–U.—The term 'benchmark CPI–U' means the consumer price index for all urban consumers (United States city average) for July 2019.

''(5) REBATE PERIOD CPI–U.—The term 'rebate period CPI–U' means, with respect to a rebate period, the consumer price index for all urban consumers (United States city average) for the last month of the rebate period.

''(6) ANNUAL RECONCILIATION OF REBATE AMOUNT.—The Secretary shall, on an annual basis, conduct a one-time reconciliation of the rebate amounts owed by a manufacturer under this section based on any changes submitted by a PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan to the number of units of a rebatable covered part D drug dispensed during the preceding year. Such reconciliation shall be completed not later than 6 months after the date by

which the Secretary reconciles payment for covered part D drugs with PDP sponsors of prescription drug plans or MA organizations offering MA–PD plans.

''(e) TREATMENT OF SUBSEQUENTLY APPROVED DRUGS.—Subject to subsection (e)(2), in the case of a rebatable covered part D drug first approved or licensed by the Food and Drug Administration after July 1, 2019—

''(1) subparagraph (A)(ii) of subsection (b)(3) shall be applied as if the term 'benchmark CPI–U' were defined under subsection (b)(4) as if the reference to 'July 2019' under such subsection were a reference to 'the first month after the last day of the six month period that begins on the day on which the drug was first marketed'; and

''(2) subsection (b)(3) shall be applied by substituting, for the benchmark unit-weighted price otherwise determined under subparagraph (B) of such subsection, the benchmark unit-weighted average price determined under paragraph (3) for the rebate period;

''(3) the benchmark unit-weighted average price determined under this paragraph for a rebate period, with respect to each dosage form and strength of a

rebatable covered part D drug, is the sum of the products of—

''(A) the new drug weighted average price determined under paragraph (4) with respect to each package size of such dosage form and strength of such drug dispensed during the six month period that begins on the day on which the drug was first marketed; and

''(B) the ratio of—

''(i) the total number of units of such package size dispensed during the six month period that begins on the day on which the drug was first marketed; to

''(ii) the total number of units of such dosage form and strength of such drug dispensed during such six month period; and

''(4) the new drug weighted average price, with respect to each package size of such dosage form and strength of such rebatable covered part D drug dispensed during the six month period that begins on the day on which the drug was first marketed, is the sum of the products of—

''(A) each price, as calculated for a unit of such drug, applicable to each package size of such dosage form and strength of such drug

during the six month period that begins on the day on which the drug was first marketed; and

"(B) the ratio of—

"(i) the number of days for which each such price is applicable during such six month period; to

"(ii) the total number of days in such six month period.

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

"(e) ADMINISTRATION.—

"(1) PERIODIC AUDITS.—The Secretary shall permit a manufacturer of a rebatable covered part D drug to conduct periodic audits, directly or through contracts, of the data and information used to determine the rebate amount for such drug under this section.

"(2) SPECIAL RULES FOR CALCULATION OF BENCHMARK UNIT-WEIGHTED PRICE AND BENCHMARK-UNIT-WEIGHTED AVERAGE PRICE.—

"(A) BENCHMARK UNIT-WEIGHTED PRICE.—In the case that the benchmark unit-weighted price of a dosage form and strength of

a rebatable covered part D drug is determined under subsection (b)(3)(B) to be $0 due to no units of such dosage form and strength of such drug being dispensed on July 1, 2019, the Secretary may use a calculation, as determined appropriate by the Secretary, to determine the benchmark-unit weighted price for such dosage form and strength of such drug that is different than the calculation described in such subsection.

''(B) BENCHMARK UNIT-WEIGHTED AVERAGE PRICE.—In the case that the benchmark unit-weighted average price of a dosage form and strength of a rebatable covered part D drug described under subsection (c) is determined under paragraph (3) of such subsection to be $0 due to no units of such dosage form and strength of such drug being dispensed during the six month period that begins on the day on which the drug was first marketed, the Secretary may use a calculation, as determined appropriate by the Secretary, to determine the benchmark-unit weighted average price for such dosage form and strength of such drug that is

different than the calculation described in such paragraph.

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

''(4) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the determination of the rebate amount under subsection (b), including with respect to a subsequently approved drug pursuant to subsection (c), including—

''(A) the determination of—

''(i) the total number of units of each rebatable covered part D drug under subsection (b)(1)(A);

''(ii) the unit-weighted average price under subsection (b)(2);

''(iii) the inflation-adjusted price under subsection (b)(3);

''(iv) the benchmark unit-weighted average price under subsection (c)(3); and

''(v) the new drug weighted average price under subsection (c)(4); and

''(B) the application of special rules for calculation of benchmark unit-weighted price

and benchmark unit-weighted average price under paragraph (2) of this subsection.

