

115TH CONGRESS
2D SESSION

S. 3411

To ensure medications are affordable.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 5, 2018

Ms. SMITH (for herself, Ms. BALDWIN, Mr. BLUMENTHAL, Mr. BOOKER, Mr. BROWN, Mr. DURBIN, Mrs. GILLIBRAND, Ms. HASSAN, Ms. KLOBUCHAR, Mr. MERKLEY, Mr. REED, Mr. SANDERS, Mr. UDALL, Ms. WARREN, and Mr. WHITEHOUSE) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To ensure medications are affordable.

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

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Affordable Medications Act”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—TRANSPARENCY

Sec. 101. Drug manufacturer reporting.

Sec. 102. Determining the public and private benefit of copayment coupons and other patient assistance programs.

TITLE II—ACCESS AND AFFORDABILITY

- Sec. 201. Negotiating fair prices for Medicare prescription drugs.
 Sec. 202. Prescription drug price spikes.
 Sec. 203. Importing affordable and safe drugs.
 Sec. 204. Requiring drug manufacturers to provide drug rebates for drugs dispensed to low-income individuals.
 Sec. 205. Cap on prescription drug cost-sharing.

TITLE III—INNOVATION

- Sec. 301. Prize fund for new and more effective treatments of bacterial infections.
 Sec. 302. Public funding for clinical trials.
 Sec. 303. Rewarding innovative drug development.
 Sec. 304. Improving program integrity.

TITLE IV—CHOICE AND COMPETITION

- Sec. 401. Preserving access to affordable generics.
 Sec. 402. 180-day exclusivity period amendments regarding first applicant status.
 Sec. 403. 180-day exclusivity period amendments regarding agreements to defer commercial marketing.
 Sec. 404. Increasing drug competition and preventing drug shortages.
 Sec. 405. Disallowance of deduction for advertising for prescription drugs.
 Sec. 406. Drug manufacturer duty to disclose drug prices to practitioners.
 Sec. 407. Excluding authorized generic drugs from calculation of average manufacturer price under the Medicaid drug rebate program.

1 **TITLE I—TRANSPARENCY**2 **SEC. 101. DRUG MANUFACTURER REPORTING.**

3 Part P of title III of the Public Health Service Act
 4 (42 U.S.C. 280g et seq.) is amended by adding at the end
 5 the following:

6 **“SEC. 399V-7. DRUG MANUFACTURER REPORTING.**

7 “(a) DEFINITIONS.—In this section:

8 “(1) INDEPENDENT CHARITY PATIENT ASSIST-
 9 ANCE PROGRAM.—The term ‘independent charity pa-
 10 tient assistance program’ means any organization
 11 described in section 501(c)(3) of the Internal Rev-
 12 enue Code of 1986 and exempt from taxation under

1 section 501(a) of such Code and which is not a pri-
2 vate foundation (as defined in section 509(a) of such
3 Code) that offers patient assistance.

4 “(2) MANUFACTURER PATIENT ASSISTANCE
5 PROGRAM.—The term ‘manufacturer patient assist-
6 ance program’ means an organization, including a
7 private foundation (as so defined), that is sponsored
8 by, or receives funding from, a manufacturer and
9 that offers patient assistance. Such term does not
10 include an independent charity patient assistance
11 program.

12 “(3) PATIENT ASSISTANCE.—The term ‘patient
13 assistance’ means assistance provided to offset the
14 cost of drugs for individuals. Such term includes free
15 products, coupons, rebates, copay or discount cards,
16 and other means of providing assistance to individ-
17 uals related to drug costs, as determined by the Sec-
18 retary.

19 “(b) REPORTING ON DOMESTIC SALES.—An applica-
20 ble manufacturer of an approved drug (including a drug
21 approved under subsection (c) or (j) of section 505 of the
22 Federal Food, Drug, and Cosmetic Act and a biological
23 product licensed under subsection (a) or (k) of section 351
24 of this Act) shall submit to the Secretary and to Congress
25 an annual report, in such format as the Secretary shall

1 require, outlining with respect to the previous calendar
2 year (except as provided in subsection (c)(3))—

3 “(1) with respect to each such drug—

4 “(A) the total expenditures of the manu-
5 facturer on—

6 “(i) domestic and foreign drug re-
7 search and development, including an
8 itemized description of—

9 “(I) basic and preclinical re-
10 search;

11 “(II) clinical research, broken out
12 by clinical trial phase;

13 “(III) development of alternative
14 dosage forms and strengths for the
15 drug molecule or combinations, in-
16 cluding the molecule;

17 “(IV) other drug development ac-
18 tivities, such as nonclinical laboratory
19 studies and record and report mainte-
20 nance;

21 “(V) pursuing new or expanded
22 indications for such drug through sup-
23 plemental applications under section
24 505 of the Federal Food, Drug, and
25 Cosmetic Act;

1 “(VI) carrying out postmarket
2 requirements related to such drug, in-
3 cluding under section 505(o)(3) of
4 such Act;

5 “(VII) carrying out risk evalua-
6 tion and mitigation strategies in ac-
7 cordance with section 505–1 of such
8 Act; and

9 “(VIII) marketing research;

10 “(ii) cost of goods sold, broken out by
11 source and cost of each component and
12 identifying specific costs that reflect inter-
13 nal transfers within the manufacturer’s
14 company;

15 “(iii) acquisition costs in total and per
16 unit sold, including costs for the purchase
17 of patents and licensing; and

18 “(iv) marketing and advertising for
19 the promotion of the drug, including a
20 breakdown of amounts aimed at con-
21 sumers, prescribers, managed care organi-
22 zations, and others;

23 “(B) the gross revenue, net revenue, gross
24 profit, and net profit to the manufacturer;

1 “(C) the total number of units of the pre-
2 scription drug that were sold in interstate com-
3 merce in the most recently completed calendar
4 year;

5 “(D) pricing information, including—

6 “(i) wholesale acquisition cost;

7 “(ii) net average price realized by
8 pharmacy benefit managers for drugs pro-
9 vided to individuals in the United States,
10 after accounting for any rebates or other
11 payments from the manufacturer to the
12 pharmacy benefit manager and from the
13 pharmacy benefit manager to the manufac-
14 turer; and

15 “(iii) the net price of the drug, after
16 accounting for discounts, rebates, or other
17 financial considerations, charged to pur-
18 chasers in each applicable country of the
19 Organisation for Economic Co-operation
20 and Development;

21 “(E) information, including the dollar
22 value to the recipient of manufacturer patient
23 assistance programs offered by the manufac-
24 turer or a manufacturer patient assistance pro-

1 gram sponsored by or associated with the man-
2 ufacturer, per patient, including—

3 “(i) the specific forms of such patient
4 assistance available, such as coupons, re-
5 bates, discount codes, or copayment cards;

6 “(ii) the total dollar value of each
7 manufacturer patient assistance program
8 and the dollar value of each program to
9 the patient, including the basis used to as-
10 sign value to the manufacturer patient as-
11 sistance program;

12 “(iii) the duration of each type of
13 such patient assistance available; and

14 “(iv) any requirements, such as in-
15 come thresholds, for how to qualify for
16 such patient assistance;

17 “(F) information on usage of patient as-
18 sistance offered by the manufacturer or a man-
19 ufacturer patient assistance program sponsored
20 by or associated with the manufacturer, includ-
21 ing—

22 “(i) the number of transactions of
23 each type of patient assistance used;

24 “(ii) the number of individuals receiv-
25 ing each type of patient assistance;

1 “(iii) the total value of each type of
2 patient assistance that was used;

3 “(iv) the average length of time that
4 each individual received each type of pa-
5 tient assistance;

6 “(v) the number of individuals who
7 were discontinued from receiving each type
8 of patient assistance; and

9 “(vi) complete documentation of the
10 terms and conditions for an individual
11 agreeing to participate in the program for
12 each type of patient assistance provided;

13 “(G) any Federal benefits received by the
14 manufacturer, including the amounts and peri-
15 ods of impact for each such benefit, including
16 tax credits, patent applications that benefitted
17 from a Federal grant, patent extensions, exclu-
18 sivity periods, and other Federal benefits with
19 respect to such drug; and

20 “(H) the percentage of research and devel-
21 opment expenditures on—

22 “(i) activities conducted by the manu-
23 facturer;

24 “(ii) activities funded by Federal enti-
25 ties; and

1 “(iii) activities conducted by other en-
2 tities such as academic institutions or
3 other drug manufacturers;

4 “(2) executive compensation for the chief execu-
5 tive officer, chief financial officer, and the 3 other
6 most highly compensated executive officers, includ-
7 ing bonuses, paid by such manufacturer, and stock
8 options affiliated with the manufacturer that were
9 offered to or accrued by such officers;

10 “(3) any additional information the manufac-
11 turer chooses to provide related to drug pricing deci-
12 sions, such as total expenditures on drug research,
13 drug development, and clinical trials on drugs that
14 failed to receive approval by the Food and Drug Ad-
15 ministration, a list of drugs and drug prices against
16 which the manufacturer compared the applicable
17 drug, and other relevant information; and

18 “(4) any other information as the Secretary
19 may require.

20 “(c) SUBMISSION OF REPORTS.—

21 “(1) IN GENERAL.—

22 “(A) SUBMISSION BY DRUG MANUFACTUR-
23 ERS.—Drug manufacturers shall submit the an-
24 nual reports required under this section sub-

1 mitted to the Secretary in a usable format, as
2 the Secretary may require.

