

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Lowering Prescription
3 Drug Prices for America’s Seniors and Families Act of
4 2020”.

5 **SEC. 2. NEGOTIATION OF PRICES FOR CERTAIN COVERED**
6 **PART D DRUGS FOLLOWING PERIOD OF EX-**
7 **CLUSIVITY.**

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

10 (1) in subsection (i), by striking “In order” and
11 inserting “Except as provided in subsection (k), in
12 order”; and

13 (2) by adding at the end the following new sub-
14 section:

15 “(k) NEGOTIATION OF PRICES FOR CERTAIN COV-
16 ERED PART D DRUGS FOLLOWING PERIOD OF EXCLU-
17 SIVITY.—

18 “(1) IN GENERAL.—Notwithstanding any other
19 provision of law, subject to paragraph (2), the Sec-
20 retary shall, for plan years beginning on or after the
21 date on which the applicable period with respect to
22 an applicable covered part D drug (as those terms
23 are defined in paragraph (3)) expires—

24 “(A) negotiate directly with pharma-
25 ceutical manufacturers the prices that may be
26 charged to PDP sponsors and MA organiza-

1 tions for such applicable covered part D drug;
2 and

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

6 “(2) USE OF MEDICAID BEST PRICE IF NEGO-
7 TIATIONS FAIL.—In the case where the Secretary is
8 not able to reach an agreement under paragraph (1)
9 with respect to an applicable covered part D drug
10 for a plan year by the date specified in paragraph
11 (1)(B), the price that a pharmaceutical manufac-
12 turer may charge to PDP sponsors and MA organi-
13 zations for such applicable covered part D drug for
14 the plan year shall be determined using the method-
15 ology used to determine the best price of a covered
16 outpatient drug under section 1927(c)(1)(C).

17 “(3) DEFINITIONS.—In this subsection:

18 “(A) APPLICABLE COVERED PART D
19 DRUG.—The term ‘applicable covered part D
20 drug’ means a covered part D drug for which
21 there is in effect—

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

1 “(ii) in the case of a biological prod-
2 uct, a patent on the structure of the bio-
3 logical product.

4 A patent shall be considered to be in effect for
5 purposes of this subparagraph during any ex-
6 tension of the patent term under section 156 of
7 title 35, United States Code.

8 “(B) APPLICABLE PERIOD.—The term ‘ap-
9 plicable period’ means, with respect to an appli-
10 cable covered part D drug, any applicable pat-
11 ent described in subparagraph (A).

12 “(4) CONDITION OF COVERAGE.—

13 “(A) IN GENERAL.—Subject to subpara-
14 graph (B), in order for coverage to be available
15 under this part for an applicable covered part
16 D drug (as defined in section 1860D–2(e)) of
17 a manufacturer with respect to a plan year be-
18 ginning on or after the date on which the appli-
19 cable period with respect to such covered part
20 D drug expires, the manufacturer must provide
21 such applicable covered part D drug to PDP
22 sponsors and MA organizations at the price ne-
23 gotiated under paragraph (1) or the price deter-
24 mined under paragraph (2), if applicable, for
25 the plan year.

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

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

10 **SEC. 3. DRUG IMPORTATION.**

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

14 **“SEC. 810. IMPORTATION BY INDIVIDUALS OF PRESCRIP-**
15 **TION DRUGS FROM CANADA.**

16 “(a) IN GENERAL.—Notwithstanding any other pro-
17 vision of this Act, not later than 180 days after the date
18 of enactment of this section, the Secretary shall promul-
19 gate regulations permitting individuals to safely import
20 into the United States a prescription drug described in
21 subsection (b).

22 “(b) PRESCRIPTION DRUG.—A prescription drug de-
23 scribed in this subsection—

24 “(1) is a prescription drug that—

1 “(A) is purchased from an approved Cana-
2 dian pharmacy;

3 “(B) is dispensed by a pharmacist licensed
4 to practice pharmacy and dispense prescription
5 drugs in Canada;

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

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

12 “(E) has the same active ingredient or in-
13 gredients, route of administration, dosage form,
14 and strength as a prescription drug approved
15 by the Secretary under chapter V; and

16 “(2) does not include—

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

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

21 “(C) an infused drug (including a peri-
22 toneal dialysis solution);

23 “(D) an intravenously injected drug;

24 “(E) a drug that is inhaled during surgery;

25 “(F) a parenteral drug;

1 “(G) a drug manufactured through one or
2 more biotechnology processes, including—

3 “(i) a therapeutic DNA plasmid prod-
4 uct;

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

7 “(iii) a monoclonal antibody product
8 for in vivo use; and

9 “(iv) a therapeutic recombinant DNA-
10 derived product;

11 “(H) a drug required to be refrigerated at
12 any time during manufacturing, packing, proc-
13 essing, or holding; or

14 “(I) a photoreactive drug.

15 “(c) APPROVED CANADIAN PHARMACY.—

16 “(1) IN GENERAL.—In this section, an ap-
17 proved Canadian pharmacy is a pharmacy that—

18 “(A) is located in Canada; and

19 “(B) the Secretary certifies—

20 “(i) is licensed to operate and dis-
21 pense prescription drugs to individuals in
22 Canada; and

23 “(ii) meets the criteria under para-
24 graph (3).

1 “(2) PUBLICATION OF APPROVED CANADIAN
2 PHARMACIES.—The Secretary shall publish on the
3 internet website of the Food and Drug Administra-
4 tion a list of approved Canadian pharmacies, includ-
5 ing the internet website address of each such ap-
6 proved Canadian pharmacy, from which individuals
7 may purchase prescription drugs in accordance with
8 subsection (a).

9 “(3) ADDITIONAL CRITERIA.—To be an ap-
10 proved Canadian pharmacy, the Secretary shall cer-
11 tify that the pharmacy—

12 “(A) has been in existence for a period of
13 at least 5 years preceding the date of such cer-
14 tification and has a purpose other than to par-
15 ticipate in the program established under this
16 section;

17 “(B) operates in accordance with phar-
18 macy standards set forth by the provincial
19 pharmacy rules and regulations enacted in Can-
20 ada;

21 “(C) has processes established by the phar-
22 macy, or participates in another established
23 process, to certify that the physical premises
24 and data reporting procedures and licenses are
25 in compliance with all applicable laws and regu-

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

4 “(D) conducts or commits to participate in
5 ongoing and comprehensive quality assurance
6 programs and implements such quality assur-
7 ance measures, including blind testing, to en-
8 sure the veracity and reliability of the findings
9 of the quality assurance program;

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

14 “(F) has established, or will establish or
15 participate in, a process for resolving grievances
16 and will be held accountable for violations of es-
17 tablished guidelines and rules;

18 “(G) does not resell products from online
19 pharmacies located outside Canada to cus-
20 tomers in the United States; and

21 “(H) meets any other criteria established
22 by the Secretary.”.

23 **SEC. 4. PRESERVING ACCESS THROUGH FTC ACTIONS.**

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

1 (1) UNLAWFUL COMPENSATION FOR DELAY.—

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

6 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS**
7 **AND BIOSIMILARS.**

8 “(a) IN GENERAL.—

9 “(1) ENFORCEMENT PROCEEDING.—The Com-
10 mission may initiate a proceeding to enforce the pro-
11 visions of this section against the parties to any
12 agreement resolving or settling, on a final or interim
13 basis, a patent infringement claim, in connection
14 with the sale of a drug product or biological product.