''(f) CIVIL MONEY PENALTY.—

''(1) IN GENERAL.—The Secretary shall impose a civil money penalty on a manufacturer that fails to comply with the requirements under subsection (a)(2) with respect to providing a rebate for a rebatable covered part D drug for a rebate period for each such failure in an amount equal to the sum of—

''(A) the rebate amount determined pursuant to subsection (b) for such drug for such rebate period; and

''(B) 25 percent of such amount.

''(2) APPLICATION.—The provisions of section 1128A (other than subsections (a) 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) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as having any effect on—

''(1) any formulary design under section 1860D–4(b)(3); or

''(2) any discounts provided under the coverage gap discount program under section 1860D–14A or

the manufacturer catastrophic discount program under section 1860D–14B.

''(h) REBATE AGREEMENT.—

''(1) IN GENERAL.—The Secretary shall enter into agreements described in paragraph (2) with manufacturers.

''(2) TERMS OF AGREEMENT.—

''(A) IN GENERAL.—A rebate agreement under this paragraph shall require the manufacturer to provide to the Secretary rebates required under subsection (a)(2)(A) with respect to a rebate period.

''(B) MANUFACTURER PROVISION OF PRICE AND DRUG PRODUCT INFORMATION.—Each manufacturer with an agreement in effect under this subsection shall report to the Secretary, with respect to each rebatable covered part D drug of the manufacturer, at a time specified by the Secretary—

''(i) for each calendar month under the rebate agreement—

''(I) each wholesale acquisition cost (as defined in section 1847A(c)(6)) applicable during the month, applicable to each National

Drug Code for the dosage form and strength of such rebatable covered part D drug; and

''(II) the number of days with respect to which each wholesale acquisition cost reported was applicable;

''(ii) the wholesale acquisition cost (as so defined) applicable on July 1, 2019, applicable to each National Drug Code for the dosage form and strength of such rebatable covered part D drug (or, in the case of a rebatable covered part D drug first approved or licensed by the Food and Drug Administration after July 1, 2019, each wholesale acquisition cost applicable to each National Drug Code of each dosage form and strength of the rebatable covered part D drug of the manufacturer during the six month period that begins on the day on which the drug was first marketed); and

''(iii) such other information as the Secretary shall require.

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services.

''(3) CIVIL MONEY PENALTIES.—The provisions of subparagraph (C) of section 1927(b)(3) shall apply with respect to information required pursuant to paragraph (2)(B) of this subsection and the failure to provide such information in the same manner and to the same extent as such provisions apply with respect to information required under subparagraph (A) of such section 1927(b)(3) and the failure to provide such information.

''(4) COORDINATION.—The Secretary may coordinate rebate agreements required under this subsection with agreements required under section 1860D–14B.

''(i) FUNDING.—

''(1) IN GENERAL.—There are appropriated to the Secretary, from the Federal Supplementary Medical Insurance Trust Fund established under section 1841—

''(A) for each of calendar years 2020 through 2025, $4,000,000; and

''(B) for each subsequent calendar year, such sums as are necessary to carry out this section.

''(2) AVAILABILITY.—Amounts appropriated under paragraph (1) shall remain available until expended.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 1860D–43(a) of the Social Security Act (42 U.S.C. 1395w–153(a)), as amended by section 121(f)(7), is amended—

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

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

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

''(4) for 2022 and each subsequent year, have entered into and have in effect an agreement described in section 1860D–14C(h)(2) with the Secretary''.

(2) Section 1927(c)(1)(C)(VI) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(VI)) is amended—

(A) by striking ''or any discounts'' and inserting ''any discounts''; and

(B) by inserting ", or any rebates under section 1860D–14C" before the period.

SEC. 129. 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, 2022.

SEC. 130. 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 125, is amended by adding at the end the following new subsection:

"(p) REPORTING POTENTIAL FRAUD, WASTE, AND ABUSE.—Beginning January 1, 2021, 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. 131. 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 126, 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 established or approved by the Secretary under subparagraph (B) with respect to payment for covered part D drugs dispensed by such pharmacy.

''(B) STANDARD PHARMACY QUALITY MEASURES.—The Secretary shall establish or approve standard quality measures from a con-

sensus 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, 2023, 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. 132. 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 2025 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 product 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 bio-

logical 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. 133. 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, 2021, 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.