3 “(B) COLLATION BY THE SECRETARY.—

4 The Secretary shall collate the reports received
5 as described in subparagraph (A) and submit
6 such collated reports to Congress, together with
7 an analysis of the reports by the Secretary that
8 includes—

9 “(i) a summary of data from the re-
10 ports;

11 “(ii) consideration of factors such as
12 trends on research and development costs,
13 Federal benefits, and manufacturer patient
14 assistance programs; and

15 “(iii) the relationship between the fac-
16 tors described in clause (ii) and prescrip-
17 tion drug prices.

18 “(C) PUBLIC AVAILABILITY.—The Sec-
19 retary shall make the reports submitted by
20 manufacturers as described in subparagraph
21 (A) and the collated reports together with the
22 analysis of the Secretary described in subpara-
23 graph (B) publicly available, including by post-
24 ing such reports to the Internet website of the
25 Department of Health and Human Services, in

1 a searchable format. In publicizing such re-
2 ports, the Secretary may redact such propri-
3 etary information as the Secretary determines
4 appropriate.

5 “(2) SINGLE REPORTS.—A drug manufacturer
6 shall submit all information required under sub-
7 section (b) with respect to each applicable drug, in
8 a single, annual report.

9 “(3) INITIAL REPORT.—

10 “(A) IN GENERAL.—An applicable drug
11 manufacturer shall submit a report pursuant to
12 this section one year after the date of enact-
13 ment of the Affordable Medications Act (except
14 as provided in subparagraph (B)) that includes
15 the information required under subsection
16 (b)(1) with respect to each calendar year since
17 the drug for which the report is required was
18 approved under section 505 of the Federal
19 Food, Drug, and Cosmetic Act, licensed under
20 section 351 of this Act, or received an exemp-
21 tion under section 505(i) of the Federal Food,
22 Drug, and Cosmetic Act or section 351(a)(3) of
23 this Act, or the calendar year in which the man-
24 ufacturer acquired the drug.

1 “(B) SMALL BUSINESSES.—In the case of
2 an applicable drug manufacturer that has fewer
3 than 500 employees, the initial report described
4 in subparagraph (A) shall be submitted by a
5 date determined by the Secretary, which shall
6 be not earlier than the date described in sub-
7 paragraph (A) and not later than the date that
8 is 3 years after the date of enactment of the Af-
9 fordable Medications Act.

10 “(d) PENALTY FOR NONCOMPLIANCE.—The Sec-
11 retary shall report to the Office of the Inspector General
12 any manufacturer’s failure to submit a complete report as
13 required under this section. Any manufacturer that fails
14 to submit a complete report required under this section
15 shall be subject to a civil penalty of up to \$200,000 for
16 each day on which the violation continues. The Secretary
17 shall collect the civil penalties under this subsection, and
18 without further appropriation, shall use such funds to sup-
19 port the programs under sections 409K and 485E, and,
20 at the discretion of the Secretary, research of the National
21 Institutes of Health and other activities authorized under
22 the Affordable Medications Act, including any amend-
23 ments made by such Act.”.

1 **SEC. 102. DETERMINING THE PUBLIC AND PRIVATE BEN-**
2 **EFIT OF COPAYMENT COUPONS AND OTHER**
3 **PATIENT ASSISTANCE PROGRAMS.**

4 (a) INFORMATION REPORTING BY INDEPENDENT
5 CHARITY PATIENT ASSISTANCE PROGRAMS.—Section
6 6033(b) of the Internal Revenue Code of 1986 is amended
7 by striking the period at the end of paragraph (16) and
8 inserting “, and” and by inserting after paragraph (16)
9 the following new paragraph:

10 “(17) the total amount of patient assistance
11 (within the meaning of section 399V–7 of the Public
12 Health Service Act) provided to individuals who are
13 prescribed drugs manufactured by any contributor to
14 the organization.”.

15 (b) GAO STUDY AND REPORT ON IMPACT OF COPAY-
16 MENT COUPONS AND OTHER PATIENT ASSISTANCE PRO-
17 GRAMS ON PRESCRIPTION DRUG PRICING AND EXPENDI-
18 TURES.—

19 (1) STUDY.—The Comptroller General of the
20 United States shall conduct a study on the impact
21 of copayment coupons and other patient assistance
22 programs on prescription drug pricing and expendi-
23 tures. Such study shall include an analysis of the
24 following:

25 (A) The extent to which copayment cou-
26 pons and patient assistance programs con-

1 tribute to inflated prescription drug prices and
2 health insurance premiums, including with re-
3 spect to—

4 (i) the Medicaid program under title
5 XIX of the Social Security Act (42 U.S.C.
6 1396 et seq.);

7 (ii) the Medicare program under title
8 XVIII of such Act (42 U.S.C. 1395 et
9 seq.);

10 (iii) the TRICARE program under
11 chapter 55 of title 10, United States Code;

12 (iv) health care under the laws admin-
13 istered by the Secretary of Veterans Af-
14 fairs;

15 (v) the commercial health insurance
16 market; and

17 (vi) the cash pay health market.

18 (B) The extent to which manufacturers of-
19 fering copayment coupons and other patient as-
20 sistance programs or sponsoring manufacturer
21 patient assistance programs report obtaining
22 tax deductions for offering or sponsoring such
23 assistance (either as business expenses or chari-
24 table deductions), including—

1 (i) the total reported value of the tax
2 deductions claimed by manufacturers for
3 offering or sponsoring patient assistance
4 programs during the 10 years preceding
5 the date of enactment of this Act;

6 (ii) a description of the methodology
7 manufacturers reported for assigning a
8 value to the tax deduction claimed by man-
9 ufacturers for offering or sponsoring pa-
10 tient assistance programs; and

11 (iii) a description of the extent to
12 which the activities of independent charity
13 patient assistance programs, which are
14 sponsored by, or receive funding from,
15 pharmaceutical manufacturers (as deter-
16 mined using tax returns, sales data, and
17 other public disclosures) provide a financial
18 benefit to the manufacturers that sponsor
19 them.

20 (C) Oversight that is conducted to ensure
21 that independent charity patient assistance pro-
22 grams adhere to guidance from the Office of
23 the Inspector General of the Department of
24 Health and Human Services on avoiding waste,
25 fraud, and abuse.

1 (2) DEFINITIONS.—In this subsection, the
 2 terms “patient assistance”, “independent charity pa-
 3 tient assistance program”, “manufacturer”, and
 4 “manufacturer patient assistance program” have the
 5 meaning given those terms under section 399V–7 of
 6 the Public Health Service Act, as added by section
 7 101.

8 (3) REPORT.—Not later than 2 years after the
 9 date of the enactment of this Act, the Comptroller
 10 General of the United States shall submit to Con-
 11 gress a report describing the findings of the study
 12 required under this subsection.

13 **TITLE II—ACCESS AND** 14 **AFFORDABILITY**

15 **SEC. 201. NEGOTIATING FAIR PRICES FOR MEDICARE PRE-** 16 **SCRIPTION DRUGS.**

17 (a) NEGOTIATING FAIR PRICES.—

18 (1) IN GENERAL.—Section 1860D–11 of the
 19 Social Security Act (42 U.S.C. 1395w–111) is
 20 amended by striking subsection (i) (relating to non-
 21 interference) and by inserting the following:

22 “(i) NEGOTIATING FAIR PRICES WITH DRUG MANU-
 23 FACTURERS.—

24 “(1) IN GENERAL.—Notwithstanding any other
 25 provision of law, in furtherance of the goals of pro-

1 viding quality care and containing costs under this
2 part, the Secretary shall, with respect to applicable
3 covered part D drugs, and may, with respect to
4 other covered part D drugs, negotiate, using the ne-
5 gotiation technique or techniques that the Secretary
6 determines will maximize savings and value to the
7 government for prescription drug plans and MA–PD
8 plans and for plan enrollees (in a manner that may
9 be similar to Federal entities and that may include,
10 but is not limited to, formularies, reference pricing,
11 discounts, rebates, other price concessions, and cov-
12 erage determinations), with drug manufacturers the
13 prices that may be charged to PDP sponsors and
14 MA organizations for such drugs for part D eligible
15 individuals who are enrolled in a prescription drug
16 plan or in an MA–PD plan. In conducting such ne-
17 gotiations, the Secretary shall consider the drug’s
18 current price, initial launch price, prevalence of dis-
19 ease and usage, and approved indications, the num-
20 ber of similarly effective alternative treatments for
21 each approved use of the drug, the budgetary impact
22 of providing coverage under this part for such drug
23 for all individuals who would likely benefit from the
24 drug, evidence on the drug’s effectiveness and safety
25 compared to similar drugs, and the quality and

1 quantity of clinical data and rigor of the applicable
2 process of approval of a drug under section 505 of
3 the Federal Food, Drug, and Cosmetic Act or a bio-
4 logical product under section 351 of the Public
5 Health Service Act.