15 “(2) PRESUMPTION AND VIOLATION.—

16 “(A) IN GENERAL.—Subject to subpara-
17 graph (B), in such a proceeding, an agreement
18 shall be presumed to have anticompetitive ef-
19 fects and shall be a violation of this section if—

20 “(i) an ANDA filer or a biosimilar bi-
21 ological product application filer receives
22 anything of value, including an exclusive li-
23 cense; and

24 “(ii) the ANDA filer or biosimilar bio-
25 logical product application filer agrees to

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

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

10 “(i) the value described in subpara-
11 graph (A)(i) is compensation solely for
12 other goods or services that the ANDA
13 filer or biosimilar biological product appli-
14 cation filer has promised to provide; or

15 “(ii) the procompetitive benefits of the
16 agreement outweigh the anticompetitive ef-
17 fects of the agreement.

18 “(b) LIMITATIONS.—In determining whether the set-
19 tling parties have met their burden under subsection
20 (a)(2)(B), the fact finder shall not presume—

21 “(1) that entry would not have occurred until
22 the expiration of the relevant patent or statutory ex-
23 clusivity; or

24 “(2) that the agreement’s provision for entry of
25 the ANDA product or biosimilar biological product

1 prior to the expiration of the relevant patent or stat-
2 utory exclusivity means that the agreement is pro-
3 competitive.

4 “(c) EXCLUSIONS.—Nothing in this section shall pro-
5 hibit a resolution or settlement of a patent infringement
6 claim in which the consideration granted by the NDA
7 holder or biological product license holder to the ANDA
8 filer or biosimilar biological product application filer, re-
9 spectively, as part of the resolution or settlement includes
10 only one or more of the following:

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

14 “(A) any patent that is the basis for the
15 patent infringement claim; or

16 “(B) any patent right or other statutory
17 exclusivity that would prevent the marketing of
18 such ANDA product or biosimilar biological
19 product.

20 “(2) A payment for reasonable litigation ex-
21 penses not to exceed \$7,500,000.

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

25 “(d) ENFORCEMENT.—

1 “(1) ENFORCEMENT.—A violation of this sec-
2 tion shall be treated as a violation of section 5.

3 “(2) JUDICIAL REVIEW.—

4 “(A) IN GENERAL.—Any party that is sub-
5 ject to a final order of the Commission, issued
6 in an administrative adjudicative proceeding
7 under the authority of subsection (a)(1), may,
8 within 30 days of the issuance of such order,
9 petition for review of such order in—

10 “(i) the United States Court of Ap-
11 peals for the District of Columbia Circuit;

12 “(ii) the United States Court of Ap-
13 peals for the circuit in which the ultimate
14 parent entity, as defined in section
15 801.1(a)(3) of title 16, Code of Federal
16 Regulations, or any successor thereto, of
17 the NDA holder or biological product li-
18 cense holder is incorporated as of the date
19 that the NDA or biological product license
20 application, as applicable, is filed with the
21 Commissioner of Food and Drugs; or

22 “(iii) the United States Court of Ap-
23 peals for the circuit in which the ultimate
24 parent entity of the ANDA filer or bio-
25 similar biological product application filer

1 is incorporated as of the date that the
2 ANDA or biosimilar biological product ap-
3 plication is filed with the Commissioner of
4 Food and Drugs.

5 “(B) TREATMENT OF FINDINGS.—In a
6 proceeding for judicial review of a final order of
7 the Commission, the findings of the Commis-
8 sion as to the facts, if supported by evidence,
9 shall be conclusive.

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

21 “(f) PENALTIES.—

22 “(1) FORFEITURE.—Each party that violates or
23 assists in the violation of this section shall forfeit
24 and pay to the United States a civil penalty suffi-
25 cient to deter violations of this section, but in no

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

19 “(2) CEASE AND DESIST.—

20 “(A) IN GENERAL.—If the Commission has
21 issued a cease and desist order with respect to
22 a party in an administrative adjudicative pro-
23 ceeding under the authority of subsection
24 (a)(1), an action brought pursuant to para-
25 graph (1) may be commenced against such

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

4 “(B) EXCEPTION.—In an action under
5 subparagraph (A), the findings of the Commis-
6 sion as to the material facts in the administra-
7 tive adjudicative proceeding with respect to the
8 violation of this section by a party shall be con-
9 clusive unless—

10 “(i) the terms of such cease and de-
11 sist order expressly provide that the Com-
12 mission’s findings shall not be conclusive;
13 or

14 “(ii) the order became final by reason
15 of section 5(g)(1), in which case such find-
16 ing shall be conclusive if supported by evi-
17 dence.

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

21 “(A) the nature, circumstances, extent,
22 and gravity of the violation;

23 “(B) with respect to the violator, the de-
24 gree of culpability, any history of violations, the
25 ability to pay, any effect on the ability to con-

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

6 “(C) other matters that justice requires.

7 “(4) REMEDIES IN ADDITION.—Remedies pro-
8 vided in this subsection are in addition to, and not
9 in lieu of, any other remedy provided by Federal
10 law. Nothing in this paragraph shall be construed to
11 affect any authority of the Commission under any
12 other provision of law.

13 “(g) DEFINITIONS.—In this section:

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

18 “(2) AGREEMENT RESOLVING OR SETTLING A
19 PATENT INFRINGEMENT CLAIM.—The term ‘agree-
20 ment resolving or settling a patent infringement
21 claim’ includes any agreement that is entered into
22 within 30 days of the resolution or the settlement of
23 the claim, or any other agreement that is contingent
24 upon, provides a contingent condition for, or is oth-

1 erwise related to the resolution or settlement of the
2 claim.

3 “(3) ANDA.—The term ‘ANDA’ means an ab-
4 breviated new drug application filed under section
5 505(j) of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 355(j)) or a new drug application filed
7 under section 505(b)(2) of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 355(b)(2)).

9 “(4) ANDA FILER.—The term ‘ANDA filer’
10 means a party that owns or controls an ANDA filed
11 with the Food and Drug Administration or has the
12 exclusive rights under such ANDA to distribute the
13 ANDA product.

14 “(5) ANDA PRODUCT.—The term ‘ANDA
15 product’ means the product to be manufactured
16 under the ANDA that is the subject of the patent
17 infringement claim.

18 “(6) BIOLOGICAL PRODUCT.—The term ‘bio-
19 logical product’ has the meaning given such term in
20 section 351(i)(1) of the Public Health Service Act
21 (42 U.S.C. 262(i)(1)).

22 “(7) BIOLOGICAL PRODUCT LICENSE APPLICA-
23 TION.—The term ‘biological product license applica-
24 tion’ means an application under section 351(a) of
25 the Public Health Service Act (42 U.S.C. 262(a)).

1 “(8) BIOLOGICAL PRODUCT LICENSE HOLD-
2 ER.—The term ‘biological product license holder’
3 means—

4 “(A) the holder of an approved biological
5 product license application for a biological prod-
6 uct;

7 “(B) a person owning or controlling en-
8 forcement of any patents that claim the biologi-
9 cal product that is the subject of such approved
10 application; or

11 “(C) the predecessors, subsidiaries, divi-
12 sions, groups, and affiliates controlled by, con-
13 trolling, or under common control with any of
14 the entities described in subparagraphs (A) and
15 (B) (such control to be presumed by direct or
16 indirect share ownership of 50 percent or great-
17 er), as well as the licensees, licensors, succes-
18 sors, and assigns of each of the entities.