Subtitle C—Miscellaneous

SEC. 141. 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, 2022, 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 2020, of at least 100 percent since the date of the enactment of this section;

''(II) during 2021, of at least 100 percent in the preceding 12 months or of at least 150 percent in the preceding 24 months;

''(III) during 2022, of at least 100 percent in the preceding 12 months or of at least 200 percent in the preceding 36 months;

''(IV) during 2023, 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, 2024, 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 2020, of at least 15 percent since the date of the enactment of this section;

"(II) during 2021, of at least 15 percent in the preceding 12 months or of at least 20 percent in the preceding 24 months;

"(III) during 2022, of at least 15 percent in the preceding 12 months or

of at least 30 percent in the preceding 36 months;

"(IV) during 2023, 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, 2024, 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, 2020, 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 develop-

ment 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;

"(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 subsection (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. 142. 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 123, 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, 2020, 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. 143. 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, 2020, 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. 144. 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. 145. 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. 146. 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. 147. 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, 2021, 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. 148. 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 II—MEDICAID

SEC. 201. 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 203 of the Prescription Drug Pricing Reduction Act of 2019, the Secretary shall issue guidance that States must follow for establishing conflict of interest policies for the pharmacy and therapeutics committee in

accordance 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. 202. 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; and

"(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. 203. 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. 204. 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 2020 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. 205. EXCLUDING AUTHORIZED GENERIC DRUGS FROM CALCULATION OF AVERAGE MANUFACTURER PRICE UNDER THE MEDICAID DRUG REBATE PROGRAM.

(a) IN GENERAL.—Subparagraph (C) of section 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r–8(k)(1)) is amended—

(1) in the subparagraph heading, by striking ''INCLUSION'' and inserting ''EXCLUSION'';

(2) by striking ''a new drug application'' and inserting ''the manufacturer's new drug application''; and

(3) by striking ''inclusive'' and inserting ''exclusive''.

(b) EXCLUDING MANUFACTURERS FROM DEFINITION OF WHOLESALER.—Section 1927(k)(11) of the Social Security Act (42 U.S.C. 1396r–8(k)(11)) is amended—

(1) by striking ''manufacturers,'';

(2) by striking ''manufacturer's and''; and

(3) by adding at the end the following: ''Such term does not include a manufacturer engaged in wholesale distribution or a manufacturer's warehouses.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the first day of the first fiscal quarter that begins after the date of enactment of this Act.

SEC. 206. IMPROVING TRANSPARENCY AND PREVENTING THE USE OF ABUSIVE SPREAD PRICING AND RELATED PRACTICES IN MEDICAID.

(a) PASS-THROUGH PRICING REQUIRED.—

(1) IN GENERAL.—Section 1927(e) of the Social Security Act (42 U.S.C. 1396r–8(e)) is amended by adding at the end the following:

''(6) PASS-THROUGH PRICING REQUIRED.—A contract between the State and a pharmacy benefit manager (referred to in this paragraph as a 'PBM'), or a contract between the State and a managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D)) that includes provisions making the entity responsible for coverage of covered outpatient drugs dispensed to individuals enrolled with the entity, shall require that payment for such drugs and related administrative services (as applicable), including payments made by a PBM on behalf of the State or entity, is based on a pass-through pricing model under which—

''(A) any payment made by the entity or the PBM (as applicable) for such a drug—

''(i) is limited to—

''(I) ingredient cost; and

''(II) a professional dispensing fee that is not less than the professional dispensing fee that the State plan or waiver would pay if the plan

or waiver was making the payment directly;

"(ii) is passed through in its entirety by the entity or PBM to the pharmacy that dispenses the drug; and

"(iii) is made in a manner that is consistent with section 1902(a)(30)(A) and sections 447.512, 447.514, and 447.518 of title 42, Code of Federal Regulations (or any successor regulation) as if such requirements applied directly to the entity or the PBM;

"(B) payment to the entity or the PBM (as applicable) for administrative services performed by the entity or PBM is limited to a reasonable administrative fee that covers the reasonable cost of providing such services;

"(C) the entity or the PBM (as applicable) shall make available to the State, and the Secretary upon request, all costs and payments related to covered outpatient drugs and accompanying administrative services incurred, received, or made by the entity or the PBM, including ingredient costs, professional dispensing fees, administrative fees, post-sale and post-in-

voice fees, discounts, or related adjustments such as direct and indirect remuneration fees, and any and all other remuneration; and

''(D) any form of spread pricing whereby any amount charged or claimed by the entity or the PBM (as applicable) is in excess of the amount paid to the pharmacies on behalf of the entity, including any post-sale or post-invoice fees, discounts, or related adjustments such as direct and indirect remuneration fees or assessments (after allowing for a reasonable administrative fee as described in subparagraph (B)) is not allowable for purposes of claiming Federal matching payments under this title.''.

