116TH CONGRESS
1ST SESSION

S. _____

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, to address current and future expiring provisions, and for other purposes.

IN THE SENATE OF THE UNITED STATES

_____

_____ introduced the following bill; which was read twice and referred to the Committee on _____

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, to address current and future expiring provisions, 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.

This Act may be cited as the ''Prescription Drug Pricing Reduction and Health and Human Services Improvements Act''.

DIVISION A—PRESCRIPTION DRUG PRICING REDUCTION ACT

SEC. 10100. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This division may be cited as the ''Prescription Drug Pricing Reduction Act of 2019''.

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

Subtitle B—Part D

Subtitle C—Miscellaneous

TITLE II—MEDICAID

TITLE I—MEDICARE

Subtitle A—Part B

SEC. 10101. 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 respect 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. 10102. 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 bio-

logical products, (through in-kind donations) to patients of low income.''.

SEC. 10103. 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. 10104. 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. 10105. 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 respect 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. 10106. 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 in-

crease 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 sec-

tion 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 wholesale 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. 10107. 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 10106, 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 quar-

ter 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 appli-

cable 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 dis-

carded 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. 10108. HHS INSPECTOR GENERAL STUDY AND REPORT ON BONA FIDE SERVICE FEES.

(a) STUDY.—The Inspector General of the Department of Health and Human Services (in this section referred to as the ''Inspector General'') shall conduct a study on the effect of the use of bona fide service fee contracting arrangements by drug manufacturers and other entities on Medicare payments for drugs and biologicals furnished under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.). Such study shall include an analysis of—

(1) the various types of entities that enter into contracting arrangements that use bona fide service fees, such as group purchasing organizations, wholesalers, providers, and pharmacies;

(2) the various types of bona fide service fee contracting arrangements used by such entities;

(3) the types of services that are paid for through such arrangements;

(4) whether manufacturers define bona fide service fees differently across different entities;

(5) how such arrangements are structured;

(6) whether the structure or use of such arrangements has changed over time;

(7) the extent, if any, to which there is consistency across manufacturers in what they consider to

be a bona fide service fee as opposed to a discount or rebate that should be excluded from the determination of average sales price pursuant to the methodology under section 1847A of the Social Security Act (42 U.S.C. 1395w–3a);

(8) the overall magnitude of bona fide service fees;

(9) what share of bona fide service fees are paid to various entities;

(10) how the magnitude of bona fide service fees compares to other fees and rebates that are included in the determination of average sales price;

(11) whether and, if so, how much, the magnitude of bona fide service fees has grown over time and how such growth compares to growth in the magnitude of other fees and rebates; and

(12) what share of bona fide service fees are based on a percentage of sales.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Inspector 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 Inspector General determines appropriate.

SEC. 10109. 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 applicable add-on payment (as defined in subparagraph (B)) for each drug or biological on a claim for a date of service exceeds the maximum add-on payment amount specified under subparagraph (C) for the drug or biological, then the payment amount otherwise determined for the drug or biological under those provi-

sions, 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. 10110. 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. 10111. GAO STUDY AND REPORT ON AVERAGE SALES PRICE.

(a) STUDY.—

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

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

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

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

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

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

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

(ii) by private payers in the commercial market.

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

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

(i) formulary placement;

(ii) utilization management considerations; or

(iii) other purposes.

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

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

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

SEC. 10112. 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 Ad-

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

''(ii) that—

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

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

''(III) for which the total manufacturing capacity of all manufacturers with an approved application for such drug or biological that is currently marketed or total number of manufacturers with an approved application for such drug or biological that is currently marketed declines

during a 6-month period, as determined by the Secretary.

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

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

(c) HHS REPORT AND RECOMMENDATIONS.—

(1) IN GENERAL.—Not later than July 1, 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 Medi-

care 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. 10121. 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) REDUCTION IN BENEFICIARY COINSURANCE.—

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

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

(B) by striking ''25 PERCENT COINSURANCE.—Subject to'' and inserting ''COINSURANCE.—

''(i) IN GENERAL.—Subject to'';

(C) in each of subclauses (I) and (II), as redesignated by subparagraph (A), by striking ''25 percent'' and inserting ''the applicable percentage (as defined in clause (ii))''; and

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

''(ii) APPLICABLE PERCENTAGE DEFINED.—For purposes of clause (i), the term 'applicable percentage' means—

''(I) for a year preceding 2022, 25 percent; and

''(II) for 2022 and each subsequent year, 20 percent.''.

(2) CONFORMING AMENDMENT.—Section 1860D–14(a)(2)(D) of the Social Security Act (42 U.S.C. 1395w–114(a)(2)(D)) is amended by striking ''25 percent'' and inserting ''the applicable percentage''.

(c) 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 at-

tributable 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.''.

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

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

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

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

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

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

''(2) MONITORING COMPLIANCE.—

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

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

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

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

''(d) ADMINISTRATION.—

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

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

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

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

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

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

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

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

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

"(5) 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 above the annual deductible specified in section 1860D–2(b)(1).

"(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—

"(i) with respect to an applicable drug dispensed for an applicable beneficiary who has incurred costs that are below the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B), 93 percent of the negotiated price of the applicable drug of a manufacturer; and

"(ii) with respect to an applicable drug dispensed for an applicable beneficiary who 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), 86 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) CLARIFICATION FOR CERTAIN CLAIMS.—With respect to the amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary, the manufacturer of the applicable drug shall provide—

"(i) the discounted price under clause (i) of subparagraph (A) only on the portion of the negotiated price of the applicable drug that falls above the deductible specified in section 1860D–2(b)(1) and below the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B); and

"(ii) the discounted price under clause (ii) of subparagraph (A) only on 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 dis-

counts provided under section 1860D–14B subtracted from the actuarial value to produce such bid; and''; and

(B) in subsection (c)(1)(C)—

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

''(i) the reinsurance'';

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

(iii) by adding at the end the following:

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

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

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

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

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

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

(1) in paragraph (2)—

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

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

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

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

(2) in paragraph (3)—

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

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

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

''(3) UPDATING RISK ADJUSTMENT METHODOLOGIES TO ACCOUNT FOR PART D MODERNIZATION REDESIGN.—The Secretary shall update the risk adjustment methodologies used to adjust bid amounts pursuant to this subsection as appropriate to take into account changes in benefits under this part pursuant to the amendments made by section 121 of the Prescription Drug Pricing Reduction Act of 2019.''.

(g) CONFORMING AMENDMENTS.—

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

(A) in subsection (a)(2)(A)(i)(I), by striking ", or an increase in the initial" and inserting "or for a year preceding 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 discount program under section 1860D–14B;".

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

SEC. 10121A. MAXIMUM MONTHLY CAP ON COST-SHARING PAYMENTS UNDER PRESCRIPTION DRUG PLANS AND MA–PD PLANS.

(a) IN GENERAL.—Section 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–102(b)), as amended by section 10121, is amended—

(1) in paragraph (2)—

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

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

"(E) MAXIMUM MONTHLY CAP ON COST-SHARING PAYMENTS.—

"(i) IN GENERAL.—For plan years beginning on or after January 1, 2022, the Secretary shall, through notice and com-

ment rulemaking, establish a process under which each PDP sponsor offering a prescription drug plan and each MA organization offering an MA–PD plan shall provide to any enrollee, including an enrollee who is a subsidy eligible individual (as defined in paragraph (3) of section 1860D–14(a)), the option to elect with respect to a plan year to have their monthly cost-sharing payments under the plan capped in accordance with this subparagraph.

''(ii) DETERMINATION OF MAXIMUM MONTHLY CAP.—For each month in the plan year after an enrollee in a prescription drug plan or an MA–PD plan has made an election pursuant to clause (i), the PDP sponsor or MA organization shall determine a maximum monthly cap (as defined in clause (iv)) for such enrollee.

''(iii) BENEFICIARY MONTHLY PAYMENTS.—With respect to an enrollee who has made an election pursuant to clause (i), for each month described in clause (ii), the PDP sponsor or MA organization shall bill such enrollee an amount (not to exceed

the maximum monthly cap) for the out-of-pocket costs of such enrollee in such month.

"(iv) MAXIMUM MONTHLY CAP DEFINED.—In this subparagraph, the term 'maximum monthly cap' means, with respect to an enrollee—

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

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

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

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

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

ditional costs incurred by the enrollee; divided by

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

"(v) ADDITIONAL REQUIREMENTS.—The following requirements shall apply with respect to the option to make an election pursuant to clause (i) under this subparagraph:

"(I) SECRETARIAL RESPONSIBILITIES.—The Secretary shall provide information to part D eligible individuals on the option to make such election through educational materials, including through the notices provided under section 1804(a).

"(II) TIMING OF ELECTION.—An enrollee in a prescription drug plan or an MA–PD plan may make such an election—

"(aa) prior to the beginning of the plan year; or

"(bb) in any month during the plan year.

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

"(aa) may not limit the option for an enrollee to make such an election to certain covered part D drugs;

"(bb) shall, prior to the plan year, notify prospective enrollees of the option to make such an election in promotional materials;

"(cc) shall include information on such option in enrollee educational materials;

"(dd) shall have in place a mechanism to notify a pharmacy during the plan year when an enrollee incurs out-of-pocket costs with respect to covered part D drugs that make it likely the enrollee may benefit from making such an election;

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

"(ff) shall ensure that such an election by an enrollee has no effect on the amount paid to pharmacies (or the timing of such payments) with respect to covered part D drugs dispensed to the enrollee; and

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

"(IV) FAILURE TO PAY AMOUNT BILLED.—If an enrollee fails to pay the amount billed for a month as required under this subparagraph, the election of the enrollee pursuant to

clause (i) shall be terminated and enrollee shall pay the cost-sharing otherwise applicable for any covered part D drugs subsequently dispensed to the enrollee up to the annual out-of-pocket threshold specified in paragraph (4)(B).

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

''(VI) TREATMENT OF UNSETTLED BALANCES.—Any unsettled balances with respect to amounts owed under this subparagraph shall be treated as plan losses and the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids.''; and

(2) in paragraph (4)—

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

"and subject to subparagraphs (F) and (G)"; and

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

"(G) INCLUSION OF COSTS PAID UNDER MAXIMUM MONTHLY CAP OPTION.—In applying subparagraph (A), with respect to an enrollee who has made an election pursuant to clause (i) of paragraph (2)(E), costs shall be treated as incurred if such costs are paid by a PDP sponsor or an MA organization under the process provided under such paragraph.".

(b) APPLICATION TO ALTERNATIVE PRESCRIPTION DRUG COVERAGE.—Section 1860D–2(c) of the Social Security Act (42 U.S.C. 1395w–102(c)) is amended by adding at the end the following new paragraph:

"(4) SAME MAXIMUM MONTHLY CAP ON COST-SHARING.—For plan years beginning on or after January 1, 2022, the maximum monthly cap on cost-sharing payments under the process provided under subsection (b)(2)(E) shall apply to such coverage.".

SEC. 10121B. REQUIRING PHARMACY-NEGOTIATED PRICE CONCESSIONS, PAYMENT, AND FEES TO BE INCLUDED IN NEGOTIATED PRICES AT THE POINT-OF-SALE UNDER PART D OF THE MEDICARE PROGRAM.

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

(1) by striking ''PRICES.—For purposes'' and inserting ''PRICES.—

''(i) IN GENERAL.—For purposes''; and

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

''(ii) PRICES NEGOTIATED WITH PHARMACY AT POINT-OF-SALE.—For plan years beginning on or after January 1, 2022, a negotiated price for a covered part D drug described in clause (i) shall be the approximate lowest possible reimbursement for such drug negotiated with the pharmacy dispensing such drug, and shall include all contingent and noncontingent price concessions, payments, and fees negotiated with such pharmacy, but shall not include positive incentive payments paid or to be paid to such pharmacy. Such nego-

tiated price shall be provided at the point-of-sale of such drug.''.

SEC. 10122. 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 rec-

ommendations, 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 remuneration 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. 10123. 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 contracted or owned pharmacy benefit manager are met; and

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

the PDP sponsor or MA organization shall conduct financial audits.

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

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

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

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

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

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

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

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

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

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

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

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

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

''(ix) CIVIL MONETARY PENALTIES.—

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

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

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

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

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

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

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

''(B) TO PHARMACIES.—

''(i) IN GENERAL.—For plan year 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. 10124. 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) DIRECT AND INDIRECT REMUNERATION REVIEW RESULTS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), in 2021 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 direct and indirect remuneration 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 discrepancies in summary and detailed direct and indirect remuneration identified by the Secretary for PDP sponsors to review.

"(ii) The extent to which PDP sponsors resubmitted summary direct and indirect remuneration reports to make changes for previous contract years.

"(iii) The extent to which resubmitted summary direct and indirect remuneration reports resulted in an increase or decrease in direct and indirect remuneration in a previous contract year.

"(B) EXCLUSION OF CERTAIN SUBMISSIONS IN CALCULATION.—The Secretary shall exclude any information in direct and indirect remuneration 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 2021 and each subsequent year, the Secretary shall make available to the public on the Internet website of the Centers for Medicare & Medicaid Services data on the results of financial audits required under section 1860D–12(b)(3)(C). Information made available under this paragraph shall include the following:

"(A) With respect to a year, the number of PDP sponsors that received each of the following (or successor categories), with an indication of the number that pertain to direct and indirect remuneration:

"(i) A notice of observations or findings.