19 “(9) BIOSIMILAR BIOLOGICAL PRODUCT.—The
20 term ‘biosimilar biological product’ means the prod-
21 uct to be manufactured under the biosimilar biologi-
22 cal product application that is the subject of the pat-
23 ent infringement claim.

24 “(10) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
25 CATION.—The term ‘biosimilar biological product ap-

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

5 “(11) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
6 CATION FILER.—The term ‘biosimilar biological
7 product application filer’ means a party that owns or
8 controls a biosimilar biological product application
9 filed with the Food and Drug Administration or has
10 the exclusive rights under such application to dis-
11 tribute the biosimilar biological product.

12 “(12) DRUG PRODUCT.—The term ‘drug prod-
13 uct’ has the meaning given such term in section
14 314.3(b) of title 21, Code of Federal Regulations (or
15 any successor regulation).

16 “(13) NDA.—The term ‘NDA’ means a new
17 drug application filed under section 505(b) of the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 355(b)).

20 “(14) NDA HOLDER.—The term ‘NDA holder’
21 means—

22 “(A) the holder of an approved NDA appli-
23 cation for a drug product;

24 “(B) a person owning or controlling en-
25 forcement of the patent listed in the Approved

1 Drug Products With Therapeutic Equivalence
2 Evaluations (commonly known as the ‘FDA Or-
3 ange Book’) in connection with the NDA; or

4 “(C) the predecessors, subsidiaries, divi-
5 sions, groups, and affiliates controlled by, con-
6 trolling, or under common control with any of
7 the entities described in subparagraphs (A) and
8 (B) (such control to be presumed by direct or
9 indirect share ownership of 50 percent or great-
10 er), as well as the licensees, licensors, succes-
11 sors, and assigns of each of the entities.

12 “(15) PARTY.—The term ‘party’ means any
13 person, partnership, corporation, or other legal enti-
14 ty.

15 “(16) PATENT INFRINGEMENT.—The term
16 ‘patent infringement’ means infringement of any
17 patent or of any filed patent application, extension,
18 reissue, renewal, division, continuation, continuation
19 in part, reexamination, patent term restoration, pat-
20 ents of addition, and extensions thereof.

21 “(17) PATENT INFRINGEMENT CLAIM.—The
22 term ‘patent infringement claim’ means any allega-
23 tion made to an ANDA filer or biosimilar biological
24 product application filer, whether or not included in
25 a complaint filed with a court of law, that its ANDA

1 or ANDA product, or biological product license ap-
2 plication or biological product, may infringe any pat-
3 ent held by, or exclusively licensed to, the NDA
4 holder or biological product license holder of the
5 drug product or biological product, as applicable.

6 “(18) STATUTORY EXCLUSIVITY.—The term
7 ‘statutory exclusivity’ means those prohibitions on
8 the approval of drug applications under clauses (ii)
9 through (iv) of section 505(c)(3)(E) (5- and 3-year
10 data exclusivity), section 527 (orphan drug exclu-
11 sivity), or section 505A (pediatric exclusivity) of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 355(c)(3)(E), 360cc, 355a), or on the licensing of
14 biological product applications under section
15 351(k)(7) (12-year exclusivity) or paragraph (2) or
16 (3) of section 351(m) (pediatric exclusivity) of the
17 Public Health Service Act (42 U.S.C. 262) or under
18 section 527 of the Federal Food, Drug, and Cos-
19 metic Act (orphan drug exclusivity).”

20 (B) EFFECTIVE DATE.—Section 27 of the
21 Federal Trade Commission Act, as added by
22 this paragraph, shall apply to all agreements
23 described in section 27(a)(1) of that Act en-
24 tered into after June 17, 2013. Section 27(f) of
25 the Federal Trade Commission Act, as added

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

4 (2) CERTIFICATION OF AGREEMENTS.—Section
5 1112 of the Medicare Prescription Drug, Improve-
6 ment, and Modernization Act of 2003 (21 U.S.C.
7 355 note) is amended by adding at the end the fol-
8 lowing:

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

22 “(1) represent the complete, final, and exclu-
23 sive agreement between the parties;

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

1 or are otherwise related to, the referenced agree-
2 ment; and

3 ““(3) include written descriptions of any oral
4 agreements, representations, commitments, or prom-
5 ises between the parties that are responsive to sub-
6 section (a) or (b) of such section 1112 and have not
7 been reduced to writing.’”.

8 (3) FORFEITURE OF 180-DAY EXCLUSIVITY PE-
9 RIOD.—Section 505(j)(5)(D)(i)(V) of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C.
11 355(j)(5)(D)(i)(V)) is amended by inserting “section
12 27 of the Federal Trade Commission Act or” after
13 “that the agreement has violated”.

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

17 (A) in subparagraph (D), by striking “or”
18 after the semicolon;

19 (B) in subparagraph (E), by inserting “or”
20 after the semicolon; and

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

23 “(F) under section 27;”.

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

1 proceeding described in section 27 of the Federal
2 Trade Commission Act, as added by paragraph (1),
3 except for an action described in section 27(f)(2) of
4 the Federal Trade Commission Act, not later than
5 6 years after the date on which the parties to the
6 agreement file the certification under section
7 1112(d) of the Medicare Prescription Drug Improve-
8 ment and Modernization Act of 2003 (21 U.S.C.
9 355 note).

10 (b) CITIZEN PETITIONS.—Section 505(q)(1) of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 355(q)(1)) is amended—

13 (1) in subparagraph (E)—

14 (A) by striking “If the Secretary” and in-
15 serting the following:

16 “(i) IN GENERAL.—If the Secretary”;

17 (B) by striking the second sentence and in-
18 serting the following:

19 “(ii) FACTORS.—In determining
20 whether a petition was submitted with the
21 primary purpose of delaying the approval
22 of an application, the Secretary shall con-
23 sider—

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

1 lied upon in the petition became
2 known to the petitioner (or reasonably
3 should have been known to the peti-
4 tioner), as certified by the petitioner
5 in accordance with subparagraph (H),
6 that the petitioner has taken an un-
7 reasonable length of time to submit
8 the petition;

9 “(II) whether the petitioner has
10 submitted multiple or serial petitions
11 raising issues that reasonably could
12 have been known to the petitioner at
13 the time of submission of the earlier
14 petition or petitions;

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

21 “(IV) whether the petition was
22 submitted without any data or infor-
23 mation in support of the scientific po-
24 sitions set forth in the petition;

1 “(V) whether the petition raises
2 the same or substantially similar
3 issues as a prior petition to which the
4 Secretary has responded substantively
5 already, particularly if the subsequent
6 submission follows the earlier response
7 closely in time;

8 “(VI) whether the petition con-
9 cerns standards for approval of a drug
10 for which the Secretary has provided
11 an opportunity for public input, such
12 as draft or final product-specific guid-
13 ance applicable to the drug, and the
14 petitioner has not provided comment
15 other than through the petition;

16 “(VII) whether the petition re-
17 quests that other applicants meet
18 standards for testing, data, or labeling
19 for a drug that are more onerous or
20 rigorous than the standards applicable
21 to, as applicable, the listed drug, ref-
22 erence product, or petitioner’s version
23 of the same drug;

24 “(VIII) the history of the peti-
25 tioner with the Food and Drug Ad-

1 ministration, such as whether the pe-
2 titioner has a history of submitting
3 petitions that the Secretary has deter-
4 mined were submitted with the pri-
5 mary purpose of delay; and

6 “(IX) other relevant consider-
7 ations, as the Secretary may describe
8 in guidance.”; and

9 (C) by adding at the end the following:

10 “(iii) PUBLIC AVAILABILITY.—The
11 Secretary shall publish on the internet
12 website of the Food and Drug Administra-
13 tion a list of any petitions that the Sec-
14 retary determines were submitted for the
15 primary purpose of delaying the approval
16 of an application.