6 “(2) USE OF LOWER OF VA OR BIG FOUR PRICE
7 IF NEGOTIATIONS FAIL.—If, after attempting to ne-
8 gotiate for a price with respect to a covered part D
9 drug under paragraph (1) for a period of 1 year, the
10 Secretary is not successful in obtaining an appro-
11 priate price for the drug (as determined by the Sec-
12 retary), the Secretary shall establish the price that
13 may be charged to PDP sponsors and MA organiza-
14 tions for such drug for part D eligible individuals
15 who are enrolled in a prescription drug plan or in
16 an MA–PD plan at an amount equal to the lesser
17 of—

18 “(A) the price paid by the Secretary of
19 Veterans Affairs to procure the drug under the
20 laws administered by the Secretary of Veterans
21 Affairs; or

22 “(B) the price paid to procure the drug
23 under section 8126 of title 38, United States
24 Code.

1 “(3) APPLICABLE COVERED PART D DRUG DE-
2 FINED.—For purposes of this subsection, the term
3 ‘applicable covered part D drug’ means a covered
4 part D drug that the Secretary determines to be ap-
5 propriate for negotiation under paragraph (1) based
6 on one or more of the following factors as applied
7 to such drug:

8 “(A) Spending on a per beneficiary basis.

9 “(B) The proportion of total spending
10 under this title.

11 “(C) Unit price increases over the pre-
12 ceding 5 years.

13 “(D) Initial launch price.

14 “(E) Availability of less expensive, simi-
15 larly effective alternative treatments.

16 “(F) Status of the drug as a follow-on to
17 previously approved drugs.

18 “(G) Any other criteria determined by the
19 Secretary.

20 “(4) PDP SPONSORS AND MA ORGANIZATION
21 MAY NEGOTIATE LOWER PRICES.—Nothing in this
22 subsection shall be construed as preventing the spon-
23 sor of a prescription drug plan, or an organization
24 offering an MA–PD plan, from obtaining a discount
25 or reduction of the price for a covered part D drug

1 below the price negotiated under paragraph (1) or
2 the price established under paragraph (2).

3 “(5) NO EFFECT ON EXISTING APPEALS PROC-
4 ESS.—Nothing in this subsection shall be construed
5 to affect the appeals procedures under subsections
6 (g) and (h) of section 1860D–4.”.

7 (2) EFFECTIVE DATE.—The amendments made
8 by this subsection shall take effect on the date of the
9 enactment of this Act and shall first apply to nego-
10 tiations and prices for plan years beginning on Jan-
11 uary 1, 2019.

12 (b) REQUIREMENT TO INCLUDE A LINK TO THE
13 MEDICARE DRUG SPENDING DASHBOARD ON THE MEDI-
14 CARE PLAN FINDER.—Beginning not later than October
15 1, 2017, the Secretary of Health and Human Services
16 shall ensure that the Medicare Plan Finder on the Medi-
17 care.gov Internet website includes a link to the Medicare
18 Drug Spending Dashboard on the CMS.gov Internet
19 website. Such link shall be easily accessible on the Medi-
20 care Plan Finder.

21 (c) REPORTS TO CONGRESS.—

22 (1) SECRETARY OF HHS.—

23 (A) IN GENERAL.—Not later than 3 years
24 after the date of the enactment of this Act, and
25 every 6 months thereafter, the Secretary of

1 Health and Human Services shall submit to
2 Congress a report on the following:

3 (i) The price negotiations conducted
4 by the Secretary under section 1860D–
5 11(i) of the Social Security Act (42 U.S.C.
6 1395w–111(i)), as amended by subsection
7 (a), including a description of—

8 (I) how such price negotiations
9 are achieving lower prices for covered
10 part D drugs (as defined in section
11 1860D–2(e) of the Social Security Act
12 (42 U.S.C. 1395w–102(e))) for Medi-
13 care beneficiaries;

14 (II) how such lower prices are
15 passed through to Medicare bene-
16 ficiaries;

17 (III) how such price negotiations
18 are affecting drug prices in the pri-
19 vate market; and

20 (IV) how such price negotiations
21 are affecting the list price of covered
22 part D drugs.

23 (ii) Data on spending under part D of
24 the Medicare program on covered part D

1 drugs, including data on covered part D
2 drugs with—

3 (I) spending on a per beneficiary
4 basis that is above the median spend-
5 ing on other drugs in the same class
6 or above the median spending of other
7 drug classes; and

8 (II) high unit cost increases over
9 the past five years, especially where
10 such increases are greater than the
11 increases for covered part D drugs in
12 general.

13 (iii) A list of the covered part D drugs
14 with no therapeutic substitute and data on
15 spending under part D of the Medicare
16 program on such drugs.

17 (iv) Access to covered part D drugs
18 and, where available, compliance rates and
19 health outcomes associated with compli-
20 ance rates.

21 (v) Appeals by enrollees with respect
22 to covered part D drugs not included on
23 plan formularies.

24 (B) PUBLIC AVAILABILITY OF REPORT.—

25 The Secretary of Health and Human Services

1 shall publish on the Internet website of the
2 Centers for Medicare & Medicaid Services a
3 copy of each report submitted under subpara-
4 graph (A), including the detailed tables, figures,
5 and data published in the report and its appen-
6 dices.

7 (2) MEDPAC.—

8 (A) STUDY.—The Comptroller General of
9 the United States shall conduct a study on the
10 price negotiations conducted by the Secretary
11 under section 1860D–11(i) of the Social Secu-
12 rity Act (42 U.S.C. 1395w–111(i)), as amended
13 by subsection (a), including an analysis of—

14 (i) how such price negotiations are
15 achieving lower prices for covered part D
16 drugs (as defined in section 1860D–2(e) of
17 the Social Security Act (42 U.S.C. 1395w–
18 102(e))) for Medicare beneficiaries;

19 (ii) who is benefitting from such lower
20 prices, such as Medicare beneficiaries, the
21 Federal Government, States, prescription
22 drug plans and MA–PD plans, or other en-
23 tities;

1 (iii) how such price negotiations are a
2 factor affecting drug prices in the private
3 market; and

4 (iv) how such price negotiations are a
5 factor affecting the list price of covered
6 part D drugs.

7 (B) REPORT.—Not later than January 1,
8 2021, the Comptroller General of the United
9 States shall submit to Congress a report on the
10 study conducted under subparagraph (A), to-
11 gether with recommendations for improving
12 such price negotiations.

13 (d) CMI TESTING OF NEGOTIATING DRUG AND BIO-
14 LOGICAL PRICES TO IMPROVE VALUE.—Section
15 1115A(b)(2) of the Social Security Act (42 U.S.C.
16 1315a(b)(2)) is amended—

17 (1) in subparagraph (A), by adding at the end
18 the following new sentence: “The models selected
19 under this subparagraph shall include at least 3 of
20 the models described in subparagraph (D), which
21 shall be implemented by not later than 18 months
22 after the date of the enactment of the Affordable
23 Medications Act”; and

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

1 “(D) MODELS OF NEGOTIATING DRUG AND
2 BIOLOGICAL PRICES TO IMPROVE VALUE.—The
3 models described in this subparagraph are the
4 following models for negotiating drug and bio-
5 logical prices under the applicable titles (includ-
6 ing under both parts B and D of title XVIII)
7 in order to improve the value of payments for
8 such drugs and biologicals under such titles:

9 “(i) Discounting or eliminating pa-
10 tient cost-sharing on high-value drugs and
11 biologicals.

12 “(ii) Value-based formularies.

13 “(iii) Indications-based pricing.

14 “(iv) Reference pricing.

15 “(v) Risk-sharing agreements based
16 on outcomes.

17 “(vi) Pricing based on comparative ef-
18 fectiveness research.

19 “(vii) Episode-based payments for
20 chemotherapy and other conditions deter-
21 mined appropriate by the Secretary.

22 “(viii) Alternative ways of paying for
23 drugs and biologicals under part B of title
24 XVIII.

1 “(ix) Other models determined appro-
2 priate by the Secretary.”.

3 **SEC. 202. PRESCRIPTION DRUG PRICE SPIKES.**

4 (a) IDENTIFICATION OF PRESCRIPTION DRUG PRICE
5 SPIKES.—

6 (1) DEFINITIONS.—In this subsection:

7 (A) APPLICABLE ENTITY.—The term “ap-
8 plicable entity” means the holder of an applica-
9 tion approved under subsection (c) or (j) of sec-
10 tion 505 of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 355) or of a license issued
12 under subsection (a) or (k) of section 351 of
13 the Public Health Service Act (42 U.S.C. 262)
14 for a prescription drug.

15 (B) AVERAGE PRICE.—The term “average
16 price” means—

17 (i) the average manufacturer price, as
18 defined in section 1927(k)(1) of the Social
19 Security Act (42 U.S.C. 1396r–8(k)(1)); or

20 (ii) in the case of a drug for which the
21 average manufacturer price is not avail-
22 able, the manufacturer’s average sales
23 price (as defined in section 1847A(c)(1) of
24 the Social Security Act (42 U.S.C. 1395w–
25 3a(c)(1))).

1 (C) COMMERCE.—The term “commerce”
2 has the meaning given such term in section 4
3 of the Federal Trade Commission Act (15
4 U.S.C. 44).

5 (D) PRESCRIPTION DRUG.—The term
6 “prescription drug” means any drug subject to
7 section 503(b)(1) of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 353(b)(1)) which
9 is covered by a Federal health care program (as
10 defined in section 1128B(f) of the Social Secu-
11 rity Act (42 U.S.C. 1320a-7b(f))).