"(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.

"(v) A disclaimed opinion.

"(B) With respect to a year, the number of PDP sponsors—

"(i) that reopened a previously closed reconciliation as a result of an audit, indicating those that pertain to direct and indirect remuneration changes; and

"(ii) for which the Secretary recouped a payment or made a payment as a result of a reopening of a previously closed reconciliation, indicating when such recoupment or payment pertains to direct and indirect remuneration.

"(3) NO IDENTIFICATION OF SPECIFIC PDP SPONSORS.—The information to be made available on the Internet website of the Centers for Medicare

& Medicaid Services described in paragraph (1) and paragraph (2) shall not identity the specific PDP sponsor to which any determination or action pertains.

''(4) DEFINITION OF DIRECT AND INDIRECT REMUNERATION.—For purposes of this subsection, the term 'direct and indirect remuneration' means direct and indirect remuneration as described in section 423.308 of title 42, Code of Federal Regulations, or any successor regulation.''.

SEC. 10125. INCREASING THE USE OF REAL-TIME BENEFIT TOOLS TO LOWER BENEFICIARY COSTS.

(a) REQUIRING PRESCRIPTION DRUG PLAN SPONSORS AND MEDICARE ADVANTAGE ORGANIZATIONS TO INCLUDE 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 prescribing 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 alternatives 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 organiza-

tions, 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 cer-

tified 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. 10126. 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. 10127. 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. 10128. 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 10121, 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 described 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 follows 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.

''(c) 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 subsequently rebatable 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 be-

gins 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 subsequently rebatable 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 subsequently rebatable 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 10121(g)(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. 10129. 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. 10130. 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 10125, 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. 10131. 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 10126, is amended by adding at the end the following new paragraph:

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

''(A) IN GENERAL.—A PDP sponsor that makes incentive payments to a pharmacy or receives price concessions paid by a pharmacy based on quality measures shall, for the purposes of such incentive payments or price concessions with respect to covered part D drugs dispensed by such pharmacy, only use measures—

''(i) established or adopted by the Secretary under subparagraph (B), as listed under clause (ii) of such subparagraph; and

''(ii) that are relevant to the performance of such pharmacy with respect to areas that the pharmacy can impact.

''(B) STANDARD PHARMACY QUALITY MEASURES.—

''(i) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall establish or adopt quality measures from one or more multi-stakeholder, consensus organizations to be used by a PDP sponsor for the purposes of determining incentive payments and price concessions described in subparagraph (A). Such measures shall be evidence-based and focus on pharmacy performance on patient health outcomes and other areas, as determined by the Secretary, that the pharmacy can impact.

''(ii) MAINTENANCE OF LIST.—The Secretary shall maintain a single list of measures established or adopted under this subparagraph.

''(C) EFFECTIVE DATE.—The requirement under subparagraph (A) shall take effect for plan years beginning on January 1, 2022, or such earlier date specified by the Secretary if the Secretary determines there are sufficient measures established or adopted under subparagraph (B) for the purposes of the requirement under subparagraph (A).''.

SEC. 10132. 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 prod-

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

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

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

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

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

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

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

SEC. 10133. 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. 10141. 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 development for such drug that was derived from Federal funds.

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

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

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

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

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

"(ii) metrics used to determine executive compensation;

"(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 manu-

facturer 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. 10142. 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 10123, 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. 10143. 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 in-

formation 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. 10144. 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 Secretary shall invite the following to the public meeting:

(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.

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

(C) TOPICS.—The public meeting agenda shall include—

(i) an overview of the types of products and product categories in the drug and medical device development pipeline and the volume of products which may meet the description of a novel medical product under subsection (c);

(ii) the anticipated expertise necessary to review the safety and effectiveness of such products at the Food and Drug Administration 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.—Nothing under this section 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 drug, including a biological product

(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. 10145. 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.—With respect to national coverage determinations, the Secretary, and with respect to local coverage determinations, the Medicare administrative contractor, may consult with patients and organizations representing patients, including patients with disabilities, in making national and local coverage determinations.''.

SEC. 10146. 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 individuals 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. 10147. 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. 10148. 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, in urban centers, and in Tribal communities 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. 10201. 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 policy 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 in-

terest, 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) is made publicly available;

''(II) is composed of members who are independent and free of any conflict, including with respect to manufacturers, medicaid managed care entities, and pharmacy benefit managers; and

''(III) includes at least 1 actively practicing physician and at least 1 actively practicing pharmacist, each of whom 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.

''(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.—

(1) IN GENERAL.—Clause (xiii) of section 1903(m)(2)(A) of the Social Security Act (42 U.S.C. 1396b(m)(2)(A)) is amended—

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

(B) 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

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

(2) APPLICATION TO PIHPS AND PAHPS.—Section 1903(m) of the Social Security Act (42 U.S.C. 1396b(m)) is amended by adding at the end the following new paragraph:

''(10) No payment shall be made under this title to a State with respect to expenditures incurred by the State for payment for services provided by an other specified entity (as defined in paragraph (9)(D)(iii)) unless such services are provided in accordance with a contract between the State and the entity which satisfies the requirements of paragraph (2)(A)(xiii).''.

(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. 10202. 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 publicly available;

"(II) be composed of members who are independent and free of any conflict, including with respect to manufacturers, medicaid managed care entities, and pharmacy benefit managers;

"(III) 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

"(IV) include at least 1 actively practicing physician and at least 1 actively practicing pharmacist, each of whom 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.

"(iii) CONFLICT OF INTEREST POLICY.—The State shall establish and imple-

ment 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 prepare 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 inserting ''and each contract under a State plan with an other specified entity (as defined in section 1903(m)(9)(D)(iii))'' after ''under section 1903(m)'';

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

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

(4) by adding at the end the following: ''Such a managed care entity or other specified 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 18 months after the date of enactment of this Act.

SEC. 10203. 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 (including other specified entities (as defined in section 1903(m)(9)(D)(iii) of the Social Security Act (42 U.S.C. 1396b(m)(9)(D)(iii)) and 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 Med-

icaid 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. 10204. 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 regular 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 con-

nection 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 FAILURE TO PROVIDE TIMELY 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. 10205. 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. 10206. 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 or other specified entity (as such terms are defined in section 1903(m)(9)(D)), 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 an amount not to exceed $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 subpara-

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

''(I) REPORT ON SPECIALTY DRUGS AND PHARMACIES.—

''(i) IN GENERAL.—Not later than 18 months 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 sur-

vey of retail prices to ensure national average 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. 10207. 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 patterns related to prescriptions filled by providers 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 available 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 (except where the inclusion of such information would jeopardize the privacy of an individual, as determined by the Secretary);

(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.—To the extent available, a report required under subsection (a) for a calendar year may include State-specific information about prescription utilization management tools under State Medicaid plans or waivers of such plans, including—

(A) a description of prescription utilization management tools under State programs to provide long-term services and supports under a State Medicaid plan or a waiver of such plan;

(B) a comparison of prescription utilization management tools applicable to populations covered under a State Medicaid plan waiver under section 1115 of the Social Security Act (42 U.S.C. 1315) and the models applicable to populations that are not covered under the waiver;

(C) a comparison of the prescription utilization management tools employed by different Medicaid managed care organizations, pharmacy benefit managers, and related entities within the State;

(D) a comparison of the prescription utilization management tools applicable to each en-

rollment 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 (including an analysis of the impact of non-filled prescriptions on identifying such patterns); 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, to the extent practicable—

(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. 10208. 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 HAS IN EFFECT A REBATE AGREEMENT AND IS IN COMPLIANCE WITH ALL APPLICABLE 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 a proposed risk-sharing value-based payment agreement is not expected to result in greater estimated Federal spending under this title than the net Federal spending that would result in the absence of such 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 Actu-

ary 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 drug 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 reimbursed 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 out-

patient 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 payment 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 (including issues related to compliance with sections 1128B and 1877) 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 re-

lated 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 pur-

chase 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 "but excluding any drugs for which payment is made by a State under a risk-sharing value-based payment agreement under subsection (l))" after "for coverage of such drugs"; 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. 10209. 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, and any subsequent rebate pe-

riod until the average manufacturer price of the drug is the same or less than the inflation-adjusted average manufacturer price determined with respect to such drug under subclause (II) 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. 10210. 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).

DIVISION B—HEALTH AND HUMAN SERVICES EXTENDERS

SEC. 20100. TABLE OF CONTENTS.

The table of contents of this division is as follows:

TITLE I—MEDICARE

SEC. 20101. EXTENSION OF WORK GPCI FLOOR.

Section 1848(e)(1)(E) of the Social Security Act (42 U.S.C. 1395w–4(e)(1)(E)) is amended by striking ''January 1, 2020'' and inserting ''January 1, 2023''.

SEC. 20102. PERMANENT EXTENSION OF INCREASED INPATIENT HOSPITAL PAYMENT ADJUSTMENT FOR CERTAIN LOW-VOLUME HOSPITALS.

(a) IN GENERAL.—Section 1886(d)(12) of the Social Security Act (42 U.S.C. 1395ww(d)(12)) is amended—

(1) in subparagraph (B)—

(A) in the heading, by striking ''APPLICABLE'' and inserting ''TEMPORARY APPLICABLE''; and

(B) in the matter preceding clause (i), by striking ''and for discharges occurring in fiscal year 2023 and subsequent fiscal years'';

(2) in subparagraph (C)(i)—

(A) in the matter preceding subclause (I), by striking ''fiscal years 2011 through 2022'' and inserting ''fiscal year 2011 and subsequent fiscal years'';

(B) in subclause (II), by adding ''and'' at the end;

(C) in subclause (III)—

(i) by striking ''each of fiscal years 2019 through 2022'' and inserting ''fiscal year 2019 and each subsequent fiscal year''; and

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

(D) by striking subclause (IV); and

(3) in subparagraph (D)—

(A) in the heading, by striking ''TEMPORARY APPLICABLE'' and inserting ''APPLICABLE'';

(B) in the matter preceding clause (i), by striking ''fiscal years 2011 through 2022'' and

inserting ''fiscal year 2011 and subsequent fiscal years''; and

(C) in clause (ii), by striking ''each of fiscal years 2019 through 2022'' and inserting ''fiscal year 2019 and each subsequent fiscal year''.

SEC. 20103. PERMANENT EXTENSION OF THE MEDICARE-DEPENDENT HOSPITAL (MDH) PROGRAM.

(a) IN GENERAL.—Section 1886(d)(5)(G) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(G)) is amended—

(1) in clause (i), by striking '', and before October 1, 2022''; and

(2) in clause (ii)(II), by striking '', and before October 1, 2022''.

(b) CONFORMING AMENDMENTS.—

(1) EXTENSION OF TARGET AMOUNT.—Section 1886(b)(3)(D) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(D)) is amended—

(A) in the matter preceding clause (i), by striking '', and before October 1, 2022''; and

(B) in clause (iv), by striking ''through fiscal year 2022'' and inserting ''or a subsequent fiscal year''.

(2) PERMITTING HOSPITALS TO DECLINE RECLASSIFICATION.—Section 13501(e)(2) of the Omnibus Budget Reconciliation Act of 1993 (42 U.S.C. 1395ww note) is amended by striking ''fiscal year 2000 through fiscal year 2022'' and inserting ''a subsequent fiscal year''.

SEC. 20104. EXTENSION OF FUNDING FOR QUALITY MEASURE ENDORSEMENT, INPUT, AND SELECTION.

(a) EXTENSION.—

(1) IN GENERAL.—Section 1890(d)(2) of the Social Security Act (42 U.S.C. 1395aaa(d)(2)) is amended—

(A) in the first sentence, by striking ''and $1,665,000 for the period beginning on October 1, 2019, and ending on December 20, 2019'' and inserting ''$22,000,000 for fiscal year 2020, and $20,000,000 for each of fiscal years 2021 and 2022''; and

(B) in the third sentence, by striking ''and 2019 and for the period beginning on October 1, 2019, and ending on December 20, 2019,'' and inserting ''through 2022''.

(2) PREVENTION OF DUPLICATE APPROPRIATIONS FOR FISCAL YEAR 2020.—Expenditures made under such section 1890(d)(2) pursuant to the

amendments made by the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Public Law 116–59) and the Further Continuing Appropriations Act, 2020, and Further Health Extenders Act of 2019, for fiscal year 2020 shall be charged to the applicable appropriation provided by the amendments made by this subsection to such section 1890(d)(2) for such fiscal year.

(b) ADDITIONAL REPORTING REQUIREMENTS.—Section 1890 of the Social Security Act (42 U.S.C. 1395aaa) is amended—

(1) in subsection (e)—

(A) by redesignating paragraphs (1) through (6) as subparagraphs (A) through (F), respectively;

(B) by striking ''CONGRESS.—By not later than'' and inserting ''CONGRESS.—

''(1) IN GENERAL.—By not later than'';

(C) in subparagraph (A), as redesignated by this paragraph, by striking the last sentence;

(D) in subparagraph (D), as so redesignated, by striking ''A description'' and inserting ''Subject to paragraph (2)(B), a description'';

(E) in subparagraph (E), as so redesignated, by striking ''The amount'' and inserting ''Subject to paragraph (2)(B), the amount'';

(F) in subparagraph (F), as so redesignated, by striking ''Estimates'' and inserting ''Subject to paragraph (2)(B), estimates''; and

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

''(2) ADDITIONAL REQUIREMENTS FOR REPORTS.—

''(A) ADDRESSING GAO REPORT.—Each of the annual reports submitted in 2020 and 2021 pursuant to paragraph (1) shall also include the following:

''(i) A comprehensive analysis detailing the ways in which the Centers for Medicare & Medicaid Services has addressed each of the recommendations set forth in the report by the Government Accountability Office (GAO–19–628) issued on September 19, 2019, and titled 'Health Care Quality: CMS Could More Effectively Ensure Its Quality Measurement Activities Promote Its Objectives'.

