117TH CONGRESS
1ST SESSION

S. _____

To provide for certain reforms with respect to the Medicare program under title XVIII of the Social Security Act, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. CRAPO (for himself, Mr. BURR, Mr. SCOTT of South Carolina, Mr. DAINES, Mr. RISCH, Ms. ERNST, Mr. MARSHALL, and Mr. TILLIS) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To provide for certain reforms with respect to the Medicare program under title XVIII of the Social Security Act, 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 ''Lower Costs, More Cures Act of 2021''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—MEDICARE AND MEDICAID PROVISIONS

Subtitle A—Medicare Part B Provisions

SEC. 101. 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 under this title''; and

(iii) by inserting ''(or 2022 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) as paragraphs (3) through (5), respectively; and

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

''(2) PHYSICIAN PAYMENT.—Beginning in 2022, the Secretary shall 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. 102. 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) is amended—

(1) by redesignating subsection (h) as subsection (i); and

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

''(h) 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, 2022, 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, 2022, the manufacturer of a refundable single-dose container or single-use package drug shall, for such drug, provide to the Secretary a refund that is equal to the amount specified in paragraph (3) for such drug for such quarter.

''(3) REFUND AMOUNT.—

''(A) IN GENERAL.—The amount of the refund specified in this paragraph is, with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after July 1, 2022, 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) if applicable, in the case of a refundable single-dose container or single-use package drug described in clause (ii), a percentage specified by the Secretary pursuant to such clause.

''(ii) TREATMENT OF DRUGS THAT HAVE UNIQUE CIRCUMSTANCES.—In the case of a refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product as that described in paragraph (8)(B), the Secretary, through notice and comment rulemaking, may increase the applicable percentage otherwise applicable under clause (i)(I) as determined appropriate by the Secretary.

''(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—

''(i) a drug or biological that is either a radiopharmaceutical or an imaging agent;

''(ii) a drug or biological for which dosage and administration instructions approved by the Commissioner of Food and Drugs require filtration during the drug preparation process, prior to dilution and administration, and require that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process; or

''(iii) a drug or biological approved by the Food and Drug Administration on or after the date of enactment of this sub-

section and with respect to which payment has been made under this part for less than 18 months.''.

SEC. 103. PROVIDING FOR VARIATION IN PAYMENT FOR CERTAIN DRUGS COVERED UNDER PART B OF THE MEDICARE PROGRAM.

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

(1) in paragraph (1)—

(A) in subparagraph (A), by inserting after ''or 106 percent'' the following: ''(or, for a multiple source drug (other than autologous cellular immunotherapy) furnished on or after January 1, 2022, the applicable percent specified in paragraph (9)(A) for the drug and quarter involved)''; and

(B) in subparagraph (B) of paragraph (1), by inserting after ''106 percent'' the following: ''(or, for a single source drug or biological (other than autologous cellular immunotherapy) furnished on or after January 1, 2022, the applicable percent specified in paragraph (9)(A) for the drug or biological and quarter involved)''; and

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

''(9) APPLICATION OF VARIABLE PERCENTAGES BASED ON PERCENTILE RANKING OF PER BENEFICIARY ALLOWED CHARGES.—

''(A) APPLICABLE PERCENT TO BE APPLIED.—

''(i) IN GENERAL.—Subject to clause (ii), with respect to a drug or biological furnished in a calendar quarter beginning on or after January 1, 2022, if the Secretary determines that the percentile rank of a drug or biological under subparagraph (B)(i)(III), with respect to per beneficiary allowed charges for all such drugs or biologicals, is—

''(I) at least equal to the 85th percentile, the applicable percent for the drug for such quarter under this subparagraph is 104 percent;

''(II) at least equal to the 70th percentile, but less than the 85th percentile, such applicable percent is 106 percent;

"(III) at least equal to the 50th percentile, but less than the 70th percentile, such applicable percent is 108 percent; or

"(IV) less than the 50th percentile, such applicable percent is 110 percent.

"(ii) CASES WHERE DATA NOT SUFFICIENTLY AVAILABLE TO COMPUTE PER BENEFICIARY ALLOWED CHARGES.—Subject to clause (iii), in the case of a drug or biological furnished for which the amount of payment is determined under subparagraph (A) or (B) of paragraph (1) and not under subsection (c)(4), for calendar quarters during a period in which data are not sufficiently available to compute a per beneficiary allowed charges for the drug or biological, the applicable percent is 106 percent.

"(B) DETERMINATION OF PERCENTILE RANK OF PER BENEFICIARY ALLOWED CHARGES OF DRUGS.—

"(i) IN GENERAL.—With respect to a calendar quarter beginning on or after

January 1, 2022, for drugs and biologicals for which the amount of payment is determined under subparagraph (A) or (B) of paragraph (1), except for drugs or biologicals for which data are not sufficiently available, the Secretary shall—

''(I) compute the per beneficiary allowed charges (as defined in subparagraph (C)) for each such drug or biological;

''(II) adjust such per beneficiary allowed charges for the quarter, to the extent provided under subparagraph (D); and

''(III) arrange such adjusted per beneficiary allowed charges for all such drugs or biologicals from high to low and rank such drugs or biologicals by percentile of such per beneficiary allowed charges.

''(ii) FREQUENCY.—The Secretary shall make the computations under clause (i)(I) every 6 months (or, if necessary, as determined by the Secretary, every 9 or 12 months) and such computations shall apply

to succeeding calendar quarters until a new computation has been made.

''(iii) APPLICABLE DATA PERIOD.—For purposes of this paragraph, the term 'applicable data period' means the most recent period for which the data necessary for making the computations under clause (i) are available, as determined by the Secretary.

''(C) PER BENEFICIARY ALLOWED CHARGES DEFINED.—In this paragraph, the term 'per beneficiary allowed charges' means, with respect to a drug or biological for which the amount of payment is determined under subparagraph (A) or (B) of paragraph (1)—

''(i) the allowed charges for the drug or biological for which payment is so made for the applicable data period, as estimated by the Secretary; divided by

''(ii) the number of individuals for whom any payment for the drug or biological was made under paragraph (1) for the applicable data period, as estimated by the Secretary.