12 (E) PRICE SPIKE.—

13 (i) IN GENERAL.—The term “price
14 spike” means an increase in the average
15 price in commerce of a prescription drug
16 for which the price spike percentage is
17 equal to or greater than the applicable
18 price increase allowance.

19 (ii) PRICE SPIKE PERCENTAGE.—The
20 price spike percentage is the percentage (if
21 any) by which—

22 (I) the average price of a pre-
23 scription drug in commerce for the
24 most recently completed calendar
25 year; exceeds

1 (II) the average price of such
 2 drug in commerce for the calendar
 3 year preceding such year.

4 (iii) APPLICABLE PRICE INCREASE AL-
 5 LOWANCE.—The applicable price increase
 6 allowance for any calendar year is the per-
 7 centage (rounded to the nearest one-tenth
 8 of 1 percent) by which the medical care
 9 component of the consumer price index for
 10 all urban consumers (as published by the
 11 Bureau of Labor Statistics) for that year
 12 exceeds such component for the preceding
 13 calendar year.

14 (F) PRICE SPIKE REVENUE.—

15 (i) IN GENERAL.—The price spike rev-
 16 enue for any calendar year is an amount
 17 equal to—

18 (I) the gross price spike revenue;

19 minus

20 (II) the adjustment amount.

21 (ii) GROSS PRICE SPIKE REVENUE.—

22 The gross price spike revenue for any cal-
 23 endar year is an amount equal to the prod-
 24 uct of—

1 (I) an amount equal to the dif-
2 ference between subclause (I) of sub-
3 paragraph (E)(ii) and subclause (II)
4 of such subparagraph; and

5 (II) the total number of units of
6 the prescription drug which were sold
7 in commerce in such calendar year.

8 (iii) ADJUSTMENT AMOUNT.—The ad-
9 justment amount is the amount, if any, of
10 the gross price spike revenue which the In-
11 spector General has determined is due sole-
12 ly to an increase in the cost of the goods
13 sold (excluding any increase in costs which
14 are related to internal transfers within the
15 applicable entity) which are necessary to
16 manufacture the prescription drug subject
17 to the price spike.

18 (G) INSPECTOR GENERAL.—The term “In-
19 spector General” means the Inspector General
20 of the Department of Health and Human Serv-
21 ices.

22 (2) SUBMISSION BY PHARMACEUTICAL COMPA-
23 NIES OF INFORMATION.—

24 (A) IN GENERAL.—For each prescription
25 drug, the applicable entity shall submit to the

1 Inspector General a quarterly report that in-
2 cludes the following:

3 (i) For each prescription drug of the
4 applicable entity—

5 (I) the total number of units of
6 the prescription drug which were sold
7 in commerce in the most recently
8 completed calendar quarter; and

9 (II) the gross revenues from sales
10 of such prescription drug in commerce
11 in the most recently completed cal-
12 endar quarter.

13 (ii) Such information related to in-
14 creased input costs as the applicable entity
15 may wish the Inspector General to consider
16 in making a determination under subclause
17 (II) of paragraph (3)(B)(ii) or an assess-
18 ment in subclause (III) of such paragraph
19 for the most recently completed calendar
20 quarter.

21 (iii) Such information related to any
22 anticipated increased input costs for the
23 subsequent calendar quarter as the appli-
24 cable entity may wish the Inspector Gen-
25 eral to consider in making a determination

1 under subclause (II) of paragraph
2 (3)(B)(ii) or an assessment in subclause
3 (III) of such paragraph for such calendar
4 quarter.

5 (B) PENALTY FOR FAILURE TO SUBMIT.—

6 (i) IN GENERAL.—An applicable enti-
7 ty described in subparagraph (A) that fails
8 to submit information to the Inspector
9 General regarding a prescription drug, as
10 required by such paragraph, before the
11 date specified in subparagraph (C) shall be
12 liable for a civil penalty, as determined
13 under clause (ii).

14 (ii) AMOUNT OF PENALTY.—The
15 amount of the civil penalty shall be equal
16 to the product of—

17 (I) an amount, as determined ap-
18 propriate by the Inspector General;
19 which is—

20 (aa) not less than 0.5 per-
21 cent of the gross revenues from
22 sales of the prescription drug de-
23 scribed in clause (i) for the most
24 recently completed calendar year;
25 and

1 (bb) not greater than 1 per-
2 cent of the gross revenues from
3 sales of such drug for the most
4 recently completed calendar year;
5 and

6 (II) the number of days in the
7 period between—

8 (aa) the applicable date
9 specified in subparagraph (C);
10 and

11 (bb) the date on which the
12 Inspector General receives the in-
13 formation described in subpara-
14 graph (A) from the applicable en-
15 tity.

16 (C) SUBMISSION DEADLINE.—An applica-
17 ble entity shall submit each quarterly report de-
18 scribed in subparagraph (A) not later than Jan-
19 uary 17, April 18, June 15, and September 15
20 of each calendar year.

21 (3) ASSESSMENT.—

22 (A) IN GENERAL.—Not later than the last
23 day in February of each year, the Inspector
24 General, in consultation with the Federal Trade
25 Commission, shall complete an assessment of

1 the information the Inspector General received
2 pursuant to paragraph (2)(A) with respect to
3 sales of prescription drugs in the most recently
4 completed calendar year.

5 (B) ELEMENTS.—The assessment required
6 by subparagraph (A) shall include the following:

7 (i) Identification of each price spike
8 relating to a prescription drug in the most
9 recently completed calendar year.

10 (ii) For each price spike identified
11 under clause (i)—

12 (I) a determination of the price
13 spike percentage and price spike rev-
14 enue;

15 (II) a determination regarding
16 the accuracy of the information sub-
17 mitted by the applicable entity regard-
18 ing increased input costs; and

19 (III) an assessment of the ration-
20 ale of the applicable entity for the
21 price spike.

22 (4) REPORT TO INTERNAL REVENUE SERV-
23 ICE.—

24 (A) IN GENERAL.—Not later than the last
25 day in February of each year, the Inspector

1 General shall transmit to the Internal Revenue
2 Service a report on the findings of the Inspector
3 General with respect to the information the In-
4 spector General received under paragraph
5 (2)(A) with respect to the most recently com-
6 pleted calendar year and the assessment carried
7 out by the Inspector General under paragraph
8 (3)(A) with respect to such information.

9 (B) CONTENTS.—The report transmitted
10 under subparagraph (A) shall include the fol-
11 lowing:

12 (i) The information received under
13 paragraph (2)(A) with respect to the most
14 recently completed calendar year.

15 (ii) The price spikes identified under
16 clause (i) of paragraph (3)(B).

17 (iii) The price spike revenue deter-
18 minations made under clause (ii)(I) of
19 such paragraph.

20 (iv) The average price of the prescrip-
21 tion drug for each month during the most
22 recently completed calendar year.

23 (v) The determinations and assess-
24 ments made under subclauses (II) and
25 (III) of clause (ii) of such paragraph.

1 (C) PUBLICATION.—Not later than the last
2 day in February of each year, the Inspector
3 General shall make the report transmitted
4 under subparagraph (A) available to the public,
5 including on the Internet website of the Inspec-
6 tor General.

7 (5) NOTIFICATION.—The Secretary of the
8 Treasury, in conjunction with the Inspector General,
9 shall notify, at such time and in such manner as the
10 Secretary of the Treasury shall provide, each appli-
11 cable entity in regard to any prescription drug which
12 has been determined to have been subject to a price
13 spike during the most recently completed calendar
14 year and the amount of the tax imposed on such ap-
15 plicable entity pursuant to section 4192 of the Inter-
16 nal Revenue Code of 1986 (as added by subsection
17 (b) of this section).

18 (b) EXCISE TAX ON PRESCRIPTION DRUGS SUBJECT
19 TO PRICE SPIKES.—

20 (1) IN GENERAL.—Subchapter E of chapter 32
21 of the Internal Revenue Code of 1986 is amended by
22 adding at the end the following new section:

23 **“SEC. 4192. PRESCRIPTION DRUGS SUBJECT TO PRICE**
24 **SPIKES.**

25 **“(a) IMPOSITION OF TAX.—**

1 “(1) IN GENERAL.—For each taxable prescrip-
2 tion drug sold by an applicable entity during the cal-
3 endar year, there is hereby imposed on such entity
4 a tax equal to the greater of—

5 “(A) the annual price spike tax for such
6 drug, or

7 “(B) subject to paragraph (2), the cumu-
8 lative price spike tax for such drug.

9 “(2) LIMITATION.—In the case of a taxable
10 prescription drug for which the applicable period (as
11 determined under subsection (c)(2)(E)(i)) is less
12 than 2 completed calendar years, the cumulative
13 price spike tax shall not apply.

14 “(b) ANNUAL PRICE SPIKE TAX.—

15 “(1) IN GENERAL.—The amount of the annual
16 price spike tax shall be equal to the applicable per-
17 centage of the price spike revenue received by the
18 applicable entity on the sale of the taxable prescrip-
19 tion drug during the calendar year.

20 “(2) APPLICABLE PERCENTAGE.—For purposes
21 of paragraph (1), the applicable percentage shall be
22 equal to—

23 “(A) in the case of a taxable prescription
24 drug which has been subject to a price spike
25 percentage equal to or greater than the applica-

1 ble price increase allowance (as defined in sec-
2 tion 202(a)(1)(E)(iii) of the Affordable Medica-
3 tions Act) but less than 15 percent, 50 percent,

4 “(B) in the case of a taxable prescription
5 drug which has been subject to a price spike
6 percentage equal to or greater than 15 percent
7 but less than 20 percent, 75 percent, and

8 “(C) in the case of a taxable prescription
9 drug which has been subject to a price spike
10 percentage equal to or greater than 20 percent,
11 100 percent.