17 “(iv) REFERRAL TO THE FEDERAL
18 TRADE COMMISSION.—The Secretary shall
19 establish procedures for referring to the
20 Federal Trade Commission any petition or
21 supplement to a petition that the Secretary
22 determines was submitted with the primary
23 purpose of delaying approval of an applica-
24 tion. Such procedures shall include notifi-
25 cation to the petitioner and an opportunity

1 for the petitioner to respond to the Sec-
2 retary prior to referral to the Federal
3 Trade Commission.”; and

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

5 “(J) TIMELINE FOR SUBMITTING PETI-
6 TIONS.—The Secretary may establish a time pe-
7 riod after the relevant information relied upon
8 in a petition became known to the petitioner (or
9 reasonably should have been known to a peti-
10 tioner), as certified by the petitioner in accord-
11 ance with subparagraph (H), and any petition
12 that is submitted after such time period has
13 passed shall be summarily denied.”.

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

16 (1) DEFINITIONS.—In this subsection:

17 (A) COMMISSION.—The term “Commis-
18 sion” means the Federal Trade Commission.

19 (B) COVERED APPLICATION.—The term
20 “covered application” means an application
21 filed pursuant to subsection (b)(2) or (j) of sec-
22 tion 505 of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 355) or section 351(k) of
24 the Public Health Service Act (42 U.S.C.
25 262(k)).

1 (C) COVERED PETITION.—The term “cov-
2 ered petition” means a petition, or a supple-
3 ment to a petition, filed under section 505(q) of
4 the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 355(q)).

6 (D) PERSON.—The term “person”—

7 (i) means an individual or entity; and

8 (ii) includes—

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

11 (II) a joint venture, subsidiary,
12 partnership, division, group, and affil-
13 iate controlled by an entity, and

14 (III) a successor and an assign of
15 a joint venture, subsidiary, partner-
16 ship, division, group, and affiliate con-
17 trolled by an entity.

18 (E) SERIES OF COVERED PETITIONS.—The
19 term “series of covered petitions” means any
20 group of more than 1 covered petition relating
21 to the same covered application.

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

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

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

12 (3) CIVIL ACTION.—

13 (A) IN GENERAL.—If the Commission has
14 reason to believe that the submission of a cov-
15 ered petition or a series of covered petitions
16 constitutes a violation of section 5(a)(1) of the
17 Federal Trade Commission Act (15 U.S.C.
18 45(a)(1)), the Commission may commence a
19 civil action to recover a civil penalty and seek
20 other appropriate relief in a district court of the
21 United States against any person that sub-
22 mitted or caused to be submitted such covered
23 petition or such series of covered petitions, in-
24 cluding successors or assigns.

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

6 (i) the Secretary of Health and
7 Human Services—

8 (I) has determined that the cov-
9 ered petition was submitted with the
10 primary purpose of delaying the ap-
11 proval of a covered application; and

12 (II) has referred such determina-
13 tion to the Federal Trade Commission
14 in writing, including a reasoned basis
15 for the determination; and

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

18 (C) EXCEPTION.—The presumption in sub-
19 paragraph (B) shall not apply if the defendant
20 establishes, by a preponderance of the evidence,
21 that the series of covered petitions that includes
22 the covered petition referred to the Commission
23 by the Secretary of Health and Human Services
24 is not a sham.

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

7 (i) any revenue earned from the sale
8 by such person of any drug product, ref-
9 erenced in a covered application that was
10 the subject of a covered petition or a series
11 of covered petitions that is a sham, during
12 the period in which the covered petition or
13 series of covered petitions was under re-
14 view by the Secretary of Health and
15 Human Services; or

16 (ii) \$50,000 for each calendar day
17 that each covered petition that is a sham
18 or that was part of a series of covered peti-
19 tions that is a sham was under review by
20 the Secretary of Health and Human Serv-
21 ices.

22 (E) ANTITRUST LAWS.—Nothing in this
23 subsection shall modify, impair, limit, or super-
24 sede the applicability of the antitrust laws as
25 defined in subsection (a) of the first section of

1 the Clayton Act (15 U.S.C. 12(a)), and of sec-
2 tion 5 of the Federal Trade Commission Act
3 (15 U.S.C. 45) to the extent that it applies to
4 unfair methods of competition.

5 (F) RULE OF CONSTRUCTION.—The civil
6 penalty provided in this paragraph is in addi-
7 tion to, and not in lieu of, any other remedies
8 provided by Federal law, including under sec-
9 tion 16 of the Clayton Act (15 U.S.C. 26) or
10 under section 13(b) of the Federal Trade Com-
11 mission Act (15 U.S.C. 53(b)). Nothing in this
12 subparagraph shall be construed to affect any
13 authority of the Commission under any other
14 provision of law.

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

18 **SEC. 5. INCREASING THE USE OF REAL-TIME BENEFIT**

19 **TOOLS TO LOWER BENEFICIARY COSTS.**

20 (a) REQUIRING PRESCRIPTION DRUG PLAN SPON-
21 SORS AND MEDICARE ADVANTAGE ORGANIZATIONS TO
22 INCLUDE REAL-TIME BENEFIT INFORMATION UNDER
23 MEDICARE PART D.—Section 1860D–4 of the Social Se-
24 curity Act (42 U.S.C. 1395w–104) is amended—

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

7 (2) by adding at the end the following new sub-
8 section:

9 “(o) REAL-TIME BENEFIT INFORMATION.—

10 “(1) IN GENERAL.—After the Secretary has
11 adopted a standard under paragraph (3) for elec-
12 tronic real-time benefit tools, and at a time deter-
13 mined appropriate by the Secretary, a PDP sponsor
14 of a prescription drug plan shall implement one or
15 more of such tools that meet the requirements de-
16 scribed in paragraph (2).

17 “(2) REQUIREMENTS.—For purposes of para-
18 graph (1), the requirements described in this para-
19 graph, with respect to an electronic real-time benefit
20 tool, are that the tool is capable of—

21 “(A) integrating with electronic prescribing
22 and electronic health record systems of pre-
23 scribing health care professionals for the trans-
24 mission of eligibility and formulary and benefit

1 information in real time to such professionals;
2 and

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

7 “(i) A list of any clinically appropriate
8 alternatives to such drug included in the
9 formulary of such plan.

