AMENDMENT TO

RULES COMMITTEE PRINT 116–41

OFFERED BY M__. _____

Strike section 2 and all that follows and insert the following:

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—MEDICARE PARTS B AND D

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" and "surgical center"; and

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

(C) in subparagraph (A)—

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

(ii) by inserting ", and the physician fee schedule under section 1848 (with respect to the practice expense component of such payment amount)" after "such section";

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

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

"(2) PHYSICIAN PAYMENT.—Beginning in 2021, 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 by adding at the end 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, 2021, the Secretary shall, with respect to a refundable single-dose container or single-use package drug (as defined in paragraph (8)), report to each manufacturer (as defined in subsection (c)(6)(A)) of such refundable single-dose container or single-use package drug the following for the calendar quarter:

''(i) Subject to subparagraph (C), information on the total number of units of the billing and payment code of such drug, if any, that were discarded during such quarter, as determined using a mechanism such as the JW modifier used as of the date of enactment of this subsection (or any such successor modifier that includes such data as determined appropriate by the Secretary).

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

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

''(C) EXCLUSION OF UNITS OF PACKAGED DRUGS.—The total number of units of the billing and payment code of a refundable single-dose container or single-use package drug of a

manufacturer furnished during a calendar quarter for purposes of subparagraph (A)(i), and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (3)(A)(ii), shall not include such units that are packaged into the payment amount for an item or service and are not separately payable.

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

''(3) REFUND AMOUNT.—

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

''(i) the product of—

''(I) the total number of units of the billing and payment code for such drug that were discarded during such quarter (as determined under paragraph (1)); and

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

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

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

''(B) APPLICABLE PERCENTAGE DEFINED.—

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

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

''(II) 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, 2021, 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, 2021, 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 clauses (ii), with respect to a drug or biological furnished in a calendar quarter beginning on or after January 1, 2021, 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, 2021, 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) array 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 arrayed 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(g) of the Social Security Act 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 further 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, 2021, 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 cellular immunotherapy)—

''(I) for each of 2021 through 2028, $1,000; and

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

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

''(I) for each of 2021 through 2028, $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.''

(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, 2021, if such payment is determined based on the average

price for the year established under section 1847A pursuant to clause (iii)(II) of such subparagraph, the provisions of subsection (b)(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, 2021, the provisions of subsection (t)(14)(I) shall apply to the establishment of the amount of payment for the drug or biological under such system in the same manner in which such provisions apply to the establishment of the amount of payment under subsection (t)(14)(A).''.

SEC. 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 12 U.S.C. 1395l(t)(16)) is amended by adding at the end the following new subparagraph:

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

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

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

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

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

Subtitle B—Drug Price Transparency

SEC. 111. REPORTING ON EXPLANATION FOR DRUG PRICE INCREASES.

(a) IN GENERAL.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

''PART W—DRUG PRICE REPORTING; DRUG VALUE FUND

''SEC. 399OO. REPORTING ON EXPLANATION FOR DRUG PRICE INCREASES.

''(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 this 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 of the Social Security Act (42 U.S.C. 1395 et seq.) or under a State Medicaid plan under title XIX of

such Act (42 U.S.C. 1396 et seq.) 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) of the Social Security Act (42 U.S.C. 1395w–3a(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, 2019; or

''(ii) 25 percent or more within three consecutive calendar years for which the first such calendar year begins on or after January 1, 2019; 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, 2019, 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 this 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 this 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 this 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 this 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 this 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, 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.

"SEC. 399OO–1. ANNUAL REPORT TO CONGRESS.

"(a) IN GENERAL.—Subject to subsection (b), 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—

"(1) summarizing the information reported pursuant to section 399OO;

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

"(3) detailing the costs and expenditures incurred by the Department of Health and Human Services in carrying out section 399OO; and

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

"(b) PROTECTED INFORMATION.—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.''.

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

SEC. 112. 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, discounts, 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, 2020, 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 infor-

mation that is prevented to be disclosed under subparagraph (A).''.

SEC. 113. STUDY OF PHARMACEUTICAL SUPPLY CHAIN INTERMEDIARIES AND MERGER ACTIVITY.

(a) INITIAL REPORT.—Not later than 1 year after the date of enactment of this Act, the Commission shall submit to the appropriate committees of Congress a report that—

(1) addresses at minimum—

(A) whether pharmacy benefit managers—

(i) charge payers a higher price than the reimbursement rate at which the pharmacy benefit managers reimburse competing pharmacies;

(ii) steer patients for anticompetitive purposes to any pharmacies, including retail, mail-order, or any other type of pharmacy, in which the pharmacy benefit manager has an ownership interest;

(iii) audit or review proprietary data, including acquisition costs, patient information, or dispensing information, of competing pharmacies that can be used for anticompetitive purposes; or

(iv) use formulary designs to increase the market share of higher cost prescription drugs and depress the market share of lower cost prescription drugs (each net of rebates and discounts);

(B) how companies and payers assess the benefits, costs, and risks of contracting with intermediaries, including pharmacy services administrative organizations, and whether more information about the roles of intermediaries should be available to consumers and payers; and

(C) whether there are any specific legal or regulatory obstacles the Commission currently faces in ensuring a competitive and transparent marketplace in the pharmaceutical supply chain, including the pharmacy benefit manager marketplace and pharmacy services administrative organizations; and

(2) provides—

(A) observations or conclusions drawn from the November 2017 roundtable entitled ''Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics'', and any similar efforts;

(B) specific actions the Commission intends to take as a result of the November 2017 roundtable, and any similar efforts, including a detailed description of relevant forthcoming actions, additional research or roundtable discussions, consumer education efforts, or enforcement actions; and

(C) policy or legislative recommendations to—

(i) improve transparency and competition in the pharmaceutical supply chain;

(ii) prevent and deter anticompetitive behavior in the pharmaceutical supply chain; and

(iii) best ensure that consumers benefit from any cost savings or efficiencies that may result from mergers and consolidations.

(b) INTERIM REPORT.—Not later than 180 days after the date of enactment of this Act, the Commission shall submit to the appropriate committees of Congress an interim report on the progress of the report required by subsection (a), along with preliminary findings and conclusions based on information collected to that date.

(c) DEFINITIONS.—In this section:

(1) APPROPRIATE COMMITTEES OF CONGRESS.—The term ''appropriate committees of Congress'' means—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on the Judiciary of the Senate; and

(C) the Committee on the Judiciary of the House of Representatives.

(2) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

SEC. 114. REQUIRING CERTAIN MANUFACTURERS TO REPORT DRUG PRICING INFORMATION WITH RESPECT TO DRUGS UNDER THE MEDICARE PROGRAM.

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

(1) in subsection (b)—

(A) in paragraph (2)(A), by inserting ''or subsection (f)(2), as applicable'' before the period at the end;

(B) in paragraph (3), in the matter preceding subparagraph (A), by inserting ''or subsection (f)(2), as applicable,'' before ''determined by''; and

(C) in paragraph (6)(A), in the matter preceding clause (i), by inserting ''or subsection (f)(2), as applicable,'' before ''determined by''; and

(2) in subsection (f)—

(A) by striking ''For requirements'' and inserting the following:

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

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

''(2) MANUFACTURERS WITHOUT A REBATE AGREEMENT UNDER TITLE XIX.—

''(A) IN GENERAL.—If the manufacturer of a drug or biological described in subparagraph (C), (E), or (G) of section 1842(o)(1) or in section 1881(b)(14)(B) that is payable under this part has not entered into and does not have in effect a rebate agreement described in subsection (b) of section 1927, for calendar quarters beginning on or after January 1, 2020, such manufacturer shall report to the Secretary the information described in subsection (b)(3)(A)(iii) of such section 1927 with respect to such drug or biological in a time and manner specified by the Secretary. For pur-

poses of applying this paragraph, a drug or biological described in the previous sentence includes items, services, supplies, and products that are payable under this part as a drug or biological.

''(B) AUDIT.—Information reported under subparagraph (A) is subject to audit by the Inspector General of the Department of Health and Human Services.

''(C) VERIFICATION.—The Secretary may survey wholesalers and manufacturers that directly distribute drugs described in subparagraph (A), when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of such a drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A

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

''(D) CONFIDENTIALITY.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph (other than the wholesale acquisition cost for purposes of carrying out this section) is confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler, except—

''(i) as the Secretary determines to be necessary to carry out this section (including the determination and implementation of the payment amount), or to carry out section 1847B;

''(ii) to permit the Comptroller General of the United States to review the information provided; and

''(iii) to permit the Director of the Congressional Budget Office to review the information provided.''.

(b) ENFORCEMENT.—Section 1847A of such Act (42 U.S.C. 1395w–3a) is further amended—

(1) in subsection (d)(4)—

(A) in subparagraph (A), by striking ''IN GENERAL'' and inserting ''MISREPRESENTATION'';

(B) in subparagraph (B), by striking ''subparagraph (B)'' and inserting ''subparagraph (A), (B), or (C)'';

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

(D) by inserting after subparagraph (A) the following new subparagraphs:

''(B) FAILURE TO PROVIDE TIMELY INFORMATION.—If the Secretary determines that a manufacturer described in subsection (f)(2) has failed to report on information described in section 1927(b)(3)(A)(iii) with respect to a drug or biological in accordance with such subsection, the Secretary shall apply a civil money penalty in an amount of $10,000 for each day the man-

ufacturer has failed to report such information and such amount shall be paid to the Treasury.

''(C) FALSE INFORMATION.—Any manufacturer required to submit information under subsection (f)(2) that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law.''; and

(2) in subsection (c)(6)(A), by striking the period at the end and inserting '', except that, for purposes of subsection (f)(2), the Secretary may, if the Secretary determines appropriate, exclude repackagers of a drug or biological from such term.''.

(c) MANUFACTURERS WITH A REBATE AGREEMENT.—

(1) IN GENERAL.—Section 1927(b)(3)(A) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(A)) is amended by adding at the end the following new sentence: ''For purposes of applying clause (iii), a drug or biological described in the flush matter following such clause includes items, services, supplies, and products that are payable under this part as a drug or biological.''.

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

(d) REPORT.—Not later than January 1, 2021, the Inspector General of the Department of Health and Human Services shall assess and submit to Congress a report on the accuracy of average sales price information submitted by manufacturers under section 1847A of the Social Security Act (42 U.S.C. 1395w–3a). Such report shall include any recommendations on how to improve the accuracy of such information.

SEC. 115. 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 section 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 dis-

tributor 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 2021), 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. 116. REQUIRING PRESCRIPTION DRUG PLAN SPONSORS TO INCLUDE REAL-TIME BENEFIT INFORMATION AS PART OF SUCH SPONSOR'S ELECTRONIC PRESCRIPTION PROGRAM UNDER THE MEDICARE PROGRAM.

Section 1860D–4(e)(2) of the Social Security Act (42 U.S.C. 1395w–104(e)(2)) is amended—

(1) in subparagraph (D), by striking ''To the extent'' and inserting ''Except as provided in subparagraph (F), to the extent''; and

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

''(F) REAL-TIME BENEFIT INFORMATION.—

''(i) IN GENERAL.—Not later than January 1, 2021, the program shall implement real-time benefit tools that are capable of integrating with a prescribing health care professional's electronic prescribing or electronic health record system for the transmission of formulary and benefit information in real time to prescribing health care professionals. With respect to a cov-

ered part D drug, such tools shall be capable of transmitting such information specific to an individual enrolled in a prescription drug plan. Such information shall include the following:

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

''(II) Cost-sharing information for such drug and such alternatives, including a description of any variance in cost-sharing based on the pharmacy dispensing such drug or such alternatives.

''(III) Information relating to whether such drug is included in the formulary of such plan and any prior authorization or other utilization management requirements applicable to such drug and such alternatives so included.

''(ii) ELECTRONIC TRANSMISSION.—The provisions of subclauses (I) and (II) of clause (ii) of subparagraph (E) shall apply to an electronic transmission described in

clause (i) in the same manner as such provisions apply with respect to an electronic transmission described in clause (i) of such subparagraph.

''(iii) SPECIAL RULE FOR 2021.—The program shall be deemed to be in compliance with clause (i) for 2021 if the program complies with the provisions of section 423.160(b)(7) of title 42, Code of Federal Regulations (or a successor regulation), for such year.

''(iv) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed as to allow a real-time benefits tool to steer an individual, without the consent of the individual, to a particular pharmacy or pharmacy setting over their preferred pharmacy setting nor prohibit the designation of a preferred pharmacy under such tool.''.

SEC. 117. SENSE OF CONGRESS REGARDING THE NEED TO EXPAND COMMERCIALLY AVAILABLE DRUG PRICING COMPARISON PLATFORMS.

It is the sense of Congress 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.

SEC. 118. TECHNICAL CORRECTIONS.

(a) IN GENERAL.—Section 3022(b) of the Public Health Service Act (42 U.S.C. 300jj–52(b)) is amended by adding at the end the following new paragraph:

''(4) APPLICATION OF AUTHORITIES UNDER INSPECTOR GENERAL ACT OF 1978.—In carrying out this subsection, the Inspector General shall have the same authorities as provided under section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if included in the enactment of the 21st Century Cures Act (Public Law 114–255).

Subtitle C—Medicare Part D Benefit Redesign

SEC. 121. 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)''; and

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

(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, 2021, in consultation with manufacturers, and allow for comment on such model agreement.

''(b) TERMS OF AGREEMENT.—

''(1) IN GENERAL.—

''(A) AGREEMENT.—An agreement under this section shall require the manufacturer to provide applicable beneficiaries access to discounted prices for applicable drugs of the man-

ufacturer that are dispensed on or after January 1, 2022.

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

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

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

''(4) LENGTH OF AGREEMENT.—

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

"(B) TERMINATION.—

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

"(ii) BY A MANUFACTURER.—A manufacturer may terminate an agreement under this section for any reason. Any

such termination shall be effective, with respect to a plan year—

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

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

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

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

''(5) EFFECTIVE DATE OF AGREEMENT.—An agreement under this section shall take effect on a

date determined appropriate by the Secretary, which may be at the start of a calendar quarter.

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

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

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

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

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

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

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

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

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

''(2) MONITORING COMPLIANCE.—

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

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

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

''(d) ADMINISTRATION.—

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

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

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

''(A) receive and transmit information between the Secretary, manufacturers, and other

individuals or entities the Secretary determines appropriate;

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

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

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

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

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

''(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 prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

''(iii) is provided through an exception or appeal.

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

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

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

"(4) DISCOUNTED PRICE.—

"(A) IN GENERAL.—The term 'discounted price' means, 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;''.

(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''.

(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.

Subtitle D—Other Medicare Part D Provisions

SEC. 131. TRANSITIONAL COVERAGE AND RETROACTIVE MEDICARE PART D COVERAGE FOR CERTAIN LOW-INCOME BENEFICIARIES.

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

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

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

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

''(1) IN GENERAL.—Beginning not later than January 1, 2021, the Secretary shall carry out a program to provide transitional coverage for covered part D drugs for LI NET eligible individuals in accordance with this subsection.

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

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

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

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

''(A) immediate access to covered part D drugs at the point-of-sale during the period that begins on the first day of the month such individual is determined to meet the requirements of clauses (ii) and (iii) of subsection (a)(3)(A) and ends on the date that coverage under a prescription drug plan or MA–PD plan takes effect with respect to such individual; and

''(B) in the case of an LI NET eligible individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)) or a

recipient of supplemental security income benefits under title XVI, retroactive coverage (in the form of reimbursement of the amounts that would have been paid under this part had such individual been enrolled in a prescription drug plan or MA–PD plan) of covered part D drugs purchased by such individual during the period that begins on the date that is the later of—

''(i) the date that such individual was first eligible for a low-income subsidy under this part; or

''(ii) the date that is 36 months prior to the date such individual enrolls in a prescription drug plan or MA–PD plan, and ends on the date that coverage under such plan takes effect.

''(4) PROGRAM ADMINISTRATION.—

''(A) SINGLE POINT OF CONTACT.—The Secretary shall, to the extent feasible, administer the program under this subsection through a contract with a single program administrator.

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

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

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

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

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

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

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

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

''(ii) Subparagraphs (A) and (B) of section 1860D–4(b)(3) (relating to require-

ments on development and application of formularies; formulary development).

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

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

SEC. 132. 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. 133. ALLOWING CERTAIN ENROLLEES OF PRESCRIPTION DRUGS PLANS AND MA–PD PLANS UNDER 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 121, is further amended—

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

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

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

''(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 may 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. 134. ESTABLISHING A MONTHLY CAP ON BENEFICIARY INCURRED COSTS FOR INSULIN PRODUCTS AND SUPPLIES UNDER A PRESCRIPTION DRUG PLAN OR MA–PD PLAN.

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

(1) in subsection (b)(2)—

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

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

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

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

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

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

''(II) for months occurring in a subsequent year, the amount applicable under this clause for months oc-

curring in the year preceding such subsequent year, increased by the annual percentage increase specified in paragraph (6) for such subsequent year and rounded to the nearest dollar.

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

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

''(I) insulin; or

''(II) a medical supply associated with the injection of insulin (as defined in regulations of the Secretary

promulgated pursuant to subsection (e)(1)(B)).''; and

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

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

(b) CONFORMING AMENDMENTS.—

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

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

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

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

SEC. 135. GROWTH RATE OF MEDICARE PART D OUT-OF-POCKET COST THRESHOLD.

(a) PROVIDING MEDICARE PART D BENEFICIARIES WITH CERTAIN 2020 OFFSET PAYMENTS.—Section 1860D–2(b)(4) of the Social Security Act (42 U.S.C. 1395w–102(b)(4)) is amended by adding at the end the following new subparagraph:

"(F) 2020 OFFSET PAYMENTS.—

"(i) IN GENERAL.—Subject to clause (iv), the Secretary shall provide for payment from the Medicare Prescription Drug Account as follows:

"(I) In the case of a specified individual (as defined in clause (ii)(I)) who as of the last day of a calendar quarter in 2020 has incurred costs for covered part D drugs so that the individual has exceeded the annual out-of-pocket threshold applied under subparagraph (B)(i)(V) for 2020, payment to the individual by not later than 15th day of the third month following the end of such quarter of the amount by which such threshold so applied exceeded the target threshold for 2020.

''(II) In the case of a specified individual who is not described in subclause (I) and who as of the last day of 2020 has incurred costs for covered part D drugs so that the individual has exceeded the target threshold for 2020, payment to the individual by not later than December 31, 2021 of the amount by which such incurred costs exceeded the target threshold for 2020.

''(ii) DEFINITIONS.—For purposes of this subparagraph:

''(I) SPECIFIED INDIVIDUAL.—The term 'specified individual' means an individual who—

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

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

''(cc) is not entitled to an income-related subsidy under section 1860D–14(a).

"(II) TARGET THRESHOLD FOR 2020.—the term 'target threshold for 2020' means the annual out-of-pocket threshold that would have been applied under subparagraph (B)(i) for 2020 if such threshold had been determined in accordance with subclause (IV) of such subparagraph instead of subclause (V) of such subparagraph.

"(iii) NOTIFICATION.—In the case of any specified individual who during 2020 has incurred costs for covered part D drugs so that the individual has exceeded the target threshold for 2020, the Secretary shall, not later than September 30, 2021, provide to such individual a notification informing such individual of such individual's right to a payment described in clause (i) and the estimated timing of such payment.

"(iv) CLARIFICATION.—The Secretary shall provide only 1 payment under this subparagraph with respect to any individual.

''(v) IMPLEMENTATION.—The Secretary may implement this subparagraph by program instruction or otherwise.''.

(b) REDUCED GROWTH RATE FOR 2021 OF MEDICARE PART D OUT-OF-POCKET COST THRESHOLD.—Section 1860D–2(b)(4)(B)(i) of the Social Security Act (42 U.S.C. 1395w–102(b)(4)(B)(i)) is amended—

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

(2) by redesignating subclause (VI) as subclause (VIII); and

(3) by inserting after subclause (V) the following new subclauses:

''(VI) for 2021, is equal to the amount that would have been applied under this subparagraph for 2020 if such amount had been determined in accordance with subclause (IV) instead of subclause (V), increased by the lesser of—

''(aa) the annual percentage increase described in paragraph (7) for 2021, plus 2 percentage points; or

''(bb) the annual percentage increase described in paragraph (6) for 2021;

''(VII) for 2022, is equal to the amount that would have been applied under this subparagraph for 2022 if the amendments made by section 1101(d)(1) of the Health Care and Education Reconciliation Act of 2010 and by section 135 of the Lower Costs, More Cures Act of 2019 had not been enacted; or''.

Subtitle E—MedPAC

SEC. 141. PROVIDING THE MEDICARE PAYMENT ADVISORY COMMISSION AND MEDICAID AND CHIP PAYMENT AND ACCESS COMMISSION WITH ACCESS TO CERTAIN DRUG PAYMENT INFORMATION, INCLUDING CERTAIN REBATE INFORMATION.

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

(1) in paragraph (2)—

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

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

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

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

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

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

''(A) The specific amounts or the identity of the source of any rebates, price concessions, or other forms of direct or indirect remuneration under such prescription drug plan.

''(B) Information submitted with the bid submitted under section 1860D–11 by such PDP sponsor.