12 “(c) CUMULATIVE PRICE SPIKE TAX.—

13 “(1) IN GENERAL.—The amount of the cumu-
14 lative price spike tax shall be equal to the applicable
15 percentage of the cumulative price spike revenue re-
16 ceived by the applicable entity on the sale of the tax-
17 able prescription drug during the calendar year.

18 “(2) APPLICABLE PERCENTAGE.—

19 “(A) IN GENERAL.—For purposes of para-
20 graph (1), the applicable percentage shall be
21 equal to—

22 “(i) in the case of a taxable prescrip-
23 tion drug which has been subject to a cu-
24 mulative price spike percentage equal to or
25 greater than the cumulative price increase

1 allowance but less than the first com-
2 pounded percentage, 50 percent,

3 “(ii) in the case of a taxable prescrip-
4 tion drug which has been subject to a cu-
5 mulative price spike percentage equal to or
6 greater than the first compounded percent-
7 age but less than the second compounded
8 percentage, 75 percent, and

9 “(iii) in the case of a taxable prescrip-
10 tion drug which has been subject to a cu-
11 mulative price spike percentage equal to or
12 greater than the second compounded per-
13 centage, 100 percent.

14 “(B) CUMULATIVE PRICE SPIKE PERCENT-
15 AGE.—The cumulative price spike percentage is
16 the percentage (if any) by which—

17 “(i) the average price of the taxable
18 prescription drug in commerce for the
19 most recently completed calendar year, ex-
20 ceeds

21 “(ii) the average price of such drug in
22 commerce for the base year.

23 “(C) CUMULATIVE PRICE INCREASE AL-
24 LOWANCE.—For purposes of clause (i) of sub-
25 paragraph (A), the cumulative price increase al-

1 lowance for any calendar year is the percentage
 2 (rounded to the nearest one-tenth of 1 percent)
 3 by which the medical care component of the
 4 consumer price index for all urban consumers
 5 (as published by the Bureau of Labor Statis-
 6 tics) for that year exceeds such component for
 7 the base year.

8 “(D) COMPOUNDED PERCENTAGES.—For
 9 purposes of subparagraph (A), the first com-
 10 pounded percentage and second compounded
 11 percentage shall be determined in accordance
 12 with the following table:

“Number of years in applicable period	First compounded percentage	Second compounded percentage
2 years	32.35	44.00
3 years	52.09	72.80
4 years	74.90	107.36
5 years	101.14	148.83.

13 “(E) APPLICABLE PERIOD AND BASE
 14 YEAR.—

15 “(i) APPLICABLE PERIOD.—The appli-
 16 cable period shall be the lesser of—

17 “(I) the 5 most recently com-
 18 pleted calendar years,

19 “(II) any completed calendar
 20 years beginning after March 29, 2019,

21 or

1 “(III) any completed calendar
2 years in which the taxable prescrip-
3 tion drug was sold in commerce.

4 “(ii) BASE YEAR.—The base year
5 shall be the calendar year immediately pre-
6 ceding the applicable period.

7 “(3) CUMULATIVE PRICE SPIKE REVENUE.—
8 For purposes of paragraph (1), the cumulative price
9 spike revenue for any taxable prescription drug shall
10 be an amount equal to—

11 “(A) an amount equal to the product of—

12 “(i) an amount (not less than zero)
13 equal to—

14 “(I) the average price of such
15 drug in commerce for the most re-
16 cently completed calendar year, minus

17 “(II) the average price of such
18 drug in commerce for the base year,
19 and

20 “(ii) the total number of units of such
21 drug which were sold in commerce in the
22 most recently completed calendar year,
23 minus

24 “(B) the adjustment amount, if any, deter-
25 mined under section 202(a)(1)(F)(iii) of the Af-

1 affordable Medications Act for such calendar
2 year.

3 “(d) DEFINITIONS.—For purposes of this section—

4 “(1) TAXABLE PRESCRIPTION DRUG.—The
5 term ‘taxable prescription drug’ means a prescrip-
6 tion drug (as defined in section 202(a)(1)(D) of the
7 Affordable Medications Act) which has been identi-
8 fied by the Inspector General of the Department of
9 Health and Human Services, under section
10 202(a)(3)(B)(i) of such Act, as being subject to a
11 price spike.

12 “(2) OTHER TERMS.—The terms ‘applicable en-
13 tity’, ‘average price’, ‘price spike’, ‘price spike per-
14 centage’, and ‘price spike revenue’ have the same
15 meaning given such terms under section 202(a)(1)
16 of the Affordable Medications Act.”.

17 (2) CLERICAL AMENDMENTS.—

18 (A) The heading of subchapter E of chap-
19 ter 32 of the Internal Revenue Code of 1986 is
20 amended by striking “**Medical Devices**”
21 and inserting “**Certain Medical Devices**
22 **and Prescription Drugs**”.

23 (B) The table of subchapters for chapter
24 32 of such Code is amended by striking the

1 item relating to subchapter E and inserting the
 2 following new item:

“SUBCHAPTER E. CERTAIN MEDICAL DEVICES AND PRESCRIPTION DRUGS”.

3 (3) The table of sections for subchapter E of
 4 chapter 32 of such Code is amended by adding at
 5 the end the following new item:

“Sec. 4192. Prescription drugs subject to price spikes.”.

6 (4) EFFECTIVE DATE.—The amendments made
 7 by this section shall apply to sales after the date of
 8 the enactment of this Act.

9 (c) REVENUES COLLECTED.—There are authorized
 10 to be appropriated to the Secretary of Health and Human
 11 Services such sums as are equal to any increase in revenue
 12 to the Treasury by reason of the provisions of this section
 13 or the amendments made by this section for the purposes
 14 of—

15 (1) funding or conducting research on the eco-
 16 nomic and policy implications of price patterns of
 17 prescription drugs;

18 (2) increasing amounts available to the Na-
 19 tional Institutes of Health for research and develop-
 20 ment of drugs;

21 (3) reducing prescription drug cost-sharing for
 22 patients; or

23 (4) reducing health insurance premiums.

1 **SEC. 203. IMPORTING AFFORDABLE AND SAFE DRUGS.**

2 (a) IN GENERAL.—Section 804 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 384) is amended to
4 read as follows:

5 **“SEC. 804. IMPORTATION OF SAFE AND AFFORDABLE**
6 **DRUGS BY WHOLESALE DISTRIBUTORS,**
7 **PHARMACIES, AND INDIVIDUALS.**

8 “(a) IN GENERAL.—Not later than 180 days after
9 the date of enactment of the Affordable Medications Act,
10 the Secretary shall promulgate regulations permitting the
11 importation of qualifying prescription drugs into the
12 United States, in accordance with this section.

13 “(b) DEFINITIONS.—For purposes of this section:

14 “(1) CERTIFIED FOREIGN SELLER.—The term
15 ‘certified foreign seller’ means a licensed foreign
16 pharmacy or foreign wholesale distributor that the
17 Secretary certifies under subsection (d)(1)(B), that
18 pays the fee required under subsection (d)(1)(C),
19 and that is included on the list described in sub-
20 section (c).

21 “(2) FOREIGN WHOLESALE DISTRIBUTOR.—
22 The term ‘foreign wholesale distributor’ means a
23 person (other than a manufacturer, a manufactur-
24 er’s co-licensed partner, a third-party logistics pro-
25 vider, or a repackager) engaged in wholesale dis-
26 tribution.

1 “(3) IMPORTER.—The term ‘importer’ means a
2 dispenser (as defined in section 581(3)) or wholesale
3 distributor registered under section 503(e) who im-
4 ports prescription drugs into the United States in
5 accordance with this section.

6 “(4) LICENSED FOREIGN PHARMACY.—The
7 term ‘licensed foreign pharmacy’ means a pharmacy
8 located in Canada, or subject to subsection (e), an-
9 other applicable country, that—

10 “(A) operates in accordance with applica-
11 ble pharmacy standards set forth by the provin-
12 cial pharmacy rules and regulations enacted in
13 Canada, or, subject to subsection (e), such ap-
14 plicable rules and regulations of the permitted
15 country in which such seller is located; and

16 “(B) is licensed to operate and dispense
17 prescription drugs to individuals in Canada, or,
18 subject to subsection (e), the permitted country
19 in which the pharmacy is located.

