116TH CONGRESS
2D SESSION

S. 3384

To allow for negotiation of prices for certain covered Medicare part D drugs, to allow for importation by individuals of prescription drugs from Canada, to preserve access to affordable generics and biosimilars, to increase the use of real-time benefit tools to lower beneficiary costs, to establish a manufacturer discount program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 3, 2020

Ms. MCSALLY introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To allow for negotiation of prices for certain covered Medicare part D drugs, to allow for importation by individuals of prescription drugs from Canada, to preserve access to affordable generics and biosimilars, to increase the use of real-time benefit tools to lower beneficiary costs, to establish a manufacturer discount program, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Lowering Prescription Drug Prices for America's Seniors and Families Act of 2020''.

SEC. 2. NEGOTIATION OF PRICES FOR CERTAIN COVERED PART D DRUGS FOLLOWING PERIOD OF EXCLUSIVITY.

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

(1) in subsection (i), by striking ''In order'' and inserting ''Except as provided in subsection (k), in order''; and

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

''(k) NEGOTIATION OF PRICES FOR CERTAIN COVERED PART D DRUGS FOLLOWING PERIOD OF EXCLUSIVITY.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, subject to paragraph (2), the Secretary shall, for plan years beginning on or after the date on which the applicable period with respect to an applicable covered part D drug (as those terms are defined in paragraph (3)) expires—

''(A) negotiate directly with pharmaceutical manufacturers the prices that may be charged to PDP sponsors and MA organiza-

tions for such applicable covered part D drug; and

"(B) complete such negotiations not later than 3 months prior to the beginning of each such plan year.

"(2) USE OF MEDICAID BEST PRICE IF NEGOTIATIONS FAIL.—In the case where the Secretary is not able to reach an agreement under paragraph (1) with respect to an applicable covered part D drug for a plan year by the date specified in paragraph (1)(B), the price that a pharmaceutical manufacturer may charge to PDP sponsors and MA organizations for such applicable covered part D drug for the plan year shall be determined using the methodology used to determine the best price of a covered outpatient drug under section 1927(c)(1)(C).

"(3) DEFINITIONS.—In this subsection:

"(A) APPLICABLE COVERED PART D DRUG.—The term 'applicable covered part D drug' means a covered part D drug for which there is in effect—

"(i) in the case of a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act, a patent on an active ingredient of the drug; or

"(ii) in the case of a biological product, a patent on the structure of the biological product.

A patent shall be considered to be in effect for purposes of this subparagraph during any extension of the patent term under section 156 of title 35, United States Code.

"(B) APPLICABLE PERIOD.—The term 'applicable period' means, with respect to an applicable covered part D drug, any applicable patent described in subparagraph (A).

"(4) CONDITION OF COVERAGE.—

"(A) IN GENERAL.—Subject to subparagraph (B), in order for coverage to be available under this part for an applicable covered part D drug (as defined in section 1860D–2(e)) of a manufacturer with respect to a plan year beginning on or after the date on which the applicable period with respect to such covered part D drug expires, the manufacturer must provide such applicable covered part D drug to PDP sponsors and MA organizations at the price negotiated under paragraph (1) or the price determined under paragraph (2), if applicable, for the plan year.

''(B) AUTHORIZING COVERAGE IN CERTAIN CIRCUMSTANCES.—Subparagraph (A) shall not apply to the dispensing of a covered part D drug if the Secretary has made a determination that the availability of the drug is essential to the health of beneficiaries under this part.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to covered part D drugs dispensed on or after January 1, 2021.

SEC. 3. DRUG IMPORTATION.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

''SEC. 810. IMPORTATION BY INDIVIDUALS OF PRESCRIPTION DRUGS FROM CANADA.

''(a) IN GENERAL.—Notwithstanding any other provision of this Act, not later than 180 days after the date of enactment of this section, the Secretary shall promulgate regulations permitting individuals to safely import into the United States a prescription drug described in subsection (b).