''(ii) A detailed description of—

"(I) any additional steps that the Centers for Medicare & Medicaid Services expects to take to address the findings and recommendations set forth in such report; and

"(II) the anticipated timing for such steps.

"(B) ENSURING DETAILED INFORMATION.—

"(i) IN GENERAL.—In the case of an annual report submitted in 2020 or a subsequent year pursuant to paragraph (1), the information required under—

"(I) paragraph (1)(D) shall also include detailed information on each of the activities described in clause (ii);

"(II) paragraph (1)(E) shall also include detailed information on the specific amounts obligated or expended on each of the activities described in clause (ii); and

"(III) paragraph (1)(F) shall also include detailed information on the specific quality measurement ac-

tivities required and future funding needed for each of the activities described in clause (ii).

''(ii) ACTIVITIES DESCRIBED.—The activities described in this clause are the following:

''(I) Measure selection activities.

''(II) Measure development activities.

''(III) Public reporting activities.

''(IV) Education and outreach activities.

''(iii) BROKEN OUT.—The information under subclauses (I), (II), and (III) of clause (i) shall also be broken out by—

''(I) site of care, including hospitals, physician offices, clinics, renal dialysis facilities, hospices, and post-acute care settings; and

''(II) type of measure, such as electronic clinical quality measures and outcome measures.''; and

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

''(f) ADDITIONAL REPORTING BY THE SECRETARY TO CONGRESS.—

''(1) IN GENERAL.—By not later than September 30 of each year (beginning with 2020), the Secretary shall submit to Congress a report on the amount of unobligated balances for appropriations relating to quality measurement. Such report shall include detailed plans on how the Secretary expects to expend such unobligated balances in the upcoming fiscal years.

''(2) SEPARATE REPORT.—The annual report required under paragraph (1) shall be separate from the annual report required under subsection (e).''.

(c) INPUT FOR REMOVAL OF MEASURES.—Section 1890(b) of the Social Security Act (42 U.S.C. 1395aaa(b)) is amended by inserting after paragraph (3) the following new paragraph:

''(4) REMOVAL OF MEASURES.—The entity may provide input to the Secretary on quality and efficiency measures described in paragraph (7)(B) that could be considered for removal.''.

SEC. 20105. EXTENSION OF FUNDING OUTREACH AND ASSISTANCE FOR LOW-INCOME PROGRAMS.

(a) ADDITIONAL FUNDING FOR STATE HEALTH INSURANCE PROGRAMS.—Subsection (a)(1)(B) of section

119 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395b–3 note), as amended by section 3306 of the Patient Protection and Affordable Care Act (Public Law 111–148), section 610 of the American Taxpayer Relief Act of 2012 (Public Law 112–240), section 1110 of the Pathway for SGR Reform Act of 2013 (Public Law 113–67), section 110 of the Protecting Access to Medicare Act of 2014 (Public Law 113–93), section 208 of the Medicare Access and CHIP Reauthorization Act of 2015 (Public Law 114–10), section 50207 of division E of the Bipartisan Budget Act of 2018 (Public Law 115–123), section 1402 of the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Public Law 116–59), and section 1402 of the Further Continuing Appropriations Act, 2020, and Further Health Extenders Act of 2019 (Public Law 116–69), is amended—

(1) in clause (ix), by inserting ''and'' at the end; and

(2) by striking clauses (x) and (xi) and inserting the following new clause:

''(xi) for each of fiscal years 2020 through 2022, of $13,000,000.''.

(b) ADDITIONAL FUNDING FOR AREA AGENCIES ON AGING.—Subsection (b)(1)(B) of such section 119, as so amended, is amended—

(1) in clause (ix), by inserting ''and'' at the end; and

(2) by striking clauses (x) and (xi) and inserting the following new clause:

''(xi) for each of fiscal years 2020 through 2022, of $7, 500,000.''.

(c) ADDITIONAL FUNDING FOR AGING AND DISABILITY RESOURCE CENTERS.—Subsection (c)(1)(B) of such section 119, as so amended, is amended—

(1) in clause (ix), by inserting ''and'' at the end; and

(2) by striking clauses (x) and (xi) and inserting the following new clause:

''(xi) for each of fiscal years 2020 through 2022, of $5,000,000.''.

(d) ADDITIONAL FUNDING FOR CONTRACT WITH THE NATIONAL CENTER FOR BENEFITS AND OUTREACH ENROLLMENT.—Subsection (d)(2) of such section 119, as so amended, is amended—

(1) in clause (ix), by inserting ''and'' at the end; and

(2) by striking clauses (x) and (xi) and inserting the following new clause:

"(xi) for each of fiscal years 2020 through 2022, of $12,000,000.".

(e) PREVENTION OF DUPLICATE APPROPRIATIONS FOR FISCAL YEAR 2020.—Expenditures made under section 119 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395b–3 note), as so amended, pursuant to the amendments made by the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Public Law 116–59) and the Further Continuing Appropriations Act, 2020, and Further Health Extenders Act of 2019 (Public Law 116–69), for fiscal year 2020 shall be charged to the applicable appropriation provided by the amendments made by this section to such section 119 for such fiscal year.

SEC. 20106. EXTENSION OF THE INDEPENDENCE AT HOME MEDICAL PRACTICE DEMONSTRATION PROGRAM UNDER THE MEDICARE PROGRAM.

(a) EXTENSION.—

(1) IN GENERAL.—Section 1866E(e)(1) of the Social Security Act (42 U.S.C. 1395cc–5(e)(1)) is amended by striking "7-year" and inserting "10-year".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect as if included in the enactment of Public Law 111–148.

(b) ADDITIONAL FUNDING.—Section 1866E(h) of the Social Security Act (42 U.S.C. 1395cc–5(h)) is amended, in the first sentence, by inserting ''and $5,000,000 for fiscal year 2020'' before the period at the end.

TITLE II—MEDICAID

SEC. 20201. PERMANENT EXTENSION OF MONEY FOLLOWS THE PERSON REBALANCING DEMONSTRATION.

(a) IN GENERAL.—Section 6071(h) of the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note) is amended—

(1) in paragraph (1)—

(A) in subparagraph (E), by striking ''and'' after the semicolon;

(B) in subparagraph (F)—

(i) by striking ''subject to subparagraph (3),''; and

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

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

''(G) $450,000,000 for each fiscal year after fiscal year 2019.'';

(2) in paragraph (2)—

(A) by striking ''Subject to paragraph (3), amounts'' and inserting ''Amounts''; and

(B) by striking ''2021'' and inserting ''2023''; and

(3) by striking paragraph (3).

(b) REDISTRIBUTION OF UNEXPENDED GRANT AWARDS.—Section 6701(e)(2) of the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note) is amended by adding at the end the following new sentence: ''Any portion of a State grant award for a fiscal year under this section that is unexpended by the State at the end of the fourth succeeding fiscal year shall be rescinded by the Secretary and added to the appropriation for the fifth succeeding fiscal year.''.

(c) RESEARCH AND EVALUATION.—Section 6071(g) of the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note) is amended—

(1) in paragraph (2), by striking ''2016'' and inserting ''2023''; and

(2) in paragraph (3), by inserting ''and for each of fiscal years 2020 through 2023,'' after ''2016,''.

(d) CHANGES TO INSTITUTIONAL RESIDENCY PERIOD REQUIREMENT.—

(1) IN GENERAL.—Section 6071(b)(2) of the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note) is amended—

(A) in subparagraph (A)(i), by striking ''90'' and inserting ''60''; and

(B) by striking the flush sentence after subparagraph (B).

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall take effect on the date that is 30 days after the date of enactment of this Act.

(e) UPDATES TO STATE APPLICATION REQUIREMENTS.—Section 6071(c) of the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note) is amended—

(1) in paragraph (3), by striking '', which shall include'' and all that follows through ''2007'';

(2) in paragraph (7)—

(A) in the paragraph heading, by striking ''REBALANCING'' and inserting ''EXPENDITURES''; and

(B) in subparagraph (B)—

(i) in clause (i), by striking ''and'' after the semicolon;

(ii) in clause (ii), by striking the period at the end and inserting a semicolon; and

(iii) by adding at the end the following:

''(iii) include a work plan that describes for each Federal fiscal year that occurs during the proposed MFP demonstration project—

''(I) the use of grant funds for each proposed initiative that is designed to accomplish the objective described in subsection (a)(1), including a funding source for each activity that is part of each such proposed initiative;

''(II) an evaluation plan that identifies expected results for each such proposed initiative; and

''(III) a sustainability plan for components of such proposed initiatives that are intended to improve transitions, which shall be updated with actual expenditure information for each Federal fiscal year that occurs during the MFP demonstration project; and

"(iv) contain assurances that grant funds used to accomplish the objective described in subsection (a)(1) shall be obligated not later than 24 months after the date on which the funds are awarded and shall be expended not later than 60 months after the date on which the funds are awarded (subject to subsection (e)(3) or unless the Secretary approves a waiver of either such requirement)."; and

(3) in paragraph (13)—

(A) in subparagraph (A), by striking "; and" and inserting ", and in such manner as will meet the reporting requirements set forth for the Transformed Medicaid Statistical Management Information System (T–MSIS);";

(B) by redesignating subparagraph (B) as subparagraph (D); and

(C) by inserting after subparagraph (A) the following:

"(B) the State shall report on a quarterly basis on the use of grant funds by distinct activity, as described in the approved work plan, and by specific population as targeted by the State;

''(C) if the State fails to report the information required under subparagraph (B), fails to report such information on a quarterly basis, or fails to make progress under the approved work plan, the State shall implement a corrective action plan and any lack of progress under the approved work plan may result in withholding of grant funds made available to the State; and''.

(f) FUNDING FOR QUALITY ASSURANCE AND IMPROVEMENT; TECHNICAL ASSISTANCE; OVERSIGHT.—Section 6071(f) of the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note) is amended by striking paragraph (2) and inserting the following:

''(2) FUNDING.—From the amounts appropriated under subsection (h)(1) for each fiscal year after 2019, $1,000,000 shall be available to the Secretary for each such fiscal year to carry out this subsection.''.

(g) BEST PRACTICES EVALUATION.—Section 6071 of the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note) is amended by adding at the end the following:

''(i) BEST PRACTICES.—

''(1) REPORT.—The Secretary, directly or through grant or contract, shall submit a report to

the President and Congress not later than September 30, 2020, that contains findings and conclusions on best practices from the State MFP demonstration projects carried out with grants made under this section. The report shall include information and analyses with respect to the following:

''(A) The most effective State strategies for transitioning beneficiaries from institutional to qualified community settings carried out under the State MFP demonstration projects and how such strategies may vary for different types of beneficiaries, such as beneficiaries who are aged, physically disabled, intellectually or developmentally disabled, or individuals with serious mental illnesses, and other targeted waiver beneficiary populations.

''(B) The most common and the most effective State uses of grant funds carried out under the State MFP demonstration projects for transitioning beneficiaries from institutional to qualified community settings and improving health outcomes, including differentiating funding for current initiatives that are designed for such purpose and funding for proposed initiatives that are designed for such purpose.

"(C) The most effective State approaches carried out under State MFP demonstration projects for improving person-centered care and planning.

"(D) Identification of program, financing, and other flexibilities available under the State MFP demonstration projects, that are not available under the traditional Medicaid program, and which directly contributed to successful transitions and improved health outcomes under the State MFP demonstration projects.

"(E) State strategies and financing mechanisms for effective coordination of housing financed or supported under State MFP demonstration projects with local housing authorities and other resources.

"(F) Effective State approaches for delivering Money Follows the Person transition services through managed care entities.

"(G) Other best practices and effective transition strategies demonstrated by States with approved MFP demonstration projects, as determined by the Secretary.

"(H) Identification and analyses of opportunities and challenges to integrating effective Money Follows the Person practices and State strategies into the traditional Medicaid program.

"(2) COLLABORATION.—In preparing the report required under this subsection, the Secretary shall collect and incorporate information from States with approved MFP demonstration projects and beneficiaries participating in such projects, and providers participating in such projects.

"(3) FUNDING.—From the amounts appropriated under subsection (h)(1) for each of fiscal years 2019 through 2020, not more than $300,000 shall be available to the Secretary for each such fiscal year to carry out this subsection.".

(h) MACPAC REPORT ON QUALIFIED SETTINGS CRITERIA.—Section 6071 of the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note), as amended by subsection (g), is amended by adding at the end the following:

"(j) MACPAC REPORT.—Prior to the final implementation date established by the Secretary for the criteria established for home and community-based settings in section 441.301(c)(4) of title 42, Code of Federal Regulations, as part of final implementation of the Home and

Community Based Services (HCBS) Final Rule published on January 16, 2014 (79 Fed. Reg. 2947) (referred to in this subsection as the 'HCBS final rule'), the Medicaid and CHIP Payment and Access Commission (MACPAC) shall submit to Congress a report that—

''(1) identifies the types of home and community-based settings and associated services that are available to eligible individuals in both the MFP demonstration program and sites in compliance with the HCBS final rule; and

''(2) if determined appropriate by the Commission, recommends policies to align the criteria for a qualified residence under subsection (b)(6) (as in effect on October 1, 2017) with the criteria in the HCBS final rule.''.