10 “(ii) Cost-sharing information and the
11 negotiated price for such drug and such al-
12 ternatives at—

13 “(I) multiple pharmacy options,
14 including the individual’s preferred
15 pharmacy and, as applicable, other re-
16 tail pharmacies and a mail order
17 pharmacy; and

18 “(II) the formulary status of
19 such drug and such alternatives and
20 any prior authorization or other utili-
21 zation management requirements ap-
22 plicable to such drug and such alter-
23 natives included in the formulary of
24 such plan.

1 “(3) STANDARDS.—In order to be treated (for
2 purposes of this subsection) as an electronic real-
3 time benefit tool described in paragraph (1), such
4 tool shall comply with technical standards adopted
5 by the Secretary in consultation with the National
6 Coordinator for Health Information Technology, the
7 National Council for Prescription Drug Programs,
8 other standard setting organizations determined ap-
9 propriate by the Secretary, and stakeholders includ-
10 ing PDP sponsors, Medicare Advantage organiza-
11 tions, health care professionals, and health informa-
12 tion technology software vendors.

13 “(4) RULE OF CONSTRUCTION.—Nothing in
14 this subsection shall be construed to prohibit the ap-
15 plication of paragraph (b)(7) of section 423.160 of
16 title 42, Code of Federal Regulations, as is to be
17 added to such section pursuant to the final rule pub-
18 lished in the Federal Register on May 23, 2019, and
19 titled ‘Modernizing Part D and Medicare Advantage
20 To Lower Drug Prices and Reduce Out-of-Pocket
21 Expenses’ (84 Fed. Reg. 23832 through 23884).”.

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

1 (1) in subparagraph (A), by striking “and” at
2 the end;

3 (2) in subparagraph (B), by striking the period
4 and inserting “; and”; and

5 (3) by adding at the end the following:

6 “(C) includes, or is capable of including, a
7 real-time benefit tool that conveys patient-spe-
8 cific real-time cost and coverage information
9 with respect to prescription drugs that, with re-
10 spect to any health information technology cer-
11 tified for electronic prescribing, the technology
12 shall be capable of incorporating the informa-
13 tion described in clauses (i) and (ii) of para-
14 graph (2)(B) of section 1860D–4(o) of the So-
15 cial Security Act at a time specified by the Sec-
16 retary but not before the Secretary adopts a
17 standard for such tools as described in para-
18 graph (1) of such section.”.

19 (c) INCLUSION OF USE OF REAL-TIME ELECTRONIC
20 INFORMATION IN SHARED DECISION MAKING UNDER
21 MIPS.—Section 1848(q)(2)(B)(iii)(IV) of the Social Se-
22 curity Act (42 U.S.C. 1395w–4(q)(2)(B)(iii)(IV)) is
23 amended by adding at the end the following new sentence:
24 “‘This subcategory shall include as an activity option, be-
25 ginning with the performance period starting on January

1 1, 2021, use of a real-time benefit tool as described in
2 1860D–4(o).”.

3 **SEC. 6. MEDICARE PART D MODERNIZATION REDESIGN.**

4 (a) **BENEFIT STRUCTURE REDESIGN.**—Section
5 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
6 102(b)) is amended—

7 (1) in paragraph (2)—

8 (A) in subparagraph (A), in the matter
9 preceding clause (i), by inserting “for a year
10 preceding 2022 and for costs above the annual
11 deductible specified in paragraph (1) and up to
12 the annual out-of-pocket threshold specified in
13 paragraph (4)(B) for 2022 and each subsequent
14 year” after “paragraph (3)”;

15 (B) in subparagraph (C)—

16 (i) in clause (i), in the matter pre-
17 ceding subclause (I), by inserting “for a
18 year preceding 2022,” after “paragraph
19 (4),”; and

20 (ii) in clause (ii)(III), by striking
21 “and each subsequent year” and inserting
22 “and 2021”; and

23 (C) in subparagraph (D)—

24 (i) in clause (i)—

1 (I) in the matter preceding sub-
2 clause (I), by inserting “for a year
3 preceding 2022,” after “paragraph
4 (4),”; and

5 (II) in subclause (I)(bb), by
6 striking “a year after 2018” and in-
7 serting “each of years 2018 through
8 2021”; and

9 (ii) in clause (ii)(V), by striking
10 “2019 and each subsequent year” and in-
11 serting “each of years 2019 through
12 2021”;

13 (2) in paragraph (3)(A)—

14 (A) in the matter preceding clause (i), by
15 inserting “for a year preceding 2022,” after
16 “and (4),”; and

17 (B) in clause (ii), by striking “for a subse-
18 quent year” and inserting “for each of years
19 2007 through 2021”;

20 (3) in paragraph (4)—

21 (A) in subparagraph (A)—

22 (i) in clause (i)—

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

1 respectively, and indenting appro-
2 priately;

3 (II) in the matter preceding item
4 (aa), as redesignated by subclause (I),
5 by striking “is equal to the greater
6 of—” and inserting “is equal to—

7 “(I) for a year preceding 2022,
8 the greater of—”;

9 (III) by striking the period at the
10 end of item (bb), as redesignated by
11 subclause (I), and inserting “; and”;
12 and

13 (IV) by adding at the end the fol-
14 lowing:

15 “(II) for 2022 and each suc-
16 ceeding year, \$0.”; and

17 (ii) in clause (ii)—

18 (I) by striking “clause (i)(I)” and
19 inserting “clause (i)(I)(aa)”;

20 (II) by adding at the end the fol-
21 lowing new sentence: “The Secretary
22 shall continue to calculate the dollar
23 amounts specified in clause (i)(I)(aa),
24 including with the adjustment under

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

3 (B) in subparagraph (B)—

4 (i) in clause (i)—

5 (I) in subclause (V), by striking
6 “or” at the end;

7 (II) in subclause (VI)—

8 (aa) by striking “for a sub-
9 sequent year” and inserting “for
10 2021”; and

11 (bb) by striking the period
12 at the end and inserting a semi-
13 colon; and

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

16 “(VII) for 2022, is equal to
17 \$3,100; or

18 “(VIII) for a subsequent year, is
19 equal to the amount specified in this
20 subparagraph for the previous year,
21 increased by the annual percentage in-
22 crease described in paragraph (6) for
23 the year involved.”; and

24 (ii) in clause (ii), by striking “clause
25 (i)(II)” and inserting “clause (i)”;

1 (C) in subparagraph (C)(i), by striking
2 “and for amounts” and inserting “and for a
3 year preceding 2022 for amounts”; and

4 (D) in subparagraph (E), by striking “In
5 applying” and inserting “For each of 2011
6 through 2021, in applying”.

7 (b) REDUCTION IN BENEFICIARY COINSURANCE.—

8 (1) IN GENERAL.—Section 1860D–2(b)(2)(A)
9 of the Social Security Act (42 U.S.C. 1395w–
10 102(b)(2)(A)), as amended by subsection (a), is
11 amended—

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

15 (B) by striking “25 PERCENT COINSUR-
16 ANCE.—Subject to” and inserting “COINSUR-
17 ANCE.—

18 “(i) IN GENERAL.—Subject to”;

19 (C) in each of subclauses (I) and (II), as
20 redesignated by subparagraph (A), by striking
21 “25 percent” and inserting “the applicable per-
22 centage (as defined in clause (ii))”; and

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

1 “(ii) APPLICABLE PERCENTAGE DE-
2 FINED.—For purposes of clause (i), the
3 term ‘applicable percentage’ means—

4 “(I) for a year preceding 2022,
5 25 percent; and

6 “(II) for 2022 and each subse-
7 quent year, 20 percent.”.