''(b) PRESCRIPTION DRUG.—A prescription drug described in this subsection—

''(1) is a prescription drug that—

''(A) is purchased from an approved Canadian pharmacy;

''(B) is dispensed by a pharmacist licensed to practice pharmacy and dispense prescription drugs in Canada;

''(C) is purchased for personal use by the individual, not for resale, in quantities that do not exceed a 90-day supply;

''(D) is filled using a valid prescription issued by a physician licensed to practice in a State in the United States; and

''(E) has the same active ingredient or ingredients, route of administration, dosage form, and strength as a prescription drug approved by the Secretary under chapter V; and

''(2) does not include—

''(A) a controlled substance (as defined in section 102 of the Controlled Substances Act);

''(B) a biological product (as defined in section 351 of the Public Health Service Act);

''(C) an infused drug (including a peritoneal dialysis solution);

''(D) an intravenously injected drug;

''(E) a drug that is inhaled during surgery;

''(F) a parenteral drug;

''(G) a drug manufactured through one or more biotechnology processes, including—

''(i) a therapeutic DNA plasmid product;

''(ii) a therapeutic synthetic peptide product of not more than 40 amino acids;

''(iii) a monoclonal antibody product for in vivo use; and

''(iv) a therapeutic recombinant DNA-derived product;

''(H) a drug required to be refrigerated at any time during manufacturing, packing, processing, or holding; or

''(I) a photoreactive drug.

''(c) APPROVED CANADIAN PHARMACY.—

''(1) IN GENERAL.—In this section, an approved Canadian pharmacy is a pharmacy that—

''(A) is located in Canada; and

''(B) the Secretary certifies—

''(i) is licensed to operate and dispense prescription drugs to individuals in Canada; and

''(ii) meets the criteria under paragraph (3).

''(2) PUBLICATION OF APPROVED CANADIAN PHARMACIES.—The Secretary shall publish on the internet website of the Food and Drug Administration a list of approved Canadian pharmacies, including the internet website address of each such approved Canadian pharmacy, from which individuals may purchase prescription drugs in accordance with subsection (a).

''(3) ADDITIONAL CRITERIA.—To be an approved Canadian pharmacy, the Secretary shall certify that the pharmacy—

''(A) has been in existence for a period of at least 5 years preceding the date of such certification and has a purpose other than to participate in the program established under this section;

''(B) operates in accordance with pharmacy standards set forth by the provincial pharmacy rules and regulations enacted in Canada;

''(C) has processes established by the pharmacy, or participates in another established process, to certify that the physical premises and data reporting procedures and licenses are in compliance with all applicable laws and regu-

lations, and has implemented policies designed to monitor ongoing compliance with such laws and regulations;

''(D) conducts or commits to participate in ongoing and comprehensive quality assurance programs and implements such quality assurance measures, including blind testing, to ensure the veracity and reliability of the findings of the quality assurance program;

''(E) agrees that laboratories approved by the Secretary shall be used to conduct product testing to determine the safety and efficacy of sample pharmaceutical products;

''(F) has established, or will establish or participate in, a process for resolving grievances and will be held accountable for violations of established guidelines and rules;

''(G) does not resell products from online pharmacies located outside Canada to customers in the United States; and

''(H) meets any other criteria established by the Secretary.''.

SEC. 4. PRESERVING ACCESS THROUGH FTC ACTIONS.

(a) PRESERVE ACCESS TO AFFORDABLE GENERICS AND BIOSIMILARS.—

(1) UNLAWFUL COMPENSATION FOR DELAY.—

(A) IN GENERAL.—The Federal Trade Commission Act (15 U.S.C. 41 et seq.) is amended by inserting after section 26 (15 U.S.C. 57c–2) the following:

"SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS AND BIOSIMILARS.

''(a) IN GENERAL.—

''(1) ENFORCEMENT PROCEEDING.—The Commission may initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product or biological product.

''(2) PRESUMPTION AND VIOLATION.—

''(A) IN GENERAL.—Subject to subparagraph (B), in such a proceeding, an agreement shall be presumed to have anticompetitive effects and shall be a violation of this section if—

''(i) an ANDA filer or a biosimilar biological product application filer receives anything of value, including an exclusive license; and

''(ii) the ANDA filer or biosimilar biological product application filer agrees to

limit or forego research, development, manufacturing, marketing, or sales of the ANDA product or biosimilar biological product, as applicable, for any period of time.