(i) APPLICATION TO CURRENT PROJECTS.—Not later than 1 year after the date of enactment of this Act, any State with an approved MFP demonstration project under section 6071 of the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note) on the date of enactment of this Act shall submit a revised application to the Secretary that contains the same information and assurances as are required for any new State applicant under the amendments made by this Act.

SEC. 20202. PERMANENT EXTENSION OF PROTECTION FOR MEDICAID RECIPIENTS OF HOME AND COMMUNITY-BASED SERVICES AGAINST SPOUSAL IMPOVERISHMENT.

(a) IN GENERAL.—Section 2404 of Public Law 111–148 (42 U.S.C. 1396r–5 note) is amended—

(1) by striking ''During the period'' and all that follows through ''section 1924(h)(1)(A)'' and inserting the following:

''(a) IN GENERAL.—Subject to subsection (b), section 1924(h)(1)(A)''; and

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

''(b) REQUIRED INFORMATION ON COMMUNITY SPOUSES.—

''(1) IN GENERAL.—The Administrator of the Centers for Medicare & Medicaid Services shall—

''(A) collect information from States on the number of individuals in the State who are community spouses (as such term is defined in section 1924(h) of the Social Security Act (42 U.S.C. 1396r–5(h)), and applied pursuant to subsection (a)) and submit such information to the Administrator; and

''(B) make publicly available information collected from States under subparagraph (A).

''(2) SUNSET.—If the Secretary of Health and Human Services determines at any point after January 1, 2025, that the Administrator of the Centers for Medicare & Medicaid Services has failed to meet the requirements of paragraph (1), section 1924(h)(1)(A) of the Social Security Act (42 U.S.C. 1396r–5(h)(1)(A)) shall be applied without regard to subsection (a) as of the date of such determination.''.

(b) RULE OF CONSTRUCTION.—Nothing in section 2404 of Public Law 111–148 (42 U.S.C. 1396r–5 note) or section 1902(a)(17) or 1924 of the Social Security Act (42 U.S.C. 1396a(a)(17), 1396r–5) shall be construed as prohibiting a State from applying an income or resource disregard under a methodology authorized under section 1902(r)(2) of such Act (42 U.S.C. 1396a(r)(2))—

(1) to the income or resources of an individual described in section 1902(a)(10)(A)(ii)(VI) of such Act (42 U.S.C. 1396a(a)(10)(A)(ii)(VI)) (including a disregard of the income or resources of such individual's spouse); or

(2) on the basis of an individual's need for home and community-based services authorized under subsection (c), (d) (i), or (k) of section 1915

of such Act (42 U.S.C. 1396n) or under section 1115 of such Act (42 U.S.C. 1315).

SEC. 20203. EXTENSION AND EXPANSION OF COMMUNITY MENTAL HEALTH SERVICES DEMONSTRATION PROGRAM.

(a) IN GENERAL.—Section 223(d) of the Protecting Access to Medicare Act of 2014 (42 U.S.C. 1396a note) is amended—

(1) in paragraph (3)—

(A) by striking ''Not more than'' and inserting ''Subject to paragraph (8), not more than''; and

(B) by striking ''December 20, 2019'' and inserting ''December 31, 2021'';

(2) in paragraph (7)(B), by striking ''December 31, 2021'' and inserting ''June 30, 2021''; and

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

''(8) ADDITIONAL PROGRAMS.—

''(A) IN GENERAL.—Not later than 6 months after the date of enactment of this paragraph, in addition to the 8 States selected under paragraph (1), the Secretary shall select 11 States to participate in 2-year demonstra-

tion programs that meet the requirements of this subsection.

''(B) SELECTION OF STATES.—

''(i) IN GENERAL.—Subject to clause (ii), in selecting States under this paragraph, the Secretary—

''(I) shall select States that—

''(aa) were awarded planning grants under subsection (c); and

''(bb) applied to participate in the demonstration programs under this subsection under paragraph (1) but, as of the date of enactment of this paragraph, were not selected to participate under paragraph (1); and

''(II) shall use the results of the Secretary's evaluation of each State's application under paragraph (1) to determine which States to select, and shall not require the submission of any additional application.

''(ii) SELECTION OF OTHER STATES.—If less than 11 of the States de-

scribed in subclause (I) of clause (i) wish to participate in demonstration programs under this subsection, the Secretary may select other States to participate in demonstration programs under this subsection, but in no case shall the Secretary select more than 11 States under this paragraph.

''(C) REQUIREMENTS FOR SELECTED STATES.—Before the launch of a demonstration program in a State selected under this paragraph, the State shall—

''(i) submit a plan to monitor certified community behavioral health clinics under the demonstration program to ensure compliance with certified community behavioral health criteria during the demonstration period; and

''(ii) commit to collecting data, notifying the Secretary of any planned changes that would deviate from the prospective payment system methodology outlined in the State's demonstration application, and obtaining approval from the Secretary for any such change before implementing the change.''.

(b) LIMITATION.—Section 223(d)(5) of the Protecting Access to Medicare Act of 2014 (42 U.S.C. 1396a note) is amended—

(1) in subparagraph (B), in the matter preceding clause (i), by striking ''The Federal matching'' and inserting ''Subject to subparagraph (C)(iii), the Federal matching''; and

(2) in subparagraph (C), by adding at the end the following new clause:

''(iii) PAYMENTS FOR AMOUNTS EXPENDED AFTER 2019.—The Federal matching percentage applicable under subparagraph (B) to amounts expended by a State participating in the demonstration program under this subsection shall—

''(I) in the case of a State participating in the demonstration program as of January 1, 2020, apply to amounts expended by the State during the 8 fiscal quarter period that begins on January 1, 2020; and

''(II) in the case of a State selected to participate in the demonstration program under paragraph (8), during first 8 fiscal quarter period

that the State participates in a demonstration program.''.

(c) GAO STUDY AND REPORT ON THE COMMUNITY AND MENTAL HEALTH SERVICES DEMONSTRATION PROGRAM.—

(1) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on the community and mental health services demonstration program conducted under section 223 of the Protecting Access to Medicare Act of 2014 (42 U.S.C. 1396a note) (referred to in this subsection as the ''demonstration program'').

(2) CONTENT OF REPORT.—The report required under paragraph (1) shall include the following information:

(A) Information on States' experiences participating in the demonstration program, including the extent to which States—

(i) measure the effects of access to certified community behavioral health clin-

ics on patient health and cost of care, including—

(I) engagement in treatment for behavioral health conditions;

(II) relevant clinical outcomes, to the extent collected;

(III) screening and treatment for comorbid medical conditions; and

(IV) use of crisis stabilization, emergency department, and inpatient care.

(B) Information on Federal efforts to evaluate the demonstration program, including—

(i) quality measures used to evaluate the program;

(ii) assistance provided to States on data collection and reporting;

(iii) assessments of the reliability and usefulness of State-submitted data; and

(iv) the extent to which such efforts provide information on the relative quality, scope, and cost of services as compared with services not provided under the demonstration program, and in comparison to

Medicaid beneficiaries with mental illness and substance use disorders not served under the demonstration program.

(C) Recommendations for improvements to the following:

(i) The reporting, accuracy, and validation of encounter data.

(ii) Accuracy in payments to certified community behavioral health clinics under State plans or waivers under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

SEC. 20204. DELAY IN MEDICAID DSH REDUCTIONS; REPORTING ON SUPPLEMENTAL PAYMENTS.

(a) DELAY IN DSH REDUCTION.—Section 1923(f)(7)(A) of the Social Security Act (42 U.S.C. 1396r–4(f)(7)(A)) is amended—

(1) in clause (i), in the matter preceding subclause (I), by striking ''For the period'' and all that follows through ''2025'' and inserting ''For each of fiscal years 2022 through 2025''; and

(2) in clause (ii), by striking ''shall be equal to—'' and all that follows through ''2025'' and inserting ''shall be equal to $8,000,000,000 for each of fiscal years 2022 through 2025''.

(b) SUPPLEMENTAL PAYMENT REPORTING REQUIREMENTS.—Section 1903 of the Social Security Act (42 U.S.C.1396b) is amended by adding at the end the following new subsection:

''(bb) SUPPLEMENTAL PAYMENTS REPORTING REQUIREMENTS.—

''(1) COLLECTION AND PUBLIC AVAILABILITY OF SUPPLEMENTAL PAYMENT DATA.—

''(A) IN GENERAL.—Not later than October 1, 2021, the Secretary shall establish a system for each State to submit reports on supplemental payments data, as a requirement for a State plan or State plan amendment that would provide for a supplemental payment.

''(B) REQUIREMENTS.—Each report submitted by a State in accordance with the requirement established under subparagraph (A) shall include the following:

''(i) An explanation of how supplemental payments made under the State plan or a State plan amendment will result in payments that are consistent with section 1902(a)(30)(A), including standards with respect to efficiency, economy, quality of care, and access, along with the stated

purpose and intended effects of the supplemental payment.

''(ii) The criteria used to determine which providers are eligible to receive the supplemental payment.

''(iii) A comprehensive description of the methodology used to calculate the amount of, and distribute, the supplemental payment to each eligible provider, including—

''(I) data on the amount of the supplemental payment made to each eligible provider, if known, or, if the total amount is distributed using a formula based on data from 1 or more fiscal years, data on the total amount of the supplemental payments for the fiscal year or years available to all providers eligible to receive a supplemental payment;

''(II) if applicable, the specific criteria with respect to Medicaid service, utilization, or cost data to be used as the basis for calculations regarding

the amount or distribution of the supplemental payment; and

"(III) the timing of the supplemental payment made to each eligible provider.

"(iv) An assurance that the total Medicaid payments made to an inpatient hospital provider, including the supplemental payment, will not exceed upper payment limits.

"(v) If not already submitted, an upper payment limit demonstration under section 447.272 of title 42, Code of Federal Regulations (as such section is in effect as of the date of enactment of this subsection).

"(C) PUBLIC AVAILABILITY.—The Secretary shall make all reports and related data submitted under this paragraph publicly available on the website of the Centers for Medicare & Medicaid Services on a timely basis.

"(D) SUPPLEMENTAL PAYMENT DEFINED.—

"(i) IN GENERAL.—Subject to clause (ii), in this paragraph, the term 'supple-

mental payment' means a payment to a provider that is in addition to any base payment made to the provider under the State plan under this title or under demonstration authority.

"(ii) DSH PAYMENTS EXCLUDED.—Such term does not include a disproportionate share hospital payment made under section 1923.".

(c) MEDICAID SHORTFALL AND THIRD PARTY PAYMENTS.—

(1) IN GENERAL.—Section 1923(g)(1)(A) of the Social Security Act (42 U.S.C. 1396r–4(g)(1)(A)) is amended to read as follows:

"(A) DETERMINATION OF UNCOMPENSATED COSTS.—

"(i) IN GENERAL.—A payment adjustment during a fiscal year shall not be considered to be consistent with subsection (c) with respect to a hospital if the payment adjustment exceeds the costs incurred during the year of furnishing hospital services by the hospital to individuals described in clause (ii) minus—

"(I) payments under this title (other than under this section) for such services; and

"(II) payments by uninsured patients for such services.

"(ii) INDIVIDUALS DESCRIBED.—For purposes of clause (i), the individuals described in this clause are the following:

"(I) Subject to clause (iii), individuals who are eligible for medical assistance under the State plan or under a waiver of such plan and for whom the State plan or waiver is the primary payor for such services.

"(II) Subject to clause (iv), individuals who have no health insurance (or other source of third party coverage) for services provided during the year, as determined by the Secretary.

"(iii) EXCLUSION OF CERTAIN PAYMENTS.—For purposes of clause (ii)(II), payments made to a hospital for services provided to indigent patients made by a State or a unit of local government within

a State shall not be considered to be a source of third party payment.''.

(2) EFFECTIVE DATE.—The amendment made by this subsection takes effect on October 1, 2020.

(d) GAO STUDY AND REPORT ON UNCOMPENSATED CARE COSTS IN HOSPITALS SERVING A DISPROPORTIONATE SHARE OF MEDICAID BENEFICIARIES AND UNINSURED PATIENTS.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and to the Committee on Finance of the Senate a report that examines uncompensated care costs, as defined for purposes of subsection (g) of section 1923 of the Social Security Act (42 U.S.C. 1396r–4), for all hospitals receiving disproportionate share hospital payments under such section. The report shall include an examination of uncompensated care costs at the State level and provide information on each State's Medicaid uncompensated care costs.

SEC. 20205. MEDICAID FUNDING FOR THE TERRITORIES.