(2) CONFORMING AMENDMENT.—Section 1903(m)(2)(A)(xiii) of such Act (42 U.S.C. 1396b(m)(2)(A)(xiii)) is amended—

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

(B) by inserting before the period at the end the following: '', and (IV) pharmacy benefit management services provided by the entity, or provided by a pharmacy benefit manager on behalf of the entity under a contract or other arrangement between the entity and the phar-

macy benefit manager, shall comply with the requirements of section 1927(e)(6)''; and

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

(3) EFFECTIVE DATE.—The amendments made by this subsection apply to contracts between States and managed care entities, other specified entities, or pharmacy benefits managers that are entered into or renewed on or after the date that is 18 months after the date of enactment of this Act.

(b) SURVEY OF RETAIL PRICES.—

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

(A) by striking ''and'' after the semicolon at the end of paragraph (1)(A)(i) and all that precedes it through ''(1)'' and inserting the following:

''(1) SURVEY OF RETAIL PRICES.—The Secretary shall conduct a survey of retail community drug prices, to include at least the national average drug acquisition cost, as follows:

''(A) USE OF VENDOR.—The Secretary may contract services for—

''(i) with respect to retail community pharmacies, the determination on a month-

ly basis of retail survey prices of the national average drug acquisition cost for covered outpatient drugs for such pharmacies, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available), the average reimbursement received for such drugs by such pharmacies from all sources of payment, including third parties, and, to the extent available, the usual and customary charges to consumers for such drugs; and'';

(B) by adding at the end of paragraph (1) the following:

''(F) SURVEY REPORTING.—In order to meet the requirement of section 1902(a)(54), a State shall require that any retail community pharmacy in the State that receives any payment, administrative fee, discount, or rebate related to the dispensing of covered outpatient drugs to individuals receiving benefits under this title, regardless of whether such payment, fee, discount, or rebate is received from the State or a managed care entity directly or from a pharmacy benefit manager or another entity

that has a contract with the State or a managed care entity, shall respond to surveys of retail prices conducted under this subsection.

''(G) SURVEY INFORMATION.—Information on retail community prices obtained under this paragraph shall be made publicly available and shall include at least the following:

''(i) The monthly response rate of the survey including a list of pharmacies not in compliance with subparagraph (F).

''(ii) The sampling frame and number of pharmacies sampled monthly.

''(iii) Characteristics of reporting pharmacies, including type (such as independent or chain), geographic or regional location, and dispensing volume.

''(iv) Reporting of a separate national average drug acquisition cost for each drug for independent retail pharmacies and chain operated pharmacies.

''(v) Information on price concessions including on and off invoice discounts, rebates, and other price concessions.

''(vi) Information on average professional dispensing fees paid.

"(H) PENALTIES.—

"(i) FAILURE TO PROVIDE TIMELY INFORMATION.—A retail community pharmacy that fails to respond to a survey conducted under this subsection on a timely basis may be subject to a civil monetary penalty in the amount of $10,000 for each day in which such information has not been provided.

"(ii) FALSE INFORMATION.—A retail community pharmacy that knowingly provides false information in response to a survey conducted under this subsection may be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information.

"(iii) OTHER PENALTIES.—Any civil money penalties imposed under this subparagraph shall be in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provi-

sions apply to a penalty or proceeding under section 1128A(a).

''(I) REPORT ON SPECIALTY PHARMACIES.—

''(i) IN GENERAL.—Not later than 1 year after the effective date of this subparagraph, the Secretary shall submit a report to Congress examining specialty drug coverage and reimbursement under this title.

''(ii) CONTENT OF REPORT.—Such report shall include a description of how State Medicaid programs define specialty drugs, how much State Medicaid programs pay for specialty drugs, how States and managed care plans determine payment for specialty drugs, the settings in which specialty drugs are dispensed (such as retail community pharmacies or specialty pharmacies), whether acquisition costs for specialty drugs are captured in the national average drug acquisition cost survey, and recommendations as to whether specialty pharmacies should be included in the survey of retail prices to ensure national aver-

age drug acquisition costs capture drugs sold at specialty pharmacies and how such specialty pharmacies should be defined.'';

(C) in paragraph (2)—

(i) in subparagraph (A), by inserting '', including payments rates under Medicaid managed care plans,'' after ''under this title''; and

(ii) in subparagraph (B), by inserting ''and the basis for such dispensing fees'' before the semicolon; and

(D) in paragraph (4), by inserting '', and $5,000,000 for fiscal year 2020 and each fiscal year thereafter,'' after ''2010''.