''(B) EXCEPTION.—Subparagraph (A) shall not apply if the parties to such agreement demonstrate by clear and convincing evidence that—

''(i) the value described in subparagraph (A)(i) is compensation solely for other goods or services that the ANDA filer or biosimilar biological product application filer has promised to provide; or

''(ii) the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

''(b) LIMITATIONS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall not presume—

''(1) that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity; or

''(2) that the agreement's provision for entry of the ANDA product or biosimilar biological product

prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is procompetitive.

''(c) EXCLUSIONS.—Nothing in this section shall prohibit a resolution or settlement of a patent infringement claim in which the consideration granted by the NDA holder or biological product license holder to the ANDA filer or biosimilar biological product application filer, respectively, as part of the resolution or settlement includes only one or more of the following:

''(1) The right to market the ANDA product or biosimilar biological product in the United States prior to the expiration of—

''(A) any patent that is the basis for the patent infringement claim; or

''(B) any patent right or other statutory exclusivity that would prevent the marketing of such ANDA product or biosimilar biological product.

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

''(3) A covenant not to sue on any claim that the ANDA product or biosimilar biological product infringes a United States patent.

''(d) ENFORCEMENT.—

''(1) ENFORCEMENT.—A violation of this section shall be treated as a violation of section 5.

''(2) JUDICIAL REVIEW.—

''(A) IN GENERAL.—Any party that is subject to a final order of the Commission, issued in an administrative adjudicative proceeding under the authority of subsection (a)(1), may, within 30 days of the issuance of such order, petition for review of such order in—

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

''(ii) the United States Court of Appeals for the circuit in which the ultimate parent entity, as defined in section 801.1(a)(3) of title 16, Code of Federal Regulations, or any successor thereto, of the NDA holder or biological product license holder is incorporated as of the date that the NDA or biological product license application, as applicable, is filed with the Commissioner of Food and Drugs; or

''(iii) the United States Court of Appeals for the circuit in which the ultimate parent entity of the ANDA filer or biosimilar biological product application filer

is incorporated as of the date that the ANDA or biosimilar biological product application is filed with the Commissioner of Food and Drugs.

''(B) TREATMENT OF FINDINGS.—In a proceeding for judicial review of a final order of the Commission, the findings of the Commission as to the facts, if supported by evidence, shall be conclusive.

''(e) ANTITRUST LAWS.—Nothing in this section shall modify, impair, limit, or supersede the applicability of the antitrust laws as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), and of section 5 of this Act to the extent that section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit, or supersede the right of an ANDA filer or biosimilar biological product application filer to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition.

''(f) PENALTIES.—

''(1) FORFEITURE.—Each party that violates or assists in the violation of this section shall forfeit and pay to the United States a civil penalty sufficient to deter violations of this section, but in no

event greater than 3 times the value received by the party that is reasonably attributable to the violation of this section. If no such value has been received by the NDA holder or biological product license holder, the penalty to the NDA holder or biological product license holder shall be sufficient to deter violations, but in no event greater than 3 times the value given to the ANDA filer or biosimilar biological product application filer reasonably attributable to the violation of this section. Such penalty shall accrue to the United States and may be recovered in a civil action brought by the Commission, in its own name by any of its attorneys designated by it for such purpose, in a district court of the United States against any party that violates this section. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

''(2) CEASE AND DESIST.—

''(A) IN GENERAL.—If the Commission has issued a cease and desist order with respect to a party in an administrative adjudicative proceeding under the authority of subsection (a)(1), an action brought pursuant to paragraph (1) may be commenced against such

party at any time before the expiration of 1 year after such order becomes final pursuant to section 5(g).

''(B) EXCEPTION.—In an action under subparagraph (A), the findings of the Commission as to the material facts in the administrative adjudicative proceeding with respect to the violation of this section by a party shall be conclusive unless—

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

''(ii) the order became final by reason of section 5(g)(1), in which case such finding shall be conclusive if supported by evidence.

''(3) CIVIL PENALTY.—In determining the amount of the civil penalty described in this section, the court shall take into account—

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

''(B) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to con-

tinue doing business, profits earned by the NDA holder or biological product license holder, compensation received by the ANDA filer or biosimilar biological product application filer, and the amount of commerce affected; and

''(C) other matters that justice requires.

''(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

''(g) DEFINITIONS.—In this section:

''(1) AGREEMENT.—The term 'agreement' means anything that would constitute an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of this Act.