(a) TREATMENT OF CAP.—Section 1108(g) of the Social Security Act (42 U.S.C. 1308(g)) is amended—

(1) in paragraph (2)—

(A) in the matter preceding subparagraph (A), by striking ''subject to and section

1323(a)(2) of the Patient Protection and Affordable Care Act paragraphs (3) and (5)'' and inserting ''subject to section 1323(a)(2) of the Patient Protection and Affordable Care Act and paragraphs (3) and (5)'';

(B) in subparagraph (A)—

(i) by striking ''Puerto Rico shall not exceed the sum of'' and inserting ''Puerto Rico shall not exceed—

''(i) except as provided in clause (ii), the sum of'';

(ii) by striking ''$100,000;'' and inserting ''$100,000; and''; and

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

''(ii) for each of fiscal years 2020 through 2023, the amount specified in paragraph (6) for each such fiscal year;'';

(C) in subparagraph (B)—

(i) by striking ''the Virgin Islands shall not exceed the sum of'' and inserting ''the Virgin Islands shall not exceed—

''(i) except as provided in clause (ii), the sum of'';

(ii) by striking ''$10,000;'' and inserting ''$10,000; and''; and

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

''(ii) for each of fiscal years 2020 through 2023, $126,000,000;'';

(D) in subparagraph (C)—

(i) by striking ''Guam shall not exceed the sum of'' and inserting ''Guam shall not exceed—

''(i) except as provided in clause (ii), the sum of'';

(ii) by striking ''$10,000;'' and inserting ''$10,000; and''; and

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

''(ii) for each of fiscal years 2020 through 2023, $127,000,000;'';

(E) in subparagraph (D)—

(i) by striking ''the Northern Mariana Islands shall not exceed the sum of'' and inserting ''the Northern Mariana Islands shall not exceed—

''(i) except as provided in clause (ii), the sum of''; and

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

''(ii) for each of fiscal years 2020 through 2023, $60,000,000; and'';

(F) in subparagraph (E)—

(i) by striking ''American Samoa shall not exceed the sum of'' and inserting ''American Samoa shall not exceed—

''(i) except as provided in clause (ii), the sum of'';

(ii) by striking ''$10,000.'' and inserting ''$10,000; and''; and

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

''(ii) for each of fiscal years 2020 through 2023, $84,000,000.''; and

(G) by adding at the end the following flush sentence:

'' ''For each fiscal year after fiscal year 2023, the total amount certified for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa under subsection (f) and this subsection for the fiscal year shall be determined as if the preceding subparagraphs were applied to each of

fiscal years 2020 through 2023 without regard to clause (ii) of each such subparagraph.''; and

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

''(6) APPLICATION TO PUERTO RICO FOR FISCAL YEARS 2020 THROUGH 2023.—

''(A) IN GENERAL.—Subject to subparagraph (B), the amount specified in this paragraph is—

''(i) for fiscal year 2020, $2,623,188,000;

''(ii) for fiscal year 2021, $2,719,072,000;

''(iii) for fiscal year 2022, $2,812,610,000; and

''(iv) for fiscal year 2023, $2,914,331,000.

''(B) ADDITIONAL INCREASE FOR PUERTO RICO.—For each of fiscal years 2020 through 2023, the amount specified in this paragraph shall be equal to the amount specified for such year under subparagraph (A) increased by $200,000,000 if the Secretary certifies that, with respect to such year, Puerto Rico's State plan under title XIX (or a waiver of such plan)

provides for payment for outpatient physician services furnished under the plan (or waiver) during the fiscal year at a rate that is not less than 70 percent of the payment rate that would apply to such services if they were furnished under part B of title XVIII during such fiscal year.

''(7) PUERTO RICO PROGRAM INTEGRITY REQUIREMENTS.—

''(A) INDEPENDENT AUDIT.—

''(i) IN GENERAL.—Not later than 6 months after the date of enactment of this paragraph, Puerto Rico shall select an independent third party to conduct an audit of Puerto Rico's Medicaid program under title XIX in each of fiscal years 2022 and 2023. Such audit shall include an examination of any part of the administration of Puerto Rico's Medicaid program, such as contracting protocols, denials of care, and financial management, that the independent third party determines to be at high risk for waste, fraud, or abuse.

''(ii) PENALTY FOR FAILURE TO SELECT A THIRD PARTY.—If Puerto Rico

does not select an independent third party to conduct the audit required under clause (i) by the date specified in such clause, the amounts specified for Puerto Rico under paragraph (6) for fiscal years 2022 and 2023 shall be reduced by $50,000,000 for each such year.

''(iii) REPORT.—Upon completion of the audit required under clause (i), the independent third party that conducted the audit shall submit a report containing the results of the audit to Congress, the Governor of Puerto Rico, and the Inspector General of the Department of Health and Human Services.

''(B) ADDITIONAL REQUIREMENTS.—

''(i) PROGRAM INTEGRITY LEAD.—Not later than 6 months after the date of enactment of this paragraph, the agency responsible for the administration of Puerto Rico's Medicaid program under title XIX shall designate an officer (other than the director of such agency) to serve as the Program Integrity Lead for such program.

"(ii) PERM REQUIREMENT.—Not later than 12 months after the date of enactment of this paragraph, Puerto Rico shall publish a plan, developed by Puerto Rico in coordination with the Administrator of the Centers for Medicare & Medicaid Services and approved by the Administrator, for how Puerto Rico will develop measures to satisfy the payment error rate measurement (PERM) requirements under subpart Q of part 431 of title 42, Code of Federal Regulations, including annual benchmarks and scheduled audits for such compliance.

"(iii) CONTRACTING REFORM.—Not later than October 1, 2020, Puerto Rico shall publish a contracting reform plan to combat fraudulent, wasteful, or abusive contracts under Puerto Rico's Medicaid program under title XIX that includes—

"(I) metrics for evaluating the success of the plan; and

"(II) a schedule for publicly releasing status reports on the plan.

''(iv) MEQC.—Not later than 12 months after the date of enactment of this paragraph, Puerto Rico shall publish a plan, developed by Puerto Rico in coordination with the Administrator of the Centers for Medicare & Medicaid Services and approved by the Administrator, for how Puerto Rico will comply with the Medicaid eligibility quality control (MEQC) requirements of section 1903(u).

''(C) FMAP REDUCTION FOR FAILURE TO MEET ADDITIONAL REQUIREMENTS.—

''(i) IN GENERAL.—For fiscal quarters during the period beginning on January 1, 2020, and ending on September 30, 2023, for each requirement described in clauses (i) through (iv) of subparagraph (B) and for each plan described in clauses (ii) and (iv) of such subparagraph, if Puerto Rico fails to satisfy such requirement or comply with the terms of such plan, the Federal medical assistance percentage applicable to Puerto Rico under section 1905(ff) for such quarter shall be reduced by a number of percentage points (not to

exceed 5 percentage points with respect to each such failure) equal to 0.5 percentage points for every fiscal quarter during such period in which Puerto Rico has failed to satisfy such requirement or comply with the terms of such plan.

''(ii) EXCEPTION FOR EXTENUATING CIRCUMSTANCES OR REASONABLE PROGRESS.—For purposes of clause (i), Puerto Rico shall be deemed to have satisfied a requirement of subparagraph (B) or complied with the terms of a plan described in such subparagraph for a fiscal quarter if—

''(I) the Secretary approves an application from Puerto Rico describing extenuating circumstances that prevented Puerto Rico from satisfying the requirement or complying with the terms of the plan; or

''(II) in the case of a requirement to comply with the terms of a plan, Puerto Rico has made objectively reasonable progress towards satisfying such terms and has submitted a time-

ly request for an exception to the Secretary.

"(8) PROGRAM INTEGRITY LEAD REQUIREMENT FOR THE VIRGIN ISLANDS, GUAM, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA.—

"(A) PROGRAM INTEGRITY LEAD REQUIREMENT.—Not later than October 1, 2020, the agency responsible for the administration of the Medicaid program under title XIX of each territory specified in subparagraph (C) shall designate an officer (other than the director of such agency) to serve as the Program Integrity Lead for such program.

"(B) FMAP REDUCTION.—If, in any fiscal quarter during the period that begins with fiscal year 2021 and ends with fiscal year 2023, a territory specified in subparagraph (C) fails to satisfy the requirement of subparagraph (A), the Federal medical assistance percentage applicable to the territory under section 1905(ff) for such quarter shall be reduced by 0.25 percentage points for every fiscal quarter during such period in which the territory has failed to satisfy such requirement, except that in no case

shall a reduction under this subparagraph exceed 5 percentage points.

''(C) SCOPE.—This paragraph shall apply to the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.''.

(b) TREATMENT OF FUNDING UNDER ENHANCED ALLOTMENT PROGRAM.—Section 1935(e) of the Social Security Act (42 U.S.C. 1396u–5(e)) is amended—

(1) in paragraph (1)(B), by striking ''if the State'' and inserting ''subject to paragraph (4), if the State'';

(2) by redesignating paragraph (4) as paragraph (5); and

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

''(4) TREATMENT OF FUNDING FOR CERTAIN FISCAL YEARS.—

''(A) PUERTO RICO.—Notwithstanding paragraph (1)(B), in the case that Puerto Rico establishes and submits to the Secretary a plan described in paragraph (2) with respect to any of fiscal years 2020 through 2023, the amount specified in paragraph (3) for Puerto Rico for such a year shall be taken into account in ap-

plying subparagraph (A)(ii) of section 1108(g)(2) for such year.

''(B) OTHER TERRITORIES.—Notwithstanding paragraph (1)(B), in the case that the Virgin Islands, Guam, the Northern Mariana Islands, or American Samoa establishes and submits to the Secretary a plan described in paragraph (2) with respect to any of fiscal years 2020 through 2025, the amount specified in paragraph (3) for the Virgin Islands, Guam, the Northern Mariana Islands, or American Samoa, as the case may be, shall be taken into account in applying, as applicable, subparagraph (B)(ii), (C)(ii), (D)(ii), or (E)(ii) of section 1108(g)(2) for such year.''.

(c) INCREASED FMAP.—Subsection (ff) of section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended to read as follows:

''(ff) TEMPORARY INCREASE IN FMAP FOR TERRITORIES FOR CERTAIN FISCAL YEARS.—Notwithstanding subsection (b) or (z)(2)—

''(1) for the period beginning October 1, 2019, and ending December 20, 2019, the Federal medical assistance percentage for Puerto Rico, the Virgin Is-

lands, Guam, the Northern Mariana Islands, and American Samoa shall be equal to 100 percent; and

''(2) for the period beginning December 21, 2019, and ending September 30, 2023, the Federal medical assistance percentage—

''(A) for Puerto Rico, shall be equal to 76 percent; and

''(B) for the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be equal to 83 percent.''.

(d) ANNUAL REPORT.—Section 1108(g) of the Social Security Act (42 U.S.C. 1308(g)), as amended by subsection (a), is further amended by adding at the end the following new paragraph:

''(9) ANNUAL REPORT.—

''(A) IN GENERAL.—Not later than the date that is 30 days after the end of each fiscal year (beginning with fiscal year 2020 and ending with fiscal year 2023), in the case that a specified territory receives a Medicaid cap increase, or an increase in the Federal medical assistance percentage for such territory under section 1905(ff), for such fiscal year, such territory shall submit to the Chair and Ranking Member of the Committee on Energy and Com-

merce of the House of Representatives and the Chair and Ranking Member of the Committee on Finance of the Senate a report that describes how such territory has used such Medicaid cap increase, or such increase in the Federal medical assistance percentage, as applicable, to increase access to health care under the State Medicaid plan of such territory under title XIX (or a waiver of such plan). Such report may include—

"(i) the extent to which such territory has, with respect to such plan (or waiver)—

"(I) increased payments to health care providers;

"(II) increased covered benefits;

"(III) expanded health care provider networks; or

"(IV) improved in any other manner the carrying out of such plan (or waiver); and

"(ii) any other information as determined necessary by such territory.

"(B) DEFINITIONS.—In this paragraph:

''(i) MEDICAID CAP INCREASE.—The term 'Medicaid cap increase' means, with respect to a specified territory and fiscal year, any increase in the amounts otherwise determined under this subsection for such territory for such fiscal year by reason of the amendments made by section 20205 Prescription Drug Pricing Reduction and Health and Human Services Improvements Act .

''(ii) SPECIFIED TERRITORY.—The term 'specified territory' means Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.''.

(e) APPLICATION OF CERTAIN DATA REPORTING AND PROGRAM INTEGRITY REQUIREMENTS TO NORTHERN MARIANA ISLANDS, AMERICAN SAMOA, AND GUAM.—

(1) IN GENERAL.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended by adding at the end the following new subsection:

''(qq) APPLICATION OF CERTAIN DATA REPORTING AND PROGRAM INTEGRITY REQUIREMENTS TO NORTHERN MARIANA ISLANDS, AMERICAN SAMOA, AND GUAM.—

Not later than October 1, 2021, the Northern Mariana Islands, American Samoa, and Guam shall—

''(1) implement methods, satisfactory to the Secretary, for the collection and reporting of reliable data to the Transformed Medicaid Statistical Information System (T–MSIS) (or a successor system); and

''(2) demonstrate progress in establishing a State medicaid fraud control unit described in section 1903(q).''.

(2) CONFORMING AMENDMENT.—Section 1902(j) of the Social Security Act (42 U.S.C. 1396a(j)) is amended—

(A) by striking ''or the requirement'' and inserting '', the requirement''; and

(B) by inserting before the period at the end the following: '', or the requirement under subsection (qq)(1) (relating to data reporting)''.

(f) ADDITIONAL PROGRAM INTEGRITY REQUIREMENTS.—

(1) DEFINITIONS.—In this subsection:

(A) INSPECTOR GENERAL.—The term ''Inspector General'' means the Inspector General of the Department of Health and Human Services.