''(D) ADJUSTMENT TO REFLECT CHANGES IN AVERAGE SALES PRICE.—In applying this paragraph for a particular calendar quarter, the Secretary shall adjust the per beneficiary allowed charges for a drug or biological by multiplying such per beneficiary allowed charges under subparagraph (C) for the applicable data period by the ratio of—

''(i) the average sales price for the drug or biological for the most recent calendar quarter used under subsection (c)(5)(B); to

''(ii) the average sales price for the drug or biological for the calendar quarter (or the weighted average for the quarters involved) included in the applicable data period.''.

(b) APPLICATION OF JUDICIAL REVIEW PROVISIONS.—Section 1847A(i) of the Social Security Act (42 U.S.C. 1395w–3a(i)), as redesignated by section 102, is amended—

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

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

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

''(6) the determination of per beneficiary allowed charges of drugs or biologicals and ranking of such charges under subsection (b)(9).''.

SEC. 104. 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), as amended by section 103, 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 (10)''; and

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

''(10) 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, 2022, if the applicable add-on payment (as defined in subpara-

graph (B)) for each drug or biological on a claim for a date of service exceeds the maximum add-on payment amount specified under subparagraph (C) for the drug or biological, then the payment amount otherwise determined for the drug or biological under those provisions, as applicable, shall be reduced by the amount of such excess.

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

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

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

''(II) the amount that would be applied under such paragraph if '100 percent' were substituted for the applicable percent (as defined in paragraph (9)) for such drug.

"(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 the applicable percent (as defined in paragraph (9)) for such drug or biological.

"(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) with respect to a drug or biological (other than autologous or allogeneric cellular immunotherapy)—

"(I) for each of 2022 through 2029, $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; or

"(ii) with respect to a drug or biological consisting of autologous or allogeneric cellular immunotherapy—

"(I) for each of 2022 through 2029, $2,000; 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)(10), 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, 2022, 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)(10) 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, 2022, 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. 105. 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, 2022, 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. 106. 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 bio-

similar biological product furnished on or after January 1, 2022, 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. 107. CREDIT UNDER THE MEDICARE MERIT-BASED INCENTIVE PAYMENT SYSTEM FOR COMPLETION OF A CLINICAL MEDICAL EDUCATION PROGRAM ON BIOSIMILAR BIOLOGICAL PRODUCTS.

Section 1848(q)(5)(C) of the Social Security Act (42 U.S.C. 1395w–4(q)(5)(C)) is amended by adding at the end the following new clause:

''(iv) CLINICAL MEDICAL EDUCATION PROGRAM ON BIOSIMILAR BIOLOGICAL PRODUCTS.—Completion of a clinical medical education program developed or im-

proved under section 352A(b) of the Public Health Service Act by a MIPS eligible professional during a performance period shall earn such eligible professional one-half of the highest potential score for the performance category described in paragraph (2)(A)(iii) for such performance period. A MIPS eligible professional may only count the completion of such a program for purposes of such category one time during the eligible professional's lifetime.''.

SEC. 108. 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 than 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.

Subtitle B—Medicare Part D Provisions

SEC. 111. MEDICARE PART D BENEFIT REDESIGN.

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

(1) in paragraph (2)—

(A) in subparagraph (A)—

(i) 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)'';

(ii) in clause (i), by inserting after ''25 percent'' the following: ''(or, for 2022 and each subsequent year, 15 percent)''; and

(iii) in clause (ii), by inserting ''(or, for 2022 and each subsequent year, 15 percent)'' after ''25 percent'';

(B) in subparagraph (C)—

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

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

(C) in subparagraph (D)—

(i) in clause (i)—

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

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

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

(2) in paragraph (3)(A)—

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

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

(3) in paragraph (4)—

(A) in subparagraph (A)—

(i) in clause (i)—

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

(II) in the matter preceding item (aa), as redesignated by subclause (I),

by striking ''is equal to the greater of—'' and inserting ''is equal to—

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

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

(IV) by adding at the end the following:

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

(ii) in clause (ii)—

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

(II) by adding at the end the following new sentence: ''The Secretary shall continue to calculate the dollar amounts specified in clause (i)(I)(aa), including with the adjustment under this clause, after 2021 for purposes of section 1860D–14(a)(1)(D)(iii).'';

(B) in subparagraph (B)—

(i) in clause (i)—

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

(II) in subclause (VI)—

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

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

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

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

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

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

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

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

(b) DECREASING REINSURANCE PAYMENT AMOUNT.—Section 1860D–15(b)(1) of the Social Security Act (42 U.S.C. 1395w–115(b)(1)) is amended—

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

''(A) for a year preceding 2022, 80 percent'';

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

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

''(B) for 2022 and each subsequent year, the sum of—

''(i) an amount equal to 20 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in

section 1860D–2(b)(4)(B) with respect to applicable drugs (as defined in section 1860D–14B(g)(2)); and

''(ii) an amount equal to 30 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) with respect to covered part D drugs that are not applicable drugs (as so defined).''.

(c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

''(a) ESTABLISHMENT.—The Secretary shall establish a manufacturer discount program (in this section referred to as the 'program'). Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance

of the duties described in subsection (c). The Secretary shall establish a model agreement for use under the program by not later than January 1, 2023, in consultation with manufacturers, and allow for comment on such model agreement.

''(b) TERMS OF AGREEMENT.—

''(1) IN GENERAL.—

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

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

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

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

"(4) LENGTH OF AGREEMENT.—

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

"(B) TERMINATION.—

"(i) BY THE SECRETARY.—The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination.

The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

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

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

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

''(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect discounts for applicable drugs of the manufacturer that

are due under the agreement before the effective date of its termination.

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

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

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

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

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

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

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

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

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

''(D) the establishment of procedures to ensure that the discounted price for an applicable drug under this section is applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries as the Secretary may specify; and

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

''(2) MONITORING COMPLIANCE.—

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

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

''(3) COLLECTION OF DATA FROM PRESCRIPTION DRUG PLANS AND MA–PD PLANS.—The Secretary may collect appropriate data from prescription drug plans and MA–PD plans in a timeframe that allows for discounted prices to be provided for applicable drugs under this section.

''(d) ADMINISTRATION.—

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

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

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

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

''(B) receive, distribute, or facilitate the distribution of funds of manufacturers to appropriate individuals or entities in order to meet the obligations of manufacturers under agreements under this section;

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

''(D) permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the third

party to determine discounts for applicable drugs of the manufacturer under the program.