''(2) AGREEMENT RESOLVING OR SETTLING A PATENT INFRINGEMENT CLAIM.—The term 'agreement resolving or settling a patent infringement claim' includes any agreement that is entered into within 30 days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is oth-

erwise related to the resolution or settlement of the claim.

''(3) ANDA.—The term 'ANDA' means an abbreviated new drug application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) or a new drug application filed under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)).

''(4) ANDA FILER.—The term 'ANDA filer' means a party that owns or controls an ANDA filed with the Food and Drug Administration or has the exclusive rights under such ANDA to distribute the ANDA product.

''(5) ANDA PRODUCT.—The term 'ANDA product' means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

''(6) BIOLOGICAL PRODUCT.—The term 'biological product' has the meaning given such term in section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)).

''(7) BIOLOGICAL PRODUCT LICENSE APPLICATION.—The term 'biological product license application' means an application under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

"(8) BIOLOGICAL PRODUCT LICENSE HOLDER.—The term 'biological product license holder' means—

"(A) the holder of an approved biological product license application for a biological product;

"(B) a person owning or controlling enforcement of any patents that claim the biological product that is the subject of such approved application; or

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

"(9) BIOSIMILAR BIOLOGICAL PRODUCT.—The term 'biosimilar biological product' means the product to be manufactured under the biosimilar biological product application that is the subject of the patent infringement claim.

"(10) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION.—The term 'biosimilar biological product ap-

plication' means an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) for licensure of a biological product as biosimilar to, or interchangeable with, a reference product.

"(11) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FILER.—The term 'biosimilar biological product application filer' means a party that owns or controls a biosimilar biological product application filed with the Food and Drug Administration or has the exclusive rights under such application to distribute the biosimilar biological product.

"(12) DRUG PRODUCT.—The term 'drug product' has the meaning given such term in section 314.3(b) of title 21, Code of Federal Regulations (or any successor regulation).

"(13) NDA.—The term 'NDA' means a new drug application filed under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

"(14) NDA HOLDER.—The term 'NDA holder' means—

"(A) the holder of an approved NDA application for a drug product;

"(B) a person owning or controlling enforcement of the patent listed in the Approved

Drug Products With Therapeutic Equivalence Evaluations (commonly known as the 'FDA Orange Book') in connection with the NDA; or

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

"(15) PARTY.—The term 'party' means any person, partnership, corporation, or other legal entity.

"(16) PATENT INFRINGEMENT.—The term 'patent infringement' means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition, and extensions thereof.

"(17) PATENT INFRINGEMENT CLAIM.—The term 'patent infringement claim' means any allegation made to an ANDA filer or biosimilar biological product application filer, whether or not included in a complaint filed with a court of law, that its ANDA

or ANDA product, or biological product license application or biological product, may infringe any patent held by, or exclusively licensed to, the NDA holder or biological product license holder of the drug product or biological product, as applicable.

''(18) STATUTORY EXCLUSIVITY.—The term 'statutory exclusivity' means those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year data exclusivity), section 527 (orphan drug exclusivity), or section 505A (pediatric exclusivity) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E), 360cc, 355a), or on the licensing of biological product applications under section 351(k)(7) (12-year exclusivity) or paragraph (2) or (3) of section 351(m) (pediatric exclusivity) of the Public Health Service Act (42 U.S.C. 262) or under section 527 of the Federal Food, Drug, and Cosmetic Act (orphan drug exclusivity).''.

(B) EFFECTIVE DATE.—Section 27 of the Federal Trade Commission Act, as added by this paragraph, shall apply to all agreements described in section 27(a)(1) of that Act entered into after June 17, 2013. Section 27(f) of the Federal Trade Commission Act, as added

by this paragraph, shall apply to agreements entered into on or after the date of enactment of this Act.

(2) CERTIFICATION OF AGREEMENTS.—Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by adding at the end the following:

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

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

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

or are otherwise related to, the referenced agreement; and

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

(3) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by inserting "section 27 of the Federal Trade Commission Act or" after "that the agreement has violated".

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

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

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

(C) inserting after subparagraph (E) the following:

"(F) under section 27;".

(5) STATUTE OF LIMITATIONS.—The Federal Trade Commission shall commence any enforcement

proceeding described in section 27 of the Federal Trade Commission Act, as added by paragraph (1), except for an action described in section 27(f)(2) of the Federal Trade Commission Act, not later than 6 years after the date on which the parties to the agreement file the certification under section 1112(d) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (21 U.S.C. 355 note).