(B) PUERTO RICO'S MEDICAID PROGRAM.—The term ''Puerto Rico's Medicaid program'' means, collectively, Puerto Rico's State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) and any waiver of such plan.

(2) AUDITS RELATING TO FRAUD, WASTE, AND ABUSE.—If the independent third party that conducts the program integrity audit of Puerto Rico's Medicaid program required under section 1108(g)(7)(A) of the Social Security Act (42 U.S.C. 1308(g)(7)(A)) notifies the Inspector General (whether in the report required in such section or otherwise) of areas that the independent third party has identified as being at a high risk for waste, fraud, and abuse, the Inspector General shall conduct, on a regular basis, audits of the administration of Puerto Rico's Medicaid program until the Inspector General determines that Puerto Rico has taken reasonable and appropriate steps to address such high risk areas.

(3) TECHNICAL REVIEW OF PUERTO RICO HEARINGS AND APPEALS PROCESSES.—Not later than January 1, 2022, the Secretary of Health and Human Services shall conduct a technical review of

the hearings and appeals processes available to individuals applying for or receiving benefits under Puerto Rico's Medicaid program and the hearings and appeals processes available to providers participating in such program to ensure that such processes comply with all applicable requirements under titles XI and XIX of the Social Security Act (42 U.S.C. 1301 et seq., 1396 et seq.) (including applicable regulations promulgated under such titles).

(4) AUDITS OF MANAGED CARE PAYMENTS.—Not later than the date that is 1 year after the date of enactment of this Act, the Inspector General shall develop and submit to Congress—

(A) a report identifying payments made under Puerto Rico's Medicaid program to managed care organizations that the Inspector General determines to be at high risk for waste, fraud, or abuse; and

(B) a plan for auditing and investigating such payments.

(5) SYSTEM FOR TRACKING FEDERAL FUNDING PROVIDED TO PUERTO RICO; MEDICAID AND CHIP SCORECARD REPORTING.—Section 1902 of the Social Security Act (42 U.S.C. 1396a), as amended by

subsection (e), is further amended by adding at the end the following new subsection:

"(rr) PROGRAM INTEGRITY REQUIREMENTS FOR PUERTO RICO.—

"(1) SYSTEM FOR TRACKING FEDERAL FUNDING PROVIDED TO PUERTO RICO.—

"(A) IN GENERAL.—Puerto Rico shall establish and maintain a system for tracking any amounts paid by the Federal Government to Puerto Rico with respect to the State plan of Puerto Rico (or a waiver of such plan). Under such system, Puerto Rico shall ensure that information is available, with respect to each quarter in a fiscal year (beginning with the first quarter beginning on or after the date that is 1 year after the date of the enactment of this subsection), on the following:

"(i) In the case of a quarter other than the first quarter of such fiscal year—

"(I) the total amount expended by Puerto Rico during any previous quarter of such fiscal year under the State plan of Puerto Rico (or a waiver of such plan); and

"(II) a description of how such amount was so expended.

"(ii) The total amount that Puerto Rico expects to expend during the quarter under the State plan of Puerto Rico (or a waiver of such plan), and a description of how Puerto Rico expects to expend such amount.

"(B) REPORT TO CMS.—For each quarter with respect to which Puerto Rico is required under subparagraph (A) to ensure that information described in such subparagraph is available, Puerto Rico shall submit to the Administrator of the Centers for Medicare & Medicaid Services a report on such information for such quarter.

"(2) SUBMISSION OF DOCUMENTATION ON CONTRACTS UPON REQUEST.—Puerto Rico shall, upon request, submit to the Administrator of the Centers for Medicare & Medicaid Services all documentation requested with respect to contracts awarded under the State plan of Puerto Rico (or a waiver of such plan).

"(3) REPORTING ON MEDICAID AND CHIP SCORECARD MEASURES.—Beginning 12 months after

the date of enactment of this subsection, Puerto Rico shall begin to report to the Administrator of the Centers for Medicare & Medicaid Services on all measures included in the Medicaid and CHIP Scorecard developed by the Centers for Medicare & Medicaid Services.''.

(6) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary of Health and Human Services $5,000,000 for each of fiscal years 2020 through 2023 to carry out this subsection.

SEC. 20206. REPORTING REQUIREMENTS FOR ELECTING COST AVOIDANCE EXCEPTIONS FOR MEDICAID AND CHIP THIRD PARTY LIABILITY.

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

(1) in subsection (a)(25)—

(A) in subparagraph (E)(i), by inserting '', and the State satisfies the reporting requirements specified in subsection (qq)'' after ''access to care''; and

(B) in subparagraph (F)(i), by striking ''care.'' and inserting ''care, and the State satisfies the reporting requirements specified in subsection (qq)''; and

(2) by adding at the end the following:

''(qq) REPORTING REQUIREMENTS FOR ELECTING COST AVOIDANCE EXCEPTIONS FOR THIRD PARTY LIABILITY.—For purposes of subparagraphs (E)(i) and (F)(i) of subsection (a)(25), the reporting requirements of this subsection are the following:

''(1) PRE-IMPLEMENTATION.—Prior to implementation of a cost avoidance exception under either such subparagraph (or, in the case of a State that on the date of enactment of this subsection has implemented a cost avoidance exception under either or both of such subparagraphs, not later than 9 months after such date of enactment), a State shall submit a baseline report on third party liability to the Secretary that—

''(A) lists the actions taken by the State to update and improve systems to verify third party liability;

''(B) includes an assessment, based on data from the 3 most recent calendar years, examining the overlap of coverage provided under the State plan under this title or under a waiv-

er of such plan and third party coverage for preventive pediatric care (including early and periodic screening, diagnostic and treatment services under section 1905(a)(4)(B)) and services provided to an individual on whose behalf child support enforcement is being carried out;

''(C) provides information on—

''(i) the proportion of children covered under the State plan or under any waiver of such plan identified as having third party coverage;

''(ii) the number and proportion of such beneficiaries whose third party coverage status was determined to be inaccurate, to the extent available;

''(iii) the number and proportion of such beneficiaries with claims under the State plan or under any waiver of such plan for pediatric preventive services;

''(iv) the number and costs of claims for child support enforcement beneficiaries that would not be categorized as pediatric preventive services;

''(v) in the case of a State that on the date of enactment of this subsection has

implemented a cost avoidance exception under subparagraph (E)(i) of subsection (a)(25), the number and proportion of claims for pediatric preventive care for which the State (or any contracted entity) employed such an exception and for which third party payment was recovered; and

''(vi) in the case of a State that on the date of enactment of this subsection has implemented a cost avoidance exception under subparagraph (F)(i) of subsection (a)(25), the number and proportion of claims for services provided to an individual on whose behalf child support enforcement is being carried out by the State for which the State (or any contracted entity) employed such an exception and for which third party payment was recovered; and

''(D) includes information on sources used by the State to identify possible third party coverage for—

''(i) Medicaid beneficiaries eligible for pediatric preventive services; and

"(ii) claims for services covered under the State plan or a waiver of such plan which are provided to an individual on whose behalf child support enforcement is being carried out by the State.

"(2) IMPLEMENTATION.—Upon implementation by State of a cost avoidance exception under subparagraph (E)(i) or (F)(i) of subsection (a)(25) (or, in the case of a State that on the date of enactment of this subsection has implemented a cost avoidance exception under either or both of such subparagraphs, not later than 9 months after such date of enactment), the State shall submit a baseline report on access to care to the Secretary that—

"(A) in the case of a State that has implemented a cost avoidance exception under subparagraph (E)(i) of such subsection, includes an analysis of access to pediatric preventive care services under the State plan or a waiver of such plan (through both fee-for-service and managed care) examining measures of access to care, including provider availability and accessibility, beneficiary utilization, and beneficiary perceptions and experiences; and

"(B) in the case of a State that has implemented a cost avoidance exception under subparagraph (F)(i) of such subsection, includes an analysis of access to services provided under the State plan or a waiver of such plan to an individual on whose behalf child support enforcement is being carried out by the State (through both fee-for-service and managed care) examining measures of access to care, including provider availability and accessibility, beneficiary utilization, and beneficiary perceptions and experiences.

"(3) ADDITIONAL REPORTS.—

"(A) ANNUAL NOTICE OF IMPLEMENTATION REPORT.—A State annually shall submit a notice to the Secretary regarding whether the State has implemented a cost avoidance exception under subparagraph (E)(i) or (F)(i) of subsection (a)(25) (or both).

"(B) UPDATED BASELINE REPORTS.—Every 3 years after implementation of a cost avoidance exception under subparagraph (E)(i) or (F)(i) of subsection (a)(25), a State shall submit to the Secretary an updated version of the baseline reports submitted by the State

under paragraphs (1) and (2) (as applicable). Each updated report submitted in accordance with this subparagraph shall include information regarding—

"(i) trends relative to the analyses of access included in the baseline report submitted under paragraph (2);

"(ii) the number of grievances from beneficiaries and providers related to cost avoidance measures;

"(iii) the number and proportion of cost-avoided claims for pediatric preventive services and for services provided to child support enforcement beneficiaries paid by the State (including under managed care); and

"(iv) the overall cost-effectiveness of implementing such cost avoidance measures for each group for which such measures are employed.

"(4) REPORT TO CONGRESS.—Beginning with the date of enactment of this subsection, the Secretary shall submit a report to Congress, on not less than an annual basis, that lists any States that have implemented a cost avoidance exception under sub-

paragraph (E)(i) or (F)(i) of subsection (a)(25) (or both) and any States that have failed to submit timely reports required under paragraphs (1), (2), and (3).

''(5) FAILURE TO REPORT.—Any State that fails to submit a timely report required under this subsection shall immediately cease to have the option to employ a cost avoidance exception under subparagraph (E)(i) or (F)(i) of subsection (a)(25) (or both) until all required reports are submitted to the Secretary and meeting the requirements of this subsection, and made publicly available as required under paragraph (6).

''(6) PUBLIC AVAILABILITY OF REPORTS.—The Secretary shall make all notices and reports submitted under this subsection publicly available on the website of the Centers for Medicare & Medicaid Services on a timely basis.''.

TITLE III—HEALTH AND HUMAN SERVICES

SEC. 20301. EXTENSION OF SEXUAL RISK AVOIDANCE EDUCATION.

(a) IN GENERAL.—Section 510 of the Social Security Act (42 U.S.C. 710) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

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

(I) by striking ''for each of fiscal years 2018 and 2019 and for the period beginning October 1, 2019, and ending December 20, 2019'' and inserting ''for each of fiscal years 2020 through 2022''; and

(II) by striking ''(or, with respect to such period, for fiscal year 2020)''; and

(ii) in subparagraph (A), by striking ''or period'' after ''fiscal year'' each place it appears; and

(B) in paragraph (2)—

(i) in subparagraph (A)—

(I) by striking ''for each of fiscal years 2018 and 2019 and for the period beginning October 1, 2019, and ending December 20, 2019'' and inserting ''for each of fiscal years 2020 through 2022''; and

(II) by striking ''(or, with respect to such period, for fiscal year 2020)''; and

(ii) in subparagraph (B)(i), by striking ''(or, with respect to such period, for fiscal year 2020)''; and

(2) in subsection (f)—

(A) in paragraph (1), by striking ''$75,000,000 for each of fiscal years 2018 and 2019 and $16,643,836 for the period beginning October 1, 2019, and ending December 20, 2019'' and inserting ''$75,000,000 for each of fiscal years 2020 through 2022''; and

(B) in paragraph (2)—

(i) by striking ''The Secretary shall reserve, for each of fiscal years 2018 and 2019 and for the period described in paragraph (1),'' and inserting ''For each fiscal year for which amounts are appropriated under paragraph (1), the Secretary shall reserve''; and

(ii) by striking ''of the amount appropriated pursuant to paragraph (1)'' and inserting ''of such amounts''.

(b) PREVENTION OF DUPLICATE APPROPRIATIONS FOR FISCAL YEAR 2020.—Expenditures made under section 510 of the Social Security Act (42 U.S.C. 710) pursuant to the amendments made by the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Public Law 116–59) and the Further Continuing Appropriations Act, 2020, and Further Health Extenders Act of 2019 (Public Law 116-69) for fiscal year 2020 shall be charged to the applicable appropriation or authorization provided by the amendments made by subsection (a) to such section for such fiscal year.

SEC. 20302. EXTENSION OF PERSONAL RESPONSIBILITY EDUCATION.