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

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

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

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

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

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

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

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

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

TITLE II—MEDICAID

SEC. 201. SUNSET OF LIMIT ON MAXIMUM REBATE AMOUNT FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS.

Section 1927(c)(2)(D) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)(D)) is amended by inserting after

''December 31, 2009,'' the following: ''and before January 1, 2023,''.

SEC. 202. MEDICAID PHARMACY AND THERAPEUTICS COMMITTEE IMPROVEMENTS.

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

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

''(ii) Subject to clause (vi), the State establishes and implements a conflict of interest policy for the pharmacy and therapeutics committee that—

''(I) is publicly accessible;

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

''(III) contains clear processes, such as recusal from voting or discussion, for

those members who report a conflict of interest, along with appropriate processes to address any instance where a member fails to report a conflict of interest.

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

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

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

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

''(II) is made publicly available.

''(iv) At the option of the State, the State's drug use review board established under subsection (g)(3) may serve as the pharmacy and therapeutics committee provided the State

ensures that such board meets the requirements of clauses (ii) and (iii).

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

''(vi) If the Secretary determines it appropriate or necessary based on the findings and recommendations of the Comptroller General of the United States in the report submitted to Congress under section 203 of the Lower Costs, More Cures Act of 2019, the Secretary shall issue guidance that States must follow for establishing conflict of interest policies for the pharmacy and therapeutics committee in accordance with the requirements of clause (ii), including appropriate standards and requirements for identifying, addressing, and reporting on conflicts of interest.''.

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

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

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

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

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

SEC. 203. GAO REPORT ON CONFLICTS OF INTEREST IN STATE MEDICAID PROGRAM DRUG USE REVIEW BOARDS AND PHARMACY AND THERAPEUTICS (P&T) COMMITTEES.

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

(b) REPORT.—Not later than 24 months after the date of enactment of this Act, the Comptroller General

shall submit to Congress a report on the investigation conducted under subsection (a) that includes the following:

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

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

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

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

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

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

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

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

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

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

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

(9) A review of strategies States may use to guard against conflicts of interest on DUR Boards and P&T Committees and to ensure compliance with

the requirements of titles XI and XIX of the Social Security Act (42 U.S.C. 1301 et seq., 1396 et seq.) and access to effective, clinically appropriate, and medically necessary drug treatments for Medicaid beneficiaries, including recommendations for such legislative and administrative actions as the Comptroller General determines appropriate.

SEC. 204. ENSURING THE ACCURACY OF MANUFACTURER PRICE AND DRUG PRODUCT INFORMATION UNDER THE MEDICAID DRUG REBATE PROGRAM.

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

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

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

''(i) AUDITS.—The Secretary shall conduct ongoing audits of the price and drug product information reported by manufacturers under subparagraph (A) for the most recently ended rebate period to ensure the accuracy and timeliness of such

information. In conducting such audits, the Secretary may employ evaluations, surveys, statistical sampling, predictive analytics and other relevant tools and methods.

''(ii) VERIFICATIONS SURVEYS OF AVERAGE MANUFACTURER PRICE AND MANUFACTURER'S AVERAGE SALES PRICE.—In addition to the audits required under clause (i), the Secretary may survey wholesalers and manufacturers (including manufacturers that directly distribute their covered outpatient drugs (in this subparagraph referred to as 'direct sellers')), when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) to make payment reported under subparagraph (A).

''(iii) PENALTIES.—In addition to other penalties as may be prescribed by law, including under subparagraph (C) of this paragraph, the Secretary may impose a civil monetary penalty in an amount not to exceed $185,000 on an annual basis on a wholesaler, manufacturer, or direct sell-

er, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with an audit or survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(iv) REPORTS.—

''(I) REPORT TO CONGRESS.—The Secretary shall, not later than 18 months after date of enactment of this subparagraph, submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate regarding additional regulatory or statutory changes that may be required in order to ensure accurate and

timely reporting and oversight of manufacturer price and drug product information, including whether changes should be made to reasonable assumption requirements to ensure such assumptions are reasonable and accurate or whether another methodology for ensuring accurate and timely reporting of price and drug product information should be considered to ensure the integrity of the drug rebate program under this section.

''(II) ANNUAL REPORTS.—The Secretary shall, on at least an annual basis, submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate summarizing the results of the audits and surveys conducted under this subparagraph during the period that is the subject of the report.

''(III) CONTENT.—Each report submitted under subclause (II) shall, with respect to the period that is the

subject of the report, include summaries of—

"(aa) error rates in the price, drug product, and other relevant information supplied by manufacturers under subparagraph (A);

"(bb) the timeliness with which manufacturers, wholesalers, and direct sellers provide information required under subparagraph (A) or under clause (i) or (ii) of this subparagraph;

"(cc) the number of manufacturers, wholesalers, and direct sellers and drug products audited under this subparagraph;

"(dd) the types of price and drug product information reviewed under the audits conducted under this subparagraph;

"(ee) the tools and methodologies employed in such audits;

''(ff) the findings of such audits, including which manufacturers, if any, were penalized under this subparagraph; and

''(gg) such other relevant information as the Secretary shall deem appropriate.

''(IV) PROTECTION OF INFORMATION.—In preparing a report required under subclause (II), the Secretary shall redact such proprietary information as the Secretary determines appropriate to prevent disclosure of, and to safeguard, such information.

''(v) APPROPRIATIONS.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary $2,000,000 for fiscal year 2020 and each fiscal year thereafter to carry out this subparagraph.''.

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

(b) INCREASED PENALTIES FOR NONCOMPLIANCE WITH REPORTING REQUIREMENTS.—

(1) INCREASED PENALTY FOR LATE REPORTING OF INFORMATION.—Section 1927(b)(3)(C)(i) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(C)(i)) is amended by striking ''increased by $10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury'' and inserting '', for each covered outpatient drug with respect to which such information is not provided, $50,000 for the first day that such information is not provided on a timely basis and $19,000 for each subsequent day that such information is not provided''.

(2) INCREASED PENALTY FOR KNOWINGLY REPORTING FALSE INFORMATION.—Section 1927(b)(3)(C)(ii) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(C)(ii)) is amended by striking ''$100,000'' and inserting ''$500,000''.

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

SEC. 205. IMPROVING TRANSPARENCY AND PREVENTING THE USE OF ABUSIVE SPREAD PRICING AND RELATED PRACTICES IN MEDICAID.

(a) PASS-THROUGH PRICING REQUIRED.—

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

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

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

"(i) is limited to—

"(I) ingredient cost; and

"(II) a professional dispensing fee that is not less than the profes-

sional dispensing fee that the State plan or waiver would pay if the plan or waiver was making the payment directly;

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

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

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

''(C) the entity or the PBM (as applicable) shall make available to the State, and the Secretary upon request, all costs and payments related to covered outpatient drugs and accompanying administrative services incurred, received, or made by the entity or the PBM, in-

cluding ingredient costs, professional dispensing fees, administrative fees, post-sale and post-invoice fees. Discounts, or related adjustments such as direct and indirect remuneration fees, and any and all remuneration; and

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

(2) CONFORMING AMENDMENT.—Clause (xiii) of section 1903(m)(2)(A) of such Act (42 U.S.C. 1396b(m)(2)(A)), as amended by section 202, is further amended—

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

(B) by inserting before the period at the end the following: '', and (V) pharmacy benefit management services provided by the entity, or

provided by a pharmacy benefit manager on behalf of the entity under a contract or other arrangement between the entity and the pharmacy benefit manager, shall comply with the requirements of section 1927(e)(6)''.

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

(b) SURVEY OF RETAIL PRICES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"(H) PENALTIES.—

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

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

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

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

''(I) REPORT ON SPECIALTY PHARMACIES.—

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

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

vey of retail prices to ensure national average drug acquisition costs capture drugs sold at specialty pharmacies and how such specialty pharmacies should be defined.'';

(C) in paragraph (2)—

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

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

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

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

(c) MANUFACTURER REPORTING OF WHOLESALE ACQUISITION COST.—Section 1927(b)(3) of such Act (42 U.S.C. 1396r–8(b)(3)), as amended by section 141, is further amended—

(1) in subparagraph (A)(i)—

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

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

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

(D) by adding at the end the following:

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

(2) in subparagraph (D)—

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

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

(C) in clause (vii), by striking the period and inserting ", and"; and

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

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

SEC. 206. T–MSIS DRUG DATA ANALYTICS REPORTS.

(a) IN GENERAL.—Not later than May 1 of each calendar year beginning with calendar year 2021, the Secretary of Health and Human Services (in this section referred to as the "Secretary") shall publish on a website of the Centers for Medicare & Medicaid Services that is accessible to the public a report of the most recently available data on provider prescribing patterns under the Medicaid program.

(b) CONTENT OF REPORT.—

(1) REQUIRED CONTENT.—Each report required under subsection (a) for a calendar year shall include the following information with respect to each State (and, to the extent available, with respect to Puerto Rico, the United States Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa):

(A) A comparison of covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act (42 U.S.C. 1396r–8(k)(2))) prescribing patterns under the State Medicaid plan or waiver of such plan (including drugs prescribed on a fee-for-service basis and drugs prescribed under managed care arrangements under such plan or waiver)—

(i) across all forms or models of reimbursement used under the plan or waiver;

(ii) within specialties and subspecialties, as defined by the Secretary;

(iii) by episodes of care for—

(I) each chronic disease category, as defined by the Secretary, that is represented in the 10 conditions that accounted for the greatest share of total spending under the plan or waiv-

er during the year that is the subject of the report;

(II) procedural groupings; and

(III) rare disease diagnosis codes;

(iv) by patient demographic characteristics, including race (to the extent that the Secretary determines that there is sufficient data available with respect to such characteristic in a majority of States), gender, and age;

(v) by patient high-utilizer or risk status; and

(vi) by high and low resource settings by facility and place of service categories, as determined by the Secretary.

(B) In the case of medical assistance for covered outpatient drugs (as so defined) provided under a State Medicaid plan or waiver of such plan in a managed care setting, an analysis of the differences in managed care prescribing patterns when a covered outpatient drug is prescribed in a managed care setting as compared to when the drug is prescribed in a fee-for-service setting.

(2) ADDITIONAL CONTENT.—A report required under subsection (a) for a calendar year may include State-specific information about prescription utilization management tools under State Medicaid plans or waivers of such plans, including—

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

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

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

(D) a comparison of the prescription utilization management tools applicable to each enrollment category under a State Medicaid plan or waiver; and

(E) a comparison of the prescription utilization management tools applicable under the State Medicaid plan or waiver by patient high-utilizer or risk status.

(3) ADDITIONAL ANALYSIS.—To the extent practicable, the Secretary shall include in each report published under subsection (a)—

(A) analyses of national, State, and local patterns of Medicaid population-based prescribing behaviors; and

(B) recommendations for administrative or legislative action to improve the effectiveness of, and reduce costs for, covered outpatient drugs under Medicaid while ensuring timely beneficiary access to medically necessary covered outpatient drugs.

(c) USE OF T–MSIS DATA.—Each report required under subsection (a) shall—

(1) be prepared using data and definitions from the Transformed Medicaid Statistical Information System (T–MSIS) data set (or a successor data set) that is not more than 24 months old on the date that the report is published; and

(2) as appropriate, include a description with respect to each State of the quality and complete-

ness of the data, as well as any necessary caveats describing the limitations of the data reported to the Secretary by the State that are sufficient to communicate the appropriate uses for the information.

(d) PREPARATION OF REPORT.—Each report required under subsection (a) shall be prepared by the Administrator for the Centers for Medicare & Medicaid Services.

(e) APPROPRIATION.—For fiscal year 2020 and each fiscal year thereafter, there is appropriated to the Secretary $2,000,000 to carry out this section.

SEC. 207. RISK-SHARING VALUE-BASED PAYMENT AGREEMENTS FOR COVERED OUTPATIENT DRUGS UNDER MEDICAID.

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

''(l) STATE OPTION TO PAY FOR COVERED OUTPATIENT DRUGS THROUGH RISK-SHARING VALUE-BASED AGREEMENTS.—

''(1) IN GENERAL.—Beginning January 1, 2022, a State shall have the option to pay (whether on a fee-for-service or managed care basis) for covered outpatient drugs that are potentially curative treatments intended for one-time use that are ad-

ministered to individuals under this title by entering into a risk-sharing value-based payment agreement with the manufacturer of the drug in accordance with the requirements of this subsection.

''(2) SECRETARIAL APPROVAL.—

''(A) IN GENERAL.—A State shall submit a request to the Secretary to enter into a risk-sharing value based payment agreement, and the Secretary shall not approve a proposed risk-sharing value-based payment agreement between a State and a manufacturer for payment for a covered outpatient drug of the manufacturer unless the following requirements are met:

''(i) MANUFACTURER IS PARTY TO REBATE AGREEMENT AND IN COMPLIANCE WITH REQUIREMENTS.—The manufacturer has a rebate agreement in effect as required under subsection (a) and (b) of this section and is in compliance with all applicable requirements under this title.

''(ii) NO INCREASE TO PROJECTED NET FEDERAL SPENDING.—

''(I) IN GENERAL.—The Chief Actuary certifies that the projected payments for each covered outpatient

drug under such proposed agreement would not result in greater estimated Federal spending under this title than the net Federal spending that would result in the absence of the agreement.

''(II) NET FEDERAL SPENDING DEFINED.—For purposes of this subsection, the term 'net Federal spending' means the amount of Federal payments the Chief Actuary estimates would be made under this title for administering a covered outpatient drug to an individual eligible for medical assistance under a State plan or a waiver of such plan, reduced by the amount of all rebates the Chief Actuary estimates would be paid with respect to the administering of such drug, including all rebates under this title and any supplemental or other additional rebates, in the absence of such an agreement.

''(III) INFORMATION.—The Chief Actuary shall make the certifications

required under this clause based on the most recently available and reliable drug pricing and product information. The State and manufacturer shall provide the Secretary and the Chief Actuary with all necessary information required to make the estimates needed for such certifications.

''(iii) LAUNCH AND LIST PRICE JUSTIFICATIONS.—The manufacturer submits all relevant information and supporting documentation necessary for pricing decisions as deemed appropriate by the Secretary, which shall be truthful and nonmisleading, including manufacturer information and supporting documentation for launch price or list price increases, and any applicable justification required under section 1128L.

''(iv) CONFIDENTIALITY OF INFORMATION; PENALTIES.—The provisions of subparagraphs (C) and (D) of subsection (b)(3) shall apply to a manufacturer that fails to submit the information and documentation required under clauses (ii) and

(iii) on a timely basis, or that knowingly provides false or misleading information, in the same manner as such provisions apply to a manufacturer with a rebate agreement under this section.

''(B) CONSIDERATION OF STATE REQUEST FOR APPROVAL.—

''(i) IN GENERAL.—The Secretary shall treat a State request for approval of a risk-sharing value-based payment agreement in the same manner that the Secretary treats a State plan amendment, and subpart B of part 430 of title 42, Code of Federal Regulations, including, subject to clause (ii), the timing requirements of section 430.16 of such title (as in effect on the date of enactment of this subsection), shall apply to a request for approval of a risk-sharing value-based payment agreement in the same manner as such subpart applies to a State plan amendment.

''(ii) TIMING.—The Secretary shall consult with the Commissioner of Food and Drugs as required under subparagraph (C) and make a determination on

whether to approve a request from a State for approval of a proposed risk-sharing value-based payment agreement (or request additional information necessary to allow the Secretary to make a determination with respect to such request for approval) within the time period, to the extent practicable, specified in section 430.16 of title 42, Code of Federal Regulations (as in effect on the date of enactment of this subsection), but in no case shall the Secretary take more than 180 days after the receipt of such request for approval or response to such request for additional information to make such a determination (or request additional information).

''(C) CONSULTATION WITH THE COMMISSIONER OF FOOD AND DRUGS.—In considering whether to approve a risk-sharing value-based payment agreement, the Secretary, to the extent necessary, shall consult with the Commissioner of Food and Drugs to determine whether the relevant clinical parameters specified in such agreement are appropriate.

''(3) INSTALLMENT-BASED PAYMENT STRUCTURE.—

''(A) IN GENERAL.—A risk-sharing value-based payment agreement shall provide for a payment structure under which, for every installment year of the agreement (subject to subparagraph (B)), the State shall pay the total installment year amount in equal installments to be paid at regular intervals over a period of time that shall be specified in the agreement.

''(B) REQUIREMENTS FOR INSTALLMENT PAYMENTS.—

''(i) TIMING OF FIRST PAYMENT.—The State shall make the first of the installment payments described in subparagraph (A) for an installment year not later than 30 days after the end of such year.

''(ii) LENGTH OF INSTALLMENT PERIOD.—The period of time over which the State shall make the installment payments described in subparagraph (A) for an installment year shall not be longer than 5 years.

''(iii) NONPAYMENT OR REDUCED PAYMENT OF INSTALLMENTS FOLLOWING

A FAILURE TO MEET CLINICAL PARAMETER.—If, prior to the payment date (as specified in the agreement) of any installment payment described in subparagraph (A) or any other alternative date or time frame (as otherwise specified in the agreement), the covered outpatient drug which is subject to the agreement fails to meet a relevant clinical parameter of the agreement, the agreement shall provide that—

"(I) the installment payment shall not be made; or

"(II) the installment payment shall be reduced by a percentage specified in the agreement that is based on the outcome achieved by the drug relative to the relevant clinical parameter.

"(4) NOTICE OF INTENT.—

"(A) IN GENERAL.—Subject to subparagraph (B), a manufacturer of a covered outpatient drug shall not be eligible to enter into a risk-sharing value-based payment agreement under this subsection with respect to such drug unless the manufacturer notifies the Secretary

that the manufacturer is interested in entering into such an agreement with respect to such drug. The decision to submit and timing of a request to enter into a proposed risk-sharing value-based payment agreement shall remain solely within the discretion of the State and shall only be effective upon Secretarial approval as required under this subsection.

''(B) TREATMENT OF SUBSEQUENTLY APPROVED DRUGS.—

''(i) IN GENERAL.—In the case of a manufacturer of a covered outpatient drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act after the date of enactment of this subsection, not more than 90 days after meeting with the Food and Drug Administration following phase II clinical trials for such drug (or, in the case of a drug described in clause (ii), not later than March 31, 2022), the manufacturer must notify the Secretary of the manufacturer's intent to enter into a risk-sharing value-based payment agreement under this sub-

section with respect to such drug. If no such meeting has occurred, the Secretary may use discretion as to whether a potentially curative treatment intended for one-time use may qualify for a risk-sharing value-based payment agreement under this section. A manufacturer notification of interest shall not have any influence on a decision for approval by the Food and Drug Administration.

''(ii) APPLICATION TO CERTAIN SUBSEQUENTLY APPROVED DRUGS.—A drug described in this clause is a covered outpatient drug of a manufacturer—

''(I) that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act after the date of enactment of this subsection; and

''(II) with respect to which, as of January 1, 2022, more than 90 days have passed after the manufacturer's meeting with the Food and Drug Ad-

ministration following phase II clinical trials for such drug.

''(iii) PARALLEL APPROVAL.—The Secretary, in coordination with the Administrator of the Centers for Medicare & Medicaid Services and the Commissioner of Food and Drugs, shall, to the extent practicable, approve a State's request to enter into a proposed risk-sharing value-based payment agreement that otherwise meets the requirements of this subsection at the time that such a drug is approved by the Food and Drug Administration to help provide that no State that wishes to enter into such an agreement is required to pay for the drug in full at one time if the State is seeking to pay over a period of time as outlined in the proposed agreement.

''(iv) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be applied or construed to modify or affect the timeframes or factors involved in the Secretary's determination of whether to approve or license a drug under section 505 of the Federal Food, Drug, and Cosmetic

Act or section 351 of the Public Health Service Act.

''(5) SPECIAL PAYMENT RULES.—

''(A) IN GENERAL.—Except as otherwise provided in this paragraph, with respect to an individual who is administered a unit of a covered outpatient drug that is purchased under a State plan by a State Medicaid agency under a risk-sharing value-based payment agreement in an installment year, the State shall remain liable to the manufacturer of such drug for payment for such unit without regard to whether the individual remains enrolled in the State plan under this title (or a waiver of such plan) for each installment year for which the State is to make installment payments for covered outpatient drugs purchased under the agreement in such year.

''(B) DEATH.—In the case of an individual described in subparagraph (A) who dies during the period described in such subparagraph, the State plan shall not be liable for any remaining payment for the unit of the covered outpatient drug administered to the individual which is

owed under the agreement described in such subparagraph.

''(C) WITHDRAWAL OF APPROVAL.—In the case of a covered outpatient drug that is the subject of a risk-sharing value-based agreement between a State and a manufacturer under this subsection, including a drug approved in accordance with section 506(c) of the Federal Food, Drug, and Cosmetic Act, and such drug is the subject of an application that has been withdrawn by the Secretary, the State plan shall not be liable for any remaining payment that is owed under the agreement.

''(D) ALTERNATIVE ARRANGEMENT UNDER AGREEMENT.—Subject to approval by the Secretary, the terms of a proposed risk-sharing value-based payment agreement submitted for approval by a State may provide that subparagraph (A) shall not apply.