(b) CITIZEN PETITIONS.—Section 505(q)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)(1)) is amended—

(1) in subparagraph (E)—

(A) by striking ''If the Secretary'' and inserting the following:

''(i) IN GENERAL.—If the Secretary'';

(B) by striking the second sentence and inserting the following:

''(ii) FACTORS.—In determining whether a petition was submitted with the primary purpose of delaying the approval of an application, the Secretary shall consider—

''(I) whether it appears, based on the date that relevant information re-

lied upon in the petition became known to the petitioner (or reasonably should have been known to the petitioner), as certified by the petitioner in accordance with subparagraph (H), that the petitioner has taken an unreasonable length of time to submit the petition;

''(II) whether the petitioner has submitted multiple or serial petitions raising issues that reasonably could have been known to the petitioner at the time of submission of the earlier petition or petitions;

''(III) whether the petition was submitted close in time to a known, first date upon which an application under subsection (b)(2) of this section or section 351(k) of the Public Health Service Act could be approved;

''(IV) whether the petition was submitted without any data or information in support of the scientific positions set forth in the petition;

''(V) whether the petition raises the same or substantially similar issues as a prior petition to which the Secretary has responded substantively already, particularly if the subsequent submission follows the earlier response closely in time;

''(VI) whether the petition concerns standards for approval of a drug for which the Secretary has provided an opportunity for public input, such as draft or final product-specific guidance applicable to the drug, and the petitioner has not provided comment other than through the petition;

''(VII) whether the petition requests that other applicants meet standards for testing, data, or labeling for a drug that are more onerous or rigorous than the standards applicable to, as applicable, the listed drug, reference product, or petitioner's version of the same drug;

''(VIII) the history of the petitioner with the Food and Drug Ad-

ministration, such as whether the petitioner has a history of submitting petitions that the Secretary has determined were submitted with the primary purpose of delay; and

''(IX) other relevant considerations, as the Secretary may describe in guidance.''; and

(C) by adding at the end the following:

''(iii) PUBLIC AVAILABILITY.—The Secretary shall publish on the internet website of the Food and Drug Administration a list of any petitions that the Secretary determines were submitted for the primary purpose of delaying the approval of an application.

''(iv) REFERRAL TO THE FEDERAL TRADE COMMISSION.—The Secretary shall establish procedures for referring to the Federal Trade Commission any petition or supplement to a petition that the Secretary determines was submitted with the primary purpose of delaying approval of an application. Such procedures shall include notification to the petitioner and an opportunity

for the petitioner to respond to the Secretary prior to referral to the Federal Trade Commission.''; and

(2) by adding at the end the following:

''(J) TIMELINE FOR SUBMITTING PETITIONS.—The Secretary may establish a time period after the relevant information relied upon in a petition became known to the petitioner (or reasonably should have been known to a petitioner), as certified by the petitioner in accordance with subparagraph (H), and any petition that is submitted after such time period has passed shall be summarily denied.''.

(c) FEDERAL TRADE COMMISSION ENFORCEMENT AGAINST SHAM PETITIONS.—

(1) DEFINITIONS.—In this subsection:

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

(B) COVERED APPLICATION.—The term ''covered application'' means an application filed pursuant to subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

(C) COVERED PETITION.—The term ''covered petition'' means a petition, or a supplement to a petition, filed under section 505(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)).

(D) PERSON.—The term ''person''—

(i) means an individual or entity; and

(ii) includes—

(I) a successor and an assign of an entity; and

(II) a joint venture, subsidiary, partnership, division, group, and affiliate controlled by an entity, and

(III) a successor and an assign of a joint venture, subsidiary, partnership, division, group, and affiliate controlled by an entity.

(E) SERIES OF COVERED PETITIONS.—The term ''series of covered petitions'' means any group of more than 1 covered petition relating to the same covered application.

(F) SHAM.—The term ''sham'' means a covered petition that is objectively baseless and that attempts to use a governmental process, as opposed to the outcome of that process, to

interfere with the business of a competitor, or a series of covered petitions that attempts to use a governmental process, as opposed to the outcome of that process, to interfere with the business of a competitor.