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

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

''(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 on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in.

''(g) DEFINITIONS.—In this section:

''(1) APPLICABLE BENEFICIARY.—The term 'applicable beneficiary' means an individual who, on the date of dispensing a covered part D drug—

''(A) is enrolled in a prescription drug plan or an MA–PD plan;

''(B) is not enrolled in a qualified retiree prescription drug plan; and

"(C) has incurred costs for covered part D drugs in the year that are equal to or exceed the annual deductible specified in section 1860D–2(b)(1) for such year.

"(2) APPLICABLE DRUG.—The term 'applicable drug' 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); 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 prescrip-

tion 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, with respect to an applicable drug of a manufacturer furnished during a year to an applicable beneficiary, 90 percent of the negotiated price of such drug.

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

"(C) SPECIAL CASE FOR CLAIMS SPANNING DEDUCTIBLE.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an

applicable beneficiary does not fall at or above the annual deductible specified in section 1860D–2(b)(1) for the year, the manufacturer of the applicable drug shall provide the discounted price under this section on only the portion of the negotiated price of the applicable drug that falls at or above such annual deductible.

''(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 an applicable drug.

''(7) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—The term 'qualified retiree prescription drug

plan' has the meaning given such term in section 11860D–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'' and inserting ''assumptions regarding—

''(I) the reinsurance''; and

(ii) by adding at the end the following:

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

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

(1) in paragraph (2)—

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

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

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

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

(2) in paragraph (3)—

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

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

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

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

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

(1) in subsection (a)—

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

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

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

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

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

''(6) have entered into and have in effect, under terms and conditions specified by the Secretary, a

contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of such section 1860D–14B.'';

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

''(b) EFFECTIVE DATE.—Paragraphs (1) through (3) of subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011, and before January 1, 2022, and paragraphs (4) through (6) of such subsection shall apply to covered part D drugs dispensed on or after January 1, 2022.''; and

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

''(2) the Secretary determines that in the period beginning on January 1, 2011, and ending on December 31, 2011 (with respect to paragraphs (1) through (3) of subsection (a)), or the period beginning on January 1, 2022, and ending December 31, 2022 (with respect to paragraphs (4) through (6) of such subsection), there were extenuating circumstances.''.

(g) CONFORMING AMENDMENTS.—

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

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

(B) in subsection (c)(1)(C)—

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

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

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

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

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

(A) in paragraph (1)—

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

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

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

(B) in paragraph (2)—

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

(ii) in subparagraph (E)—

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

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

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

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

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

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

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

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

SEC. 112. ALLOWING THE OFFERING OF ADDITIONAL PRESCRIPTION DRUG PLANS UNDER MEDICARE PART D.

(a) RESCINDING AND ISSUANCE OF NEW GUIDANCE.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall—

(1) rescind sections of any sub-regulatory guidance that limit the number of prescription drug plans in each PDP region that may be offered by a PDP sponsor under part D of title XVIII of the Social Security Act (42 U.S.C. 1395w–101 et seq.); and

(2) issue new guidance specifying that a PDP sponsor may offer up to 4 (or a greater number if determined appropriate by the Secretary) prescription drug plans in each PDP region, except in cases where the PDP sponsor may offer up to 2 additional plans in a PDP region pursuant to section 1860D–11(d)(4) of the Social Security Act (42 U.S.C. 1395w–111(d)(4)), as added by subsection (b).

(b) OFFERING OF ADDITIONAL PLANS.—Section 1860D–11(d) of the Social Security Act (42 U.S.C. 1395w–111(d)) is amended by adding at the end the following new paragraph:

"(4) OFFERING OF ADDITIONAL PLANS.—

"(A) IN GENERAL.—For plan year 2022 and each subsequent plan year, a PDP sponsor may offer up to 2 additional prescription drug plans in a PDP region (in addition to any limit established by the Secretary under this part) provided that the PDP sponsor complies with subparagraph (B) with respect to at least one such prescription drug plan.

"(B) REQUIREMENTS.—In order to be eligible to offer up to 2 additional plans in a PDP region pursuant to subparagraph (A), a PDP sponsor must ensure that, with respect to at least one such prescription drug plan, the sponsor or any entity that provides pharmacy benefits management services under a contract with any such sponsor or plan does not receive direct or indirect remuneration, as defined in section 423.308 of title 42, Code of Federal Regulations (or any successor regulation), unless at least 25 percent of the aggregate reductions in price or other remuneration received by the PDP sponsor or entity from drug manufacturers with respect to the plan and plan year—

"(i) are reflected at the point-of-sale to the enrollee; or

"(ii) are used to reduce total beneficiary cost-sharing estimated by the PDP sponsor for prescription drug coverage under the plan in the annual bid submitted by the PDP sponsor under section 1860D–11(b).

"(C) DEFINITION OF REDUCTIONS IN PRICE.—For purposes of subparagraph (B), the term 'reductions in price' refers only to collectible amounts, as determined by the Secretary, which excludes amounts which after adjudication and reconciliation with pharmacies and manufacturers are duplicate in nature, contrary to other contractual clauses, or otherwise ineligible (such as due to beneficiary disenrollment or coordination of benefits).".

(c) RULE OF CONSTRUCTION.—Nothing in the provisions of, or amendments made by, this section shall be construed as limiting the ability of the Secretary to increase any limit otherwise applicable on the number of prescription drug plans that a PDP sponsor may offer, at the discretion of the PDP sponsor, in a PDP region

under part D of title XVIII of the Social Security Act (42 U.S.C. 1395w–101 et seq.).

SEC. 113. ALLOWING CERTAIN ENROLLEES OF PRESCRIPTION DRUG PLANS AND MA–PD PLANS UNDER THE MEDICARE PROGRAM TO SPREAD OUT COST-SHARING UNDER CERTAIN CIRCUMSTANCES.

(a) STANDARD PRESCRIPTION DRUG COVERAGE.—Section 1860D–2(b)(2) of the Social Security Act (42 U.S.C. 1395w–102(b)(2)), as amended by section 111, is amended—

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

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

''(E) ENROLLEE OPTION REGARDING SPREADING COST-SHARING.—

''(i) IN GENERAL.—The Secretary shall establish by regulation a process under which, with respect to plan year 2022 and subsequent plan years, a prescription drug plan or an MA–PD plan shall, in the case of a part D eligible individual enrolled with such plan for such

plan year with respect to whom the plan projects that the dispensing of a covered part D drug to such individual will result in the individual incurring costs within a 30-day period that are equal to a significant percentage (as specified by the Secretary pursuant to such regulation) of the annual out-of-pocket threshold specified in paragraph (4)(B) for such plan year, provide such individual with the option to make the coinsurance payment required under subparagraph (A) for such costs in the form of equal monthly installments over the remainder of such plan year.