''(E) GUIDANCE.—Not later than January 1, 2022, the Secretary shall issue guidance to States establishing a process for States to notify the Secretary when an individual who is administered a unit of a covered outpatient drug that is purchased by a State plan under a risk-

sharing value-based payment agreement ceases to be enrolled under the State plan under this title (or a waiver of such plan) or dies before the end of the installment period applicable to such unit under the agreement.

''(6) TREATMENT OF PAYMENTS UNDER RISK-SHARING VALUE-BASED AGREEMENTS FOR PURPOSES OF AVERAGE MANUFACTURER PRICE; BEST PRICE.—The Secretary shall treat any payments made to the manufacturer of a covered outpatient drug under a risk-sharing value-based payment agreement under this subsection during a rebate period in the same manner that the Secretary treats payments made under a State supplemental rebate agreement under sections 447.504(c)(19) and 447.505(c)(7) of title 42, Code of Federal Regulations (or any successor regulations) for purposes of determining average manufacturer price and best price under this section with respect to the covered outpatient drug and a rebate period and for purposes of offsets required under subsection (b)(1)(B).

''(7) ASSESSMENTS AND REPORT TO CONGRESS.—

''(A) ASSESSMENTS.—

''(i) IN GENERAL.—Not later than 180 days after the end of each assessment period of any risk-sharing value-based payment agreement for a State approved under this subsection, the Secretary shall conduct an evaluation of such agreement which shall include an evaluation by the Chief Actuary to determine whether program spending under the risk-sharing value-based payment agreement aligned with the projections for the agreement made under paragraph (2)(A)(ii), including an assessment of whether actual Federal spending under this title under the agreement was less or more than net Federal spending would have been in the absence of the agreement.

''(ii) ASSESSMENT PERIOD.—For purposes of clause (i)—

''(I) the first assessment period for a risk-sharing value-based payment agreement shall be the period of time over which payments are scheduled to be made under the agreement for the first 10 individuals who are

administered covered outpatient drugs under the agreement except that such period shall not exceed the 5-year period after the date on which the Secretary approves the agreement; and

''(II) each subsequent assessment period for a risk-sharing value-based payment agreement shall be the 5-year period following the end of the previous assessment period.

''(B) RESULTS OF ASSESSMENTS.—

''(i) TERMINATION OPTION.—If the Secretary determines as a result of the assessment by the Chief Actuary under subparagraph (A) that the actual Federal spending under this title for any covered outpatient drug that was the subject of the State's risk-sharing value-based payment agreement was greater than the net Federal spending that would have resulted in the absence of the agreement, the Secretary may terminate approval of such agreement and shall immediately conduct an assessment under this paragraph of any other ongoing risk-sharing value-based

payment agreement to which the same manufacturer is a party.

''(ii) REPAYMENT REQUIRED.—

''(I) IN GENERAL.—If the Secretary determines as a result of the assessment by the Chief Actuary under subparagraph (A) that the Federal spending under the risk-sharing value-based agreement for a covered outpatient drug that was subject to such agreement was greater than the net Federal spending that would have resulted in the absence of the agreement, the manufacturer shall repay the difference to the State and Federal governments in a timely manner as determined by the Secretary.

''(II) TERMINATION FOR FAILURE TO PAY.—The failure of a manufacturer to make repayments required under subclause (I) in a timely manner shall result in immediate termination of all risk-sharing value-based agreements to which the manufacturer is a party.

"(III) ADDITIONAL PENALTIES.—In the case of a manufacturer that fails to make repayments required under subclause (I), the Secretary may treat such manufacturer in the same manner as a manufacturer that fails to pay required rebates under this section, and the Secretary may—

"(aa) suspend or terminate the manufacturer's rebate agreement under this section; and

"(bb) pursue any other remedy that would be available if the manufacturer had failed to pay required rebates under this section.

"(C) REPORT TO CONGRESS.—Not later than 5 years after the first risk-sharing value-based payment agreement is approved under this subsection, the Secretary shall submit to Congress and make available to the public a report that includes—

"(i) an assessment of the impact of risk-sharing value-based payment agree-

ments on access for individuals who are eligible for benefits under a State plan or waiver under this title to medically necessary covered outpatient drugs and related treatments;

''(ii) an analysis of the impact of such agreements on overall State and Federal spending under this title;

''(iii) an assessment of the impact of such agreements on drug prices, including launch price and price increases; and

''(iv) such recommendations to Congress as the Secretary deems appropriate.

''(8) GUIDANCE AND REGULATIONS.—

''(A) IN GENERAL.—Not later than January 1, 2022, the Secretary shall issue guidance to States seeking to enter into risk-sharing value-based payment agreements under this subsection that includes a model template for such agreements. The Secretary may issue any additional guidance or promulgate regulations as necessary to implement and enforce the provisions of this subsection.

''(B) MODEL AGREEMENTS.—

"(i) IN GENERAL.—If a State expresses an interest in pursuing a risk-sharing value-based payment agreement under this subsection with a manufacturer for the purchase of a covered outpatient drug, the Secretary may share with such State any risk-sharing value-based agreement between a State and the manufacturer for the purchase of such drug that has been approved under this subsection. While such shared agreement may serve as a template for a State that wishes to propose, the use of a previously approved agreement shall not affect the submission and approval process for approval of a proposed risk-sharing value-based payment agreement under this subsection, including the requirements under paragraph (2)(A).

"(ii) CONFIDENTIALITY.—In the case of a risk-sharing value-based payment agreement that is disclosed to a State by the Secretary under this subparagraph and that is only in effect with respect to a single State, the confidentiality of information

provisions described in subsection (b)(3)(D) shall apply to such information.

''(C) OIG CONSULTATION.—

''(i) IN GENERAL.—The Secretary shall consult with the Office of the Inspector General of the Department of Health and Human Services to determine whether there are potential program integrity concerns with agreement approvals or templates and address accordingly.

''(ii) OIG POLICY UPDATES AS NECESSARY.—The Inspector General of the Department of Health and Human Services shall review and update, as necessary, any policies or guidelines of the Office of the Inspector General of the Department of Human Services (including policies related to the enforcement of section 1128B) to accommodate the use of risk-sharing value-based payment agreements in accordance with this section.

''(9) RULES OF CONSTRUCTION.—

''(A) MODIFICATIONS.—Nothing in this subsection or any regulations promulgated under this subsection shall prohibit a State

from requesting a modification from the Secretary to the terms of a risk-sharing value-based payment agreement. A modification that is expected to result in any increase to projected net State or Federal spending under the agreement shall be subject to recertification by the Chief Actuary as described in paragraph (2)(A)(ii) before the modification may be approved.

''(B) REBATE AGREEMENTS.—Nothing in this subsection shall be construed as requiring a State to enter into a risk-sharing value-based payment agreement or as limiting or superseding the ability of a State to enter into a supplemental rebate agreement for a covered outpatient drug.

''(C) FFP FOR PAYMENTS UNDER RISK-SHARING VALUE-BASED PAYMENT AGREEMENTS.—Federal financial participation shall be available under this title for any payment made by a State to a manufacturer for a covered outpatient drug under a risk-sharing value-based payment agreement in accordance with this subsection, except that no Federal financial participation shall be available for any

payment made by a State to a manufacturer under such an agreement on and after the effective date of a disapproval of such agreement by the Secretary.

''(D) CONTINUED APPLICATION OF OTHER PROVISIONS.—Except as expressly provided in this subsection, nothing in this subsection or in any regulations promulgated under this subsection shall affect the application of any other provision of this Act.

''(10) APPROPRIATIONS.—For fiscal year 2020 and each fiscal year thereafter, there are appropriated to the Secretary $5,000,000 for the purpose of carrying out this subsection.

''(11) DEFINITIONS.—In this subsection:

''(A) CHIEF ACTUARY.—The term 'Chief Actuary' means the Chief Actuary of the Centers for Medicare & Medicaid Services.

''(B) INSTALLMENT YEAR.—The term 'installment year' means, with respect to a risk-sharing value-based payment agreement, a 12-month period during which a covered outpatient drug is administered under the agreement.

''(C) POTENTIALLY CURATIVE TREATMENT INTENDED FOR ONE-TIME USE.—The term 'po-

tentially curative treatment intended for one-time use' means a treatment that consists of the administration of a covered outpatient drug that—

''(i) is a form of gene therapy for a rare disease, as defined by the Commissioner of Food and Drugs, designated under section 526 of the Federal Food, Drug, and Cosmetics Act, and approved under section 505 of such Act or licensed under subsection (a) or (k) of section 351 of the Public Health Service Act to treat a serious or life-threatening disease or condition;

''(ii) if administered in accordance with the labeling of such drug, is expected to result in either—

''(I) the cure of such disease or condition; or

''(II) a reduction in the symptoms of such disease or condition to the extent that such disease or condition is not expected to lead to early mortality; and

''(iii) is expected to achieve a result described in clause (ii), which may be achieved over an extended period of time, after not more than 3 administrations.

''(D) RELEVANT CLINICAL PARAMETER.—The term 'relevant clinical parameter' means, with respect to a covered outpatient drug that is the subject of a risk-sharing value-based payment agreement—

''(i) a clinical endpoint specified in the drug's labeling or supported by one or more of the compendia described in section 1861(t)(2)(B)(ii)(I) that—

''(I) is able to be measured or evaluated on an annual basis for each year of the agreement on an independent basis by a provider or other entity; and

''(II) is required to be achieved (based on observed metrics in patient populations) under the terms of the agreement; or

''(ii) a surrogate endpoint (as defined in section 507(e)(9) of the Federal Food, Drug, and Cosmetic Act), including those

developed by patient-focused drug development tools, that—

"(I) is able to be measured or evaluated on an annual basis for each year of the agreement on an independent basis by a provider or other entity; and

"(II) has been qualified by the Food and Drug Administration.

"(E) RISK-SHARING VALUE-BASED PAYMENT AGREEMENT.—The term 'risk-sharing value-based payment agreement' means an agreement between a State plan and a manufacturer—

"(i) for the purchase of a covered outpatient drug of the manufacturer that is a potentially curative treatment intended for one-time use;

"(ii) under which payment for such drug shall be made pursuant to an installment-based payment structure that meets the requirements of paragraph (3);

"(iii) which conditions payment on the achievement of at least 2 relevant clinical

parameters (as defined in subparagraph (C));

''(iv) which provides that—

''(I) the State plan will directly reimburse the manufacturer for the drug; or

''(II) a third party will reimburse the manufacture in a manner approved by the Secretary; and

''(v) is approved by the Secretary in accordance with paragraph (2).

''(F) TOTAL INSTALLMENT YEAR AMOUNT.—The term 'total installment year amount' means, with respect to a risk-sharing value-based payment agreement for the purchase of a covered outpatient drug and an installment year, an amount equal to the product of—

''(i) the unit price of the drug charged under the agreement; and

''(ii) the number of units of such drug administered under the agreement during such installment year.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 1903(i)(10)(A) of the Social Security Act (42 U.S.C. 1396b(i)(10)(A)) is amended by striking ''or unless section 1927(a)(3) applies'' and inserting '', section 1927(a)(3) applies with respect to such drugs, or such drugs are the subject of a risk-sharing value-based payment agreement under section 1927(l)''.

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

(A) in paragraph (1)(A), by inserting ''(except for drugs for which payment is made by a State under a risk-sharing value-based payment agreement under subsection (l))'' after ''under the State plan for such period''; and

(B) in paragraph (3)—

(i) in subparagraph (C)(i), by inserting ''or subsection (l)(2)(A)'' after ''subparagraph (A)''; and

(ii) in subparagraph (D), in the matter preceding clause (i), by inserting '', under subsection (l)(2)(A),'' after ''under this paragraph''.

SEC. 208. APPLYING MEDICAID DRUG REBATE REQUIREMENT TO DRUGS PROVIDED AS PART OF OUTPATIENT HOSPITAL SERVICES.

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

''(3) LIMITING DEFINITION.—

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

''(i) Inpatient hospital services.

''(ii) Hospice services.

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

''(iv) Physicians' services.

''(v) Outpatient hospital services.

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

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

''(viii) Renal dialysis.

''(B) OTHER EXCLUSIONS.—Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication.

''(C) STATE OPTION.—At the option of a State, such term may include any drug, biological product, or insulin for which the State is the primary payer under this title or a demonstration project concerning this title, and that is provided on an outpatient basis as part of, or as incident to and in the same setting as, described in clause (iv) or (v) of subparagraph (A) and for which payment is made as part of payment for such services.

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

best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.''.

(b) EFFECTIVE DATE; IMPLEMENTATION GUIDANCE.—

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

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

TITLE III—FOOD AND DRUG ADMINISTRATION

Subtitle A—CREATES Act

SEC. 301. ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) DEFINITIONS.—In this section—

(1) the term ''commercially reasonable, market-based terms'' means—

(A) a nondiscriminatory price for the sale of the covered product at or below, but not greater than, the most recent wholesale acquisition cost for the drug, as defined in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B));

(B) a schedule for delivery that results in the transfer of the covered product to the eligible product developer consistent with the timing under subsection (b)(2)(A)(iv); and

(C) no additional conditions are imposed on the sale of the covered product;

(2) the term ''covered product''—

(A) means—

(i) any drug approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) any combination of a drug or biological product described in clause (i); or

(iii) when reasonably necessary to support approval of an application under

section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or section 351 of the Public Health Service Act (42 U.S.C. 262), as applicable, or otherwise meet the requirements for approval under either such section, any product, including any device, that is marketed or intended for use with such a drug or biological product; and

(B) does not include any drug or biological product that appears on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), unless—

(i) the drug or biological product has been on the drug shortage list in effect under such section 506E continuously for more than 6 months; or

(ii) the Secretary determines that inclusion of the drug or biological product as a covered product is likely to contribute to alleviating or preventing a shortage;

(3) the term ''device'' has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

(4) the term ''eligible product developer'' means a person that seeks to develop a product for approval pursuant to an application for approval under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or for licensing pursuant to an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k));

(5) the term ''license holder'' means the holder of an application approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the holder of a license under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) for a covered product;

(6) the term ''REMS'' means a risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1);

(7) the term ''REMS with ETASU'' means a REMS that contains elements to assure safe use under section 505–1(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f));

(8) the term ''Secretary'' means the Secretary of Health and Human Services;

(9) the term ''single, shared system of elements to assure safe use'' means a single, shared system of elements to assure safe use under section 505–1(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f)); and

(10) the term ''sufficient quantities'' means an amount of a covered product that the eligible product developer determines allows it to—

(A) conduct testing to support an application under—

(i) subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

(ii) section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); and

(B) fulfill any regulatory requirements relating to approval of such an application.

(b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITIES OF A COVERED PRODUCT.—

(1) IN GENERAL.—An eligible product developer may bring a civil action against the license holder for a covered product seeking relief under this subsection in an appropriate district court of the United States alleging that the license holder has declined

to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.

(2) ELEMENTS.—

(A) IN GENERAL.—To prevail in a civil action brought under paragraph (1), an eligible product developer shall prove, by a preponderance of the evidence—

(i) that—

(I) the covered product is not subject to a REMS with ETASU; or

(II) if the covered product is subject to a REMS with ETASU—

(aa) the eligible product developer has obtained a covered product authorization from the Secretary in accordance with subparagraph (B); and

(bb) the eligible product developer has provided a copy of the covered product authorization to the license holder;

(ii) that, as of the date on which the civil action is filed, the product developer has not obtained sufficient quantities of

the covered product on commercially reasonable, market-based terms;

(iii) that the eligible product developer has submitted a written request to purchase sufficient quantities of the covered product to the license holder and such request—

(I) was sent to a named corporate officer of the license holder;

(II) was made by certified or registered mail with return receipt requested;

(III) specified an individual as the point of contact for the license holder to direct communications related to the sale of the covered product to the eligible product developer and a means for electronic and written communications with that individual; and

(IV) specified an address to which the covered product was to be shipped upon reaching an agreement to transfer the covered product; and

(iv) that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product on commercially reasonable, market-based terms—

(I) for a covered product that is not subject to a REMS with ETASU, by the date that is 31 days after the date on which the license holder received the request for the covered product; and

(II) for a covered product that is subject to a REMS with ETASU, by 31 days after the later of—

(aa) the date on which the license holder received the request for the covered product; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with subparagraph (B).

(B) AUTHORIZATION FOR COVERED PRODUCT SUBJECT TO A REMS WITH ETASU.—

(i) REQUEST.—An eligible product developer may submit to the Secretary a written request for the eligible product developer to be authorized to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU.

(ii) AUTHORIZATION.—Not later than 120 days after the date on which a request under clause (i) is received, the Secretary shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for purposes of—

(I) development and testing that does not involve human clinical trials, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or

(II) development and testing that involves human clinical trials, if the eligible product developer has—

(aa)(AA) submitted protocols, informed consent documents, and informational mate-

rials for testing that include protections that provide safety protections comparable to those provided by the REMS for the covered product; or

(BB) otherwise satisfied the Secretary that such protections will be provided; and

(bb) met any other requirements the Secretary may establish.

(iii) NOTICE.—A covered product authorization issued under this subparagraph shall state that the provision of the covered product by the license holder under the terms of the authorization will not be a violation of the REMS for the covered product.

(3) AFFIRMATIVE DEFENSE.—In a civil action brought under paragraph (1), it shall be an affirmative defense, on which the defendant has the burden of persuasion by a preponderance of the evidence—

(A) that, on the date on which the eligible product developer requested to purchase suffi-

cient quantities of the covered product from the license holder—

(i) neither the license holder nor any of its agents, wholesalers, or distributors was engaged in the manufacturing or commercial marketing of the covered product; and

(ii) neither the license holder nor any of its agents, wholesalers, or distributors otherwise had access to inventory of the covered product to supply to the eligible product developer on commercially reasonable, market-based terms;

(B) that—

(i) the license holder sells the covered product through agents, distributors, or wholesalers;

(ii) the license holder has placed no restrictions, explicit or implicit, on its agents, distributors, or wholesalers to sell covered products to eligible product developers; and

(iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially rea-

sonable, market-based terms from the agents, distributors, or wholesalers of the license holder; or

(C) that the license holder made an offer to the individual specified pursuant to paragraph (2)(A)(iii)(III), by a means of communication (electronic, written, or both) specified pursuant to such paragraph, to sell sufficient quantities of the covered product to the eligible product developer at commercially reasonable market-based terms—

(i) for a covered product that is not subject to a REMS with ETASU, by the date that is 14 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 7 days after the date on which the eligible product developer received such offer from the license holder; or

(ii) for a covered product that is subject to a REMS with ETASU, by the date that is 20 days after the date on which the license holder received the request for the

covered product, and the eligible product developer did not accept such offer by the date that is 10 days after the date on which the eligible product developer received such offer from the license holder.

(4) REMEDIES.—

(A) IN GENERAL.—If an eligible product developer prevails in a civil action brought under paragraph (1), the court shall—

(i) order the license holder to provide to the eligible product developer without delay sufficient quantities of the covered product on commercially reasonable, market-based terms;

(ii) award to the eligible product developer reasonable attorney's fees and costs of the civil action; and

(iii) award to the eligible product developer a monetary amount sufficient to deter the license holder from failing to provide eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—

(I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or

(II) that the license holder failed to comply with an order issued under clause (i).

(B) MAXIMUM MONETARY AMOUNT.—A monetary amount awarded under subparagraph (A)(iii) shall not be greater than the revenue that the license holder earned on the covered product during the period—

(i) beginning on—

(I) for a covered product that is not subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder received the request; or

(II) for a covered product that is subject to a REMS with ETASU, the date that is 31 days after the later of—

(aa) the date on which the license holder received the request; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with paragraph (2)(B); and

(ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.

(C) AVOIDANCE OF DELAY.—The court may issue an order under subparagraph (A)(i) before conducting further proceedings that may be necessary to determine whether the eligible product developer is entitled to an award under clause (ii) or (iii) of subparagraph (A), or the amount of any such award.

(c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim under Federal, State, or local law arising out of the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered product during development or testing activities described in this section, includ-

ing transportation, handling, use, or disposal of the covered product by the eligible product developer.

(d) NO VIOLATION OF REMS.—Section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) is amended by adding at the end the following new subsection:

''(l) PROVISION OF SAMPLES NOT A VIOLATION OF STRATEGY.—The provision of samples of a covered product to an eligible product developer (as those terms are defined in section 301(a) of the Lower Costs, More Cures Act of 2019) shall not be considered a violation of the requirements of any risk evaluation and mitigation strategy that may be in place under this section for such drug.''.

(e) RULE OF CONSTRUCTION.—

(1) DEFINITION.—In this subsection, the term ''antitrust laws''—

(A) has the meaning given the term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12); and

(B) includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(2) ANTITRUST LAWS.—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

SEC. 302. REMS APPROVAL PROCESS FOR SUBSEQUENT FILERS.

Section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), as amended by section 301, is further amended—

(1) in subsection (g)(4)(B)—

(A) in clause (i) by striking ''or'' after the semicolon;

(B) in clause (ii) by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(iii) accommodate different, comparable aspects of the elements to assure safe use for a drug that is the subject of an application under section 505(j), and the applicable listed drug.'';

(2) in subsection (i)(1), by striking subparagraph (C) and inserting the following:

''(C)(i) Elements to assure safe use, if required under subsection (f) for the listed drug, which, subject to clause (ii), for a drug that is

the subject of an application under section 505(j) may use—

''(I) a single, shared system with the listed drug under subsection (f); or

''(II) a different, comparable aspect of the elements to assure safe use under subsection (f).