(a) IN GENERAL.—Section 513 of the Social Security Act (42 U.S.C. 713) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A)—

(I) in the matter preceding clause (i), by striking ''for each of fiscal years 2010 through 2019 and for the period beginning October 1, 2019, and ending December 20, 2019'' and inserting ''for each of fiscal years 2020 through 2022''; and

(II) in clause (i), by striking ''or period'';

(ii) in subparagraph (B)(i), by striking ''The previous sentence shall not apply with respect to State allotments under this paragraph for the period beginning October 1, 2019, and ending December 20, 2019.''; and

(iii) in subparagraph (C)(i)—

(I) by striking ''or the period described in subparagraph (A)''; and

(II) by striking ''or period'';

(B) in paragraph (3)—

(i) by striking ''or the period described in paragraph (1)(A)''; and

(ii) by striking ''or period''; and

(C) in paragraph (4)—

(i) in subparagraph (A)—

(I) by striking ''2019 and for the period described in paragraph (1)(A)'' and inserting ''2022'';

(II) by striking ''2019 and for the period so described'' and inserting ''2022''; and

(III) by striking ''or the period so described'';

(ii) in subsection (B)(i), by striking ''the period described in paragraph (1)(A)'' and inserting ''fiscal year 2022'';

(2) in subsection (c)—

(A) in paragraph (1), by striking ''Subject to paragraph (3), from the amount'' and inserting ''From the amount'';

(B) in paragraph (2), by striking ''Subject to paragraph (3), from the amount'' and inserting ''From the amount''; and

(C) by striking paragraph (3); and

(3) in subsection (f), by striking ''$75,000,000 for each of fiscal years 2010 through 2019 and $16,643,836 for the period beginning October 1, 2019, and ending December 20, 2019'' and inserting ''$75,000,000 for each of fiscal years 2020 through 2022''.

(b) PREVENTION OF DUPLICATE APPROPRIATIONS FOR FISCAL YEAR 2020.—Expenditures made under section 513 of the Social Security Act (42 U.S.C. 713) pursuant to the amendments made by the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Public Law 116–59) and the Further Continuing Appro-

priations Act, 2020, and Further Health Extenders Act of 2019 (Public Law 116-69) for fiscal year 2020 shall be charged to the applicable appropriation or authorization provided by the amendments made by subsection (a) to such section for such fiscal year.

SEC. 20303. EXTENSION OF DEMONSTRATION PROJECTS TO ADDRESS HEALTH PROFESSIONS WORKFORCE NEEDS.

(a) IN GENERAL.—Section 2008(c)(1) of the Social Security Act (42 U.S.C. 1397g(c)(1)) is amended by striking ''2019'' and inserting ''2022''.

(b) PREVENTION OF DUPLICATE APPROPRIATIONS FOR FISCAL YEAR 2020.—Expenditures made under section 2008 of the Social Security Act (42 U.S.C. 1397g) pursuant to the amendments made by the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Public Law 116–59) and the Further Continuing Appropriations Act, 2020, and Further Health Extenders Act of 2019 (Public Law 116-69) for fiscal year 2020 shall be charged to the applicable appropriation or authorization provided by the amendment made by subsection (a) to such section for such fiscal year.

SEC. 20304. EXTENSION OF THE MATERNAL, INFANT, AND EARLY CHILDHOOD HOME VISITING PROGRAM.

Section 511(j)(1)(H) of the Social Security Act (42 U.S.C. 711(j)(1)(H)) is amended by striking ''2022'' and inserting ''2024''.

TITLE IV—OTHER HEALTH AND HUMAN SERVICES

SEC. 20401. EXTENSION OF APPROPRIATIONS TO THE PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND; EXTENSION OF CERTAIN HEALTH INSURANCE FEES.

(a) IN GENERAL.—Section 9511(b)(1) of the Internal Revenue Code of 1986 is amended—

(1) in subsection (b)(1)—

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

''(F) For each of fiscal years 2020 through 2029—

''(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance and self-insured plans) for such fiscal year; and

"(ii) an amount equal to the excess, if any, of—

"(I) an amount equal to—

"(aa) for fiscal year 2020, $655,500,000,

"(bb) for fiscal year 2021, $665,000,000,

"(cc) for fiscal year 2022, $693,500,000,

"(dd) for fiscal year 2023, $731,500,000,

"(ee) for fiscal year 2024, $760,000,000,

"(ff) for fiscal year 2025, $798,000,000,

"(gg) for fiscal year 2026, $845,500,000,

"(hh) for fiscal year 2027, $883,500,000,

"(ii) for fiscal year 2028, $931,000,000, and

"(jj) for fiscal year 2029, $969,000,000, over

"(II) the amount described in clause (i) for such fiscal year."; and

(B) by striking ''and (E)(ii)'' in the last sentence and inserting ''(E)(ii), and (F)(ii)'';

(2) in subsection (d)(2)(A), by striking ''2019'' and inserting ''2029''; and

(3) in subsection (f), by striking ''December 20, 2019'' and inserting ''September 30, 2029''.

(b) HEALTH INSURANCE POLICIES.—Section 4375(e) of the Internal Revenue Code of 1986 is amended by striking ''2019'' and inserting ''2029''.

(c) SELF-INSURED HEALTH PLANS.—Section 4376(e) of the Internal Revenue Code of 1986 is amended by striking ''2019'' and inserting ''2029''.

(d) IDENTIFICATION OF RESEARCH PRIORITIES.—Subsection (d)(1)(A) of section 1181 of the Social Security Act (42 U.S.C. 1320e) is amended by adding at the end the following: ''Such national priorities shall include research with respect to intellectual and developmental disabilities. Such priorities should reflect a balance between long-term priorities and short-term priorities, and be responsive to changing medical evidence and health care treatments.''.

(e) CONSIDERATION OF FULL RANGE OF OUTCOMES DATA.—Subsection (d)(2) of such section 1181 is amended by adding at the end the following subparagraph:

"(F) CONSIDERATION OF FULL RANGE OF OUTCOMES DATA.—Research shall be designed, as appropriate, to take into account and capture the full range of clinical and patient-centered outcomes relevant to, and that meet the needs of, patients, clinicians, purchasers, and policy-makers in making informed health decisions. In addition to the relative health outcomes and clinical effectiveness, clinical and patient-centered outcomes shall include the potential burdens and economic impacts of the utilization of medical treatments, items, and services on different stakeholders and decision-makers respectively. These potential burdens and economic impacts include medical out-of-pocket costs, including health plan benefit and formulary design, non-medical costs to the patient and family, including caregiving, effects on future costs of care, workplace productivity and absenteeism, and healthcare utilization.".

(f) BOARD COMPOSITION.—Subsection (f) of such section 1181 is amended—

(1) in paragraph (1)—

(A) in subparagraph (C)—

(i) in the matter preceding clause (i)—

(I) by striking ''Seventeen'' and inserting ''At least nineteen, but no more than twenty-one''; and

(II) by striking '', not later than 6 months after the date of enactment of this section,''; and

(ii) in clause (iii), by striking ''3'' and inserting ''at least 3, but no more than 5''; and

(2) in paragraph (3)—

(A) in the first sentence—

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

(ii) by inserting the following before the period at the end: ''to the extent necessary to preserve the evenly staggered terms of the Board.''; and

(B) by inserting the following after the first sentence: ''Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of that term and thereafter may be eligible for

reappointment to a full term. A member may serve after the expiration of that member's term until a successor has been appointed.''.

(g) METHODOLOGY COMMITTEE APPOINTMENTS.—Such section 1181 is amended—

(1) in subsection (d)(6)(B), by striking ''Comptroller General of the United States'' and inserting ''Board''; and

(2) in subsection (h)(4)—

(A) in subparagraph (A)(ii), by striking ''Comptroller General'' and inserting ''Board''; and

(B) in the first sentence of subparagraph (B), by striking ''and of the Government Accountability Office''.

(h) REPORTS BY THE COMPTROLLER GENERAL OF THE UNITED STATES.—Subsection (g)(2)(A) of such section 1181 is amended—

(1) by striking clause (iv) and inserting the following:

''(iv) Not less frequently than every 5 years, the overall effectiveness of activities conducted under this section and the dissemination, training, and capacity building activities conducted under section 937 of

the Public Health Service Act. Such review shall include the following:

"(I) A description of those activities and the financial commitments related to research, training, data capacity building, and dissemination and uptake of research findings.

"(II) The extent to which the Institute and the Agency for Healthcare Research and Quality have collaborated with stakeholders, including provider and payer organizations, to facilitate the dissemination and uptake of research findings.

"(III) An analysis of available data and performance metrics, such as the estimated public availability and dissemination of research findings and uptake and utilization of research findings in clinical guidelines and decision support tools, on the extent to which such research findings are used by health care decision-makers, the effect of the dissemination of such findings on changes in medical practice

and reducing practice variation and disparities in health care, and the effect of the research conducted and disseminated on innovation and the health care economy of the United States.''; and

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

''(vi) Not less frequently than every 5 years, any barriers that researchers funded by the Institute have encountered in conducting studies or clinical trials, including challenges covering the cost of any medical treatments, services, and items described in subsection (a)(2)(B) for purposes of the research study.''.

SEC. 20402. EXTENSION OF THE TEMPORARY ASSISTANCE FOR NEEDY FAMILIES PROGRAM AND RELATED PROGRAMS.

(a) TANF AND RELATED PROGRAMS.—

(1) FAMILY ASSISTANCE GRANTS.—Section 403(a)(1) of the Social Security Act (42 U.S.C. 603(a)(1)) is amended in each of subparagraphs (A) and (C) by striking ''2017 and 2018'' and inserting ''2020 through 2022''.

(2) HEALTHY MARRIAGE PROMOTION AND RESPONSIBLE FATHERHOOD GRANTS.—Section 403(a)(2)(D) of such Act (42 U.S.C. 603(a)(2)(D)) is amended—

(A) by striking ''2017 and 2018'' and inserting ''2020 through 2022''; and

(B) by striking ''for fiscal year 2017 or 2018''.

(3) CONTINGENCY FUND.—Section 403(b)(2) of such Act (42 U.S.C. 603(b)(2)) is amended by striking ''for fiscal year 2018'' and inserting ''for each of fiscal years 2020 through 2022''.

(4) TRIBAL FAMILY ASSISTANCE GRANTS.—Paragraphs (1)(A) and (2)(A) of section 412(a) of such Act (42 U.S.C. 612(a)) are each amended by striking ''2017 and 2018'' and inserting ''2020 through 2022''.

(5) CHILD CARE.—Section 418(a)(3) of such Act (42 U.S.C. 618(a)(3)) is amended by striking ''2017 and 2018'' and inserting ''2020 through 2022''.

(6) GRANTS TO THE TERRITORIES.—Section 1108(b)(2) of such Act (42 U.S.C. 1308(b)(2)) is amended by striking ''2017 and 2018'' and inserting ''2020 through 2022''.

(7) PREVENTION OF DUPLICATE APPROPRIATIONS FOR FISCAL YEAR 2020.—Expenditures made under part A of title IV of the Social Security Act(42 U.S.C. 601 et seq.) and section 1108(b) of such Act (42 U.S.C. 1308(b)) pursuant to the amendments made by the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Public Law 116–59) and the Further Continuing Appropriations Act, 2020, and Further Health Extenders Act of 2019 (Public Law 116-69) for fiscal year 2020 shall be charged to the applicable appropriation or authorization provided by the amendments made by this subsection to such part and such section 1108(b) for such fiscal year.

(b) MEASURING AND UNDERSTANDING OUTCOMES.—Section 411(a) of the Social Security Act (42 U.S.C. 611(a)) is amended by redesignating paragraph (7) as paragraph (8) and inserting after paragraph (6) the following:

''(7) REPORT ON ENGAGEMENT, EMPLOYMENT AND OUTCOMES.—

''(A) IN GENERAL.—The Secretary shall publish on the website of the Department of Health and Human Services the information described in this paragraph beginning in fiscal

year 2021, and shall enter into an agreement with each State specifying the manner by which the information and data described in this paragraph shall be collected and reported to the Secretary (if such information is not already provided to the Secretary).

''(i) OUTCOMES FOR EXITING RECIPIENTS.—Information and data regarding individuals in families who formerly received assistance (disaggregated by type of family, reason for exit, and participation in work activities during the preceding fiscal year) under the State program funded under this part or under any State program funded with qualified State expenditures (as defined in section 409(a)(7)(B)(i)), with respect to the following:

''(I) The percentage with at least 1 formerly work-eligible individual employed during the 2nd quarter after exiting from the program.

''(II) The percentage with at least 1 formerly work-eligible indi-

vidual employed during the 4th quarter after exiting from the program.

''(III) The median earnings when at least 1 formerly work-eligible individual is employed during the 2d quarter after exiting from the program.

''(IV) The percentage with at least 1 formerly work-eligible individual employed during any of the first 4 quarters after exiting from the program.

''(V) The distribution of income and earnings, including relative to poverty and deep poverty, for each of the first 4 quarters ending after the quarter of exit from assistance.

''(VI) The percentage who, at the time of exit from the program, were subject to the following:

''(aa) A penalty under section 407(e).

''(bb) A sanction or penalty described in section 404 or 408.

"(cc) A penalty or sanction not described in item (aa) or (bb).

"(ii) ENGAGEMENT AND OUTCOMES OF RECIPIENTS.—

"(I) ESTABLISHMENT OF ENTRY COHORT; REPORTS.—Each eligible State shall annually establish an entry cohort of work-eligible individuals who enter the State program funded under this part or under any State program funded with qualified State expenditures (as defined in section 409(a)(7)(B)(i)), and shall collect and report the following information relative to the current quarter being reported:

"(aa) Earnings in each of the 4 quarters immediately preceding the assignment into the entry cohort quarter.

"(bb) Standard measures of employment, earnings, receipt of assistance, and participation in work activities (as defined in sec-

tion 407(d)) in each of the first 8 quarters following the assignment into the entry cohort quarter.

''(II) ALL RECIPIENTS.—The percentage of recipients of assistance under the State program funded under this part or under any State program funded with qualified State expenditures (as defined in section 409(a)(7)(B)(i)) who have not attained 24 years of age and who obtain a high school degree or its recognized equivalent while receiving the assistance.