20 “(5) QUALIFYING PRESCRIPTION DRUG.—The
21 term ‘qualifying prescription drug’—

22 “(A) means a prescription drug that—

23 “(i) is approved for use in patients,
24 and marketed, in Canada, or subject to
25 subsection (e), approved for use in pa-

1 tients, and marketed, in another permitted
2 country;

3 “(ii) is manufactured in a facility reg-
4 istered under subsection (b)(1) or (i) of
5 section 510 that is in compliance with good
6 manufacturing practices regulations of the
7 Food and Drug Administration;

8 “(iii) has the same active ingredient
9 or ingredients, route of administration, and
10 strength as a prescription drug approved
11 under chapter V, or, for purposes of sub-
12 paragraph (B)(iv), is biosimilar to an ap-
13 proved biological product and has the same
14 route of administration and strength as the
15 approved biological product; and

16 “(iv) is labeled in accordance with—

17 “(I) the laws of Canada, or an-
18 other country from which importation
19 is permitted pursuant to subsection
20 (e); and

21 “(II) the requirements promul-
22 gated by the Secretary, which shall in-
23 clude labeling in English;

24 “(B) with respect to importers only, in-
25 cludes—

1 “(i) peritoneal dialysis solution;

2 “(ii) insulin;

3 “(iii) a drug for which a risk evalua-
4 tion and mitigation strategy is required
5 under section 505–1;

6 “(iv) biological products, as defined in
7 section 351 of the Public Health Service
8 Act that are proteins (except any chemi-
9 cally synthesized polypeptides) or analo-
10 gous products; and

11 “(v) intravenously infused drugs; and

12 “(C) does not include—

13 “(i) a controlled substance (as defined
14 in section 102 of the Controlled Sub-
15 stances Act);

16 “(ii) an anesthetic drug inhaled dur-
17 ing surgery; or

18 “(iii) a compounded drug.

19 “(6) VALID PRESCRIPTION.—The term ‘valid
20 prescription’ means a prescription that is issued for
21 a legitimate medical purpose in the usual course of
22 professional practice by—

23 “(A) a practitioner who has conducted at
24 least one in-person medical evaluation of the
25 patient; or

1 “(B) a covering practitioner.

2 “(c) PUBLICATION OF CERTIFIED FOREIGN SELL-
3 ERS.—The Secretary shall publish on a dedicated Internet
4 website a list of certified foreign sellers, including the
5 Internet website address, physical address, and telephone
6 number of each such certified foreign seller.

7 “(d) ADDITIONAL CRITERIA.—

8 “(1) CERTIFIED FOREIGN SELLERS.—

9 “(A) IN GENERAL.—To be a certified for-
10 eign seller, such seller shall—

11 “(i) be certified by the Secretary in
12 accordance with subparagraph (B);

13 “(ii) pay the registration fee estab-
14 lished under subparagraph (C); and

15 “(iii) sell only qualifying prescription
16 drugs to importers or individuals who im-
17 port prescription drugs into the United
18 States in accordance with this section.

19 “(B) CERTIFICATION.—To be a certified
20 foreign seller, the Secretary shall certify that
21 such seller—

22 “(i) is a foreign wholesale distributor
23 or licensed foreign pharmacy operating an
24 establishment, which may include an online
25 foreign pharmacy, that is located in Can-

1 ada, or, subject to subsection (e), another
2 permitted country;

3 “(ii) is engaged in the distribution or
4 dispensing of a prescription drug that is
5 imported or offered for importation into
6 the United States;

7 “(iii) has been in existence for a pe-
8 riod of at least 5 years preceding the date
9 of such certification and has a purpose
10 other than to participate in the program
11 established under this section;

12 “(iv) in the case of a certified foreign
13 seller that is a licensed foreign pharmacy,
14 agrees to dispense a qualifying prescription
15 drug to an individual in the United States
16 only after receiving a valid prescription, as
17 described in paragraph (2)(C);

18 “(v) has processes established by the
19 seller, or participates in another estab-
20 lished process, to certify that the physical
21 premises and data reporting procedures
22 and licenses are in compliance with all ap-
23 plicable laws and regulations of Canada,
24 or, subject to subsection (e), the permitted
25 country in which the seller is located, and

1 has implemented policies designed to mon-
2 itor ongoing compliance with such laws
3 and regulations;

4 “(vi) conducts or commits to partici-
5 pate in ongoing and comprehensive quality
6 assurance programs and implements such
7 quality assurance measures, including
8 blind testing, to ensure the veracity and re-
9 liability of the findings of the quality as-
10 surance program;

11 “(vii) agrees that, pursuant to sub-
12 section (g), laboratories approved by the
13 Secretary may be authorized to conduct
14 product testing to determine the chemical
15 authenticity of sample pharmaceutical
16 products;

17 “(viii) agrees to notify the Secretary,
18 importers, and individuals of product re-
19 calls in Canada, or pursuant to subsection
20 (e), the permitted country in which the
21 seller is located, and agrees to cease, or re-
22 frain from, exporting such product;

23 “(ix) has established, or will establish
24 or participate in, a process for resolving
25 grievances, as defined by the Secretary,

1 and will be held accountable for violations
2 of established guidelines and rules;

3 “(x) except as otherwise permitted
4 under this section, does not sell products
5 that the seller could not otherwise legally
6 sell in Canada, or, subject to subsection
7 (e), the permitted country in which such
8 seller is located to customers in the United
9 States; and

10 “(xi) meets any other criteria estab-
11 lished by the Secretary.

12 “(C) CERTIFICATION FEE.—Not later than
13 30 days before the start of each fiscal year, the
14 Secretary shall establish a fee to be collected
15 from foreign sellers for such fiscal year that are
16 certified under subparagraph (B), in an amount
17 that is sufficient, and not more than necessary,
18 to pay the costs of administering the program
19 under this section, and enforcing this section
20 pursuant to section 303(h), for that fiscal year.

21 “(D) RECERTIFICATION.—A certification
22 under subparagraph (B) shall be in effect for a
23 period of 2 years, or until there is a material
24 change in the circumstances under which the
25 foreign seller meets the requirements under

1 such subparagraph, whichever occurs earlier. A
2 foreign seller may reapply for certification
3 under such subparagraph (B), in accordance
4 with a process established by the Secretary.

5 “(2) INDIVIDUALS.—An individual may import
6 a qualifying prescription drug described in sub-
7 section (b) from Canada or another country pursu-
8 ant to subsection (e) if such drug—

9 “(A) is dispensed, including through an
10 online pharmacy, by a certified foreign seller
11 that is a licensed foreign pharmacy;

12 “(B) is purchased for personal use by the
13 individual, not for resale, in quantities that do
14 not exceed a 90-day supply; and

15 “(C) is filled only after providing to the li-
16 censed foreign pharmacy a valid prescription
17 issued by a health care practitioner licensed to
18 practice in a State in the United States.

19 “(e) IMPORTATION FROM OTHER COUNTRIES.—Be-
20 ginning on the date that is 2 years after the date on which
21 final regulations are promulgated to carry out this section,
22 if, based on a review of the evidence obtained after such
23 effective date, including the reports submitted under sec-
24 tion 2(d) of the Affordable Medications Act, that importa-
25 tion of qualifying prescription drugs from Canada under

1 this section resulted in cost savings for consumers in the
2 United States and increased access to safe medication, the
3 Secretary shall have the authority to permit importation
4 of qualifying prescription drugs by importers and individ-
5 uals from, in addition to Canada, any country that—

6 “(1) is a member of the Organisation for Eco-
7 nomic Co-operation and Development; and

8 “(2) has statutory or regulatory standards for
9 the approval and sale of prescription drugs that are
10 comparable to the standards in the United States
11 and that—

12 “(A) authorizes the approval of drugs only
13 if a drug has been determined to be safe and
14 effective by experts employed by or acting on
15 behalf of a governmental entity and qualified by
16 scientific training and experience to evaluate
17 the safety and effectiveness of drugs;

18 “(B) requires that any determination of
19 safety and effectiveness described in subpara-
20 graph (A) be made on the basis of adequate
21 and well-controlled investigations, including
22 clinical investigations, as appropriate, con-
23 ducted by experts qualified by scientific training
24 and experience to evaluate the safety and effec-
25 tiveness of drugs;

1 “(C) requires the methods used in, and the
2 facilities and controls used for, the manufac-
3 ture, processing, and packing of drugs in the
4 country to be adequate to preserve the identity,
5 quality, purity, and strength of the drugs; and

6 “(D) requires the reporting of adverse re-
7 actions to drugs and establish procedures to re-
8 call, and withdraw approval of, drugs found not
9 to be safe or effective.

10 “(f) LABELING.—Any qualifying prescription drug
11 imported that meets the labeling requirements described
12 in subsection (b)(5)(A)(iv) is deemed not misbranded for
13 purposes of section 502.

14 “(g) DRUG TESTING LABORATORIES.—The Sec-
15 retary may approve one or more laboratories to conduct
16 random testing of prescription drugs sold by certified for-
17 eign sellers to assess the chemical authenticity of such
18 drugs.

19 “(h) UNFAIR AND DISCRIMINATORY ACTS AND PRAC-
20 TICES.—It is unlawful for a manufacturer, directly or indi-
21 rectly (including by being a party to a licensing agreement
22 or other agreement)—

23 “(1) to discriminate by charging a higher price
24 for a prescription drug sold to a certified foreign
25 seller that sells such drug to an importer in accord-

1 ance with this section than the price that is charged,
2 inclusive of rebates or other incentives to the coun-
3 try from which the drug is exported, to another per-
4 son that is in the same country and that does not
5 import such a drug into the United States in accord-
6 ance with this section;

7 “(2) except with respect to a prescription drug
8 on the drug shortage list under section 506E, dis-
9 criminate by denying, restricting, or delaying sup-
10 plies of a prescription drug to a certified foreign sell-
11 er, on account of such seller’s status as a certified
12 foreign seller, that sells such drug to an importer in
13 accordance with this section, or by publicly, pri-
14 vately, or otherwise refusing to do business with
15 such a certified foreign seller on account of such
16 seller’s status as a certified foreign seller;

17 “(3) cause there to be a difference (including a
18 difference in active ingredient, route of administra-
19 tion, bioequivalence, strength, formulation, manufac-
20 turing establishment, manufacturing process, or per-
21 son that manufactures the drug) between a prescrip-
22 tion drug for distribution in the United States and
23 the drug for distribution in Canada or another per-
24 mitted country, subject to subsection (e), for the

1 purpose of avoiding sales by certified foreign sellers;
2 or

3 “(4) except with respect to a prescription drug
4 on the drug shortage list under section 506E, en-
5 gage in any other action to restrict, prohibit, or
6 delay the importation of a prescription drug under
7 this section.