''(ii) The Secretary may require a drug that is the subject of an application under section 505(j) and the listed drug to use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the elements to assure safe use could satisfy the requirements of subsection (f).'';

(3) in subsection (i), by adding at the end the following:

''(3) SHARED REMS.—If the Secretary approves, in accordance with paragraph (1)(C)(i)(II), a different, comparable aspect of the elements to assure safe use under subsection (f) for a drug that is the subject of an abbreviated new drug application under section 505(j), the Secretary may require that such different comparable aspect of the elements to

assure safe use can be used with respect to any other drug that is the subject of an application under section 505(j) or 505(b) that references the same listed drug.''; and

(4) by adding at the end the following:

''(m) SEPARATE REMS.—When used in this section, the terms 'different, comparable aspect of the elements to assure safe use' or 'different, comparable approved risk evaluation and mitigation strategies' means a risk evaluation and mitigation strategy for a drug that is the subject of an application under section 505(j) that uses different methods or operational means than the strategy required under subsection (a) for the applicable listed drug, or other application under section 505(j) with the same such listed drug, but achieves the same level of safety as such strategy.''.

SEC. 303. RULE OF CONSTRUCTION.

(a) IN GENERAL.—Nothing in this subtitle, the amendments made by this subtitle, or in section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), shall be construed as—

(1) prohibiting a license holder from providing an eligible product developer access to a covered product in the absence of an authorization under this subtitle; or

(2) in any way negating the applicability of a REMS with ETASU, as otherwise required under such section 505–1, with respect to such covered product.

(b) DEFINITIONS.—In this section, the terms ''covered product'', ''eligible product developer'', ''license holder'', and ''REMS with ETASU'' have the meanings given such terms in section 301(a).

Subtitle B—Pay-for-Delay

SEC. 311. UNLAWFUL AGREEMENTS.

(a) AGREEMENTS PROHIBITED.—Subject to subsections (b) and (c), it shall be unlawful for an NDA or BLA holder and a subsequent filer (or for two subsequent filers) to enter into, or carry out, an agreement resolving or settling a covered patent infringement claim on a final or interim basis if under such agreement—

(1) a subsequent filer directly or indirectly receives from such holder (or in the case of such an agreement between two subsequent filers, the other subsequent filer) anything of value, including a license; and

(2) the subsequent filer agrees to limit or forego research on, or development, manufacturing, marketing, or sales, for any period of time, of the covered product that is the subject of the application

described in subparagraph (A) or (B) of subsection (g)(8).

(b) EXCLUSION.—It shall not be unlawful under subsection (a) if a party to an agreement described in such subsection demonstrates by clear and convincing evidence that the value described in subsection (a)(1) is compensation solely for other goods or services that the subsequent filer has promised to provide.

(c) LIMITATION.—Nothing in this section shall prohibit an agreement resolving or settling a covered patent infringement claim in which the consideration granted by the NDA or BLA holder to the subsequent filer (or from one subsequent filer to another) as part of the resolution or settlement includes only one or more of the following:

(1) The right to market the covered product that is the subject of the application described in subparagraph (A) or (B) of subsection (g)(8) in the United States before the expiration of—

(A) any patent that is the basis of the covered patent infringement claim; or

(B) any patent right or other statutory exclusivity that would prevent the marketing of such covered product.

(2) A payment for reasonable litigation expenses not to exceed $7,500,000 in the aggregate.

(3) A covenant not to sue on any claim that such covered product infringes a patent.

(d) ENFORCEMENT BY FEDERAL TRADE COMMISSION.—

(1) GENERAL APPLICATION.—The requirements of this section apply, according to their terms, to an NDA or BLA holder or subsequent filer that is—

(A) a person, partnership, or corporation over which the Commission has authority pursuant to section 5(a)(2) of the Federal Trade Commission Act (15 U.S.C. 45(a)(2)); or

(B) a person, partnership, or corporation over which the Commission would have authority pursuant to such section but for the fact that such person, partnership, or corporation is not organized to carry on business for its own profit or that of its members.

(2) UNFAIR OR DECEPTIVE ACTS OR PRACTICES ENFORCEMENT AUTHORITY.—

(A) IN GENERAL.—A violation of this section shall be treated as an unfair or deceptive act or practice in violation of section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)).

(B) POWERS OF COMMISSION.—Except as provided in subparagraph (C) and paragraphs (1)(B) and (3)—

(i) the Commission shall enforce this section in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section; and

(ii) any NDA or BLA holder or subsequent filer that violates this section shall be subject to the penalties and entitled to the privileges and immunities provided in the Federal Trade Commission Act.

(C) JUDICIAL REVIEW.—In the case of a cease and desist order issued by the Commission under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) for violation of this section, a party to such order may obtain judicial review of such order as provided in such section 5, except that—

(i) such review may only be obtained in—

(I) the United States Court of Appeals for the District of Columbia Circuit;

(II) the United States Court of Appeals for the circuit in which the ultimate parent entity, as defined in section 801.1(a)(3) of title 16, Code of Federal Regulations, or any successor thereto, of the NDA or BLA holder (if any such holder is a party to such order) is incorporated as of the date that the application described in subparagraph (A) or (B) of subsection (g)(8) or an approved application that is deemed to be a license for a biological product under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148; 124 Stat. 817) is submitted to the Commissioner of Food and Drugs; or

(III) the United States Court of Appeals for the circuit in which the

ultimate parent entity, as so defined, of any subsequent filer that is a party to such order is incorporated as of the date that the application described in subparagraph (A) or (B) of subsection (g)(8) is submitted to the Commissioner of Food and Drugs; and

(ii) the petition for review shall be filed in the court not later than 30 days after such order is served on the party seeking review.

(3) ADDITIONAL ENFORCEMENT AUTHORITY.—

(A) CIVIL PENALTY.—The Commission may commence a civil action to recover a civil penalty in a district court of the United States against any NDA or BLA holder or subsequent filer that violates this section.

(B) SPECIAL RULE FOR RECOVERY OF PENALTY IF CEASE AND DESIST ORDER ISSUED.—

(i) IN GENERAL.—If the Commission has issued a cease and desist order in a proceeding under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) for violation of this section—

(I) the Commission may commence a civil action under subparagraph (A) to recover a civil penalty against any party to such order at any time before the expiration of the 1-year period beginning on the date on which such order becomes final under section 5(g) of such Act (15 U.S.C. 45(g)); and

(II) in such civil action, the findings of the Commission as to the material facts in such proceeding shall be conclusive, unless—

(aa) the terms of such order expressly provide that the Commission's findings shall not be conclusive; or

(bb) such order became final by reason of section 5(g)(1) of such Act (15 U.S.C. 45(g)(1)), in which case such findings shall be conclusive if supported by evidence.

(ii) RELATIONSHIP TO PENALTY FOR VIOLATION OF AN ORDER.—The penalty

provided in clause (i) for violation of this section is separate from and in addition to any penalty that may be incurred for violation of an order of the Commission under section 5(l) of the Federal Trade Commission Act (15 U.S.C. 45(l)).

(C) AMOUNT OF PENALTY.—

(i) IN GENERAL.—The amount of a civil penalty imposed in a civil action under subparagraph (A) on a party to an agreement described in subsection (a) shall be sufficient to deter violations of this section, but in no event greater than—

(I) if such party is the NDA or BLA holder (or, in the case of an agreement between two subsequent filers, the subsequent filer who gave the value described in subsection (a)(1)), the greater of—

(aa) 3 times the value received by such NDA or BLA holder (or by such subsequent filer) that is reasonably attributable to the violation of this section; or

(bb) 3 times the value given to the subsequent filer (or to the other subsequent filer) reasonably attributable to the violation of this section; and

(II) if such party is the subsequent filer (or, in the case of an agreement between two subsequent filers, the subsequent filer who received the value described in subsection (a)(1)), 3 times the value received by such subsequent filer that is reasonably attributable to the violation of this section.

(ii) FACTORS FOR CONSIDERATION.—In determining such amount, the court shall take into account—

(I) the nature, circumstances, extent, and gravity of the violation;

(II) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the NDA or BLA holder (or, in the case of an

agreement between two subsequent filers, the subsequent filer who gave the value described in subsection (a)(1)), compensation received by the subsequent filer (or, in the case of an agreement between two subsequent filers, the subsequent filer who received the value described in subsection (a)(1)), and the amount of commerce affected; and

(III) other matters that justice requires.

(D) INJUNCTIONS AND OTHER EQUITABLE RELIEF.—In a civil action under subparagraph (A), the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law.

(5) PRESERVATION OF AUTHORITY OF COMMISSION.—Nothing in this section shall be construed to

affect any authority of the Commission under any other provision of law.

(e) FEDERAL TRADE COMMISSION RULEMAKING.—The Commission may, in its discretion, by rule promulgated under section 553 of title 5, United States Code, exempt from this section certain agreements described in subsection (a) if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers.

(f) ANTITRUST LAWS.—Nothing in this section shall modify, impair, limit, or supersede the applicability of the antitrust laws as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), and of section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit, or supersede the right of a subsequent filer to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition.

(g) DEFINITIONS.—In this section:

(1) AGREEMENT RESOLVING OR SETTLING A COVERED PATENT INFRINGEMENT CLAIM.—The term ''agreement resolving or settling a covered pat-

ent infringement claim'' means any agreement that—

(A) resolves or settles a covered patent infringement claim; or

(B) is contingent upon, provides for a contingent condition for, or is otherwise related to the resolution or settlement of a covered patent infringement claim.

(2) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

(3) COVERED PATENT INFRINGEMENT CLAIM.—The term ''covered patent infringement claim'' means an allegation made by the NDA or BLA holder to a subsequent filer (or, in the case of an agreement between two subsequent filers, by one subsequent filer to another), whether or not included in a complaint filed with a court of law, that—

(A) the submission of the application described in subparagraph (A) or (B) of paragraph (9), or the manufacture, use, offering for sale, sale, or importation into the United States of a covered product that is the subject of such an application—

(i) in the case of an agreement between an NDA or BLA holder and a sub-

sequent filer, infringes any patent owned by, or exclusively licensed to, the NDA or BLA holder of the covered product; or

(ii) in the case of an agreement between two subsequent filers, infringes any patent owned by the subsequent filer; or

(B) in the case of an agreement between an NDA or BLA holder and a subsequent filer, the covered product to be manufactured under such application uses a covered product as claimed in a published patent application.

(4) COVERED PRODUCT.—The term ''covered product'' means a drug (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g))), including a biological product (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(5) NDA OR BLA HOLDER.—The term ''NDA or BLA holder'' means—

(A) the holder of—

(i) an approved new drug application filed under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) for a covered product; or

(ii) a biologics license application filed under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product;

(B) a person owning or controlling enforcement of the patent on—

(i) the list published under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) in connection with the application described in subparagraph (A)(i); or

(ii) any list published under section 351 of the Public Health Service Act (42 U.S.C. 262) comprised of patents associated with biologics license applications filed under section 351(a) of such Act (42 U.S.C. 262(a)); or

(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any entity described in subparagraph (A) or (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

(6) PATENT.—The term ''patent'' means a patent issued by the United States Patent and Trademark Office.

(7) STATUTORY EXCLUSIVITY.—The term ''statutory exclusivity'' means those prohibitions on the submission or approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year exclusivity), clauses (ii) through (iv) of section 505(j)(5)(F) (5-year and 3-year exclusivity), section 505(j)(5)(B)(iv) (180-day exclusivity), section 527 (orphan drug exclusivity), section 505A (pediatric exclusivity), or section 505E (qualified infectious disease product exclusivity) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 355(j)(5)(F), 360cc, 355a, 355f), or prohibitions on the submission or licensing of biologics license applications under section 351(k)(6) (interchangeable biological product exclusivity) or section 351(k)(7) (biological product reference product exclusivity) of the Public Health Service Act (42 U.S.C. 262(k)(6), (7)).

(8) SUBSEQUENT FILER.—The term ''subsequent filer'' means—

(A) in the case of a drug, a party that owns or controls an abbreviated new drug appli-

cation submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) or a new drug application submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21U.S.C. 355(b)(2)) and filed under section 505(b)(1) of such Act (21 U.S.C. 355(b)(1)) or has the exclusive rights to distribute the covered product that is the subject of such application; or

(B) in the case of a biological product, a party that owns or controls an application filed with the Food and Drug Administration under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) or has the exclusive rights to distribute the biological product that is the subject of such application.

(h) EFFECTIVE DATE.—This section applies with respect to agreements described in subsection (a) entered into on or after the date of the enactment of this Act.

SEC. 312. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 1111(7) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by inserting ''or the owner of a patent for which

a claim of infringement could reasonably be asserted against any person for making, using, offering to sell, selling, or importing into the United States a biological product that is the subject of a biosimilar biological product application'' before the period at the end.

(b) CERTIFICATION OF AGREEMENTS.—Section 1112 of such Act (21 U.S.C. 355 note) is amended by adding at the end the following:

''(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement under subsection (a) or (b) that is required to be filed under subsection (c) shall, within 30 days of such filing, execute and file with the Assistant Attorney General and the Commission a certification as follows: 'I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification—

'''(1) represent the complete, final, and exclusive agreement between the parties;

'''(2) include any ancillary agreements that are contingent upon, provide a contingent condition for,

were entered into within 30 days of, or are otherwise related to, the referenced agreement; and

"'(3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.'.".

SEC. 313. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by inserting "section 311 of the Lower Costs, More Cures Act of 2019 or" after "that the agreement has violated".

SEC. 314. COMMISSION LITIGATION AUTHORITY.

Section 16(a)(2) of the Federal Trade Commission Act (15 U.S.C. 56(a)(2)) is amended—

(1) in subparagraph (D), by striking "or" after the semicolon;

(2) in subparagraph (E), by inserting "or" after the semicolon; and

(3) by inserting after subparagraph (E) the following:

"(F) under section 311(d)(3)(A) of the Lower Costs, More Cures Act of 2019;".

SEC. 315. STATUTE OF LIMITATIONS.

(a) IN GENERAL.—Except as provided in subsection (b), the Commission shall commence any administrative proceeding or civil action to enforce section 311 of this Act not later than 6 years after the date on which the parties to the agreement file the Notice of Agreement as provided by section 1112(c)(2) and (d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note).

(b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND DESIST ORDER.—If the Commission has issued a cease and desist order under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) for violation of section 311 of this Act and the proceeding for the issuance of such order was commenced within the period required by subsection (a) of this section, such subsection does not prohibit the commencement, after such period, of a civil action under section 311(d)(3)(A) against a party to such order or a civil action under subsection (l) of such section 5 for violation of such order.

Subtitle C—BLOCKING Act

SEC. 321. CHANGE CONDITIONS OF FIRST GENERIC EXCLUSIVITY TO SPUR ACCESS AND COMPETITION.

(a) IN GENERAL.—Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amended—

(1) in subclause (I), by striking ''180 days after'' and all that follows through the period at the end and inserting the following: ''180 days after the earlier of—

''(aa) the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant; or

''(bb) the applicable date specified in subclause (III).''; and

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

''(III) APPLICABLE DATE.—The applicable date specified in this subclause, with respect to an application for a drug described in subclause (I), is the date on which each of the following conditions is first met:

''(aa) The approval of such an application could be made effective, but for the eligibility of a first applicant for 180-day exclusivity under this clause.

''(bb) At least 30 months have passed since the date of submission of

an application for the drug by at least one first applicant.

''(cc) Approval of an application for the drug submitted by at least one first applicant is not precluded under clause (iii).

''(dd) No application for the drug submitted by any first applicant is approved at the time the conditions under items (aa), (bb), and (cc) are all met, regardless of whether such an application is subsequently approved.''.

(b) INFORMATION.—The Secretary of Health and Human Services shall—

(1) not later than 120 days after the date of enactment of this Act, publish, as appropriate and available, information sufficient to allow applicants to assess whether the conditions described in section 505(j)(5)(B)(iv)(III) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) are satisfied for all applications where the exclusivity period under clause (iv)(I) of section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (as amended by such subsection) has not expired; and

(2) publish updates to such information to reflect the most recent information available to the Secretary.

Subtitle D—Purple Book

SEC. 331. PUBLIC LISTING.

Section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is amended by adding at the end the following:

''(9) PUBLIC LISTING.—

''(A) IN GENERAL.—

''(i) INITIAL PUBLICATION.—Not later than 180 days after the date of enactment of the Lower Costs, More Cures Act of 2019, the Secretary shall publish and make available to the public in a searchable, electronic format—

''(I) a list in alphabetical order of the nonproprietary or proper name of each biological product for which a biologics license under subsection (a) or this subsection is in effect, or that has been deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price

Competition and Innovation Act of 2009, as of such date of enactment;

''(II) the date of approval of the marketing application and the application number; and

''(III) the marketing or licensure status of the biological product for which a biologics license under subsection (a) or this subsection is in effect or that has been deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

''(ii) REVISIONS.—Every 30 days after the publication of the first list under clause (i), the Secretary shall revise the list to include each biological product which has been licensed under subsection (a) or this subsection during the 30-day period.

''(iii) PATENT INFORMATION.—Not later than 30 days after a list of patents under subsection (l)(3)(A), or a supplement to such list under subsection (l)(7), has been provided by the reference product

sponsor to the subsection (k) applicant respecting a biological product included on the list published under this subparagraph, the reference product sponsor shall provide such list of patents (or supplement thereto) and their corresponding expiry dates to the Secretary, and the Secretary shall, in revisions made under clause (ii), include such information for such biological product. Within 30 days of providing any subsequent or supplemental list of patents to any subsequent subsection (k) applicant under subsection (l)(3)(A) or (l)(7), the reference product sponsor shall update the information provided to the Secretary under this clause with any additional patents from such subsequent or supplemental list and their corresponding expiry dates.

''(iv) LISTING OF EXCLUSIVITIES.—For each biological product included on the list published under this subparagraph, the Secretary shall specify each exclusivity period that is applicable and has not concluded under paragraph (6) or paragraph (7).

"(B) WITHDRAWAL OR SUSPENSION OF LICENSURE.—If the licensing of a biological product was withdrawn or suspended for safety, purity, or potency reasons, it may not be published in the list under subparagraph (A). If the withdrawal or suspension occurred after its publication in such list, the reference product sponsor shall notify the Secretary that—

"(i) the biological product shall be immediately removed from such list—

"(I) for the same period as the withdrawal or suspension; or

"(II) if the biological product has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety, purity, or potency reasons; and

"(ii) a notice of the removal shall be published in the Federal Register.".

SEC. 332. REVIEW AND REPORT ON TYPES OF INFORMATION TO BE LISTED.

Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) solicit public comment regarding the type of information, if any, that should be added to or removed from the list required by paragraph (9) of section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), as added by section 331; and

(2) transmit to Congress an evaluation of such comments, including any recommendations about the types of information that should be added to or removed from the list.

Subtitle E—Orange Book

SEC. 341. ORANGE BOOK.

(a) SUBMISSION OF PATENT INFORMATION FOR BRAND NAME DRUGS.—Paragraph (1) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended to read as follows:

''(b)(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—

''(A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;

''(B) a full list of the articles used as components of such drug;

''(C) a full statement of the composition of such drug;

''(D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

''(E) such samples of such drug and of the articles used as components thereof as the Secretary may require;

''(F) specimens of the labeling proposed to be used for such drug;

''(G) any assessments required under section 505B; and

''(H) patent information, with respect to each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug, and consistent with the following requirements:

''(i) The applicant shall file with the application the patent number and the expiration date of—

''(I) any patent which claims the drug for which the applicant submitted the application and is a drug substance (including active ingredient) patent or a drug product (including formulation and composition) patent; and

''(II) any patent which claims the method of using such drug.

''(ii) If an application is filed under this subsection for a drug and a patent of the type described in clause (i) which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include such patent information.

Upon approval of the application, the Secretary shall publish the information submitted under subparagraph (H). The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and

minorities in clinical trials required by subparagraph (A).''.

(b) CONFORMING CHANGES TO REQUIREMENTS FOR SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—Section 505(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended—

(1) by inserting after ''the patent number and the expiration date of any patent which'' the following: ''fulfills the criteria in subsection (b) and'';

(2) by inserting after the first sentence the following: ''Patent information that is not the type of patent information required by subsection (b) shall not be submitted.''; and

(3) by inserting after ''could not file patent information under subsection (b) because no patent'' the following: ''of the type required to be submitted in subsection (b)''.

(c) LISTING OF EXCLUSIVITIES.—Subparagraph (A) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

''(iv) For each drug included on the list, the Secretary shall specify each exclusivity period that is applicable and has not concluded under—

"(I) clause (ii), (iii), or (iv) of subsection (c)(3)(E) of this section;

"(II) clause (iv) or (v) of paragraph (5)(B) of this subsection;

"(III) clause (ii), (iii), or (iv) of paragraph (5)(F) of this subsection;

"(IV) section 505A;

"(V) section 505E; or

"(VI) section 527(a).".

(d) REMOVAL OF INVALID PATENTS.—

(1) IN GENERAL.—Section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

"(D)(i) The holder of an application approved under subsection (c) for a drug on the list shall notify within 14 days the Secretary in writing if either of the following occurs:

"(I) The Patent Trial and Appeals Board issues a decision from which no appeal has been or can be taken that a patent for such drug is invalid.