8 (2) CONFORMING AMENDMENT.—Section
9 1860D–14(a)(2)(D) of the Social Security Act (42
10 U.S.C. 1395w–114(a)(2)(D)) is amended by striking
11 “25 percent” and inserting “the applicable percent-
12 age”.

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

16 (1) in paragraph (1)—

17 (A) by striking “equal to 80 percent” and
18 inserting “equal to—

19 “(A) for a year preceding 2022, 80 per-
20 cent”;

21 (B) in subparagraph (A), as added by
22 paragraph (1), by striking the period at the end
23 and inserting “; and”; and

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

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

2 “(i) an amount equal to the applicable
3 percentage specified in paragraph (5)(A) of
4 such allowable reinsurance costs attrib-
5 utable to that portion of gross prescription
6 drug costs as specified in paragraph (3) in-
7 curred in the coverage year after such indi-
8 vidual has incurred costs that exceed the
9 annual out-of-pocket threshold specified in
10 section 1860D–2(b)(4)(B) with respect to
11 applicable drugs (as defined in section
12 1860D–14B(g)(2)); and

13 “(ii) an amount equal to the applica-
14 ble percentage specified in paragraph
15 (5)(B) of allowable reinsurance costs at-
16 tributable to that portion of gross prescrip-
17 tion drug costs as specified in paragraph
18 (3) incurred in the coverage year after
19 such individual has incurred costs that ex-
20 ceed the annual out-of-pocket threshold
21 specified in section 1860D–2(b)(4)(B) with
22 respect to covered part D drugs that are
23 not applicable drugs (as so defined).”; and

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

1 “(5) APPLICABLE PERCENTAGE SPECIFIED.—

2 For purposes of paragraph (1)(B), the applicable
3 percentage specified in this paragraph is—

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

6 “(i) for 2022, 60 percent;

7 “(ii) for 2023, 40 percent; and

8 “(iii) for 2024 and each subsequent
9 year, 20 percent; and

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

12 “(i) for 2022, 80 percent;

13 “(ii) for 2023, 60 percent; and

14 “(iii) for 2024 and each subsequent
15 year, 40 percent.”.

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

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

22 **“SEC. 1860D–14B. MANUFACTURER DISCOUNT PROGRAM.**

23 “(a) ESTABLISHMENT.—The Secretary shall estab-
24 lish a manufacturer discount program (in this section re-
25 ferred to as the ‘program’). Under the program, the Sec-

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

8 “(b) TERMS OF AGREEMENT.—

9 “(1) IN GENERAL.—

10 “(A) AGREEMENT.—An agreement under
11 this section shall require the manufacturer to
12 provide applicable beneficiaries access to dis-
13 counted prices for applicable drugs of the man-
14 ufacturer that are dispensed on or after Janu-
15 ary 1, 2022.

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

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

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

3 “(3) COMPLIANCE WITH REQUIREMENTS FOR
4 ADMINISTRATION OF PROGRAM.—Each manufac-
5 turer with an agreement in effect under this section
6 shall comply with requirements imposed by the Sec-
7 retary or a third party with a contract under sub-
8 section (d)(3), as applicable, for purposes of admin-
9 istering the program, including any determination
10 under subparagraph (A) of subsection (c)(1) or pro-
11 cedures established under such subsection (c)(1).

12 “(4) LENGTH OF AGREEMENT.—

13 “(A) IN GENERAL.—An agreement under
14 this section shall be effective for an initial pe-
15 riod of not less than 12 months and shall be
16 automatically renewed for a period of not less
17 than 1 year unless terminated under subpara-
18 graph (B).

19 “(B) TERMINATION.—

20 “(i) BY THE SECRETARY.—The Sec-
21 retary may provide for termination of an
22 agreement under this section for a knowing
23 and willful violation of the requirements of
24 the agreement or other good cause shown.
25 Such termination shall not be effective ear-

1 lier than 30 days after the date of notice
2 to the manufacturer of such termination.
3 The Secretary shall provide, upon request,
4 a manufacturer with a hearing concerning
5 such a termination, and such hearing shall
6 take place prior to the effective date of the
7 termination with sufficient time for such
8 effective date to be repealed if the Sec-
9 retary determines appropriate.

10 “(ii) BY A MANUFACTURER.—A man-
11 ufacturer may terminate an agreement
12 under this section for any reason. Any
13 such termination shall be effective, with re-
14 spect to a plan year—

15 “(I) if the termination occurs be-
16 fore January 30 of a plan year, as of
17 the day after the end of the plan year;
18 and

19 “(II) if the termination occurs on
20 or after January 30 of a plan year, as
21 of the day after the end of the suc-
22 ceeding plan year.

23 “(iii) EFFECTIVENESS OF TERMI-
24 NATION.—Any termination under this sub-
25 paragraph shall not affect discounts for

1 applicable drugs of the manufacturer that
2 are due under the agreement before the ef-
3 fective date of its termination.

4 “(iv) NOTICE TO THIRD PARTY.—The
5 Secretary shall provide notice of such ter-
6 mination to a third party with a contract
7 under subsection (d)(3) within not less
8 than 30 days before the effective date of
9 such termination.

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

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

16 “(1) ADMINISTRATION OF PROGRAM.—Admin-
17 istering the program, including—

18 “(A) the determination of the amount of
19 the discounted price of an applicable drug of a
20 manufacturer;

21 “(B) the establishment of procedures
22 under which discounted prices are provided to
23 applicable beneficiaries at pharmacies or by
24 mail order service at the point-of-sale of an ap-
25 plicable drug;

1 “(C) the establishment of procedures to
2 ensure that, not later than the applicable num-
3 ber of calendar days after the dispensing of an
4 applicable drug by a pharmacy or mail order
5 service, the pharmacy or mail order service is
6 reimbursed for an amount equal to the dif-
7 ference between—

8 “(i) the negotiated price of the appli-
9 cable drug; and

10 “(ii) the discounted price of the appli-
11 cable drug;

12 “(D) the establishment of procedures to
13 ensure that the discounted price for an applica-
14 ble drug under this section is applied before any
15 coverage or financial assistance under other
16 health benefit plans or programs that provide
17 coverage or financial assistance for the pur-
18 chase or provision of prescription drug coverage
19 on behalf of applicable beneficiaries as the Sec-
20 retary may specify; and

21 “(E) providing a reasonable dispute resolu-
22 tion mechanism to resolve disagreements be-
23 tween manufacturers, applicable beneficiaries,
24 and the third party with a contract under sub-
25 section (d)(3).

1 “(2) MONITORING COMPLIANCE.—

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

5 “(B) NOTIFICATION.—If a third party
6 with a contract under subsection (d)(3) deter-
7 mines that the manufacturer is not in compli-
8 ance with such agreement, the third party shall
9 notify the Secretary of such noncompliance for
10 appropriate enforcement under subsection (e).

11 “(3) COLLECTION OF DATA FROM PRESCRIP-
12 TION DRUG PLANS AND MA–PD PLANS.—The Sec-
13 retary may collect appropriate data from prescrip-
14 tion drug plans and MA–PD plans in a timeframe
15 that allows for discounted prices to be provided for
16 applicable drugs under this section.