(2) EFFECTIVE DATE.—The amendments made by this subsection take effect on the 1st day of the 1st quarter that begins on or after the date that is 18 months after the date of enactment of this Act.

(c) MANUFACTURER REPORTING OF WHOLESALE ACQUISITION COST.—Section 1927(b)(3) of such Act (42 U.S.C. 1396r–8(b)(3)) is amended—

(1) in subparagraph (A)(i)—

(A) in subclause (I), by striking ''and'' after the semicolon;

(B) in subclause (II), by adding ''and'' after the semicolon;

(C) by moving the left margins of subclause (I) and (II) 2 ems to the right; and

(D) by adding at the end the following:

''(III) in the case of rebate periods that begin on or after the date of enactment of this subclause, on the wholesale acquisition cost (as defined in section 1847A(c)(6)(B)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act);''; and

(2) in subparagraph (D)—

(A) in the matter preceding clause (i), by inserting ''and clause (vii) of this subparagraph'' after ''1847A'';

(B) in clause (v), by striking ''and'' after the comma;

(C) in clause (vi), by striking the period and inserting '', and''; and

(D) by inserting after clause (vi) the following:

"(vii) to the Secretary to disclose (through a website accessible to the public) the most recently reported wholesale acquisition cost (as defined in section 1847A(c)(6)(B)) for each covered outpatient drug (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), as reported under subparagraph (A)(i)(III).".

SEC. 207. T–MSIS DRUG DATA ANALYTICS REPORTS.

(a) IN GENERAL.—Not later than May 1 of each calendar year beginning with calendar year 2021, the Secretary of Health and Human Services (in this section referred to as the "Secretary") shall publish on a 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 waiver 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 utiliza-

tion 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 completeness 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 2020 and each fiscal year thereafter, there is appropriated to the Secretary $2,000,000 to carry out this section.

SEC. 208. 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, 2022, 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 administered 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 subsection (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, 2022), the manufacturer must notify the Secretary of the manufacturer's intent to enter into a risk-sharing value-based payment agreement under this subsection 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, 2022, more than 90 days have passed after the manufacturer's meeting with the Food and Drug Administration 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, 2022, 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 agreements 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, 2022, 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 2020 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 'potentially 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;

''(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. 209. 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, 2022, 100 percent of the average manufacturer price of the drug; and

"(II) for rebate periods beginning on or after October 1, 2022, 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, 2021, 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)''.

SEC. 210. APPLYING MEDICAID DRUG REBATE REQUIREMENT TO DRUGS PROVIDED AS PART OF OUTPATIENT HOSPITAL SERVICES.

(a) IN GENERAL.—Section 1927(k)(3) of the Social Security Act (42 U.S.C. 1396r–8(k)(3)) is amended to read as follows:

''(3) LIMITING DEFINITION.—

''(A) IN GENERAL.—The term 'covered outpatient drug' does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):

''(i) Inpatient hospital services.

''(ii) Hospice services.

''(iii) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

''(iv) Physicians' services.

''(v) Outpatient hospital services.

''(vi) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

''(vii) Other laboratory and x-ray services.

''(viii) Renal dialysis.

''(B) OTHER EXCLUSIONS.—Such term also does not include any such drug or product for which a National Drug Code number is not

required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication.

''(C) STATE OPTION.—At the option of a State, such term may include any drug, biological product, or insulin provided on an outpatient basis as part of, or as incident to and in the same setting as, described in clause (iv) or (v) of subparagraph (A) (such as a drug, biological product, or insulin being provided as part of a bundled payment).

''(D) NO EFFECT ON BEST PRICE.—Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.''.

(b) EFFECTIVE DATE; IMPLEMENTATION GUIDANCE.—

(1) IN GENERAL.—The amendment made by subsection (a) shall take effect on the date that is 1 year after the date of enactment of this Act.

(2) IMPLEMENTATION AND GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance and relevant informational bulletins for States, manufacturers (as defined in section 1927(k)(5) of the Social Security Act (42 U.S.C. 1396r–8(k)(5)), and other relevant stakeholders, including health care providers, regarding implementation of the amendment made by subsection (a).

Calendar No. 225

116TH CONGRESS
1ST SESSION

S. 2543

[Report No. 116–120]

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.

SEPTEMBER 25, 2019

Read twice and placed on the calendar