"(II) A court issues a decision from which no appeal has been or can be taken that a patent for such drug is invalid.

''(ii) The holder of an approved application shall include in any notification under clause (i) a copy of the decision described in subclause (I) or (II) of clause (i).

''(iii) The Secretary shall remove from the list any patent that is determined to be invalid in a decision described in subclause (I) or (II) of clause (i)—

''(I) promptly; but

''(II) not before the expiration of any 180-day exclusivity period under paragraph (5)(B)(iv) that relies on a certification described in paragraph (2)(A)(vii)(IV) that such patent was invalid.''.

(2) APPLICABILITY.—Subparagraph (D) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), as added by paragraph (1), applies only with respect to a decision described in such subparagraph that is issued on or after the date of enactment of this Act.

(e) REVIEW AND REPORT.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) solicit public comment regarding the types of patent information that should be included on the list under section 507(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)); and

(2) transmit to the Congress an evaluation of such comments, including any recommendations about the types of patent information that should be included on or removed from such list.

SEC. 342. GAO REPORT TO CONGRESS.

(a) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Comptroller General of the United States (referred to in this section as the ''Comptroller General'') shall submit to the Committee on Energy and Commerce of the House of Representatives a report on the patents included in the list published under section 505(j)(7) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(7)), including an analysis and evaluation of the types of patents included in such list and the claims such patents make about the products they claim.

(b) CONTENTS.—The Comptroller General shall include in the report under subsection (a)—

(1) data on the number of—

(A) patents included in the list published under paragraph (7) of section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)), that claim the active ingredient or formulation of a drug in combination with a device that is used for delivery of the drug, to-

gether comprising the finished dosage form of the drug; and

(B) claims in each patent that claim a device that is used for the delivery of the drug, but do not claim such device in combination with an active ingredient or formulation of a drug;

(2) data on the date of inclusion in the list under paragraph (7) of such section 505(j) for all patents under such list, as compared to patents that claim a method of using the drug in combination with a device;

(3) an analysis regarding the impact of including on the list under paragraph (7) of such section 505(j) certain types of patent information for drug product applicants and approved application holders, including an analysis of whether—

(A) the listing of the patents described in paragraph (1)(A) delayed the market entry of one or more drugs approved under such section 505(j); and

(B) not listing the patents described in paragraph (1)(A) would delay the market entry of one or more such drugs; and

(4) recommendations about which kinds of patents relating to devices described in paragraph (1)(A) should be submitted to the Secretary of Health and Human Services for inclusion on the list under paragraph (7) of such section 505(j) and which patents should not be required to be so submitted.

Subtitle F—Advancing Education on Biosimilars

SEC. 351. EDUCATION ON BIOLOGICAL PRODUCTS.

(a) WEBSITE; CONTINUING EDUCATION.—Subpart 1 of part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by adding at the end the following:

"SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.

''(a) INTERNET WEBSITE.—

''(1) IN GENERAL.—The Secretary shall maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

''(2) CONTENT.—Educational materials provided under paragraph (1) may include—

''(A) explanations of key statutory and regulatory terms, including 'biosimilar' and 'interchangeable', and clarification regarding the use of interchangeable biosimilar biological products;

''(B) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;

''(C) an explanation of the process for reporting adverse events for biological products, including biosimilar biological products and interchangeable biosimilar biological products; and

''(D) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under section 351(k) and reference products (as defined in section 351(i)), includ-

ing the standards for review and licensing of each such type of biological product.

"(3) FORMAT.—The educational materials provided under paragraph (1) may be—

"(A) in formats such as webinars, continuing medical education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and

"(B) tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

"(4) OTHER INFORMATION.—In addition to the information described in paragraph (2), the Secretary shall continue to publish the following information:

"(A) The action package of each biological product licensed under subsection (a) or (k).

"(B) The summary review of each biological product licensed under subsection (a) or (k).

"(5) CONFIDENTIAL AND TRADE SECRET INFORMATION.—This subsection does not authorize the disclosure of any trade secret, confidential com-

mercial or financial information, or other matter described in section 552(b) of title 5.

''(b) CONTINUING EDUCATION.—The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.''.

(b) APPLICATION UNDER THE MEDICARE MERIT-BASED INCENTIVE PAYMENT SYSTEM.—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 improved 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.''.

Subtitle G—Streamlining Transition of Biological Products

SEC. 361. STREAMLINING THE TRANSITION OF BIOLOGICAL PRODUCTS.

Section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148) is amended—

(1) by striking ''An approved application'' and inserting the following:

''(A) IN GENERAL.—An approved application'';

(2) by adding at the end the following:

''(B) TREATMENT OF CERTAIN APPLICATIONS.—

''(i) IN GENERAL.—With respect to an application for a biological product submitted under subsection (b) or (j) of section 505 of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 355) that is filed not later than March 23, 2019, the Secretary shall continue to review such application under such section 505, even if such review continues after March 23, 2020.

''(ii) EFFECT ON LISTED DRUGS.—Only for purposes of carrying out clause (i), with respect to any applicable listed drug with respect to such application, the following shall apply:

''(I) Any drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to subparagraph (A) and that is referenced in an application described in clause (i), shall continue to be identified as a listed drug on the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and the information for such drug on such list shall not be revised after March 20, 2020, until—

''(aa) such drug is removed from such list in accordance with subclause (III) or subparagraph (C) of such section 505(j)(7); or

''(bb) this subparagraph no longer has force or effect.

''(II) Any drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to subparagraph (A) and that is referenced in an application described in clause (i) shall be subject only to requirements applicable to biological products licensed under such section.

''(III) Upon approval under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act of an application described in clause (i), the Secretary shall remove from the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act any listed drug that is a biological product that

has been deemed licensed under section 351 of the Public Health Service Act pursuant to subparagraph (A) and that is referenced in such approved application, unless such listed drug is referenced in one or more additional applications described in clause (i).

''(iii) DEEMED LICENSURE.—Upon approval of an application described in clause (i), such approved application shall be deemed to be a license for the biological product under section 351 of the Public Health Service Act, pursuant to subparagraph (A), and any period of exclusivity, as applicable, shall be determined in accordance with such section.

''(iv) RULE OF CONSTRUCTION.—

''(I) APPLICATION OF CERTAIN PROVISIONS.—

''(aa) PATENT CERTIFICATION OR STATEMENT.—An application described in clause (i) shall contain a patent certification or statement described in,

as applicable, section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act or clauses (vii) and (viii) of section 505(j)(2)(A) of such Act and, with respect to any listed drug referenced in such application, comply with related requirements concerning any timely filed patent information listed pursuant to section 505(j)(7).

''(bb) DATE OF APPROVAL.—The earliest possible date on which any pending application described in clause (i) may be approved shall be determined based on—

''(AA) the last expiration date of any applicable period of exclusivity that would prevent such approval and that is described in section 505(c)(3)(E), 505(j)(5)(B)(iv), 505(j)(5)(F), 505A, 505E, or 527 of the Federal Food,

Drug, and Cosmetic Act; and

''(BB) if the application was submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act and references any listed drug, the last applicable date determined under subparagraph (A), (B), or (C) of section 505(c)(3) of such Act, or, if the application was submitted under section 505(j) of such Act, the last applicable date determined under clause (i), (ii), or (iii) of section 505(j)(5)(B).

''(II) RULE OF CONSTRUCTION WITH RESPECT TO EXCLUSIVITY.—Nothing in this subparagraph shall be construed to affect section 351(k)(7)(D) of the Public Health Service Act.

''(v) AUTHORIZED DISCLOSURE.—The Secretary may continue to review an application after March 23, 2020, pursuant to clause (i), and continue to identify any applicable listed drug pursuant to clause (ii) on the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, even if such review or listing may reveal the existence of such application and the identity of any listed drug for which the investigations described in section 505(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act are relied upon by the applicant for approval of the pending application. Nothing in this subparagraph shall be construed as authorizing the Secretary to disclose any other information that is a trade secret or confidential information described in section 552(b)(4) of title 5, United States Code.

''(vi) SUNSET.—Beginning on October 1, 2022, this subparagraph shall have no force or effect and any applications described in clause (i) that have not been approved shall be deemed withdrawn.''.

Subtitle H—Over-the-Counter Monograph Safety, Innovation, and Reform

SEC. 370. SHORT TITLE; REFERENCES IN SUBTITLE.

(a) SHORT TITLE.—This subtitle may be cited as the ''Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019''.

(b) REFERENCES.—Except as otherwise specified, any reference to ''this Act'' contained in this subtitle shall be treated as referring only to the provisions of this subtitle.

PART 1—OTC DRUG REVIEW

SEC. 371. REGULATION OF CERTAIN NONPRESCRIPTION DRUGS THAT ARE MARKETED WITHOUT AN APPROVED DRUG APPLICATION.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505F of such Act (21 U.S.C. 355g) the following:

''SEC. 505G. REGULATION OF CERTAIN NONPRESCRIPTION DRUGS THAT ARE MARKETED WITHOUT AN APPROVED DRUG APPLICATION.

''(a) NONPRESCRIPTION DRUGS MARKETED WITHOUT AN APPROVED APPLICATION.—Nonprescription drugs marketed without an approved drug application under section 505, as of the date of the enactment of this

section, shall be treated in accordance with this subsection.

''(1) DRUGS SUBJECT TO A FINAL MONOGRAPH; CATEGORY I DRUGS SUBJECT TO A TENTATIVE FINAL MONOGRAPH.—A drug is deemed to be generally recognized as safe and effective under section 201(p)(1), not a new drug under section 201(p), and not subject to section 503(b)(1), if—

''(A) the drug is—

''(i) in conformity with the requirements for nonprescription use of a final monograph issued under part 330 of title 21, Code of Federal Regulations (except as provided in paragraph (2)), the general requirements for nonprescription drugs, and conditions or requirements under subsections (b), (c), and (k); and

''(ii) except as permitted by an order issued under subsection (b) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (c), in a dosage form that, immediately prior to the date of the enactment of this section, has been used to a material

extent and for a material time under section 201(p)(2); or

''(B) the drug is—

''(i) classified in category I for safety and effectiveness under a tentative final monograph that is the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal Regulations;

''(ii) in conformity with the proposed requirements for nonprescription use of such tentative final monograph, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsections (b), (c), and (k); and

''(iii) except as permitted by an order issued under subsection (b) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (c), in a dosage form that, immediately prior to the date of the enactment of this section, has been used to a material

extent and for a material time under section 201(p)(2).

''(2) TREATMENT OF SUNSCREEN DRUGS.—With respect to sunscreen drugs subject to this section, the applicable requirements in terms of conformity with a final monograph, for purposes of paragraph (1)(A)(i), shall be the requirements specified in part 352 of title 21, Code of Federal Regulations, as published on May 21, 1999, beginning on page 27687 of volume 64 of the Federal Register, except that the applicable requirements governing effectiveness and labeling shall be those specified in section 201.327 of title 21, Code of Federal Regulations.

''(3) CATEGORY III DRUGS SUBJECT TO A TENTATIVE FINAL MONOGRAPH; CATEGORY I DRUGS SUBJECT TO PROPOSED MONOGRAPH OR ADVANCE NOTICE OF PROPOSED RULEMAKING.—A drug that is not described in paragraph (1), (2), or (4) is not required to be the subject of an application approved under section 505, and is not subject to section 503(b)(1), if—

''(A) the drug is—

''(i) classified in category III for safety or effectiveness in the preamble of a

proposed rule establishing a tentative final monograph that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

''(ii) in conformity with—

''(I) the conditions of use, including indication and dosage strength, if any, described for such category III drug in such preamble or in an applicable subsequent proposed rule;

''(II) the proposed requirements for drugs classified in such tentative final monograph in category I in the most recently proposed rule establishing requirements related to such tentative final monograph and in any final rule establishing requirements that are applicable to the drug; and

''(III) the general requirements for nonprescription drugs and conditions or requirements under subsection (b) or (k); and

''(iii) in a dosage form that, immediately prior to the date of the enactment

of this section, had been used to a material extent and for a material time under section 201(p)(2); or

''(B) the drug is—

''(i) classified in category I for safety and effectiveness under a proposed monograph or advance notice of proposed rulemaking that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

''(ii) in conformity with the requirements for nonprescription use of such proposed monograph or advance notice of proposed rulemaking, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsection (b) or (k); and

''(iii) in a dosage form that, immediately prior to the date of the enactment of this section, has been used to a material extent and for a material time under section 201(p)(2).

"(4) CATEGORY II DRUGS DEEMED NEW DRUGS.—A drug that is classified in category II for safety or effectiveness under a tentative final monograph or that is subject to a determination to be not generally recognized as safe and effective in a proposed rule that is the most recently applicable proposal issued under part 330 of title 21, Code of Federal Regulations, shall be deemed to be a new drug under section 201(p), misbranded under section 502(ee), and subject to the requirement for an approved new drug application under section 505 beginning on the day that is 180 calendar days after the date of the enactment of this section, unless, before such day, the Secretary determines that it is in the interest of public health to extend the period during which the drug may be marketed without such an approved new drug application.

"(5) DRUGS NOT GRASE DEEMED NEW DRUGS.—A drug that the Secretary has determined not to be generally recognized as safe and effective under section 201(p)(1) under a final determination issued under part 330 of title 21, Code of Federal Regulations, shall be deemed to be a new drug under section 201(p), misbranded under section 502(ee),

and subject to the requirement for an approved new drug application under section 505.

''(6) OTHER DRUGS DEEMED NEW DRUGS.—Except as provided in subsection (m), a drug is deemed to be a new drug under section 201(p) and misbranded under section 502(ee) if the drug—

''(A) is not subject to section 503(b)(1); and

''(B) is not described in paragraph (1), (2), (3), (4), or (5), or subsection (b)(1)(B).

''(b) ADMINISTRATIVE ORDERS.—

''(1) IN GENERAL.—

''(A) DETERMINATION.—The Secretary may, on the initiative of the Secretary or at the request of one or more requestors, issue an administrative order determining whether there are conditions under which a specific drug, a class of drugs, or a combination of drugs, is determined to be—

''(i) not subject to section 503(b)(1); and

''(ii) generally recognized as safe and effective under section 201(p)(1).

''(B) EFFECT.—A drug or combination of drugs shall be deemed to not require approval

under section 505 if such drug or combination of drugs—

''(i) is determined by the Secretary to meet the conditions specified in clauses (i) and (ii) of subparagraph (A);

''(ii) is marketed in conformity with an administrative order under this subsection;

''(iii) meets the general requirements for nonprescription drugs; and

''(iv) meets the requirements under subsections (c) and (k).

''(C) STANDARD.—The Secretary shall find that a drug is not generally recognized as safe and effective under section 201(p)(1) if—

''(i) the evidence shows that the drug is not generally recognized as safe and effective under section 201(p)(1); or

''(ii) the evidence is inadequate to show that the drug is generally recognized as safe and effective under section 201(p)(1).

''(2) ADMINISTRATIVE ORDERS INITIATED BY THE SECRETARY.—

''(A) IN GENERAL.—In issuing an administrative order under paragraph (1) upon the Secretary's initiative, the Secretary shall—

''(i) make reasonable efforts to notify informally, not later than 2 business days before the issuance of the proposed order, the sponsors of drugs who have a listing in effect under section 510(j) for the drugs or combination of drugs that will be subject to the administrative order;

''(ii) after any such reasonable efforts of notification—

''(I) issue a proposed administrative order by publishing it on the website of the Food and Drug Administration and include in such order the reasons for the issuance of such order; and

''(II) publish a notice of availability of such proposed order in the Federal Register;

''(iii) except as provided in subparagraph (B), provide for a public comment period with respect to such proposed order of not less than 45 calendar days; and

''(iv) if, after completion of the proceedings specified in clauses (i) through (iii), the Secretary determines that it is appropriate to issue a final administrative order—

''(I) issue the final administrative order, together with a detailed statement of reasons, which order shall not take effect until the time for requesting judicial review under paragraph (3)(D)(ii) has expired;

''(II) publish a notice of such final administrative order in the Federal Register;

''(III) afford requestors of drugs that will be subject to such order the opportunity for formal dispute resolution up to the level of the Director of the Center for Drug Evaluation and Research, which initially must be requested within 45 calendar days of the issuance of the order, and, for subsequent levels of appeal, within 30 calendar days of the prior decision; and

''(IV) except with respect to drugs described in paragraph (3)(B), upon completion of the formal dispute resolution procedure, inform the persons which sought such dispute resolution of their right to request a hearing.

''(B) EXCEPTIONS.—When issuing an administrative order under paragraph (1) on the Secretary's initiative proposing to determine that a drug described in subsection (a)(3) is not generally recognized as safe and effective under section 201(p)(1), the Secretary shall follow the procedures in subparagraph (A), except that—

''(i) the proposed order shall include notice of—

''(I) the general categories of data the Secretary has determined necessary to establish that the drug is generally recognized as safe and effective under section 201(p)(1); and

''(II) the format for submissions by interested persons;

''(ii) the Secretary shall provide for a public comment period of no less than 180

calendar days with respect to such proposed order, except when the Secretary determines, for good cause, that a shorter period is in the interest of public health; and

''(iii) any person who submits data in such comment period shall include a certification that the person has submitted all evidence created, obtained, or received by that person that is both within the categories of data identified in the proposed order and relevant to a determination as to whether the drug is generally recognized as safe and effective under section 201(p)(1).

''(3) HEARINGS; JUDICIAL REVIEW.—

''(A) IN GENERAL.—Only a person who participated in each stage of formal dispute resolution under subclause (III) of paragraph (2)(A)(iv) of an administrative order with respect to a drug may request a hearing concerning a final administrative order issued under such paragraph with respect to such drug. If a hearing is sought, such person must submit a request for a hearing, which shall be based solely on information in the administrative record, to the Secretary not later than 30

calendar days after receiving notice of the final decision of the formal dispute resolution procedure.

"(B) NO HEARING REQUIRED WITH RESPECT TO ORDERS RELATING TO CERTAIN DRUGS.—

"(i) IN GENERAL.—The Secretary shall not be required to provide notice and an opportunity for a hearing pursuant to paragraph (2)(A)(iv) if the final administrative order involved relates to a drug—

"(I) that is described in subsection (a)(3)(A); and

"(II) with respect to which no human or non-human data studies relevant to the safety or effectiveness of such drug have been submitted to the administrative record since the issuance of the most recent tentative final monograph relating to such drug.

"(ii) HUMAN DATA STUDIES AND NON-HUMAN DATA DEFINED.—In this subparagraph:

''(I) The term 'human data studies' means clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics studies, or bioavailability studies.

''(II) The term 'non-human data' means data from testing other than with human subjects which provides information concerning safety or effectiveness.

''(C) HEARING PROCEDURES.—

''(i) DENIAL OF REQUEST FOR HEARING.—If the Secretary determines that information submitted in a request for a hearing under subparagraph (A) with respect to a final administrative order issued under paragraph (2)(A)(iv) does not identify the existence of a genuine and substantial question of material fact, the Secretary may deny such request. In making such a determination, the Secretary may consider only information and data that are based on relevant and reliable scientific principles and methodologies.

''(ii) SINGLE HEARING FOR MULTIPLE RELATED REQUESTS.—If more than one request for a hearing is submitted with respect to the same administrative order under subparagraph (A), the Secretary may direct that a single hearing be conducted in which all persons whose hearing requests were granted may participate.

''(iii) PRESIDING OFFICER.—The presiding officer of a hearing requested under subparagraph (A) shall—

''(I) be designated by the Secretary;

''(II) not be an employee of the Center for Drug Evaluation and Research; and

''(III) not have been previously involved in the development of the administrative order involved or proceedings relating to that administrative order.

''(iv) RIGHTS OF PARTIES TO HEARING.—The parties to a hearing requested under subparagraph (A) shall have the right to present testimony, including testi-

mony of expert witnesses, and to cross-examine witnesses presented by other parties. Where appropriate, the presiding officer may require that cross-examination by parties representing substantially the same interests be consolidated to promote efficiency and avoid duplication.

''(v) FINAL DECISION.—

''(I) At the conclusion of a hearing requested under subparagraph (A), the presiding officer of the hearing shall issue a decision containing findings of fact and conclusions of law. The decision of the presiding officer shall be final.

''(II) The final decision may not take effect until the period under subparagraph (D)(ii) for submitting a request for judicial review of such decision expires.

''(D) JUDICIAL REVIEW OF FINAL ADMINISTRATIVE ORDER.—

''(i) IN GENERAL.—The procedures described in section 505(h) shall apply with respect to judicial review of final ad-

ministrative orders issued under this subsection in the same manner and to the same extent as such section applies to an order described in such section except that the judicial review shall be taken by filing in an appropriate district court of the United States in lieu of the appellate courts specified in such section.

''(ii) PERIOD TO SUBMIT A REQUEST FOR JUDICIAL REVIEW.—A person eligible to request a hearing under this paragraph and seeking judicial review of a final administrative order issued under this subsection shall file such request for judicial review not later than 60 calendar days after the latest of—

''(I) the date on which notice of such order is published;

''(II) the date on which a hearing with respect to such order is denied under subparagraph (B) or (C)(i);

''(III) the date on which a final decision is made following a hearing under subparagraph (C)(v); or

''(IV) if no hearing is requested, the date on which the time for requesting a hearing expires.