''(B) STATISTICAL ADJUSTMENT MODEL FOR EMPLOYMENT OUTCOMES.—The Secretary, in consultation with the Secretary of Labor and relevant experts, shall develop recommendations by October 1, 2020, on how to establish and disseminate an objective statistical model that will allow the Secretary to make adjustments to the data reported pursuant to subclauses (I) through (IV) of subparagraph (A)(i) of this paragraph, based on economic conditions and

the characteristics of participants. To the extent practicable, the recommendations shall be compatible with the statistical adjustment model developed under section 116(b)(3)(A)(viii) of the Workforce Innovation and Opportunity Act (29 U.S.C. 3141(b)(3)(A)(viii)) and, with respect to a State, the State adjusted levels of performance established for the State under that section.''.

(c) UNIFORM WORK REQUIREMENT FOR FAMILIES.—

(1) ELIMINATION OF SEPARATE PARTICIPATION RATE REQUIREMENTS FOR 2-PARENT FAMILIES.—Section 407 of the Social Security Act (42 U.S.C. 607) is amended—

(A) in subsection (a)—

(i) by striking all through ''A State'' the 1st place it appears and inserting the following:

''(a) PARTICIPATION RATE REQUIREMENTS.—A State''; and

(B) by striking paragraph (2);

(C) in subsection (b)—

(i) in the subsection heading, by striking ''RATES'' and inserting ''RATE'';

(ii) in paragraph (1)(A), by striking ''(a)(1)'' and inserting ''(a)'';

(iii) by striking paragraph (2);

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

(v) in paragraph (3) (as redesignated by subparagraph (D)), by striking ''paragraphs (1)(B) and (2)(B)'' and inserting ''paragraph (1)(B)''; and

(vi) in paragraph (4), (as so redesignated), by striking ''rates'' and inserting ''rate''; and

(D) in subsection (c)—

(i) in paragraph (1), by striking all through ''For purposes'' the 1st place it appears and inserting the following:

''(1) GENERAL RULES.—For purposes''; and

(ii) in paragraph (2)(D)—

(I) by striking ''paragraphs (1)(B)(i) and (2)(B) of subsection (b)'' and inserting ''subsection (b)(1)(B)(i)''; and

(II) by striking ''in all families and in 2-parent families, respectively,''.

(2) CONFORMING AMENDMENT.—The paragraph heading for section 409(a)(3) of such Act (42 U.S.C. 609(a)(3)) is amended by striking ''RATES'' and inserting ''RATE''.

(d) MEASURING TANF SPENDING ON LOW-INCOME FAMILIES.—Section 411 of the Social Security Act (42 U.S.C. 611) is amended by adding at the end the following:

''(e) REQUIREMENT TO REPORT SPENDING ON LOW-INCOME FAMILIES.—

''(1) STATE REPORTING.—With respect to fiscal year 2020, not later than July 1, 2021, and, with respect to each fiscal year beginning after that date, not later than such date as the Secretary shall require, each eligible State shall submit to the Secretary an estimate with respect to the fiscal year of the amount and percent of State spending of the grant made under section 403(a)(1) and any qualified State expenditures (as so defined) that consists of benefits and services—

''(A) for families in the State whose income is below the income official poverty line

(as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved; and

''(B) for families in the State whose income is below twice the income official poverty line (as so defined) applicable to a family of the size involved.

''(2) REPORT BY THE SECRETARY.—For any State that reports State spending on families with income above the level specified in paragraph (1)(B), the Secretary shall request information from the State on the types of benefits and services provided to such families and report this information on the Internet website of the Department of Health and Human Services.''.

(e) INCLUSION OF POVERTY REDUCTION AS A PROGRAM PURPOSE.—Section 401(a) of the Social Security Act (42 U.S.C. 601(a)) is amended in the matter preceding paragraph (1), by striking ''in operating'' and inserting ''to reduce child poverty by operating''.

(f) TECHNICAL CORRECTIONS.—

(1) DATA EXCHANGE STANDARDS.—Section 411(d) of the Social Security Act 42 U.S.C. 611(d)) is amended to read as follows:

''(d) DATA EXCHANGE STANDARDIZATION FOR IMPROVED INTEROPERABILITY.—The Secretary shall designate data exchange standards to govern programs funded under this part using the same process, and subject to the same requirements, to designate such standards as the process and requirements that apply to the designation of data exchange standards for parts B and E under section 440.''.

(2) APPLICATION OF CERTAIN PROVISIONS TO TRIBAL FAMILY ASSISTANCE PLANS.—Section 412(h) of such Act (42 U.S.C. 612(h)) is amended to read as follows:

''(h) APPLICATION OF OTHER PROVISIONS OF THIS PART.—The following sections of this part shall apply to an Indian tribe with an approved tribal family assistance plan:

''(1) Section 411 (relating to data collection and reporting).

''(2) Section 413 (relating to evaluations and technical assistance).''.

SEC. 20403. ADDRESSING EXPIRATION OF CHILD WELFARE DEMONSTRATION PROJECTS AND SUPPORTING FAMILY FIRST IMPLEMENTATION.

(a) SHORT TITLE.—This section may be cited as the ''Family First Transition Act''.

(b) EVIDENCE STANDARD TRANSITION.—

(1) TEMPORARY SUSPENSION OF REQUIREMENT THAT AT LEAST 50 PERCENT OF A STATE'S REIMBURSEMENT FOR PREVENTION AND FAMILY SERVICES AND PROGRAMS BE FOR PROGRAMS AND SERVICES THAT MEET THE WELL-SUPPORTED PRACTICE REQUIREMENT.—With respect to quarters in fiscal years 2020 and 2021, section 474(a)(6)(A) of the Social Security Act (42 U.S.C. 674(a)(6)(A)) shall be applied without regard to clause (ii) of such section.

(2) SUPPORTED PRACTICES TEMPORARILY TREATED AS WELL-SUPPORTED PRACTICES.—With respect to quarters in fiscal years 2022 and 2023, practices that meet the criteria specified for supported practices in section 471(e)(4)(C) of the Social Security Act (42 U.S.C. 671(e)(4)(C)) shall be considered well-supported practices for purposes of section 474(a)(6)(A)(ii) of such Act (42 U.S.C. 674(a)(6)(A)(ii)).

(c) ENHANCED FUNDING FOR TRANSITION ACTIVITIES.—

(1) TRANSITION FUNDING.—

(A) APPROPRIATION.—Out of any money in the Treasury of the United States not otherwise appropriated, there are appropriated to the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') to carry out this subsection $500,000,000 for fiscal year 2020, which shall remain available through fiscal year 2021.

(B) DISTRIBUTION OF FUNDS.—

(i) IN GENERAL.—The Secretary shall allot the amount appropriated by subparagraph (A) of this paragraph in accordance with section 423 of the Social Security Act (42 U.S.C. 623), and shall pay each State to which an allotment is so made, the total amount so allotted, subject to clause (ii) of this subparagraph.

(ii) RESERVATION OF FUNDS FOR INDIAN TRIBES AND TRIBAL ORGANIZATIONS.—Before applying clause (i) of this subparagraph, the Secretary shall reserve 3 percent of the amount appropriated by

subparagraph (A) of this paragraph for allotment to the Indian tribes and tribal organizations with a plan approved under subpart 1 of part B of title IV of the Social Security Act, based on each tribe or tribal organization's share of the total tribal child population among all such tribes and tribal organizations.

(2) FUNDING CERTAINTY FOR STATES WITH EXPIRING DEMONSTRATION PROJECTS.—

(A) IN GENERAL.—Out of any money in the Treasury of the United States not otherwise appropriated, there are appropriated to the Secretary, for payment to each State that was operating a demonstration project approved under section 1130 of the Social Security Act on September 30, 2019, for each fiscal year specified in subparagraph (B) of this paragraph, an amount equal to the amount (if any) by which—

(i)(I) the applicable percentage for the fiscal year so specified of the maximum capped allocation due to the State or sub-State jurisdiction for fiscal year 2019 for foster care maintenance, administration, or

training costs, under the demonstration project, as specified in section 4.3 of the State waiver terms and conditions document capped allocation payment table in effect on August 31, 2019; or

(II) if the terms and conditions do not specify a maximum amount payable for fiscal year 2019 for the State or sub-State jurisdiction (due to the use of a comparison jurisdiction to ensure cost neutrality), the final cost neutrality limit for the State or sub-State jurisdiction for fiscal year 2018, as most recently reported by the State or sub-State jurisdiction as of September 30, 2019, for foster care maintenance, administration, or training costs under the demonstration project that were included in the waiver; exceeds

(ii) the total amount payable to the State or sub-State jurisdiction under part E of title IV of such Act for the fiscal year so specified for foster care expenditures (whether payable under paragraph (1) or (3) of section 474(a) of such Act) that were maintenance, administration, or

training costs of the demonstration project taken into account by the Secretary in determining the total amount referred to in clause (i) of this subparagraph.

(B) APPLICABLE PERCENTAGE DEFINED.—In this subparagraph, the term ''applicable percentage'' means—

(i) 90 percent, in the case of fiscal year 2020; or

(ii) 75 percent, in the case of fiscal year 2021.

(C) SPECIAL RULE.—The calculation under subparagraph (A) with respect to a State shall be made without regard to—

(i) any change approved after August 31, 2019, in the capped allocation or the terms and conditions referred to in clause (i) of subparagraph (A) with respect to the State; or

(ii) any change made after such date to the financial form submitted by the State that is used in determining the capped allocation.

(D) DISTRIBUTION OF FUNDS.—Each State that receives funds under this paragraph

shall distribute the funds to jurisdictions in the State that were operating demonstration projects under section 1130 of the Social Security Act in a manner consistent with each sub-State jurisdiction's proportionate loss as compared with fiscal year 2019.

(E) RECONCILIATION PROCESS.—Each State seeking a payment under this paragraph shall report expenditures pursuant to part E of title IV of the Social Security Act (42 U.S.C. 670 et seq.) in a manner determined by the Secretary and the Secretary shall account for any revisions to spending for fiscal years 2020 and 2021 after the end of the respective fiscal year that are reported by the State agency administering the State plan approved under such part, and received by the Department of Health and Human Services, within 2 years after the last day of the fiscal quarter in which the expenditure was made.

(F) AVAILABILITY OF FUNDS.—The amounts made available for payments to States under this paragraph for a fiscal year shall remain available through the end of the third succeeding fiscal year.

(3) USE OF FUNDS.—

(A) IN GENERAL.—In addition to the purposes specified in part B of title IV of the Social Security Act (42 U.S.C. 671 et seq.), a State may use funds provided under this subsection for activities previously funded under a demonstration project under section 1130 of such Act (42 U.S.C. 1320a–9) to reduce any adverse fiscal impacts as jurisdictions transition funding sources for the projects, and for activities directly associated with the implementation of title VII of division E of Public Law 115–123 (also known as the Family First Prevention Services Act).

(B) LIMITATION.—None of the funds provided under this subsection may be used to match Federal funds under any program.

(d) REPORTING ON ENHANCED FUNDING FOR TRANSITION ACTIVITIES.—

(1) IN GENERAL.—Each State to which funds are paid under subsection (c) of this section shall submit to the Secretary, in a manner specified by the Secretary, a written report on—

(A) how the grant is used to implement each part of title VII of division E of Public

Law 115–123 (also known as the Family First Prevention Services Act), with a separate statement with respect to each such part;

(B) all programs, services, and operational costs to which the grant is put;

(C) the characteristics of the families and children served by use of the grant; and

(D)(i) the use by the State of amounts provided for each fiscal year to continue activities previously funded under a waiver provided under section 1130 of the Social Security Act (42 U.S.C. 1320a–9); and

(ii)(I) the plan of the State to transition the activities so that needed activities can be provided under the State plan approved under part E of title IV of the Social Security Act (42 U.S.C. 670 et seq.); or

(II) if expenditures for the activities would not be eligible for payment under the State plan approved under such part E—

(aa) the reason therefor; and

(bb) the funding sources the State plans to use to cover the costs of needed activities.

(2) APPLICABILITY OF OTHER LAWS.—For purposes of subpart 2 of part B of title IV of the Social Security Act (42 U.S.C. 629 et seq.), each report required by paragraph (1) of this subsection shall be considered to be required by section 432(a)(8) of such Act (42 U.S.C. 629b(a)(8)), and shall contain such additional information as the Secretary may require.

(e) DEFINITION OF STATE.—In this section, the term ''State'' has the meaning given the term in section 431(a)(4) of the Social Security Act (42 U.S.C. 629a(a)(4)).

(f) RENAMING OF TITLE IV–B–2 OF THE SOCIAL SECURITY ACT.—The subpart heading for subpart 2 of part B of title IV of the Social Security Act is amended by striking ''**Promoting Safe and Stable Families**'' and inserting ''**MaryLee Allen Promoting Safe and Stable Families Program**''.

(g) EFFECTIVE DATE.—This section and the amendments made by this section shall take effect as if included in the Bipartisan Budget Act of 2018 on the date of the enactment of such Act.

(h) TECHNICAL CORRECTION.—Section 50701 of the Bipartisan Budget Act of 2018 (42 U.S.C. 1305 note; Public Law 115–123) is amended by striking ''Bipartisan

Budget Act of 2018'' and inserting ''Family First Prevention Services Act''.