17 “(d) ADMINISTRATION.—

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

22 “(2) LIMITATION.—In providing for the imple-
23 mentation of this section, the Secretary shall not re-
24 ceive or distribute any funds of a manufacturer
25 under the program.

1 “(3) CONTRACT WITH THIRD PARTIES.—The
2 Secretary shall enter into a contract with one or
3 more third parties to administer the requirements
4 established by the Secretary in order to carry out
5 this section. At a minimum, the contract with a
6 third party under the preceding sentence shall re-
7 quire that the third party—

8 “(A) receive and transmit information be-
9 tween the Secretary, manufacturers, and other
10 individuals or entities the Secretary determines
11 appropriate;

12 “(B) receive, distribute, or facilitate the
13 distribution of funds of manufacturers to ap-
14 propriate individuals or entities in order to
15 meet the obligations of manufacturers under
16 agreements under this section;

17 “(C) provide adequate and timely informa-
18 tion to manufacturers, consistent with the
19 agreement with the manufacturer under this
20 section, as necessary for the manufacturer to
21 fulfill its obligations under this section; and

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

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

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

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

12 “(6) FUNDING.—For purposes of carrying out
13 this section, the Secretary shall provide for the
14 transfer, from the Federal Supplementary Medical
15 Insurance Trust Fund under section 1841 to the
16 Centers for Medicare & Medicaid Services Program
17 Management Account, of \$4,000,000 for each of fis-
18 cal years 2020 through 2023, to remain available
19 until expended.”.

20 “(e) ENFORCEMENT.—

21 “(1) AUDITS.—Each manufacturer with an
22 agreement in effect under this section shall be sub-
23 ject to periodic audit by the Secretary.

24 “(2) CIVIL MONEY PENALTY.—

1 “(A) IN GENERAL.—The Secretary shall
2 impose a civil money penalty on a manufacturer
3 that fails to provide applicable beneficiaries dis-
4 counts for applicable drugs of the manufacturer
5 in accordance with such agreement for each
6 such failure in an amount the Secretary deter-
7 mines is commensurate with the sum of—

8 “(i) the amount that the manufac-
9 turer would have paid with respect to such
10 discounts under the agreement, which will
11 then be used to pay the discounts which
12 the manufacturer had failed to provide;
13 and

14 “(ii) 25 percent of such amount.

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

21 “(f) CLARIFICATION REGARDING AVAILABILITY OF
22 OTHER COVERED PART D DRUGS.—Nothing in this sec-
23 tion shall prevent an applicable beneficiary from pur-
24 chasing a covered part D drug that is not an applicable
25 drug (including a generic drug or a drug that is not on

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

3 “(g) DEFINITIONS.—In this section:

4 “(1) APPLICABLE BENEFICIARY.—The term
5 ‘applicable beneficiary’ means an individual who, on
6 the date of dispensing a covered part D drug—

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

9 “(B) is not enrolled in a qualified retiree
10 prescription drug plan; and

11 “(C) has incurred costs for covered part D
12 drugs in the year that are above the annual de-
13 ductible specified in section 1860D–2(b)(1).

14 “(2) APPLICABLE DRUG.—The term ‘applicable
15 drug’ means, with respect to an applicable bene-
16 ficiary, a covered part D drug—

17 “(A) approved under a new drug applica-
18 tion under section 505(c) of the Federal Food,
19 Drug, and Cosmetic Act or, in the case of a bio-
20 logic product, licensed under section 351 of the
21 Public Health Service Act (including a product
22 licensed under subsection (k) of such section
23 351); and

24 “(B)(i) if the PDP sponsor of the prescrip-
25 tion drug plan or the MA organization offering

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

5 “(ii) if the PDP sponsor of the prescrip-
6 tion drug plan or the MA organization offering
7 the MA–PD plan does not use a formulary, for
8 which benefits are available under the prescrip-
9 tion drug plan or MA–PD plan that the appli-
10 cable beneficiary is enrolled in; or

11 “(iii) is provided through an exception or
12 appeal.

13 “(3) APPLICABLE NUMBER OF CALENDAR
14 DAYS.—The term ‘applicable number of calendar
15 days’ means—

16 “(A) with respect to claims for reimburse-
17 ment submitted electronically, 14 days; and

18 “(B) with respect to claims for reimburse-
19 ment submitted otherwise, 30 days.

20 “(4) DISCOUNTED PRICE.—

21 “(A) IN GENERAL.—The term ‘discounted
22 price’ means—

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

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

5 “(ii) with respect to an applicable
6 drug dispensed for an applicable bene-
7 ficiary who has incurred costs for covered
8 part D drugs in the year that are equal to
9 or exceed the annual out-of-pocket thresh-
10 old specified in section 1860D–2(b)(4)(B),
11 86 percent of the negotiated price of the
12 applicable drug of a manufacturer.

13 “(B) CLARIFICATION.—Nothing in this
14 section shall be construed as affecting the re-
15 sponsibility of an applicable beneficiary for pay-
16 ment of a dispensing fee for an applicable drug.

17 “(C) CLARIFICATION FOR CERTAIN
18 CLAIMS.—With respect to the amount of the ne-
19 gotiated price of an individual claim for an ap-
20 plicable drug with respect to an applicable bene-
21 ficiary, the manufacturer of the applicable drug
22 shall provide—

23 “(i) the discounted price under clause
24 (i) of subparagraph (A) only on the portion
25 of the negotiated price of the applicable

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

5 “(ii) the discounted price under clause
6 (ii) of subparagraph (A) only on the por-
7 tion of the negotiated price of the applica-
8 ble drug that falls at or above such annual
9 out-of-pocket threshold.

10 “(5) MANUFACTURER.—The term ‘manufac-
11 turer’ means any entity which is engaged in the pro-
12 duction, preparation, propagation, compounding,
13 conversion, or processing of prescription drug prod-
14 ucts, either directly or indirectly by extraction from
15 substances of natural origin, or independently by
16 means of chemical synthesis, or by a combination of
17 extraction and chemical synthesis. Such term does
18 not include a wholesale distributor of drugs or a re-
19 tail pharmacy licensed under State law.

20 “(6) NEGOTIATED PRICE.—The term ‘nego-
21 tiated price’ has the meaning given such term in sec-
22 tion 1860D–2(d)(1)(B), except that such negotiated
23 price shall not include any dispensing fee for the ap-
24 plicable drug.

1 “(7) QUALIFIED RETIREE PRESCRIPTION DRUG
2 PLAN.—The term ‘qualified retiree prescription drug
3 plan’ has the meaning given such term in section
4 1860D–22(a)(2).”.

5 (2) SUNSET OF MEDICARE COVERAGE GAP DIS-
6 COUNT PROGRAM.—Section 1860D–14A of the So-
7 cial Security Act (42 U.S.C. 1395–114a) is amend-
8 ed—

9 (A) in subsection (a), in the first sentence,
10 by striking “The Secretary” and inserting
11 “Subject to subsection (h), the Secretary”; and

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

14 “(h) SUNSET OF PROGRAM.—

15 “(1) IN GENERAL.—The program shall not
16 apply to applicable drugs dispensed on or after Janu-
17 ary 1, 2022, and, subject to paragraph (2), agree-
18 ments under this section shall be terminated as of
19 such date.