''(4) EXPEDITED PROCEDURE WITH RESPECT TO ADMINISTRATIVE ORDERS INITIATED BY THE SECRETARY.—

''(A) IMMINENT HAZARD TO THE PUBLIC HEALTH.—

''(i) IN GENERAL.—In the case of a determination by the Secretary that a drug, class of drugs, or combination of drugs subject to this section poses an imminent hazard to the public health, the Secretary, after first making reasonable efforts to notify, not later than 48 hours before issuance of such order under this subparagraph, sponsors who have a listing in effect under section 510(j) for such drug or combination of drugs—

''(I) may issue an interim final administrative order for such drug, class of drugs, or combination of drugs under paragraph (1), together with a detailed statement of the reasons for such order;

''(II) shall publish in the Federal Register a notice of availability of any such order; and

''(III) shall provide for a public comment period of at least 45 calendar days with respect to such interim final order.

''(ii) NONDELEGATION.—The Secretary may not delegate the authority to issue an interim final administrative order under this subparagraph.

''(B) SAFETY LABELING CHANGES.—

''(i) IN GENERAL.—In the case of a determination by the Secretary that a change in the labeling of a drug, class of drugs, or combination of drugs subject to this section is reasonably expected to mitigate a significant or unreasonable risk of a serious adverse event associated with use of the drug, the Secretary may—

''(I) make reasonable efforts to notify informally, not later than 48 hours before the issuance of the interim final order, the sponsors of drugs who have a listing in effect

under section 510(j) for such drug or combination of drugs;

''(II) after reasonable efforts of notification, issue an interim final administrative order in accordance with paragraph (1) to require such change, together with a detailed statement of the reasons for such order;

''(III) publish in the Federal Register a notice of availability of such order; and

''(IV) provide for a public comment period of at least 45 calendar days with respect to such interim final order.

''(ii) CONTENT OF ORDER.—An interim final order issued under this subparagraph with respect to the labeling of a drug may provide for new warnings and other information required for safe use of the drug.

''(C) EFFECTIVE DATE.—An order under subparagraph (A) or (B) shall take effect on a date specified by the Secretary.

''(D) FINAL ORDER.—After the completion of the proceedings in subparagraph (A) or (B), the Secretary shall—

''(i) issue a final order in accordance with paragraph (1);

''(ii) publish a notice of availability of such final administrative order in the Federal Register; and

''(iii) afford sponsors of such drugs that will be subject to such an order the opportunity for formal dispute resolution up to the level of the Director of the Center for Drug Evaluation and Research, which must initially be within 45 calendar days of the issuance of the order, and for subsequent levels of appeal, within 30 calendar days of the prior decision.

''(E) HEARINGS.—A sponsor of a drug subject to a final order issued under subparagraph (D) and that participated in each stage of formal dispute resolution under clause (iii) of such subparagraph may request a hearing on such order. The provisions of subparagraphs (A), (B), and (C) of paragraph (3), other than paragraph (3)(C)(v)(II), shall apply with re-

spect to a hearing on such order in the same manner and to the same extent as such provisions apply with respect to a hearing on an administrative order issued under paragraph (2)(A)(iv).

''(F) TIMING.—

''(i) FINAL ORDER AND HEARING.—The Secretary shall—

''(I) not later than 6 months after the date on which the comment period closes under subparagraph (A) or (B), issue a final order in accordance with paragraph (1); and

''(II) not later than 12 months after the date on which such final order is issued, complete any hearing under subparagraph (E).

''(ii) DISPUTE RESOLUTION REQUEST.—The Secretary shall specify in an interim final order issued under subparagraph (A) or (B) such shorter periods for requesting dispute resolution under subparagraph (D)(iii) as are necessary to meet the requirements of this subparagraph.

''(G) JUDICIAL REVIEW.—A final order issued pursuant to subparagraph (F) shall be subject to judicial review in accordance with paragraph (3)(D).

''(5) ADMINISTRATIVE ORDER INITIATED AT THE REQUEST OF A REQUESTOR.—

''(A) IN GENERAL.—In issuing an administrative order under paragraph (1) at the request of a requestor with respect to certain drugs, classes of drugs, or combinations of drugs—

''(i) the Secretary shall, after receiving a request under this subparagraph, determine whether the request is sufficiently complete and formatted to permit a substantive review;

''(ii) if the Secretary determines that the request is sufficiently complete and formatted to permit a substantive review, the Secretary shall—

''(I) file the request; and

''(II) initiate proceedings with respect to issuing an administrative order in accordance with paragraphs (2) and (3); and

"(iii) except as provided in paragraph (6), if the Secretary determines that a request does not meet the requirements for filing or is not sufficiently complete and formatted to permit a substantive review, the requestor may demand that the request be filed over protest, and the Secretary shall initiate proceedings to review the request in accordance with paragraph (2)(A).

"(B) REQUEST TO INITIATE PROCEEDINGS.—

"(i) IN GENERAL.—A requestor seeking an administrative order under paragraph (1) with respect to certain drugs, classes of drugs, or combinations of drugs, shall submit to the Secretary a request to initiate proceedings for such order in the form and manner as specified by the Secretary. Such requestor may submit a request under this subparagraph for the issuance of an administrative order—

"(I) determining whether a drug is generally recognized as safe and effective under section 201(p)(1), exempt from section 503(b)(1), and not

required to be the subject of an approved application under section 505; or

''(II) determining whether a change to a condition of use of a drug is generally recognized as safe and effective under section 201(p)(1), exempt from section 503(b)(1), and not required to be the subject of an approved application under section 505, if, absent such a changed condition of use, such drug is—

''(aa) generally recognized as safe and effective under section 201(p)(1) in accordance with subsection (a)(1), (a)(2), or an order under this subsection; or

''(bb) subject to subsection (a)(3), but only if such requestor initiates such request in conjunction with a request for the Secretary to determine whether such drug is generally recognized as safe and effective under section 201(p)(1), which is filed by the

Secretary under subparagraph (A)(ii).

''(ii) EXCEPTION.—The Secretary is not required to complete review of a request for a change described in clause (i)(II) if the Secretary determines that there is an inadequate basis to find the drug is generally recognized as safe and effective under section 201(p)(1) under paragraph (1) and issues a final order announcing that determination.

''(iii) WITHDRAWAL.—The requestor may withdraw a request under this paragraph, according to the procedures set forth pursuant to subsection (d)(2)(B). Notwithstanding any other provision of this section, if such request is withdrawn, the Secretary may cease proceedings under this subparagraph.

''(C) EXCLUSIVITY.—

''(i) IN GENERAL.—A final administrative order issued in response to a request under this section shall have the effect of authorizing solely the order requestor (or the licensees, assignees, or suc-

cessors in interest of such requestor with respect to the subject of such order), for a period of 18 months following the effective date of such final order and beginning on the date the requestor may lawfully market such drugs pursuant to the order, to market drugs—

''(I) incorporating changes described in clause (ii); and

''(II) subject to the limitations under clause (iv).

''(ii) CHANGES DESCRIBED.—A change described in this clause is a change subject to an order specified in clause (i), which—

''(I) provides for a drug to contain an active ingredient (including any ester or salt of the active ingredient) not previously incorporated in a drug described in clause (iii); or

''(II) provides for a change in the conditions of use of a drug, for which new human data studies conducted or sponsored by the requestor (or for which the requestor has an exclusive

right of reference) were essential to the issuance of such order.

"(iii) DRUGS DESCRIBED.—The drugs described in this clause are drugs—

"(I) specified in subsection (a)(1), (a)(2), or (a)(3);

"(II) subject to a final order issued under this section;

"(III) subject to a final sunscreen order (as defined in section 586(2)(A)); or

"(IV) described in subsection (m)(1), other than drugs subject to an active enforcement action under chapter III of this Act.

"(iv) LIMITATIONS ON EXCLUSIVITY.—

"(I) IN GENERAL.—Only one 18-month period under this subparagraph shall be granted, under each order described in clause (i), with respect to changes (to the drug subject to such order) which are either—

"(aa) changes described in clause (ii)(I), relating to active ingredients; or

"(bb) changes described in clause (ii)(II), relating to conditions of use.

"(II) NO EXCLUSIVITY ALLOWED.—No exclusivity shall apply to changes to a drug which are—

"(aa) the subject of a Tier 2 OTC monograph order request (as defined in section 744L);

"(bb) safety-related changes, as defined by the Secretary, or any other changes the Secretary considers necessary to assure safe use; or

"(cc) changes related to methods of testing safety or efficacy.

"(v) NEW HUMAN DATA STUDIES DEFINED.—In this subparagraph, the term 'new human data studies' means clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics stud-

ies, or bioavailability studies, the results of which—

"(I) have not been relied on by the Secretary to support—

"(aa) a proposed or final determination that a drug described in subclause (I), (II), or (III) of clause (iii) is generally recognized as safe and effective under section 201(p)(1); or

"(bb) approval of a drug that was approved under section 505; and

"(II) do not duplicate the results of another study that was relied on by the Secretary to support—

"(aa) a proposed or final determination that a drug described in subclause (I), (II), or (III) of clause (iii) is generally recognized as safe and effective under section 201(p)(1); or

"(bb) approval of a drug that was approved under section 505.

''(6) INFORMATION REGARDING SAFE NON-PRESCRIPTION MARKETING AND USE AS CONDITION FOR FILING A GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE REQUEST.—

''(A) IN GENERAL.—In response to a request under this section that a drug described in subparagraph (B) be generally recognized as safe and effective, the Secretary—

''(i) may file such request, if the request includes information specified under subparagraph (C) with respect to safe nonprescription marketing and use of such drug; or

''(ii) if the request fails to include information specified under subparagraph (C), shall refuse to file such request and require that nonprescription marketing of the drug be pursuant to a new drug application as described in subparagraph (D).

''(B) DRUG DESCRIBED.—A drug described in this subparagraph is a nonprescription drug which contains an active ingredient not previously incorporated in a drug—

''(i) specified in subsection (a)(1), (a)(2), or (a)(3);

''(ii) subject to a final order under this section; or

''(iii) subject to a final sunscreen order (as defined in section 586(2)(A)).

''(C) INFORMATION DEMONSTRATING PRIMA FACIE SAFE NONPRESCRIPTION MARKETING AND USE.—Information specified in this subparagraph, with respect to a request described in subparagraph (A)(i), is—

''(i) information sufficient for a prima facie demonstration that the drug subject to such request has a verifiable history of being marketed and safely used by consumers in the United States as a nonprescription drug under comparable conditions of use;

''(ii) if the drug has not been previously marketed in the United States as a nonprescription drug, information sufficient for a prima facie demonstration that the drug was marketed and safely used under comparable conditions of marketing and use in a country listed in section 802(b)(1)(A) or designated by the Sec-

retary in accordance with section 802(b)(1)(B)—

''(I) for such period as needed to provide reasonable assurances concerning the safe nonprescription use of the drug; and

''(II) during such time was subject to sufficient monitoring by a regulatory body considered acceptable by the Secretary for such monitoring purposes, including for adverse events associated with nonprescription use of the drug; or

''(iii) if the Secretary determines that information described in clause (i) or (ii) is not needed to provide a prima facie demonstration that the drug can be safely marketed and used as a nonprescription drug, such other information the Secretary determines is sufficient for such purposes.

''(D) MARKETING PURSUANT TO NEW DRUG APPLICATION.—In the case of a request described in subparagraph (A)(ii), the drug subject to such request may be resubmitted for filing only if—

''(i) the drug is marketed as a non-prescription drug, under conditions of use comparable to the conditions specified in the request, for such period as the Secretary determines appropriate (not to exceed 5 consecutive years) pursuant to an application approved under section 505; and

''(ii) during such period, 1,000,000 retail packages of the drug, or an equivalent quantity as determined by the Secretary, were distributed for retail sale, as determined in such manner as the Secretary finds appropriate.

''(E) RULE OF APPLICATION.—Except in the case of a request involving a drug described in section 586(9), as in effect on January 1, 2017, if the Secretary refuses to file a request under this paragraph, the requestor may not file such request over protest under paragraph (5)(A)(iii).

''(7) PACKAGING.—An administrative order issued under paragraph (2), (4)(A), or (5) may include requirements for the packaging of a drug to encourage use in accordance with labeling. Such re-

quirements may include unit dose packaging, requirements for products intended for use by pediatric populations, requirements to reduce risk of harm from unsupervised ingestion, and other appropriate requirements. This paragraph does not authorize the Food and Drug Administration to require standards or testing procedures as described in part 1700 of title 16, Code of Federal Regulations.

''(8) FINAL AND TENTATIVE FINAL MONOGRAPHS FOR CATEGORY I DRUGS DEEMED FINAL ADMINISTRATIVE ORDERS.—

''(A) IN GENERAL.—A final monograph or tentative final monograph described in subparagraph (B) shall be deemed to be a final administrative order under this subsection and may be amended, revoked, or otherwise modified in accordance with the procedures of this subsection.

''(B) MONOGRAPHS DESCRIBED.—For purposes of subparagraph (A), a final monograph or tentative final monograph is described in this subparagraph if it—

''(i) establishes conditions of use for a drug described in paragraph (1) or (2) of subsection (a); and

''(ii) represents the most recently promulgated version of such conditions, including as modified, in whole or in part, by any proposed or final rule.

''(C) DEEMED ORDERS INCLUDE HARMONIZING TECHNICAL AMENDMENTS.—The deemed establishment of a final administrative order under subparagraph (A) shall be construed to include any technical amendments to such order as the Secretary determines necessary to ensure that such order is appropriately harmonized, in terms of terminology or cross-references, with the applicable provisions of this Act (and regulations thereunder) and any other orders issued under this section.

''(c) PROCEDURE FOR MINOR CHANGES.—

''(1) IN GENERAL.—Minor changes in the dosage form of a drug that is described in paragraph (1) or (2) of subsection (a) or the subject of an order issued under subsection (b) may be made by a requestor without the issuance of an order under subsection (b) if—

''(A) the requestor maintains such information as is necessary to demonstrate that the change—

''(i) will not affect the safety or effectiveness of the drug; and

''(ii) will not materially affect the extent of absorption or other exposure to the active ingredient in comparison to a suitable reference product; and

''(B) the change is in conformity with the requirements of an applicable administrative order issued by the Secretary under paragraph (3).

''(2) ADDITIONAL INFORMATION.—

''(A) ACCESS TO RECORDS.—A sponsor shall submit records requested by the Secretary relating to such a minor change under section 704(a)(4), within 15 business days of receiving such a request, or such longer period as the Secretary may provide.

''(B) INSUFFICIENT INFORMATION.—If the Secretary determines that the information contained in such records is not sufficient to demonstrate that the change does not affect the safety or effectiveness of the drug or materially affect the extent of absorption or other exposure to the active ingredient, the Secretary—

''(i) may so inform the sponsor of the drug in writing; and

''(ii) if the Secretary so informs the sponsor, shall provide the sponsor of the drug with a reasonable opportunity to provide additional information.

''(C) FAILURE TO SUBMIT SUFFICIENT INFORMATION.—If the sponsor fails to provide such additional information within a time prescribed by the Secretary, or if the Secretary determines that such additional information does not demonstrate that the change does not—

''(i) affect the safety or effectiveness of the drug; or

''(ii) materially affect the extent of absorption or other exposure to the active ingredient in comparison to a suitable reference product,

the drug as modified is a new drug under section 201(p) and shall be deemed to be misbranded under section 502(ee).

''(3) DETERMINING WHETHER A CHANGE WILL AFFECT SAFETY OR EFFECTIVENESS.—

''(A) IN GENERAL.—The Secretary shall issue one or more administrative orders speci-

fying requirements for determining whether a minor change made by a sponsor pursuant to this subsection will affect the safety or effectiveness of a drug or materially affect the extent of absorption or other exposure to an active ingredient in the drug in comparison to a suitable reference product, together with guidance for applying those orders to specific dosage forms.

''(B) STANDARD PRACTICES.—The orders and guidance issued by the Secretary under subparagraph (A) shall take into account relevant public standards and standard practices for evaluating the quality of drugs, and may take into account the special needs of populations, including children.

''(d) CONFIDENTIALITY OF INFORMATION SUBMITTED TO THE SECRETARY.—

''(1) IN GENERAL.—Subject to paragraph (2), any information, including reports of testing conducted on the drug or drugs involved, that is submitted by a requestor in connection with proceedings on an order under this section (including any minor change under subsection (c)) and is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section

1905 of title 18, United States Code, shall not be disclosed to the public unless the requestor consents to that disclosure.

''(2) PUBLIC AVAILABILITY.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall—

''(i) make any information submitted by a requestor in support of a request under subsection (b)(5)(A) available to the public not later than the date on which the proposed order is issued; and

''(ii) make any information submitted by any other person with respect to an order requested (or initiated by the Secretary) under subsection (b), available to the public upon such submission.

''(B) LIMITATIONS ON PUBLIC AVAILABILITY.—Information described in subparagraph (A) shall not be made public if—

''(i) the information pertains to pharmaceutical quality information, unless such information is necessary to establish standards under which a drug is generally recognized as safe and effective under section 201(p)(1);

''(ii) the information is submitted in a requestor-initiated request, but the requestor withdraws such request, in accordance with withdrawal procedures established by the Secretary, before the Secretary issues the proposed order;

''(iii) the Secretary requests and obtains the information under subsection (c) and such information is not submitted in relation to an order under subsection (b); or

''(iv) the information is of the type contained in raw datasets.

''(e) UPDATES TO DRUG LISTING INFORMATION.—A sponsor who makes a change to a drug subject to this section shall submit updated drug listing information for the drug in accordance with section 510(j) within 30 calendar days of the date when the drug is first commercially marketed, except that a sponsor who was the order requestor with respect to an order subject to subsection (b)(5)(C) (or a licensee, assignee, or successor in interest of such requestor) shall submit updated drug listing information on or before the date when the drug is first commercially marketed.

''(f) APPROVALS UNDER SECTION 505.—The provisions of this section shall not be construed to preclude a person from seeking or maintaining the approval of an application for a drug under sections 505(b)(1), 505(b)(2), and 505(j). A determination under this section that a drug is not subject to section 503(b)(1), is generally recognized as safe and effective under section 201(p)(1), and is not a new drug under section 201(p) shall constitute a finding that the drug is safe and effective that may be relied upon for purposes of an application under section 505(b)(2), so that the applicant shall be required to submit for purposes of such application only information needed to support any modification of the drug that is not covered by such determination under this section.

''(g) PUBLIC AVAILABILITY OF ADMINISTRATIVE ORDERS.—The Secretary shall establish, maintain, update (as determined necessary by the Secretary but no less frequently than annually), and make publicly available, with respect to orders issued under this section—

''(1) a repository of each final order and interim final order in effect, including the complete text of the order; and

''(2) a listing of all orders proposed and under development under subsection (b)(2), including—

''(A) a brief description of each such order; and

''(B) the Secretary's expectations, if resources permit, for issuance of proposed orders over a 3-year period.

''(h) DEVELOPMENT ADVICE TO SPONSORS OR REQUESTORS.—The Secretary shall establish procedures under which sponsors or requestors may meet with appropriate officials of the Food and Drug Administration to obtain advice on the studies and other information necessary to support submissions under this section and other matters relevant to the regulation of nonprescription drugs and the development of new nonprescription drugs under this section.

''(i) PARTICIPATION OF MULTIPLE SPONSORS OR REQUESTORS.—The Secretary shall establish procedures to facilitate efficient participation by multiple sponsors or requestors in proceedings under this section, including provision for joint meetings with multiple sponsors or requestors or with organizations nominated by sponsors or requestors to represent their interests in a proceeding.

''(j) ELECTRONIC FORMAT.—All submissions under this section shall be in electronic format.

''(k) EFFECT ON EXISTING REGULATIONS GOVERNING NONPRESCRIPTION DRUGS.—

''(1) REGULATIONS OF GENERAL APPLICABILITY TO NONPRESCRIPTION DRUGS.—Except as provided in this subsection, nothing in this section supersedes regulations establishing general requirements for nonprescription drugs, including regulations of general applicability contained in parts 201, 250, and 330 of title 21, Code of Federal Regulations, or any successor regulations. The Secretary shall establish or modify such regulations by means of rulemaking in accordance with section 553 of title 5, United States Code.

''(2) REGULATIONS ESTABLISHING REQUIREMENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

''(A) The provisions of section 310.545 of title 21, Code of Federal Regulations, as in effect on the day before the date of the enactment of this section, shall be deemed to be a final order under subsection (b).

''(B) Regulations in effect on the day before the date of the enactment of this section, establishing requirements for specific nonprescription drugs marketed pursuant to this section (including such requirements in parts 201 and 250 of title 21, Code of Federal Regulations), shall be deemed to be final orders

under subsection (b), only as they apply to drugs—

"(i) subject to paragraph (1), (2), (3), or (4) of subsection (a); or

"(ii) otherwise subject to an order under this section.