''(ii) SIGNIFICANT PERCENTAGE LIMITATIONS.—In specifying a significant percentage pursuant to the regulation established by the Secretary under clause (i), the Secretary shall not specify a percentage that is less than 30 percent or greater than 100 percent.''.

(b) 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 ENROLLEE OPTION REGARDING SPREADING COST-SHARING.—For plan year 2022 and subsequent plan years, the coverage provides the enrollee option regarding spreading cost-sharing described in and required under subsection (b)(2)(E).''.

SEC. 114. CONTINUATION OF PART D SENIOR SAVINGS MODEL.

Section 1115A of the Social Security Act (42 U.S.C. 1315a) is amended by adding at the end the following new subsection:

''(h) PART D SENIOR SAVINGS MODEL.—Notwithstanding any other provision of law, the Secretary shall provide for the continued implementation on a permanent basis of the Part D Senior Savings Model under this section, under the same parameters under which such model was implemented for plan year 2021.''.

SEC. 115. 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) is amended by adding at the end the following new subsection:

''(p) REPORTING POTENTIAL FRAUD, WASTE, AND ABUSE.—Beginning January 1, 2022, 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. 116. ESTABLISHMENT OF PHARMACY QUALITY MEASURES UNDER MEDICARE PART D.

Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) is amended by adding at the end the following new paragraph:

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

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

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

"(C) EFFECTIVE DATE.—The requirement under subparagraph (A) shall take effect for plan years beginning on or after January 1, 2023, or such earlier date specified by the Secretary if the Secretary determines there are sufficient measures established or approved under subparagraph (B) to meet the requirement under subparagraph (A).".

Subtitle C—Medicaid Provisions

SEC. 121. PRICE REPORTING CLARIFICATIONS FOR GENE THERAPY OUTCOMES-BASED AGREEMENTS.

(a) QUARTERLY PRICE REPORTING OBLIGATION.—Section 1927(b)(3) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)) is amended by adding at the end the following new subparagraph:

"(E) OUTCOMES-BASED AGREEMENTS.—

"(i) IN GENERAL.—Beginning January 1, 2022, in the case of a covered outpatient drug that is a single course transformative therapy (as defined in subsection (k)(12)) and is sold under an outcomes-based agreement (as defined in subsection (k)(13)) during a rebate period, the manufacturer of such drug shall report (in addition to any other information required under this paragraph) the pricing structure for such drug based on pre-defined outcomes or measures specified in such outcomes-based agreement.

"(ii) ACCESS TO OUTCOMES-BASED AGREEMENTS FOR STATE PLANS.—As a condition of excluding a refund, rebate, reimbursement, free item, withholding, or repayment made under an outcomes-based agreement with respect to a covered outpatient drug from the best price or average manufacturer price of the drug for a rebate period (as described in subsection (c)(1)(C)(i)(VII) or (k)(1)(B)(i)(VI), as applicable), the manufacturer shall—

''(I) make available to each State plan the opportunity to enter into an outcomes-based agreement for such drug and rebate period; and

''(II) certify to the Secretary that the manufacturer has made such opportunity so available to each State plan.

''(iii) RULES OF CONSTRUCTION.—Nothing in this subparagraph shall be construed as—

''(I) requiring a manufacturer to execute an outcomes-based agreement with a State for a covered outpatient drug that is a single course transformative therapy (as defined in subsection (k)(12)); ;

''(II) precluding the execution of a rebate agreement under this section for such a drug; or

''(III) limiting States' ability to join together for a multi-State contract with a single manufacturer to establish an outcomes-based agreement for such a drug.''.

(b) DEFINITION OF BEST PRICE.—Section 1927(c)(1)(C) of the Social Security Act (42 U.S.C. 1396–8(c)(1)(C)) is amended—

(1) in clause (i)—

(A) in subclause (V), by striking ''and'';

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

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

''(VII) subject to subsection (b)(3)(E)(ii), with respect to a covered outpatient drug that is a single course transformative therapy (as defined in subsection (k)(12)) and is sold under an outcomes-based agreement (as defined in subsection (k)(13)) during the rebate period, any prices resulting from—

''(aa) a refund, rebate, reimbursement, or free goods from the manufacturer or third party on behalf of the manufacturer; or

''(bb) the withholding or reduction of a payment to the man-

ufacturer or third party on behalf of the manufacturer;

that is triggered by a patient who fails to achieve outcomes or measures defined under the terms of such outcomes-based agreement during the period for which such agreement is effective.''; and

(2) in clause (ii)—

(A) in subclause (I), by striking the semicolon at the end and inserting '', except any price adjustment described in clause (i)(VII);'';

(B) in subclause (III), by striking ''and'';

(C) in subclause (IV)—

(i) by moving the left margin of such subclause 2 ems to the right; and

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

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

''(V) in the case of a covered outpatient drug that is a single course transformative therapy (as defined in subsection (k)(12)) and is sold under an outcomes-based agreement (as de-

fined in subsection (k)(13)) that provides that payment for such drug is made in installments over the course of such agreement, shall be determined as if the aggregate price per the terms of the agreement was paid in full in the first installment during the rebate period.''.

(c) DEFINITION OF AVERAGE MANUFACTURER PRICE.—Section 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r–8(k)(1)) is amended—

(1) in subparagraph (B)(i)—

(A) in subclause (IV), by striking at the end ''and'';

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

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

''(VI) subject to subsection (b)(3)(E)(ii), with respect to a covered outpatient drug that is a single course transformative therapy (as defined in paragraph (12)) and is sold under an outcomes-based agreement (as defined

in paragraph (13)) during the rebate period—

''(aa) a refund, rebate, reimbursement, or free goods from the manufacturer or third party on behalf of the manufacturer; or

''(bb) the withholding or reduction of a payment to the manufacturer or third party on behalf of the manufacturer;

that is triggered by a patient who fails to achieve outcomes or measures defined under the terms of such outcomes-based agreement during the period for which such agreement is effective.''; and

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

''(D) SPECIAL RULE FOR CERTAIN OUTCOMES-BASED AGREEMENTS.—For the purpose of subparagraph (A), in determining the average price paid to the manufacturer for a covered outpatient drug that is a single course transformative therapy (as defined in paragraph (12)) and is sold under an outcomes-

based agreement (as defined in paragraph (13)) that provides that payment for such drug is made in installments over the course of such agreement, such price shall be determined as if the aggregate price per the terms of the agreement was paid in full in the first installment during the rebate period.''.