(2) VIOLATION.—A person submitting or causing the submission of a covered petition or a series of covered petitions that is a sham shall be liable for engaging in an unfair method of competition under section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)).

(3) CIVIL ACTION.—

(A) IN GENERAL.—If the Commission has reason to believe that the submission of a covered petition or a series of covered petitions constitutes a violation of section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)), the Commission may commence a civil action to recover a civil penalty and seek other appropriate relief in a district court of the United States against any person that submitted or caused to be submitted such covered petition or such series of covered petitions, including successors or assigns.

(B) PRESUMPTION.—In a civil action under subparagraph (A), a covered petition shall be presumed to be part of a series of covered petitions that is a sham under paragraph (2) of this subsection if—

(i) the Secretary of Health and Human Services—

(I) has determined that the covered petition was submitted with the primary purpose of delaying the approval of a covered application; and

(II) has referred such determination to the Federal Trade Commission in writing, including a reasoned basis for the determination; and

(ii) the covered petition was part of a series of covered petitions.

(C) EXCEPTION.—The presumption in subparagraph (B) shall not apply if the defendant establishes, by a preponderance of the evidence, that the series of covered petitions that includes the covered petition referred to the Commission by the Secretary of Health and Human Services is not a sham.

(D) CIVIL PENALTY.—In an action under subparagraph (A), any person that has been found liable for a violation of section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)) shall be subject to a civil penalty for each violation of not more than the greater of—

(i) any revenue earned from the sale by such person of any drug product, referenced in a covered application that was the subject of a covered petition or a series of covered petitions that is a sham, during the period in which the covered petition or series of covered petitions was under review by the Secretary of Health and Human Services; or

(ii) $50,000 for each calendar day that each covered petition that is a sham or that was part of a series of covered petitions that is a sham was under review by the Secretary of Health and Human Services.

(E) ANTITRUST LAWS.—Nothing in this subsection shall modify, impair, limit, or supersede the applicability of the antitrust laws as defined in subsection (a) of the first section of

the Clayton Act (15 U.S.C. 12(a)), and of section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that it applies to unfair methods of competition.

(F) RULE OF CONSTRUCTION.—The civil penalty provided in this paragraph is in addition to, and not in lieu of, any other remedies provided by Federal law, including under section 16 of the Clayton Act (15 U.S.C. 26) or under section 13(b) of the Federal Trade Commission Act (15 U.S.C. 53(b)). Nothing in this subparagraph shall be construed to affect any authority of the Commission under any other provision of law.

(4) APPLICABILITY.—This subsection shall apply to any covered petition submitted on or after the date of enactment of this Act.

SEC. 5. INCREASING THE USE OF REAL-TIME BENEFIT TOOLS TO LOWER BENEFICIARY COSTS.

(a) REQUIRING PRESCRIPTION DRUG PLAN SPONSORS AND MEDICARE ADVANTAGE ORGANIZATIONS TO INCLUDE REAL-TIME BENEFIT INFORMATION UNDER MEDICARE PART D.—Section 1860D–4 of the Social Security Act (42 U.S.C. 1395w–104) is amended—

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

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

''(o) REAL-TIME BENEFIT INFORMATION.—

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

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

''(A) integrating with electronic prescribing and electronic health record systems of prescribing health care professionals for the transmission of eligibility and formulary and benefit

information in real time to such professionals; and

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

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

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

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

''(II) the formulary status of such drug and such alternatives and any prior authorization or other utilization management requirements applicable to such drug and such alternatives included in the formulary of such plan.

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

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

(b) REQUIRING QUALIFIED ELECTRONIC HEALTH RECORDS TO INCLUDE REAL-TIME BENEFIT TOOLS.—Section 3000(13) of the Public Health Service Act (42 U.S.C. 300jj(13)) is amended—

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

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

(3) by adding at the end the following:

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

(c) INCLUSION OF USE OF REAL-TIME ELECTRONIC INFORMATION IN SHARED DECISION MAKING UNDER MIPS.—Section 1848(q)(2)(B)(iii)(IV) of the Social Security Act (42 U.S.C. 1395w–4(q)(2)(B)(iii)(IV)) is amended by adding at the end the following new sentence: ''This subcategory shall include as an activity option, beginning with the performance period starting on January

1, 2021, use of a real-time benefit tool as described in 1860D–4(o).''.