20 “(2) CONTINUED APPLICATION FOR APPLICA-
21 BLE DRUGS DISPENSED PRIOR TO SUNSET.—The
22 provisions of this section (including all responsibil-
23 ities and duties) shall continue to apply after Janu-
24 ary 1, 2022, with respect to applicable drugs dis-
25 pensed prior to such date.”.

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

5 (A) in subsection (b)(2)(C)(iii)—

6 (i) by striking “assumptions regarding
7 the reinsurance” and inserting “assump-
8 tions regarding—

9 “(I) the reinsurance”; and

10 (ii) by adding at the end the fol-
11 lowing:

12 “(II) for 2022 and each subse-
13 quent year, the manufacturer dis-
14 counts provided under section 1860D–
15 14B subtracted from the actuarial
16 value to produce such bid; and”;

17 (B) in subsection (c)(1)(C)—

18 (i) by striking “an actuarial valuation
19 of the reinsurance” and inserting “an ac-
20 tuarial valuation of—

21 “(i) the reinsurance”;

22 (ii) in clause (i), as added by clause
23 (i) of this subparagraph, by adding “and”
24 at the end; and

1 (iii) by adding at the end the fol-
 2 lowing:

3 “(ii) for 2022 and each subsequent
 4 year, the manufacturer discounts provided
 5 under section 1860D–14B;”.

6 (4) CLARIFICATION REGARDING EXCLUSION OF
 7 MANUFACTURER DISCOUNTS FROM TROOP.—Section
 8 1860D–2(b)(4) of the Social Security Act (42
 9 U.S.C. 1395w–102(b)(4)) is amended—

10 (A) in subparagraph (C), by inserting “
 11 and subject to subparagraph (F)” after “sub-
 12 paragraph (E)”; and

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

15 “(F) CLARIFICATION REGARDING EXCLU-
 16 SION OF MANUFACTURER DISCOUNTS.—In ap-
 17 plying subparagraph (A), incurred costs shall
 18 not include any manufacturer discounts pro-
 19 vided under section 1860D–14B.”.

20 (e) DETERMINATION OF ALLOWABLE REINSURANCE
 21 COSTS.—Section 1860D–15(b) of the Social Security Act
 22 (42 U.S.C. 1395w–115(b)) is amended—

23 (1) in paragraph (2)—

24 (A) by striking “COSTS.—For purposes”
 25 and inserting “COSTS.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (B), for purposes”; and

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

5 “(B) INCLUSION OF MANUFACTURER DIS-
6 COUNTS ON APPLICABLE DRUGS.—For purposes
7 of applying subparagraph (A), the term ‘allow-
8 able reinsurance costs’ shall include the portion
9 of the negotiated price (as defined in section
10 1860D–14B(g)(6)) of an applicable drug (as
11 defined in section 1860D–14B(g)(2)) that was
12 paid by a manufacturer under the manufacturer
13 discount program under section 1860D–14B.”;
14 and

15 (2) in paragraph (3)—

16 (A) in the first sentence, by striking “For
17 purposes” and inserting “Subject to paragraph
18 (2)(B), for purposes”; and

19 (B) in the second sentence, by inserting
20 “or, in the case of an applicable drug, by a
21 manufacturer” after “by the individual or
22 under the plan”.

23 (f) UPDATING RISK ADJUSTMENT METHODOLOGIES
24 TO ACCOUNT FOR PART D MODERNIZATION REDE-
25 SIGN.—Section 1860D–15(c) of the Social Security Act

1 (42 U.S.C. 1395w–115(c)) is amended by adding at the
2 end the following new paragraph:

3 “(3) UPDATING RISK ADJUSTMENT METH-
4 ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA-
5 TION REDESIGN.—The Secretary shall update the
6 risk adjustment methodologies used to adjust bid
7 amounts pursuant to this subsection as appropriate
8 to take into account changes in benefits under this
9 part pursuant to the amendments made by section
10 121 of the Lowering Prescription Drug Prices for
11 America’s Seniors and Families Act of 2020.”.

12 (g) CONFORMING AMENDMENTS.—

13 (1) Section 1860D–2 of the Social Security Act
14 (42 U.S.C. 1395w–102) is amended—

15 (A) in subsection (a)(2)(A)(i)(I), by strik-
16 ing “, or an increase in the initial” and insert-
17 ing “or for a year preceding 2022 an increase
18 in the initial”;

19 (B) in subsection (c)(1)(C)—

20 (i) in the subparagraph heading, by
21 striking “AT INITIAL COVERAGE LIMIT”;
22 and

23 (ii) by inserting “for a year preceding
24 2022 or the annual out-of-pocket threshold
25 specified in subsection (b)(4)(B) for the

1 year for 2022 and each subsequent year”
2 after “subsection (b)(3) for the year” each
3 place it appears;

4 (C) in subsection (d)(1)(A), by striking “or
5 an initial” and inserting “or for a year pre-
6 ceding 2022 an initial”.

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

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

13 (A) in paragraph (1)—

14 (i) in subparagraph (C), by striking
15 “The continuation” and inserting “For a
16 year preceding 2022, the continuation”;

17 (ii) in subparagraph (E), by striking
18 “The elimination” and inserting “For a
19 year preceding 2022, the elimination”; and

20 (iii) in subparagraph (D)(iii), by strik-
21 ing “1860D–2(b)(4)(A)(i)(I)” and insert-
22 ing “1860D–2(b)(4)(A)(i)(I)(aa)”; and

23 (B) in paragraph (2)—

24 (i) in subparagraph (C), by striking
25 “The continuation” and inserting “For a

1 year preceding 2022, the continuation”;

2 and

3 (ii) in subparagraph (E)—

4 (I) by inserting “for a year pre-
5 ceding 2022,” after “subsection (e)”;

6 and

7 (II) by striking “1860D-
8 2(b)(4)(A)(i)(I)” and inserting
9 “1860D-2(b)(4)(A)(i)(I)(aa)”.

10 (4) Section 1860D-21(d)(7) of the Social Secu-
11 rity Act (42 U.S.C. 1395w-131(d)(7)) is amended
12 by striking “section 1860D-2(b)(B)(4)(B)(i)” and
13 inserting “section 1860D-2(b)(B)(4)(C)(i)”.

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

17 (A) by striking “the value of any discount”

18 and inserting the following: “the value of—

19 “(i) for years prior to 2022, any dis-
20 count”;

21 (B) in clause (i), as inserted by subpara-
22 graph (A) of this paragraph, by striking the pe-
23 riod at the end and inserting “; and”; and

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

1 “(ii) for 2022 and each subsequent
2 year, any discount provided pursuant to
3 section 1860D–14B.”.

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

6 (A) by inserting “for a year before 2022”
7 after “1860D–2(b)(3)”; and

8 (B) by inserting “for such year” before the
9 period.

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

13 “(1) participate in—

14 “(A) for 2011 through 2021, the Medicare
15 coverage gap discount program under section
16 1860D–14A; and

17 “(B) for 2022 and each subsequent year,
18 the manufacturer discount program under sec-
19 tion 1860D–14B;”.

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

23 **SEC. 7. SEVERABILITY.**

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

1 ment to any person or circumstance is held to be unconsti-
2 tutional, the remainder of this Act, the amendments made
3 by this Act, and the application of the provisions of such
4 Act or amendments to any person or circumstance shall
5 not be affected.

○