(d) OTHER DEFINITIONS.—Section 1927(k) of the Social Security Act (42 U.S.C. 1396r–8(k)) is amended by adding at the end the following paragraphs:

''(12) SINGLE COURSE TRANSFORMATIVE THERAPY.—The term 'single course transformative therapy' means a treatment that consists of the administration of a covered outpatient drug that—

''(A) is a form of gene therapy, as defined by the Commissioner of Food and Drugs, that is—

''(i) designated under section 526 of the Federal Food, Drug, and Cosmetics Act; and

''(ii) licensed under subsection (a) or (k) of section 351 of the Public Health Service Act for a serious or life-threatening rare disease or condition;

"(B) if administered in accordance with the 'Indications and Usage' section of its label, is expected to result in—

"(i) the cure of such disease or condition;

"(ii) a reduction in the symptoms of such disease or condition to the extent that it is expected to—

"(I) extend life expectancy for those individuals with such disease or condition;

"(II) prevent, eliminate, or halt progression of comorbidities related to such disease or condition in such individuals; or

"(III) allow such individuals to achieve or maintain maximum functional capacity in performing daily activities; or

"(iii) prevention or elimination of episodes, illnesses, injuries, or disabilities related to such disease or condition; and

"(C) is expected to achieve a result described in subparagraph (B), which may be

achieved over an extended period of time, following a single prescribed course of treatment.

''(13) OUTCOMES-BASED AGREEMENT.—The term 'outcomes-based agreement' means a written contract between a manufacturer and purchaser in which the aggregate price over the course of the contract of the covered outpatient drug is based on the achievement of pre-defined outcomes or measures and adjusted accordingly.''.

(e) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 2022.

SEC. 122. ANTI-KICKBACK STATUTE AND PHYSICIAN SELF-REFERRAL SAFE HARBORS.

(a) EXCLUSION FROM ANTIKICKBACK PROHIBITION.—Section 1128B(b)(3) of the Social Security Act (42 U.S.C. 1320a–7b(b)(3)) is amended—

(1) in subclause (J)—

(A) by moving the left margin of such subparagraph 2 ems to the left; and

(B) by striking ''and'' after the semicolon at the end;

(2) in subclause (K)—

(A) by moving the left margin of such subparagraph 2 ems to the left; and

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

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

''(L) any remuneration provided by a manufacturer or third party on behalf of a manufacturer to a plan under an outcomes-based agreement (as defined in section 1927(k)(13)) in the event a patient fails to achieve outcomes or measures defined in such agreement following the administration of a covered outpatient drug that is a single course transformative therapy (as defined in section 1927(k)(12).''.

(b) EXCLUSION FROM PHYSICIAN SELF-REFERRAL PROHIBITION.—Section 1877(h)(1)(C) of the Social Security Act (42 U.S.C. 1395nn(h)(1)(C)) is amended by adding at the end the following new clause:

''(iv) Any amounts paid under an outcomes-based agreement (as defined in section 1927(k)(13)).''.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 2022.

SEC. 123. GAO STUDY AND REPORT ON USE OF OUTCOMES-BASED AGREEMENTS.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on the extent to which outcomes-based agreements (as defined in section 1927(k)(13) of the Social Security Act (42 U.S.C. 1396r–8(k)(13)) for rare disease gene therapies facilitate patient access to such therapies, improve patient outcomes, lower overall health system costs, and lower costs for patients in Federal health care programs. In conducting such study, the Comptroller General shall—

(1) study the impact of this subtitle on–

(A) mitigating socioeconomic disparities in accessing rare disease gene therapies through its requirement that State Medicaid programs have access to the same outcomes-based agreement remedy terms that are available in the commercial market for the gene therapy; and

(B) the Medicaid Drug Rebate Program, the 340B Drug Pricing Program, and the Medicare Part B program, including compliance with such programs; and

(2) with respect to rare disease gene therapies sold under an outcomes-based agreement (as so defined), conduct an audit of manufacturers offering State Medicaid programs the same remedy terms for

non-responding patients as offered to commercial insurance plans during a particular rebate period, as described in subsections (c)(1)(C)(i)(VII) and (k)(1)(B)(i)(VI) of section 1927 of the Social Security Act (42 U.S.C. 1396r–8), as added by this subtitle.

(b) REPORT.—Not later than June 30, 2027, the Comptroller General of the United States shall submit to Congress a report containing the results of the study conducted under subsection (a).

TITLE II—DRUG PRICE TRANSPARENCY PROVISIONS

SEC. 201. REPORTING ON EXPLANATION FOR DRUG PRICE INCREASES.

(a) IN GENERAL.—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 PRICE REPORTING.

"(a) DEFINITIONS.—In this section:

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

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

under section 351 of the Public Health Service Act; or

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

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

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

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

''(ii) administered or otherwise dispensed to treat a disease or condition affecting more than 200,000 persons in the United States; and

''(iii) not a vaccine; and

''(B) for which, during the previous calendar year, at least 1 dollar of the total amount

of sales were for individuals enrolled under the Medicare program under title XVIII or under a State Medicaid plan under title XIX or under a waiver of such plan.

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

''(b) REPORT.—

''(1) REPORT REQUIRED.—The manufacturer of a qualifying drug shall submit a report to the Secretary—

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

''(i) 10 percent or more within a single calendar year beginning on or after January 1, 2021; or

''(ii) 25 percent or more within three consecutive calendar years for which the first such calendar year begins on or after January 1, 2021; and

''(B) in the case that the qualifying drug is first covered under title XVIII with respect to an applicable year, if the estimated cost or

spending under such title per individual or per user of such drug (as estimated by the Secretary) for such applicable year (or per course of treatment in such applicable year, as defined by the Secretary) is at least $26,000.