8 “(i) INFORMATION AND RECORDS.—

9 “(1) BIENNIAL REPORTS.—Each importer shall
10 submit biennial reports to the Secretary which shall
11 contain, for each qualifying prescription drug im-
12 ported into the United States—

13 “(A) the unique facility identifier of the
14 manufacturer of the drug, described in section
15 510;

16 “(B) the transaction information described
17 in section 581(26) (other than the information
18 described in subparagraph (C)); and

19 “(C) the price paid by the importer for the
20 drug.

21 “(2) MAINTENANCE OF RECORDS BY SEC-
22 RETARY.—The Secretary shall maintain information
23 and documentation submitted under paragraph (1)
24 for such period of time as the Secretary determines
25 to be appropriate.

1 “(j) SUSPENSION OF IMPORTATION.—

2 “(1) PATTERNS OF NONCOMPLIANCE.—The
3 Secretary shall require that importation of a specific
4 qualifying prescription drug or importation by a spe-
5 cific certified foreign seller or importer pursuant to
6 this section be immediately suspended if the Sec-
7 retary determines that there is a pattern of importa-
8 tion of such specific drug or by such specific seller
9 or importer that involves counterfeit drugs, drugs
10 that have been recalled or withdrawn, or drugs in
11 violation of any requirement of this section, until an
12 investigation is completed and the Secretary deter-
13 mines that importation of such drug or by such sell-
14 er or importer does not endanger the public health.

15 “(2) TEMPORARY SUSPENSION.—The Secretary
16 may require that importation of a specific qualifying
17 prescription drug or importation by a specific cer-
18 tified foreign seller or importer pursuant to this sec-
19 tion be temporarily suspended if, with respect to
20 such drug, seller, or importer, there is a violation of
21 any requirement of this section or if the Secretary
22 determines that importation of such drug or by such
23 seller or importer might endanger the public health.
24 Such temporary suspension shall apply until the Sec-
25 retary completes an investigation and determines

1 that importation of such drug or by such seller or
2 importer does not endanger the public health.

3 “(k) SUPPLY CHAIN SECURITY.—

4 “(1) PURCHASE FROM REGISTERED FACILITIES
5 AND CERTIFIED FOREIGN SELLERS.—

6 “(A) IN GENERAL.—Except as provided in
7 subparagraph (B), certified foreign sellers who
8 sell qualifying prescription drugs for importa-
9 tion into the United States pursuant to this
10 section may purchase such drugs only from
11 manufacturers or entities registered under sec-
12 tion 510 or other certified foreign sellers.

13 “(B) EXCEPTION.—Certified foreign sellers
14 who sell qualifying prescription drugs for im-
15 portation into the United States pursuant to
16 this section may purchase such drugs from for-
17 eign sellers in Canada or another permitted
18 country, even if such foreign seller is not a
19 manufacturer registered under section 510 or a
20 certified foreign seller, if the Secretary enters
21 into a memorandum of understanding or coop-
22 erative agreement with Canada, or such other
23 permitted country, to ensure compliance, to the
24 extent appropriate and feasible, with subchapter
25 H of chapter V. The Secretary shall seek to

1 enter into such a memorandum of under-
2 standing or cooperative agreement with Canada
3 and each country from which importation is
4 permitted under subsection (e).

5 “(2) IMPORTATION TRACING.—Certified foreign
6 sellers shall provide importers with the unique facil-
7 ity identifier associated with the manufacturer reg-
8 istered under section 510 of the qualifying prescrip-
9 tion drug and the information under paragraph
10 (25), paragraph (26) (other than subparagraph (C)),
11 and subparagraphs (D), (F), and (G) of paragraph
12 (27) of section 581. Certified foreign sellers shall
13 provide such information to individuals purchasing
14 such drugs, upon request.

15 “(1) REMS.—In the case of an importer that imports
16 a qualifying prescription drug, where the drug with the
17 same active ingredient or ingredients (or that is biosimilar
18 to an approved biological product), route of administra-
19 tion, and strength that is approved under chapter V or
20 section 351 of the Public Health Service Act is subject
21 to elements to assure safe use under section 505–1, such
22 importer shall be subject to such elements to assure safe
23 use, as applicable and appropriate.

24 “(m) CONSTRUCTION.—Nothing in this section limits
25 the authority of the Secretary relating to the importation

1 of prescription drugs, other than with respect to section
2 801(d)(1) as provided in this section.”.

3 (b) PENALTIES WITH RESPECT TO ONLINE PHAR-
4 MACIES.—Section 303 of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 333) is amended by adding at
6 the end the following:

7 “(h) In the case of person operating an Internet
8 website, whether in the United States or in another coun-
9 try, that violates section 301(aa) by—

10 “(1) selling, by means of the Internet, with the
11 intent to defraud or mislead or with reckless dis-
12 regard for safety of the public, an adulterated or
13 counterfeit drug to an individual in the United
14 States; or

15 “(2) dispenses, by means of the Internet, a
16 drug to an individual in the United States who the
17 person knows or has reasonable cause to believe,
18 does not possess a valid prescription for that drug,
19 such person shall be imprisoned for not more than
20 10 years or fined not more than \$250,000.”.

21 (c) NO PREEMPTION.—Nothing in this section, in-
22 cluding the amendments made by this section, shall be
23 construed to preempt, alter, displace, abridge, or supplant
24 any remedy available under any State or Federal law, in-

1 cluding common law, that provides a remedy for civil re-
2 lief.

3 (d) REPORTS.—

4 (1) HHS.—Not later than 1 year after the date
5 on which final regulations are promulgated to carry
6 out section 804 of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 384), as amended by sub-
8 section (a), and every 2 years thereafter, the Sec-
9 retary of Health and Human Services, after con-
10 sultation with appropriate Federal agencies, shall
11 submit to Congress and make public a report on the
12 importation of drugs into the United States.

13 (2) GAO REPORT.—Not later than 18 months
14 after the first report is submitted under paragraph
15 (1), the Comptroller General of the United States
16 shall submit to Congress a report containing an
17 analysis of the implementation of the amendments
18 made by this section, including a review of drug
19 safety and cost-savings and expenses, including cost-
20 savings to consumers in the United States and
21 trans-shipment and importation tracing processes,
22 resulting from such implementation.

1 **SEC. 204. REQUIRING DRUG MANUFACTURERS TO PROVIDE**
2 **DRUG REBATES FOR DRUGS DISPENSED TO**
3 **LOW-INCOME INDIVIDUALS.**

4 (a) IN GENERAL.—Section 1860D–2 of the Social
5 Security Act (42 U.S.C. 1395w–102) is amended—

6 (1) in subsection (e)(1), in the matter preceding
7 subparagraph (A), by inserting “and subsection (f)”
8 after “this subsection”; and

9 (2) by adding at the end the following new sub-
10 section:

11 “(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR
12 REBATE ELIGIBLE INDIVIDUALS.—

13 “(1) REQUIREMENT.—

14 “(A) IN GENERAL.—For plan years begin-
15 ning on or after January 1, 2019, in this part,
16 the term ‘covered part D drug’ does not include
17 any drug or biological product that is manufac-
18 tured by a manufacturer that has not entered
19 into and have in effect a rebate agreement de-
20 scribed in paragraph (2).

21 “(B) 2020 PLAN YEAR REQUIREMENT.—

22 Any drug or biological product manufactured by
23 a manufacturer that declines to enter into a re-
24 bate agreement described in paragraph (2) for
25 the period beginning on January 1, 2020, and
26 ending on December 31, 2020, shall not be in-

1 cluded as a ‘covered part D drug’ for the subse-
2 quent plan year.

3 “(2) REBATE AGREEMENT.—A rebate agree-
4 ment under this subsection shall require the manu-
5 facturer to provide to the Secretary a rebate for
6 each rebate period (as defined in paragraph (6)(B))
7 ending after December 31, 2019, in the amount
8 specified in paragraph (3) for any covered part D
9 drug of the manufacturer dispensed after December
10 31, 2019, to any rebate eligible individual (as de-
11 fined in paragraph (6)(A)) for which payment was
12 made by a PDP sponsor or MA organization under
13 this part for such period, including payments passed
14 through the low-income and reinsurance subsidies
15 under sections 1860D–14 and 1860D–15(b), respec-
16 tively. Such rebate shall be paid by the manufac-
17 turer to the Secretary not later than 30 days after
18 the date of receipt of the information described in
19 section 1860D–12(b)(7), including as such section is
20 applied under section 1857(f)(3), or 30 days after
21 the receipt of information under subparagraph (D)
22 of paragraph (3), as determined by the Secretary.
23 Insofar as not inconsistent with this subsection, the
24 Secretary shall establish terms and conditions of
25 such agreement relating to compliance, penalties,

1 and program evaluations, investigations, and audits
2 that are similar to the terms and conditions for re-
3 bate agreements under paragraphs (3) and (4) of
4 section 1927(b).