"(3) WITHDRAWAL OF REGULATIONS.—The Secretary shall withdraw regulations establishing final monographs and the procedures governing the over-the-counter drug review under part 330 and other relevant parts of title 21, Code of Federal Regulations (as in effect on the day before the date of the enactment of this section), or make technical changes to such regulations to ensure conformity with appropriate terminology and cross references. Notwithstanding subchapter II of chapter 5 of title 5, United States Code, any such withdrawal or technical changes shall be made without public notice and comment and shall be effective upon publication through notice in the Federal Register (or upon such date as specified in such notice).

"(l) GUIDANCE.—The Secretary shall issue guidance that specifies—

''(1) the procedures and principles for formal meetings between the Secretary and sponsors or requestors for drugs subject to this section;

''(2) the format and content of data submissions to the Secretary under this section;

''(3) the format of electronic submissions to the Secretary under this section;

''(4) consolidated proceedings for appeal and the procedures for such proceedings where appropriate; and

''(5) for minor changes in drugs, recommendations on how to comply with the requirements in orders issued under subsection (c)(3).

''(m) RULE OF CONSTRUCTION.—

''(1) IN GENERAL.—This section shall not affect the treatment or status of a nonprescription drug—

''(A) that is marketed without an application approved under section 505 as of the date of the enactment of this section;

''(B) that is not subject to an order issued under this section; and

''(C) to which paragraphs (1), (2), (3), (4), or (5) of subsection (a) do not apply.

''(2) TREATMENT OF PRODUCTS PREVIOUSLY FOUND TO BE SUBJECT TO TIME AND EXTENT REQUIREMENTS.—

''(A) Notwithstanding subsection (a), a drug described in subparagraph (B) may only be lawfully marketed, without an application approved under section 505, pursuant to an order issued under this section.

''(B) A drug described in this subparagraph is a drug which, prior to the date of the enactment of this section, the Secretary determined in a proposed or final rule to be ineligible for review under the OTC drug review (as such phrase 'OTC drug review' was used in section 330.14 of title 21, Code of Federal Regulations, as in effect on the day before the date of the enactment of this section).

''(3) PRESERVATION OF AUTHORITY.—

''(A) Nothing in paragraph (1) shall be construed to preclude or limit the applicability of any provision of this Act other than this section.

''(B) Nothing in subsection (a) shall be construed to prohibit the Secretary from issuing an order under this section finding a drug to be

not generally recognized as safe and effective under section 201(p)(1), as the Secretary determines appropriate.

''(n) INVESTIGATIONAL NEW DRUGS.—A drug is not subject to this section if an exemption for investigational use under section 505(i) is in effect for such drug.

''(o) INAPPLICABILITY OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to collections of information made under this section.

''(p) INAPPLICABILITY OF NOTICE AND COMMENT RULEMAKING AND OTHER REQUIREMENTS.—The requirements of subsection (b) shall apply with respect to orders issued under this section instead of the requirements of subchapter II of chapter 5 of title 5, United States Code.

''(q) DEFINITIONS.—In this section:

''(1) The term 'nonprescription drug' refers to a drug not subject to the requirements of section 503(b)(1).

''(2) The term 'sponsor' refers to any person marketing, manufacturing, or processing a drug that—

''(A) is listed pursuant to section 510(j); and

''(B) is or will be subject to an administrative order under this section of the Food and Drug Administration.

''(3) The term 'requestor' refers to any person or group of persons marketing, manufacturing, processing, or developing a drug.''.

(b) GAO STUDY.—Not later than 4 years after the date of enactment of this Act, the Comptroller General of the United States shall submit a study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate addressing the effectiveness and overall impact of exclusivity under section 505G of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and section 586C of such Act (21 U.S.C. 360fff–3), including the impact of such exclusivity on consumer access. Such study shall include—

(1) an analysis of the impact of exclusivity under such section 505G for nonprescription drug products, including—

(A) the number of nonprescription drug products that were granted exclusivity and the indication for which the nonprescription drug products were determined to be generally recognized as safe and effective;

(B) whether the exclusivity for such drug products was granted for—

(i) a new active ingredient (including any ester or salt of the active ingredient); or

(ii) changes in the conditions of use of a drug, for which new human data studies conducted or sponsored by the requestor were essential;

(C) whether, and to what extent, the exclusivity impacted the requestor's or sponsor's decision to develop the drug product;

(D) an analysis of the implementation of the exclusivity provision in such section 505G, including—

(i) the resources used by the Food and Drug Administration;

(ii) the impact of such provision on innovation, as well as research and development in the nonprescription drug market;

(iii) the impact of such provision on competition in the nonprescription drug market;

(iv) the impact of such provision on consumer access to nonprescription drug products;

(v) the impact of such provision on the prices of nonprescription drug products; and

(vi) whether the administrative orders initiated by requestors under such section 505G have been sufficient to encourage the development of nonprescription drug products that would likely not be otherwise developed, or developed in as timely a manner; and

(E) whether the administrative orders initiated by requestors under such section 505G have been sufficient incentive to encourage innovation in the nonprescription drug market; and

(2) an analysis of the impact of exclusivity under such section 586C for sunscreen ingredients, including—

(A) the number of sunscreen ingredients that were granted exclusivity and the specific ingredient that was determined to be generally recognized as safe and effective;

(B) whether, and to what extent, the exclusivity impacted the requestor's or sponsor's decision to develop the sunscreen ingredient;

(C) whether, and to what extent, the sunscreen ingredient granted exclusivity had previously been available outside of the United States;

(D) an analysis of the implementation of the exclusivity provision in such section 586C, including—

(i) the resources used by the Food and Drug Administration;

(ii) the impact of such provision on innovation, as well as research and development in the sunscreen market;

(iii) the impact of such provision on competition in the sunscreen market;

(iv) the impact of such provision on consumer access to sunscreen products;

(v) the impact of such provision on the prices of sunscreen products; and

(vi) whether the administrative orders initiated by requestors under such section 505G have been utilized by sunscreen ingredient sponsors and whether such proc-

ess has been sufficient to encourage the development of sunscreen ingredients that would likely not be otherwise developed, or developed in as timely a manner; and

(E) whether the administrative orders initiated by requestors under such section 586C have been sufficient incentive to encourage innovation in the sunscreen market.

(c) CONFORMING AMENDMENT.—Section 751(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379r(d)(1)) is amended—

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

(A) by striking ''final regulation promulgated'' and inserting ''final order under section 505G''; and

(B) by striking ''and not misbranded''; and

(2) in subparagraph (A), by striking ''regulation in effect'' and inserting ''regulation or order in effect''.

SEC. 372. MISBRANDING.

Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(ee) If it is a nonprescription drug that is subject to section 505G, is not the subject of an application ap-

proved under section 505, and does not comply with the requirements under section 505G.

''(ff) If it is a drug and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744M.''.

SEC. 373. DRUGS EXCLUDED FROM THE OVER-THE-COUNTER DRUG REVIEW.

(a) IN GENERAL.—Nothing in this Act (or the amendments made by this Act) shall apply to any nonprescription drug (as defined in section 505G(q) of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act) which was excluded by the Food and Drug Administration from the Over-the-Counter Drug Review in accordance with the paragraph numbered 25 on page 9466 of volume 37 of the Federal Register, published on May 11, 1972.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to preclude or limit the applicability of any other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 374. TREATMENT OF SUNSCREEN INNOVATION ACT.

(a) REVIEW OF NONPRESCRIPTION SUNSCREEN ACTIVE INGREDIENTS.—

(1) APPLICABILITY OF SECTION 505G FOR PENDING SUBMISSIONS.—

(A) IN GENERAL.—A sponsor of a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that, as of the date of enactment of this Act, is subject to a proposed sunscreen order under section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3) may elect, by means of giving written notification to the Secretary of Health and Human Services within 180 calendar days of the enactment of this Act, to transition into the review of such ingredient or combination of ingredients pursuant to the process set out in section 505G of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act.

(B) ELECTION EXERCISED.—Upon receipt by the Secretary of Health and Human Services of a timely notification under subparagraph (A)—

(i) the proposed sunscreen order involved is deemed to be a request for an order under subsection (b) of section 505G of the Federal Food, Drug, and Cosmetic

Act, as added by section 1001 of this Act; and

(ii) such order is deemed to have been accepted for filing under subsection (b)(6)(A)(i) of such section 505G.

(C) ELECTION NOT EXERCISED.—If a notification under subparagraph (A) is not received by the Secretary of Health and Human Services within 180 calendar days of the date of enactment of this Act, the review of the proposed sunscreen order described in subparagraph (A)—

(i) shall continue under section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3); and

(ii) shall not be eligible for review under section 505G, added by section 1001 of this Act.

(2) DEFINITIONS.—In this subsection, the terms ''sponsor'', ''nonprescription'', ''sunscreen active ingredient'', and ''proposed sunscreen order'' have the meanings given to those terms in section 586 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff).

(b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

(1) FINAL SUNSCREEN ORDERS.—Paragraph (3) of section 586C(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3(e)) is amended to read as follows:

''(3) RELATIONSHIP TO ORDERS UNDER SECTION 505G.—A final sunscreen order shall be deemed to be a final order under section 505G.''.

(2) MEETINGS.—Paragraph (7) of section 586C(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3(b)) is amended—

(A) by striking ''A sponsor may request'' and inserting the following:

''(A) IN GENERAL.—A sponsor may request''; and

(B) by adding at the end the following:

''(B) CONFIDENTIAL MEETINGS.—A sponsor may request one or more confidential meetings with respect to a proposed sunscreen order, including a letter deemed to be a proposed sunscreen order under paragraph (3), to discuss matters relating to data requirements to support a general recognition of safety and effectiveness involving confidential information and public information related to such proposed sunscreen order, as appropriate. The Secretary

shall convene a confidential meeting with such sponsor in a reasonable time period. If a sponsor requests more than one confidential meeting for the same proposed sunscreen order, the Secretary may refuse to grant an additional confidential meeting request if the Secretary determines that such additional confidential meeting is not reasonably necessary for the sponsor to advance its proposed sunscreen order, or if the request for a confidential meeting fails to include sufficient information upon which to base a substantive discussion. The Secretary shall publish a post-meeting summary of each confidential meeting under this subparagraph that does not disclose confidential commercial information or trade secrets. This subparagraph does not authorize the disclosure of confidential commercial information or trade secrets subject to 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.''.

(3) EXCLUSIVITY.—Section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3) is amended by adding at the end the following:

''(f) EXCLUSIVITY.—

''(1) IN GENERAL.—A final sunscreen order shall have the effect of authorizing solely the order requestor (or the licensees, assignees, or successors in interest of such requestor with respect to the subject of such request and listed under paragraph (5)) for a period of 18 months, to market a sunscreen ingredient under this section incorporating changes described in paragraph (2) subject to the limitations under paragraph (4), beginning on the date the requestor (or any licensees, assignees, or successors in interest of such requestor with respect to the subject of such request and listed under paragraph (5)) may lawfully market such sunscreen ingredient pursuant to the order.

''(2) CHANGES DESCRIBED.—A change described in this paragraph is a change subject to an order specified in paragraph (1) that permits a sunscreen to contain an active sunscreen ingredient not previously incorporated in a marketed sunscreen listed in paragraph (3).

''(3) MARKETED SUNSCREEN.—The marketed sunscreen ingredients described in this paragraph are sunscreen ingredients—

''(A) marketed in accordance with a final monograph for sunscreen drug products set

forth at part 352 of title 21, Code of Federal Regulations (as published at 64 Fed. Reg. 27687); or

''(B) marketed in accordance with a final order issued under this section.

''(4) LIMITATIONS ON EXCLUSIVITY.—Only one 18-month period may be granted per ingredient under paragraph (1).

''(5) LISTING OF LICENSEES, ASSIGNEES, OR SUCCESSORS IN INTEREST.—Requestors shall submit to the Secretary at the time when a drug subject to such request is introduced or delivered for introduction into interstate commerce, a list of licensees, assignees, or successors in interest under paragraph (1).''.

(4) SUNSET PROVISION.—Subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff et seq.) is amended by adding at the end the following:

''SEC. 586H. SUNSET.

''This subchapter shall cease to be effective at the end of fiscal year 2022.''.

(5) TREATMENT OF FINAL SUNSCREEN ORDER.—The Federal Food, Drug, and Cosmetic

Act is amended by striking section 586E of such Act (21 U.S.C. 360fff–5).

(c) TREATMENT OF AUTHORITY REGARDING FINALIZATION OF SUNSCREEN MONOGRAPH.—

(1) IN GENERAL.—

(A) REVISION OF FINAL SUNSCREEN ORDER.—Not later than November 26, 2019, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall amend and revise the final administrative order concerning nonprescription sunscreen (referred to in this subsection as the ''sunscreen order'') for which the content, prior to the date of enactment of this Act, was represented by the final monograph for sunscreen drug products set forth in part 352 of title 21, Code of Federal Regulations (as in effect on May 21, 1999).

(B) ISSUANCE OF REVISED SUNSCREEN ORDER; EFFECTIVE DATE.—A revised sunscreen order described in subparagraph (A) shall be—

(i) issued in accordance with the procedures described in section 505G(c)(2) of the Federal Food, Drug, and Cosmetic Act;

(ii) issued in proposed form not later than May 28, 2019;

(iii) effective not later than November 26, 2020; and

(iv) issued by the Secretary at least 1 year prior to the effective date of the revised order.

(2) REPORTS.—If a revised sunscreen order issued under paragraph (1) does not include provisions related to the effectiveness of various sun protection factor levels, and does not address all dosage forms known to the Secretary to be used in sunscreens marketed in the United States without a new drug application approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), the Secretary shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on the rationale for omission of such provisions from such order, and a plan and timeline to compile any information necessary to address such provisions through such order.

(d) TREATMENT OF NON-SUNSCREEN TIME AND EXTENT APPLICATIONS.—

(1) IN GENERAL.—Any application described in section 586F of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–6) that was submitted to the Secretary pursuant to section 330.14 of title 21, Code of Federal Regulations, as such provisions were in effect immediately prior to the date of enactment date of this Act, shall be extinguished as of such date of enactment, subject to paragraph (2).

(2) ORDER REQUEST.—Nothing in paragraph (1) precludes the submission of an order request under section 505G(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act, with respect to a drug that was the subject of an application extinguished under paragraph (1).

SEC. 375. ANNUAL UPDATE TO CONGRESS ON APPROPRIATE PEDIATRIC INDICATION FOR CERTAIN OTC COUGH AND COLD DRUGS.

(a) IN GENERAL.—Subject to subsection (c), the Secretary of Health and Human Services shall, beginning not later than 1 year after the date of enactment of this Act, annually submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a letter describing the progress of the Food and Drug Administration—

(1) in evaluating the cough and cold monograph described in subsection (b) with respect to children under age 6; and

(2) as appropriate, revising such cough and cold monograph to address such children through the order process under section 505G(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act.

(b) COUGH AND COLD MONOGRAPH DESCRIBED.—The cough and cold monograph described in this subsection consists of the conditions under which nonprescription drugs containing antitussive, expectorant, nasal decongestant, or antihistamine active ingredients (or combinations thereof) are generally recognized as safe and effective, as specified in part 341 of title 21, Code of Federal Regulations (as in effect immediately prior to the date of enactment of this Act), and included in an order deemed to be established under section 505G(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 1001 of this Act.

(c) DURATION OF AUTHORITY.—The requirement under subsection (a) shall terminate as of the date of a letter submitted by the Secretary of Health and Human Services pursuant to such subsection in which the Secretary indicates that the Food and Drug Administration

has completed its evaluation and revised, in a final order, as applicable, the cough and cold monograph as described in subsection (a)(2).

SEC. 376. TECHNICAL CORRECTIONS.

(a) IMPORTS AND EXPORTS.—Section 801(e)(4)(E)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)(E)(iii)) is amended by striking ''subparagraph'' each place such term appears and inserting ''paragraph''.

(b) FDA REAUTHORIZATION ACT OF 2017.—

(1) IN GENERAL.—Section 905(b)(4) of the FDA Reauthorization Act of 2017 (Public Law115–52) is amended by striking ''Section 744H(e)(2)(B)'' and inserting ''Section 744H(f)(2)(B)''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect as of the enactment of the FDA Reauthorization Act of 2017 (Public Law 115–52).

PART 2—USER FEES

SEC. 381. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This part may be cited as the ''Over-the-Counter Monograph User Fee Act of 2019''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this part will be dedicated to OTC monograph drug activities, as set forth in

the goals identified for purposes of part 10 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 382. FEES RELATING TO OVER-THE-COUNTER DRUGS.

Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by inserting after part 9 the following:

"PART 10—FEES RELATING TO OVER-THE-COUNTER DRUGS

"SEC. 744L. DEFINITIONS.

''In this part:

''(1) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control, both of the business entities.

''(2) The term 'contract manufacturing organization facility' means an OTC monograph drug facility where neither the owner of such manufacturing facility nor any affiliate of such owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States.

''(3) The term 'costs of resources allocated for OTC monograph drug activities' means the expenses in connection with OTC monograph drug activities for—

''(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and costs related to contracts with such contractors;

''(B) management of information, and the acquisition, maintenance, and repair of computer resources;

''(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

"(D) collecting fees under section 744M and accounting for resources allocated for OTC monograph drug activities.

"(4) The term 'FDA establishment identifier' is the unique number automatically generated by Food and Drug Administration's Field Accomplishments and Compliance Tracking System (FACTS) (or any successor system).

"(5) The term 'OTC monograph drug' means a nonprescription drug without an approved new drug application which is governed by the provisions of section 505G.

"(6) The term 'OTC monograph drug activities' means activities of the Secretary associated with OTC monograph drugs and inspection of facilities associated with such products, including the following activities:

"(A) The activities necessary for review and evaluation of OTC monographs and OTC monograph order requests, including—

"(i) orders proposing or finalizing applicable conditions of use for OTC monograph drugs;

"(ii) orders affecting status regarding general recognition of safety and effective-

ness of an OTC monograph ingredient or combination of ingredients under specified conditions of use;

''(iii) all OTC monograph drug development and review activities, including intra-agency collaboration;

''(iv) regulation and policy development activities related to OTC monograph drugs;

''(v) development of product standards for products subject to review and evaluation;

''(vi) meetings referred to in section 505G(i);

''(vii) review of labeling prior to issuance of orders related to OTC monograph drugs or conditions of use; and

''(viii) regulatory science activities related to OTC monograph drugs.

''(B) Inspections related to OTC monograph drugs.

''(C) Monitoring of clinical and other research conducted in connection with OTC monograph drugs.

''(D) Safety activities with respect to OTC monograph drugs, including—

''(i) collecting, developing, and reviewing safety information on OTC monograph drugs, including adverse event reports;

''(ii) developing and using improved adverse event data-collection systems, including information technology systems; and

''(iii) developing and using improved analytical tools to assess potential safety risks, including access to external databases.

''(E) Other activities necessary for implementation of section 505G.

''(7) The term 'OTC monograph order request' means a request for an order submitted under section 505G(b)(5).

''(8) The term 'Tier 1 OTC monograph order request' means any OTC monograph order request not determined to be a Tier 2 OTC monograph order request.

''(9)(A) The term 'Tier 2 OTC monograph order request' means, subject to subparagraph (B), an OTC monograph order request for—

''(i) the reordering of existing information in the drug facts label of an OTC monograph drug;

''(ii) the addition of information to the other information section of the drug facts label of an OTC monograph drug, as limited by section 201.66(c)(7) of title 21, Code of Federal Regulations (or any successor regulations);

''(iii) modification to the directions for use section of the drug facts label of an OTC monograph drug, if such changes conform to changes made pursuant to section 505G(c)(3)(A);

''(iv) the standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph;

''(v) a change to ingredient nomenclature to align with nomenclature of a standards-setting organization; or

''(vi) addition of an interchangeable term in accordance with section 330.1 of title 21, Code of Federal Regulations (or any successor regulations).

''(B) The Secretary may, based on program implementation experience or other factors found appropriate by the Secretary, characterize any OTC

monograph order request as a Tier 2 OTC monograph order request (including recharacterizing a request from Tier 1 to Tier 2) and publish such determination in a proposed order issued pursuant to section 505G.

''(10)(A) The term 'OTC monograph drug facility' means a foreign or domestic business or other entity that—

''(i) is—

''(I) under one management, either direct or indirect; and

''(II) at one geographic location or address engaged in manufacturing or processing the finished dosage form of an OTC monograph drug;

''(ii) includes a finished dosage form manufacturer facility in a contractual relationship with the sponsor of one or more OTC monograph drugs to manufacture or process such drugs; and

''(iii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: production of clinical research supplies, testing, or placement of outer packaging on packages con-

taining multiple products, for such purposes as creating multipacks, when each monograph drug product contained within the overpackaging is already in a final packaged form prior to placement in the outer overpackaging.

''(B) For purposes of subparagraph (A)(i)(II), separate buildings or locations within close proximity are considered to be at one geographic location or address if the activities conducted in such buildings or locations are—

''(i) closely related to the same business enterprise;

''(ii) under the supervision of the same local management; and

''(iii) under a single FDA establishment identifier and capable of being inspected by the Food and Drug Administration during a single inspection.

''(C) If a business or other entity would meet criteria specified in subparagraph (A), but for being under multiple management, the business or other entity is deemed to constitute multiple facilities, one per management entity, for purposes of this paragraph.

''(11) The term 'OTC monograph drug meeting' means any meeting regarding the content of a proposed OTC monograph order request.