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

''(A) in the case of a report with respect to an increase in the price of a qualifying drug that occurs during the period beginning on January 1, 2021, and ending on the day that is 60 days after the date of enactment of this section, not later than 90 days after such date of enactment;

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

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

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

''(1) with respect to the qualifying drug—

''(A) the percentage by which the manufacturer will raise the wholesale acquisition cost of the drug within the calendar year or three consecutive calendar years as described in subsection (b)(1)(A) or (b)(1)(B), if applicable, and the effective date of such price increase;

''(B) an explanation for, and description of, each price increase for such drug that will occur during the calendar year period described in subsection (b)(1)(A) or the three consecutive calendar year period described in subsection (b)(1)(B), as applicable;

''(C) if known and different from the manufacturer of the qualifying drug, the identity of—

''(i) the sponsor or sponsors of any investigational new drug applications under section 505(i) of the Federal Food, Drug, and Cosmetic Act for clinical investigations

with respect to such drug, for which the full reports are submitted as part of the application—

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

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

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

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

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

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

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

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

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

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

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

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

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

''(L) the total costs associated with marketing and advertising for the qualifying drug;

''(2) with respect to the manufacturer—

''(A) the total revenue and the net profit of the manufacturer for each of the 1-year period described in subsection (b)(1)(A) or the 3-year period described in subsection (b)(1)(B), as applicable;

''(B) all stock-based performance metrics used by the manufacturer to determine executive compensation for each of the 1-year period

described in subsection (b)(1)(A) or the 3-year period described in subsection (b)(1)(B), as applicable; and

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

''(i) drug research and development; or

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

''(3) such other related information as the Secretary considers appropriate and as specified by the Secretary through notice-and-comment rulemaking.

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

''(e) CIVIL MONETARY PENALTY.—Any manufacturer of a qualifying drug that fails to submit a report for the drug as required by this section, following notification by the Secretary to the manufacturer that the manufacturer is not in compliance with this section, shall be

subject to a civil monetary penalty of $75,000 for each day on which the violation continues.

''(f) FALSE INFORMATION.—Any manufacturer that submits a report for a drug as required by this section that knowingly provides false information in such report is subject to a civil monetary penalty in an amount not to exceed $75,000 for each item of false information.

''(g) PUBLIC POSTING.—

''(1) IN GENERAL.—Subject to paragraph (3), the Secretary shall post each report submitted under subsection (b) on the public website of the Department of Health and Human Services the day the price increase of a qualifying drug is scheduled to go into effect.

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

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

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

''(3) PROTECTED INFORMATION.—Nothing in this section shall be construed to authorize the public disclosure of information submitted by a manufacturer that is prohibited from disclosure by applicable laws concerning the protection of trade secrets, commercial information, and other information covered under such laws.

''(h) ANNUAL REPORT TO CONGRESS.—

''(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall submit to Congress, and post on the public website of the Department of Health and Human Services in a way that is user-friendly to the public and written in plain language that consumers can readily understand, an annual report—

''(A) summarizing the information reported pursuant to this section;

''(B) including copies of the reports and supporting detailed economic analyses submitted pursuant to this section;

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

''(D) explaining how the Department of Health and Human Services is improving con-

sumer and provider information about drug value and drug price transparency.

''(2) PROTECTED INFORMATION.—Nothing in this subsection shall be construed to authorize the public disclosure of information submitted by a manufacturer that is prohibited from disclosure by applicable laws concerning the protection of trade secrets, commercial information, and other information covered under such laws.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of enactment of this Act.

SEC. 202. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.

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

(1) in subsection (c), in the matter preceding paragraph (1), by inserting ''(other than as permitted under subsection (e))'' after ''disclosed by the Secretary''; and

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

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

''(1) IN GENERAL.—In order to allow the comparison of PBMs' ability to negotiate rebates, dis-

counts, direct and indirect remuneration fees, administrative fees, and price concessions and the amount of such rebates, discounts, direct and indirect remuneration fees, administrative fees, and price concessions that are passed through to plan sponsors, beginning January 1, 2022, the Secretary shall make available on the Internet website of the Department of Health and Human Services the information with respect to the second preceding calendar year provided to the Secretary on generic dispensing rates (as described in paragraph (1) of subsection (b)) and information provided to the Secretary under paragraphs (2) and (3) of such subsection that, as determined by the Secretary, is with respect to each PBM.

''(2) AVAILABILITY OF DATA.—In carrying out paragraph (1), the Secretary shall ensure the following:

''(A) CONFIDENTIALITY.—The information described in such paragraph is displayed in a manner that prevents the disclosure of information, with respect to an individual drug or an individual plan, on rebates, discounts, direct and indirect remuneration fees, administrative fees, and price concessions.

''(B) CLASS OF DRUG.—The information described in such paragraph is made available by class of drug, using an existing classification system, but only if the class contains such number of drugs, as specified by the Secretary (but not fewer than three drugs), to ensure confidentiality of proprietary information or other information that is prevented to be disclosed under subparagraph (A).''.

SEC. 203. MAKING PRESCRIPTION DRUG MARKETING SAMPLE INFORMATION REPORTED BY MANUFACTURERS AVAILABLE TO CERTAIN INDIVIDUALS AND ENTITIES.

(a) IN GENERAL.—Section 1128H of the Social Security Act (42 U.S.C. 1320a–7i) is amended—

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

(2) by inserting after subsection (a) the following new subsections:

''(b) DATA SHARING AGREEMENTS.—

''(1) IN GENERAL.—The Secretary shall enter into agreements with the specified data sharing individuals and entities described in paragraph (2) under which—

"(A) upon request of such an individual or entity, as applicable, the Secretary makes available to such individual or entity the information submitted under subsection (a) by manufacturers and authorized distributors of record; and

"(B) such individual or entity agrees to not disclose publicly or to another individual or entity any information that identifies a particular practitioner or health care facility.

"(2) SPECIFIED DATA SHARING INDIVIDUALS AND ENTITIES.—For purposes of paragraph (1), the specified data sharing individuals and entities described in this paragraph are the following:

"(A) OVERSIGHT AGENCIES.—Health oversight agencies (as defined in section 164.501 of title 45, Code of Federal Regulations), including the Centers for Medicare & Medicaid Services, the Office of the Inspector General of the Department of Health and Human Services, the Government Accountability Office, the Congressional Budget Office, the Medicare Payment Advisory Commission, and the Medicaid and CHIP Payment and Access Commission.