SEC. 6. MEDICARE PART D MODERNIZATION REDESIGN.

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

(1) in paragraph (2)—

(A) in subparagraph (A), in the matter preceding clause (i), by inserting ''for a year preceding 2022 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2022 and each subsequent year'' after ''paragraph (3)'';

(B) in subparagraph (C)—

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

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

(C) in subparagraph (D)—

(i) in clause (i)—

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

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

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

(2) in paragraph (3)(A)—

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

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

(3) in paragraph (4)—

(A) in subparagraph (A)—

(i) in clause (i)—

(I) by redesignating subclauses (I) and (II) as items (aa) and (bb),

respectively, and indenting appropriately;

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

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

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

(IV) by adding at the end the following:

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

(ii) in clause (ii)—

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

(II) by adding at the end the following new sentence: ''The Secretary shall continue to calculate the dollar amounts specified in clause (i)(I)(aa), including with the adjustment under

this clause, after 2021 for purposes of section 1860D–14(a)(1)(D)(iii).'';

(B) in subparagraph (B)—

(i) in clause (i)—

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

(II) in subclause (VI)—

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

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

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

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

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

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

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

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

(b) REDUCTION IN BENEFICIARY COINSURANCE.—

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

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

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

''(i) IN GENERAL.—Subject to'';

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

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

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

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

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

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

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

(1) in paragraph (1)—

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

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

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

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

''(B) for a subsequent year, the sum of—

''(i) an amount equal to the applicable percentage specified in paragraph (5)(A) of such allowable reinsurance costs attributable to that portion of gross prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) with respect to applicable drugs (as defined in section 1860D–14B(g)(2)); and

''(ii) an amount equal to the applicable percentage specified in paragraph (5)(B) of allowable reinsurance costs attributable to that portion of gross prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) with respect to covered part D drugs that are not applicable drugs (as so defined).''; and

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

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

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

''(i) for 2022, 60 percent;

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

''(iii) for 2024 and each subsequent year, 20 percent; and

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

''(i) for 2022, 80 percent;

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

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

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

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

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

''(a) ESTABLISHMENT.—The Secretary shall establish a manufacturer discount program (in this section referred to as the 'program'). Under the program, the Sec-

retary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of the duties described in subsection (c). The Secretary shall establish a model agreement for use under the program by not later than January 1, 2021, in consultation with manufacturers, and allow for comment on such model agreement.

''(b) TERMS OF AGREEMENT.—

''(1) IN GENERAL.—

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

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

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

it can demonstrate to the Secretary compliance with the requirements under the program.

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

''(4) LENGTH OF AGREEMENT.—

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

''(B) TERMINATION.—

''(i) BY THE SECRETARY.—The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective ear-

lier 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.

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

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

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

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

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

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

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

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

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

''(2) MONITORING COMPLIANCE.—

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

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

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

''(d) ADMINISTRATION.—

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

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

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

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

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

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

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

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

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

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

''(6) FUNDING.—For purposes of carrying out this section, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of $4,000,000 for each of fiscal years 2020 through 2023, to remain available until expended.''.

''(e) ENFORCEMENT.—

''(1) AUDITS.—Each manufacturer with an agreement in effect under this section shall be subject to periodic audit by the Secretary.

''(2) CIVIL MONEY PENALTY.—

''(A) IN GENERAL.—The Secretary shall impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with such agreement for each such failure in an amount the Secretary determines is commensurate with the sum of—

''(i) the amount that the manufacturer would have paid with respect to such discounts under the agreement, which will then be used to pay the discounts which the manufacturer had failed to provide; and

''(ii) 25 percent of such amount.

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

''(f) CLARIFICATION REGARDING AVAILABILITY OF OTHER COVERED PART D DRUGS.—Nothing in this section shall prevent an applicable beneficiary from purchasing a covered part D drug that is not an applicable drug (including a generic drug or a drug that is not on

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

''(g) DEFINITIONS.—In this section:

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

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

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

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

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

''(A) approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (including a product licensed under subsection (k) of such section 351); and

''(B)(i) if the PDP sponsor of the prescription drug plan or the MA organization offering

the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

''(ii) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

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

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

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

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

''(4) DISCOUNTED PRICE.—

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

''(i) with respect to an applicable drug dispensed for an applicable beneficiary who has incurred costs that are below the an-

nual out-of-pocket threshold specified in section 1860D–2(b)(4)(B), 93 percent of the negotiated price of the applicable drug of a manufacturer; and

''(ii) with respect to an applicable drug dispensed for an applicable beneficiary who has incurred costs for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B), 86 percent of the negotiated price of the applicable drug of a manufacturer.