''(12) The term 'person' includes an affiliate of a person.

''(13) The terms 'requestor' and 'sponsor' have the meanings given such terms in section 505G.

''SEC. 744M. AUTHORITY TO ASSESS AND USE OTC MONOGRAPH FEES.

''(a) TYPES OF FEES.—Beginning with fiscal year 2019, the Secretary shall assess and collect fees in accordance with this section as follows:

''(1) FACILITY FEE.—

''(A) IN GENERAL.—Each person that owns a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period shall be assessed an annual fee for each such facility as determined under subsection (c).

''(B) EXCEPTIONS.—

''(i) A fee shall not be assessed under subparagraph (A) if the identified OTC monograph drug facility—

''(I) has ceased all activities related to OTC monograph drugs prior to January 31, 2019, for the first program year, and December 31 of the fiscal year for subsequent fiscal years; and

''(II) has updated its registration to reflect such change under the requirements for drug establishment registration set forth in section 510.

''(ii) The amount of the fee for a contract manufacturing organization facility shall be equal to two-thirds of the amount of the fee for an OTC monograph drug facility that is not a contract manufacturing organization facility.

''(C) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (c).

''(D) DUE DATE.—

''(i) FOR FIRST PROGRAM YEAR.—For fiscal year 2019, the facility fees required under subparagraph (A) shall be due 45 calendar days after publication of the Fed-

eral Register notice provided for under subsection (c)(4)(A).

''(ii) SUBSEQUENT FISCAL YEARS.—For each fiscal year after fiscal year 2019, the facility fees required under subparagraph (A) shall be due on the later of—

''(I) the first business day of June of such year; or

''(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year.

''(2) OTC MONOGRAPH ORDER REQUEST FEE.—

''(A) IN GENERAL.—Each person that submits an OTC monograph order request shall be subject to a fee for an OTC monograph order request. The amount of such fee shall be—

''(i) for a Tier 1 OTC monograph order request, $500,000, adjusted for inflation for the fiscal year (as determined under subsection (c)(1)(B)); and

''(ii) for a Tier 2 OTC monograph order request, $100,000 adjusted for infla-

tion for the fiscal year (as determined under subsection (c)(1)(B)).

"(B) DUE DATE.—The OTC monograph order request fees required under subparagraph (A) shall be due on the date of submission of the OTC monograph order request.

"(C) EXCEPTION FOR CERTAIN SAFETY CHANGES.—A person who is named as the requestor in an OTC monograph order shall not be subject to a fee under subparagraph (A) if the Secretary finds that the OTC monograph order request seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen—

"(i) a contraindication, warning, or precaution;

"(ii) a statement about risk associated with misuse or abuse; or

"(iii) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug.

"(D) REFUND OF FEE IF ORDER REQUEST IS RECATEGORIZED AS A TIER 2 OTC MONOGRAPH ORDER REQUEST.—If the Secretary determines that an OTC monograph request ini-

tially characterized as Tier 1 shall be re-characterized as a Tier 2 OTC monograph order request, and the requestor has paid a Tier 1 fee in accordance with subparagraph (A)(i), the Secretary shall refund the requestor the difference between the Tier 1 and Tier 2 fees determined under subparagraphs (A)(i) and (A)(ii), respectively.

''(E) REFUND OF FEE IF ORDER REQUEST REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any order request which is refused for filing or was withdrawn before being accepted or refused for filing.

''(F) FEES FOR ORDER REQUESTS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—An OTC monograph order request that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest.

''(G) REFUND OF FEE IF ORDER REQUEST WITHDRAWN.—If an order request is withdrawn

after the order request was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the order request after the application was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

''(3) REFUNDS.—

''(A) IN GENERAL.—Other than refunds provided pursuant to any of subparagraphs (D) through (G) of paragraph (2), the Secretary shall not refund any fee paid under paragraph (1) except as provided in subparagraph (B).

''(B) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under paragraph (1) or (2), a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

''(4) NOTICE.—Within the timeframe specified in subsection (c), the Secretary shall publish in the Federal Register the amount of the fees under paragraph (1) for such fiscal year.

''(b) FEE REVENUE AMOUNTS.—

''(1) FISCAL YEAR 2019.—For fiscal year 2019, fees under subsection (a)(1) shall be established to generate a total facility fee revenue amount equal to the sum of—

''(A) the annual base revenue for fiscal year 2019 (as determined under paragraph (3));

''(B) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(2)); and

''(C) additional direct cost adjustments (as determined under subsection (c)(3)).

''(2) SUBSEQUENT FISCAL YEARS.—For each of the fiscal years 2020 through 2023, fees under subsection (a)(1) shall be established to generate a total facility fee revenue amount equal to the sum of—

''(A) the annual base revenue for the fiscal year (as determined under paragraph (3));

''(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

''(C) the dollar amount equal to the operating reserve adjustment for the fiscal year, if

applicable (as determined under subsection (c)(2));

''(D) additional direct cost adjustments (as determined under subsection (c)(3)); and

''(E) additional dollar amounts for each fiscal year as follows:

''(i) $7,000,000 for fiscal year 2020.

''(ii) $6,000,000 for fiscal year 2021.

''(iii) $7,000,000 for fiscal year 2022.

''(iv) $3,000,000 for fiscal year 2023.

''(3) ANNUAL BASE REVENUE.—For purposes of paragraphs (1)(A) and (2)(A), the dollar amount of the annual base revenue for a fiscal year shall be—

''(A) for fiscal year 2019, $8,000,000; and

''(B) for fiscal years 2020 through 2023, the dollar amount of the total revenue amount established under this subsection for the previous fiscal year, not including any adjustments made under subsection (c)(2) or (c)(3).

''(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

''(1) INFLATION ADJUSTMENT.—

''(A) IN GENERAL.—For purposes of subsection (b)(2)(B), the dollar amount of the inflation adjustment to the annual base revenue

for fiscal year 2020 and each subsequent fiscal year shall be equal to the product of—

"(i) such annual base revenue for the fiscal year under subsection (b)(2); and

"(ii) the inflation adjustment percentage under subparagraph (C).

"(B) OTC MONOGRAPH ORDER REQUEST FEES.—For purposes of subsection (a)(2), the dollar amount of the inflation adjustment to the fee for OTC monograph order requests for fiscal year 2020 and each subsequent fiscal year shall be equal to the product of—

"(i) the applicable fee under subsection (a)(2) for the preceding fiscal year; and

"(ii) the inflation adjustment percentage under subparagraph (C).

"(C) INFLATION ADJUSTMENT PERCENTAGE.—The inflation adjustment percentage under this subparagraph for a fiscal year is equal to—

"(i) for each of fiscal years 2020 and 2021, the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Balti-

more, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data; and

''(ii) for each of fiscal years 2022 and 2023, the sum of—

''(I) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years; and

''(II) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3

years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years.

''(2) OPERATING RESERVE ADJUSTMENT.—

''(A) IN GENERAL.—For fiscal year 2019 and subsequent fiscal years, for purposes of subsections (b)(1)(B) and (b)(2)(C), the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenue and fees if such an adjustment is necessary to provide operating reserves of carryover user fees for OTC monograph drug activities for not more than the number of weeks specified in subparagraph (B).

''(B) NUMBER OF WEEKS.—The number of weeks specified in this subparagraph is—

''(i) 3 weeks for fiscal year 2019;

''(ii) 7 weeks for fiscal year 2020;

''(iii) 10 weeks for fiscal year 2021;

''(iv) 10 weeks for fiscal year 2022; and

''(v) 10 weeks for fiscal year 2023.

''(C) DECREASE.—If the Secretary has carryover balances for such process in excess of 10 weeks of the operating reserves referred to in subparagraph (A), the Secretary shall decrease the fee revenue and fees referred to in such subparagraph to provide for not more than 10 weeks of such operating reserves.

''(D) RATIONALE FOR ADJUSTMENT.—If an adjustment under this paragraph is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (4) establishing fee revenue and fees for the fiscal year involved.

''(3) ADDITIONAL DIRECT COST ADJUSTMENT.—The Secretary shall, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees for purposes of subsection (b)(2)(D) by an amount equal to—

''(A) $14,000,000 for fiscal year 2019;

''(B) $7,000,000 for fiscal year 2020;

''(C) $4,000,000 for fiscal year 2021;

''(D) $3,000,000 for fiscal year 2022; and

''(E) $3,000,000 for fiscal year 2023.

''(4) ANNUAL FEE SETTING.—

''(A) FISCAL YEAR 2019.—The Secretary shall, not later than the second Monday in March of 2019—

''(i) establish OTC monograph drug facility fees for fiscal year 2019 under subsection (a), based on the revenue amount for such year under subsection (b) and the adjustments provided under this subsection; and

''(ii) publish fee revenue, facility fees, and OTC monograph order requests in the Federal Register.

''(B) SUBSEQUENT FISCAL YEARS.—The Secretary shall, not later than the second Monday in March of each fiscal year that begins after September 30, 2019—

''(i) establish for each such fiscal year, based on the revenue amounts under subsection (b) and the adjustments provided under this subsection—

''(I) OTC monograph drug facility fees under subsection (a)(1); and

''(II) OTC monograph order request fees under subsection (a)(2); and

''(ii) publish such fee revenue amounts, facility fees, and OTC monograph order request fees in the Federal Register.

''(d) IDENTIFICATION OF FACILITIES.—Each person that owns an OTC monograph drug facility shall submit to the Secretary the information required under this subsection each year. Such information shall, for each fiscal year—

''(1) be submitted as part of the requirements for drug establishment registration set forth in section 510; and

''(2) include for each such facility, at a minimum, identification of the facility's business operation as that of an OTC monograph drug facility.

''(e) EFFECT OF FAILURE TO PAY FEES.—

''(1) OTC MONOGRAPH DRUG FACILITY FEE.—

''(A) IN GENERAL.—Failure to pay the fee under subsection (a)(1) within 20 calendar days of the due date as specified in subparagraph (D) of such subsection shall result in the following:

''(i) The Secretary shall place the facility on a publicly available arrears list.

''(ii) All OTC monograph drugs manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 502(ff).

''(B) APPLICATION OF PENALTIES.—The penalties under this paragraph shall apply until the fee established by subsection (a)(1) is paid.

''(2) ORDER REQUESTS.—An OTC monograph order request submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person under this section have been paid.

''(3) MEETINGS.—A person subject to fees under this section shall be considered ineligible for OTC monograph drug meetings until all such fees owed by such person have been paid.

''(f) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are au-

thorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for OTC monograph drug activities.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—Subject to subparagraph (C), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year.

''(B) USE OF FEES AND LIMITATION.—The fees authorized by this section shall be available to defray increases in the costs of the resources allocated for OTC monograph drug activities (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activi-

ties), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $12,000,000, multiplied by the adjustment factor applicable to the fiscal year involved under subsection (c)(1).

''(C) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (B) in any fiscal year if the costs funded by appropriations and allocated for OTC monograph drug activities are not more than 15 percent below the level specified in such subparagraph.

''(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2019), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2019 through 2023, there is authorized to be appropriated for fees under this section an amount equal to the total amount of fees assessed for such fiscal year under this section.

''(g) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(h) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in OTC monograph drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

''SEC. 744N. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2019, and not later than 120 calendar days after the end of each fiscal year thereafter for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 2001(b) of the Over-the-Counter Mono-

graph Safety, Innovation, and Reform Act of 2019 during such fiscal year and the future plans of the Food and Drug Administration for meeting such goals.

''(b) FISCAL REPORT.—Not later than 120 calendar days after the end of fiscal year 2019 and each subsequent fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

''(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the internet website of the Food and Drug Administration.

''(d) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for OTC monograph drug activities for the first 5 fiscal years after fiscal year 2023, and for the reauthorization of this part

for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Energy and Commerce of the House of Representatives;

''(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(C) scientific and academic experts;

''(D) health care professionals;

''(E) representatives of patient and consumer advocacy groups; and

''(F) the regulated industry.

''(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

''(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

''(B) publish such recommendations in the Federal Register;

''(C) provide for a period of 30 calendar days for the public to provide written comments on such recommendations;

''(D) hold a meeting at which the public may present its views on such recommendations; and

''(E) after consideration of such public views and comments, revise such recommendations as necessary.

''(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2023, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.''.

Subtitle I—Other Provisions

SEC. 391. PROTECTING ACCESS TO BIOLOGICAL PRODUCTS.

Section 351(k)(7) of the Public Health Service Act (42 U.S.C. 262(k)(7)) is amended by adding at the end the following:

''(D) DEEMED LICENSES.—

''(i) NO ADDITIONAL EXCLUSIVITY THROUGH DEEMING.—An approved application that is deemed to be a license for a biological product under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 shall not be treated as having been first licensed under subsection (a) for purposes of subparagraphs (A) and (B).

"(ii) APPLICATION OF LIMITATIONS ON EXCLUSIVITY.—Subparagraph (C) shall apply with respect to a reference product referred to in such subparagraph that was the subject of an approved application that was deemed to be a license pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

"(iii) APPLICABILITY.—The exclusivity periods described in section 527, section 505A(b)(1)(A)(ii), and section 505A(c)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act shall continue to apply to a biological product after an approved application for the biological product is deemed to be a license for the biological product under subsection (a) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.".

SEC. 392. ORPHAN DRUG CLARIFICATION.

Section 527(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(c)) is amended by adding at the end the following:

''(3) APPLICABILITY.—This subsection applies to any drug designated under section 526 for which an application was approved under section 505 of this Act or licensed under section 351 of the Public Health Service Act after the date of enactment of the FDA Reauthorization Act of 2017, regardless of the date on which such drug was designated under section 526.''.

SEC. 393. CONDITIONS OF USE FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

Section 351(k)(2)(A)(iii) of the Public Health Service Act (42 U.S.C. 262(k)(2)(A)(iii) is amended—

(1) in subclause (I), by striking ''; and'' and inserting a semicolon;

(2) in subclause (II), by striking the period and inserting ''; and'' ; and

(3) by adding at the end the following:

''(III) may include information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product.''.

SEC. 394. CLARIFYING THE MEANING OF NEW CHEMICAL ENTITY.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 505 (21 U.S.C. 355)—

(A) in subsection (c)(3)(E)—

(i) in clause (ii), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(ii) in clause (iii), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(B) in subsection (j)(5)(F)—

(i) in clause (ii), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal

Regulations (or any successor regulations))''; and

(ii) in clause (iii), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(C) in subsection (l)(2)(A)(i), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(D) in subsection (s), in the matter preceding paragraph (1), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(E) in subsection (u)(1), in the matter preceding subparagraph (A)—

(i) by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(ii) by striking ''same active ingredient'' and inserting ''same active moiety'';

(2) in section 512(c)(2)(F) (21 U.S.C. 360b(c)(2)(F))—

(A) in clause (i), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(B) in clause (ii), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(C) in clause (v), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as

defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(3) in section 524(a)(4)(C) (21 U.S.C. 360n(a)(4)(C)), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(4) in section 529(a)(4)(A)(ii) (21 U.S.C. 360ff(a)(4)(A)(ii)), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(5) in section 565A(a)(4)(D) (21 U.S.C. 360bbb–4a(a)(4)(D)), by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''.

TITLE IV—REVENUE PROVISIONS

SEC. 401. PERMANENT EXTENSION OF REDUCTION IN MEDICAL EXPENSE DEDUCTION FLOOR.

(a) IN GENERAL.—Section 213(a) of the Internal Revenue Code of 1986 is amended by striking ''10 percent'' and inserting ''7.5 percent''.

(b) CONFORMING AMENDMENTS.—

(1) Section 213 of such Code is amended by striking subsection (f).

(2) Section 56(b)(1) of such Code is amended by striking subparagraph (B) and by redesignating subparagraphs (C), (D), (E), and (F), as subparagraphs (B), (C), (D), and (E), respectively.

(c) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years ending after December 31, 2019.

SEC. 402. SAFE HARBOR FOR HIGH DEDUCTIBLE HEALTH PLANS WITHOUT DEDUCTIBLE FOR INSULIN.

(a) IN GENERAL.—Section 223(c)(2)(C) of the Internal Revenue Code of 1986 is amended by inserting ''or for insulin or any device for the delivery of insulin'' before the period at the end.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to months beginning after the date of the enactment of this Act.

SEC. 403. INCLUSION OF CERTAIN OVER-THE-COUNTER MEDICAL PRODUCTS AS QUALIFIED MEDICAL EXPENSES.

(a) HSAS.—Section 223(d)(2) of the Internal Revenue Code of 1986 is amended—

(1) by striking the last sentence of subparagraph (A) and inserting the following: ''For purposes of this subparagraph, amounts paid for menstrual care products shall be treated as paid for medical care.''; and

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

''(D) MENSTRUAL CARE PRODUCT.—For purposes of this paragraph, the term 'menstrual care product' means a tampon, pad, liner, cup, sponge, or similar product used by individuals with respect to menstruation or other genital-tract secretions.''.

(b) ARCHER MSAS.—Section 220(d)(2)(A) of such Code is amended by striking the last sentence and inserting the following: ''For purposes of this subparagraph, amounts paid for menstrual care products (as defined in

section 223(d)(2)(D)) shall be treated as paid for medical care.''.

(c) HEALTH FLEXIBLE SPENDING ARRANGEMENTS AND HEALTH REIMBURSEMENT ARRANGEMENTS.—Section 106 of such Code is amended by striking subsection (f) and inserting the following new subsection:

''(f) REIMBURSEMENTS FOR MENSTRUAL CARE PRODUCTS.—For purposes of this section and section 105, expenses incurred for menstrual care products (as defined in section 223(d)(2)(D)) shall be treated as incurred for medical care.''.

(d) EFFECTIVE DATES.—

(1) DISTRIBUTIONS FROM SAVINGS ACCOUNTS.—The amendment made by subsections (a) and (b) shall apply to amounts paid after December 31, 2019.

(2) REIMBURSEMENTS.—The amendment made by subsection (c) shall apply to expenses incurred after December 31, 2019.

TITLE V—MISCELLANEOUS

SEC. 501. PAYMENT FOR BIOSIMILAR BIOLOGICAL PRODUCTS DURING INITIAL PERIOD.

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

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

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

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

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

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

''(B) LIMITATION ON PAYMENT AMOUNT FOR BIOSIMILAR BIOLOGICAL PRODUCTS DURING INITIAL PERIOD.—In the case of a biosimilar biological product furnished on or after July 1, 2020, in lieu of applying subparagraph (A) during the initial period described in such subparagraph with respect to the biosimilar biological product, the amount payable under this section for the biosimilar biological product is the lesser of the following:

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

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

SEC. 502. GAO STUDY AND REPORT ON AVERAGE SALES PRICE.

(a) STUDY.—

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

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

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

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

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

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

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

(ii) by private payers in the commercial market.

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

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

(i) formulary placement;

(ii) utilization management considerations; or

(iii) other purposes.

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

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

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

SEC. 503. 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, 2021, the PDP sponsor of a prescription drug plan shall report to the Secretary, as specified by the Secretary—

"(1) any substantiated or suspicious activities (as defined by the Secretary) with respect to the

program under this part as it relates to fraud, waste, and abuse; and

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

SEC. 504. 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).''.

SEC. 505. 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 de-

scribed 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. 506. 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. 507. MEDPAC REPORT ON SHIFTING COVERAGE OF CERTAIN MEDICARE PART B DRUGS TO MEDICARE PART D.

(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the ''Commission'') shall conduct a study on shifting coverage of certain drugs and biologicals for which payment is currently made under part B of title XVIII of the Social Security Act (42 U.S.C.

1395j et seq.) to part D of such title (42 U.S.C. 1395w–21 et seq.). Such study shall include an analysis of—

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

(2) the feasibility and policy implications of shifting coverage of drugs and biologicals for which payment is currently made under such part B to such part D.

(b) REPORT.—

(1) IN GENERAL.—Not later than June 30, 2021, the Commission shall submit to Congress a report containing the results of the study conducted under subsection (a).

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

(A) formulary design under such part D;

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

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

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

(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. 508. REQUIREMENT THAT DIRECT-TO-CONSUMER ADVERTISEMENTS FOR PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS INCLUDE TRUTHFUL AND NON-MISLEADING PRICING INFORMATION.

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

"SEC. 1150C. REQUIREMENT THAT DIRECT-TO-CONSUMER ADVERTISEMENTS FOR PRESCRIPTION DRUGS AND BIOLOGICAL PRODUCTS INCLUDE TRUTHFUL AND NON-MISLEADING PRICING INFORMATION.

''(a) IN GENERAL.—The Secretary shall require that each direct-to-consumer advertisement for a prescription

drug or biological product for which payment is available under title XVIII or XIX includes an appropriate disclosure of truthful and non-misleading pricing information with respect to the drug or product.

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

SEC. 509. 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 inserting ''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 one-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.

SEC. 510. WAIVING MEDICARE COINSURANCE FOR COLORECTAL CANCER SCREENING TESTS.

Section 1833(a) of the Social Security Act (42 U.S.C. 1395l(a)) is amended—

(1) by moving the flush text following paragraph (9) 2 ems to the left; and

(2) by adding at the end of such flush text the following new sentence: ''For items and services furnished on or after January 1, 2021, paragraph (1)(Y) shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.''.

☒