"(B) RESEARCHERS.—Individuals who conduct scientific research (as defined in sec-

tion 164.501 of title 45, Code of Federal Regulations) in relevant areas as determined by the Secretary.

''(C) PAYERS.—Private and public health care payers, including group health plans, health insurance coverage offered by health insurance issuers, Federal health programs, and State health programs.

''(3) EXEMPTION FROM FREEDOM OF INFORMATION ACT.—Except as described in paragraph (1), the Secretary may not be compelled to disclose the information submitted under subsection (a) to any individual or entity. For purposes of section 552 of title 5, United States Code (commonly referred to as the Freedom of Information Act), this paragraph shall be considered a statute described in subsection (b)(3)(B) of such section.

''(c) PENALTIES.—

''(1) DATA SHARING AGREEMENTS.—Subject to paragraph (3), any specified data sharing individual or entity described in subsection (b)(2) that violates the terms of a data sharing agreement the individual or entity has with the Secretary under subsection (b)(1) shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000,

for each such violation. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

''(2) FAILURE TO REPORT.—Subject to paragraph (3), any manufacturer or authorized distributor of record of an applicable drug under subsection (a) that fails to submit information required under such subsection in a timely manner in accordance with rules or regulations promulgated to carry out such subsection shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000, for each such failure. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

''(3) LIMITATION.—The total amount of civil money penalties imposed under paragraph (1) or (2) with respect to a year and an individual or entity described in paragraph (1) or a manufacturer or distributor described in paragraph (2), respectively, shall not exceed $150,000.

''(d) DRUG SAMPLE DISTRIBUTION INFORMATION.—

''(1) IN GENERAL.—Not later than January 1 of each year (beginning with 2022), the Secretary

shall maintain a list containing information related to the distribution of samples of applicable drugs. Such list shall provide the following information with respect to the preceding year:

''(A) The name of the manufacturer or authorized distributor of record of an applicable drug for which samples were requested or distributed under this section.

''(B) The quantity and class of drug samples requested.

''(C) The quantity and class of drug samples distributed.

''(2) PUBLIC AVAILABILITY.—The Secretary shall make the information in such list available to the public on the Internet website of the Food and Drug Administration.''.

(b) FDA MAINTENANCE OF INFORMATION.—The Food and Drug Administration shall maintain information available to affected reporting companies to ensure their ability to fully comply with the requirements of section 1128H of the Social Security Act.

(c) PROHIBITION ON DISTRIBUTION OF SAMPLES OF OPIOIDS.—Section 503(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(d)) is amended—

(1) by moving the margin of paragraph (4) 2 ems to the left; and

(2) by adding at the end the following:

''(5) No person may distribute a drug sample of a drug that is—

''(A) an applicable drug (as defined in section 1128H(e) of the Social Security Act);

''(B) a controlled substance (as defined in section 102 of the Controlled Substances Act) for which the findings required under section 202(b)(2) of such Act have been made; and

''(C) approved under section 505 for use in the management or treatment of pain (other than for the management or treatment of a substance use disorder).''.

(d) MEDPAC REPORT.—Not later than 3 years after the date of the enactment of this Act, the Medicare Payment Advisory Commission shall conduct a study on the impact of drug samples on provider prescribing practices and health care costs and may, as the Commission deems appropriate, make recommendations on such study.

SEC. 204. SENSE OF THE SENATE REGARDING THE NEED TO EXPAND COMMERCIALLY AVAILABLE DRUG PRICING COMPARISON PLATFORMS.

It is the sense of the Senate that—

(1) commercially available drug pricing comparison platforms can, at no cost, help patients find the lowest price for their medications at their local pharmacy;

(2) such platforms should be integrated, to the maximum extent possible, in the health care delivery ecosystem; and

(3) pharmacy benefit managers should work to disclose generic and brand name drug prices to such platforms to ensure that—

(A) patients can benefit from the lowest possible price available to them; and

(B) overall drug prices can be reduced as more educated purchasing decisions are made based on price transparency.

TITLE III—REVENUE PROVISION

SEC. 301. INCLUSION OF INSULIN AND OTHER TREATMENTS FOR CHRONIC CONDITIONS AS PREVENTIVE CARE.

(a) IN GENERAL.—Subparagraph (C) of section 223(c)(2) of the Internal Revenue Code of 1986 is amended—

(1) by striking ''DEDUCTIBLE.—A plan'' and inserting ''DEDUCTIBLE.—

''(i) IN GENERAL.—A plan'', and

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

''(ii) SPECIAL RULE.—The term 'preventive care' includes such drugs (including insulin), devices, supplies, and medical services or screenings prescribed for the prevention or avoidance of a disease or condition, or the regular treatment and maintenance of a chronic disease or condition, as are determined by the Secretary, in consultation with the Secretary of Health and Human Services, to be—

''(I) low in cost,

''(II) supported by medical evidence to have a high cost efficiency in preventing exacerbation of a chronic condition or the development of a secondary condition, and

''(III) likely (as documented by clinical evidence), when prescribed for a class of individuals, to prevent exacerbation of the chronic condition of such individuals or the development of a secondary condition requiring significantly higher cost treatments.''.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to taxable years beginning after the date of the enactment of this Act.

(2) TREASURY GUIDANCE IN EFFECT ON DATE OF ENACTMENT.—

(A) IN GENERAL.—No inference shall be drawn by reason of the amendments made by this Act with respect to the effectiveness of the provisions of Internal Revenue Service Notice 2019-45 on the date of the enactment of this Act, and such notice shall continue to apply as in effect on July 17, 2019, unless amended by the Secretary of the Treasury (or the Secretary's delegate) pursuant to the amendments made by this Act or pursuant to subparagraph (B).

(B) CONTINUED PUBLICATION AND UPDATE OF LIST.—

(i) IN GENERAL.—The Secretary of the Treasury (or the Secretary's delegate) may publish, and update from time to time as such Secretary (or delegate) deems appropriate, a list of the drugs, devices, supplies, and services identified under section

223(c)(2)(C)(ii) of the Internal Revenue Code of 1986, in consultation with the Secretary of Health and Human Services (or such Secretary's delegate), as preventive care.