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

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

''(i) the discounted price under clause (i) of subparagraph (A) only on the portion of the negotiated price of the applicable

drug that falls above the deductible specified in section 1860D–2(b)(1) and below the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B); and

''(ii) the discounted price under clause (ii) of subparagraph (A) only on the portion of the negotiated price of the applicable drug that falls at or above such annual out-of-pocket threshold.

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

''(6) NEGOTIATED PRICE.—The term 'negotiated price' has the meaning given such term in section 1860D–2(d)(1)(B), except that such negotiated price shall not include any dispensing fee for the applicable drug.

''(7) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—The term 'qualified retiree prescription drug plan' has the meaning given such term in section 1860D–22(a)(2).''.

(2) SUNSET OF MEDICARE COVERAGE GAP DISCOUNT PROGRAM.—Section 1860D–14A of the Social Security Act (42 U.S.C. 1395–114a) is amended—

(A) in subsection (a), in the first sentence, by striking ''The Secretary'' and inserting ''Subject to subsection (h), the Secretary''; and

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

''(h) SUNSET OF PROGRAM.—

''(1) IN GENERAL.—The program shall not apply to applicable drugs dispensed on or after January 1, 2022, and, subject to paragraph (2), agreements under this section shall be terminated as of such date.

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

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

(A) in subsection (b)(2)(C)(iii)—

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

''(I) the reinsurance''; and

(ii) by adding at the end the following:

''(II) for 2022 and each subsequent year, the manufacturer discounts provided under section 1860D–14B subtracted from the actuarial value to produce such bid; and''; and

(B) in subsection (c)(1)(C)—

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

''(i) the reinsurance'';

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

(iii) by adding at the end the following:

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

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

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

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

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

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

(1) in paragraph (2)—

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

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

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

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

(2) in paragraph (3)—

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

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

(f) UPDATING RISK ADJUSTMENT METHODOLOGIES TO ACCOUNT FOR PART D MODERNIZATION REDESIGN.—Section 1860D–15(c) of the Social Security Act

(42 U.S.C. 1395w–115(c)) is amended by adding at the end the following new paragraph:

''(3) UPDATING RISK ADJUSTMENT METHODOLOGIES TO ACCOUNT FOR PART D MODERNIZATION REDESIGN.—The Secretary shall update the risk adjustment methodologies used to adjust bid amounts pursuant to this subsection as appropriate to take into account changes in benefits under this part pursuant to the amendments made by section 121 of the Lowering Prescription Drug Prices for America's Seniors and Families Act of 2020.''.

(g) CONFORMING AMENDMENTS.—

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

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

(B) in subsection (c)(1)(C)—

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

(ii) by inserting ''for a year preceding 2022 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the

year for 2022 and each subsequent year'' after ''subsection (b)(3) for the year'' each place it appears;

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

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

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

(A) in paragraph (1)—

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

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

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

(B) in paragraph (2)—

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

year preceding 2022, the continuation''; and

(ii) in subparagraph (E)—

(I) by inserting ''for a year preceding 2022,'' after ''subsection (c)''; and

(II) by striking ''1860D–2(b)(4)(A)(i)(I)'' and inserting ''1860D–2(b)(4)(A)(i)(I)(aa)''.

(4) Section 1860D–21(d)(7) of the Social Security Act (42 U.S.C. 1395w–131(d)(7)) is amended by striking ''section 1860D–2(b)(B)(4)(B)(i)'' and inserting ''section 1860D–2(b)(B)(4)(C)(i)''.

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

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

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

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

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

''(ii) for 2022 and each subsequent year, any discount provided pursuant to section 1860D–14B.''.

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

(A) by inserting ''for a year before 2022'' after ''1860D–2(b)(3)''; and

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

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

''(1) participate in—

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

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

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

SEC. 7. SEVERABILITY.

If any provision of this Act, an amendment made by this Act, or the application of such provision or amend-

ment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such Act or amendments to any person or circumstance shall not be affected.

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