(ii) INCLUSION OF CERTAIN DIABETIC SUPPLIES.—As soon as practicable after the date of the enactment of this Act, the list in effect under Internal Revenue Service Notice 2019-45 shall be amended to include insulin delivery devices and related supplies, and continuous glucose monitoring systems and related supplies.

TITLE IV—MISCELLANEOUS PROVISIONS

SEC. 401. IMPROVING COORDINATION BETWEEN THE FOOD AND DRUG ADMINISTRATION AND THE CENTERS FOR MEDICARE & MEDICAID SERVICES.

(a) IN GENERAL.—

(1) PUBLIC MEETING.—

(A) IN GENERAL.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall convene a public meeting for the

purposes of discussing and providing input on improvements to coordination between the Food and Drug Administration and the Centers for Medicare & Medicaid Services in preparing for the availability of novel medical products described in subsection (c) on the market in the United States.

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

(i) representatives of relevant Federal agencies, including representatives from each of the medical product centers within the Food and Drug Administration and representatives from the coding, coverage, and payment offices within the Centers for Medicare & Medicaid Services;

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

(iii) representatives of commercial health insurance payers;

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

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

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

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

(ii) the anticipated expertise necessary to review the safety and effectiveness of such products at the Food and Drug 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.—No information discussed as a part of the public meeting under this paragraph shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code.

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

(A) DRAFT GUIDANCE.—Not later than 18 months after the public meeting under paragraph (1), the Secretary shall update the final

guidance titled ''National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development'' to address any opportunities to improve the availability and coordination of information as described in clauses (iv) through (vi) of paragraph (1)(C).

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

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

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

(2) Recommendations to—

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

(B) decrease the length of time to make national and local coverage determinations under the Medicare program (as those terms are defined in subparagraph (A) and (B), respectively, of section 1862(l)(6) of the Social Security Act (42 U.S.C. 1395y(l)(6)));

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

(D) identify potential mechanisms to incorporate novel payment designs similar to those in development in commercial insurance plans and State plans under title XIX of such Act

(42 U.S.C. 1396 et seq.) into the Medicare program.

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

SEC. 402. PATIENT CONSULTATION IN MEDICARE NATIONAL AND LOCAL COVERAGE DETERMINATIONS IN ORDER TO MITIGATE BARRIERS TO INCLUSION OF SUCH PERSPECTIVES.

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

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

SEC. 403. 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, 2023, 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;

(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; and

(E) the feasibility and policy implications of creating a methodology to preserve the healthcare provider's ability to take title of the drug, including a methodology under which—

(i) prescription drug plans negotiate reimbursement rates and other arrangements with drug manufacturers on behalf of a wholesaler;

(ii) wholesalers purchase the drugs from the manufacturers at the negotiated rate and ship them through distributors to physicians to administer to patients;

(iii) physicians and hospitals purchase the drug from the wholesaler via the distributor;

(iv) after administering the drug, the physician submits a claim to the MAC for their drug administration fee;

(v) to be reimbursed for the purchase of the drug from the distributor, the physician furnishes the claim for the drug itself to the wholesaler and the wholesaler would refund the cost of the drug to the physician; and

(vi) the wholesaler passes this claim to the PDP to receive reimbursement.

SEC. 404. AUTHORITY TO REQUIRE THAT DIRECT-TO-CONSUMER ADVERTISEMENTS FOR PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS INCLUDE TRUTHFUL AND NON-MISLEADING PRICING INFORMATION.

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

''SEC. 1150D. AUTHORITY TO REQUIRE THAT DIRECT-TO-CONSUMER ADVERTISEMENTS FOR PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS INCLUDE TRUTHFUL AND NON-MISLEADING PRICING INFORMATION.

''(a) IN GENERAL.—The Secretary may require that each direct-to-consumer advertisement for a prescription drug or biological product for which payment is available under title XVIII or XIX includes an internet website address that provides an appropriate disclosure of truthful and non-misleading pricing information with respect to the drug or product.

''(b) DETERMINATION BY CMS.—The Secretary, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall determine the components of the requirement under subsection (a), such as the forms of advertising, the manner of disclosure, the price point listing, and the price information for disclosure.''.

SEC. 405. CHIEF PHARMACEUTICAL NEGOTIATOR AT THE OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE.

(a) IN GENERAL.—Section 141 of the Trade Act of 1974 (19 U.S.C. 2171) is amended—

(1) in subsection (b)(2)—

(A) by striking ''and one Chief Innovation and Intellectual Property Negotiator'' and in-

serting ''one Chief Innovation and Intellectual Property Negotiator, and one Chief Pharmaceutical Negotiator'';

(B) by striking ''or the Chief Innovation and Intellectual Property Negotiator'' and inserting ''the Chief Innovation and Intellectual Property Negotiator, or the Chief Pharmaceutical Negotiator''; and

(C) by striking ''and the Chief Innovation and Intellectual Property Negotiator'' and inserting ''the Chief Innovation and Intellectual Property Negotiator, and the Chief Pharmaceutical Negotiator''; and

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

''(7) The principal function of the Chief Pharmaceutical Negotiator shall be to conduct trade negotiations and to enforce trade agreements relating to United States pharmaceutical products and services. The Chief Pharmaceutical Negotiator shall be a vigorous advocate on behalf of United States pharmaceutical interests. The Chief Pharmaceutical Negotiator shall perform such other functions as the United States Trade Representative may direct.''.

(b) COMPENSATION.—Section 5314 of title 5, United States Code, is amended by striking ''Chief Innovation and Intellectual Property Negotiator, Office of the United States Trade Representative.'' and inserting the following:

''Chief Innovation and Intellectual Property Negotiator, Office of the United States Trade Representative.

''Chief Pharmaceutical Negotiator, Office of the United States Trade Representative.''.

(c) REPORT REQUIRED.—Not later than the date that is one year after the appointment of the first Chief Pharmaceutical Negotiator pursuant to paragraph (2) of section 141(b) of the Trade Act of 1974, as amended by subsection (a), and annually thereafter, the United States Trade Representative shall submit to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives a report describing in detail—

(1) enforcement actions taken by the United States Trade Representative during the 1-year period preceding the submission of the report to ensure the protection of United States pharmaceutical products and services; and

(2) other actions taken by the United States Trade Representative to advance United States pharmaceutical products and services.