5 “(3) REBATE FOR REBATE ELIGIBLE MEDICARE
6 DRUG PLAN ENROLLEES.—

7 “(A) IN GENERAL.—The amount of the re-
8 bate specified under this paragraph for a manu-
9 facturer for a rebate period, with respect to
10 each dosage form and strength of any covered
11 part D drug provided by such manufacturer
12 and dispensed to a rebate eligible individual,
13 shall be equal to the product of—

14 “(i) the total number of units of such
15 dosage form and strength of the drug so
16 provided and dispensed for which payment
17 was made by a PDP sponsor or an MA or-
18 ganization under this part for the rebate
19 period, including payments passed through
20 the low-income and reinsurance subsidies
21 under sections 1860D–14 and 1860D–
22 15(b), respectively; and

23 “(ii) the amount (if any) by which—

24 “(I) the Medicaid rebate amount
25 (as defined in subparagraph (B)) for

1 such form, strength, and period; ex-
2 ceeds

3 “(II) the average Medicare drug
4 program rebate eligible rebate amount
5 (as defined in subparagraph (C)) for
6 such form, strength, and period.

7 “(B) MEDICAID REBATE AMOUNT.—For
8 purposes of this paragraph, the term ‘Medicaid
9 rebate amount’ means, with respect to each
10 dosage form and strength of a covered part D
11 drug provided by the manufacturer for a rebate
12 period—

13 “(i) in the case of a single source
14 drug or an innovator multiple source drug,
15 the amount specified in paragraph
16 (1)(A)(ii)(II) or (2)(C) of section 1927(c)
17 plus the amount, if any, specified in sub-
18 paragraph (A)(ii) of paragraph (2) of such
19 section, for such form, strength, and pe-
20 riod; or

21 “(ii) in the case of any other covered
22 outpatient drug, the amount specified in
23 paragraph (3)(A)(i) of such section for
24 such form, strength, and period.

1 “(C) AVERAGE MEDICARE DRUG PROGRAM
2 REBATE ELIGIBLE REBATE AMOUNT.—For pur-
3 poses of this subsection, the term ‘average
4 Medicare drug program rebate eligible rebate
5 amount’ means, with respect to each dosage
6 form and strength of a covered part D drug
7 provided by a manufacturer for a rebate period,
8 the sum, for all PDP sponsors under part D
9 and MA organizations administering an MA-
10 PD plan under part C, of—

11 “(i) the product, for each such spon-
12 sor or organization, of—

13 “(I) the sum of all rebates, dis-
14 counts, or other price concessions (not
15 taking into account any rebate pro-
16 vided under paragraph (2) or any dis-
17 counts under the program under sec-
18 tion 1860D–14A) for such dosage
19 form and strength of the drug dis-
20 pensed, calculated on a per-unit basis,
21 but only to the extent that any such
22 rebate, discount, or other price con-
23 cession applies equally to drugs dis-
24 pensed to rebate eligible Medicare
25 drug plan enrollees and drugs dis-

1 pensed to PDP and MA–PD enrollees
2 who are not rebate eligible individuals;
3 and

4 “(II) the number of the units of
5 such dosage and strength of the drug
6 dispensed during the rebate period to
7 rebate eligible individuals enrolled in
8 the prescription drug plans adminis-
9 tered by the PDP sponsor or the MA–
10 PD plans administered by the MA or-
11 ganization; divided by

12 “(ii) the total number of units of such
13 dosage and strength of the drug dispensed
14 during the rebate period to rebate eligible
15 individuals enrolled in all prescription drug
16 plans administered by PDP sponsors and
17 all MA–PD plans administered by MA or-
18 ganizations.

19 “(D) USE OF ESTIMATES.—The Secretary
20 may establish a methodology for estimating the
21 average Medicare drug program rebate eligible
22 rebate amounts for each rebate period based on
23 bid and utilization information under this part
24 and may use these estimates as the basis for
25 determining the rebates under this section. If

1 the Secretary elects to estimate the average
2 Medicare drug program rebate eligible rebate
3 amounts, the Secretary shall establish a rec-
4 onciliation process for adjusting manufacturer
5 rebate payments not later than 3 months after
6 the date that manufacturers receive the infor-
7 mation collected under section 1860D-
8 12(b)(7)(B).

9 “(4) LENGTH OF AGREEMENT.—The provisions
10 of paragraph (4) of section 1927(b) (other than
11 clauses (iv) and (v) of subparagraph (B)) shall apply
12 to rebate agreements under this subsection in the
13 same manner as such paragraph applies to a rebate
14 agreement under such section.

15 “(5) OTHER TERMS AND CONDITIONS.—The
16 Secretary shall establish other terms and conditions
17 of the rebate agreement under this subsection, in-
18 cluding terms and conditions related to compliance,
19 that are consistent with this subsection.

20 “(6) DEFINITIONS.—In this subsection and sec-
21 tion 1860D-12(b)(7):

22 “(A) REBATE ELIGIBLE INDIVIDUAL.—The
23 term ‘rebate eligible individual’ means—

24 “(i) a subsidy eligible individual (as
25 defined in section 1860D-14(a)(3)(A));

1 “(ii) a Medicaid beneficiary treated as
2 a subsidy eligible individual under clause
3 (v) of section 1860D–14(a)(3)(B); and

4 “(iii) any part D eligible individual
5 not described in clause (i) or (ii) who is de-
6 termined for purposes of the State plan
7 under title XIX to be eligible for medical
8 assistance under clause (i), (iii), or (iv) of
9 section 1902(a)(10)(E).

10 “(B) REBATE PERIOD.—The term ‘rebate
11 period’ has the meaning given such term in sec-
12 tion 1927(k)(8).”.

13 (b) REPORTING REQUIREMENT FOR THE DETER-
14 MINATION AND PAYMENT OF REBATES BY MANUFACTUR-
15 ERS RELATED TO REBATE FOR REBATE ELIGIBLE MEDI-
16 CARE DRUG PLAN ENROLLEES.—

17 (1) REQUIREMENTS FOR PDP SPONSORS.—Sec-
18 tion 1860D–12(b) of the Social Security Act (42
19 U.S.C. 1395w–112(b)) is amended by adding at the
20 end the following new paragraph:

21 “(7) REPORTING REQUIREMENT FOR THE DE-
22 TERMINATION AND PAYMENT OF REBATES BY MANU-
23 FACTURERS RELATED TO REBATE FOR REBATE ELI-
24 GIBLE MEDICARE DRUG PLAN ENROLLEES.—

1 “(A) IN GENERAL.—For purposes of the
2 rebate under section 1860D–2(f) for contract
3 years beginning on or after January 1, 2019,
4 each contract entered into with a PDP sponsor
5 under this part with respect to a prescription
6 drug plan shall require that the sponsor comply
7 with subparagraphs (B) and (C).

8 “(B) REPORT FORM AND CONTENTS.—Not
9 later than a date specified by the Secretary, a
10 PDP sponsor of a prescription drug plan under
11 this part shall report to each manufacturer—

12 “(i) information (by National Drug
13 Code number) on the total number of units
14 of each dosage, form, and strength of each
15 drug of such manufacturer dispensed to re-
16 bate eligible Medicare drug plan enrollees
17 under any prescription drug plan operated
18 by the PDP sponsor during the rebate pe-
19 riod;

20 “(ii) information on the price dis-
21 counts, price concessions, and rebates for
22 such drugs for such form, strength, and
23 period;

24 “(iii) information on the extent to
25 which such price discounts, price conces-

1 sions, and rebates apply equally to rebate
2 eligible Medicare drug plan enrollees and
3 PDP enrollees who are not rebate eligible
4 Medicare drug plan enrollees; and

5 “(iv) any additional information that
6 the Secretary determines is necessary to
7 enable the Secretary to calculate the aver-
8 age Medicare drug program rebate eligible
9 rebate amount (as defined in paragraph
10 (3)(C) of such section), and to determine
11 the amount of the rebate required under
12 this section, for such form, strength, and
13 period.

14 Such report shall be in a form consistent with
15 a standard reporting format established by the
16 Secretary.

17 “(C) SUBMISSION TO SECRETARY.—Each
18 PDP sponsor shall promptly transmit a copy of
19 the information reported under subparagraph
20 (B) to the Secretary for the purpose of audit
21 oversight and evaluation.

22 “(D) CONFIDENTIALITY OF INFORMA-
23 TION.—The provisions of subparagraph (D) of
24 section 1927(b)(3), relating to confidentiality of
25 information, shall apply to information reported

1 by PDP sponsors under this paragraph in the
2 same manner that such provisions apply to in-
3 formation disclosed by manufacturers or whole-
4 salers under such section, except—

5 “(i) that any reference to ‘this sec-
6 tion’ in clause (i) of such subparagraph
7 shall be treated as being a reference to this
8 section;

9 “(ii) the reference to the Director of
10 the Congressional Budget Office in clause
11 (iii) of such subparagraph shall be treated
12 as including a reference to the Medicare
13 Payment Advisory Commission; and

14 “(iii) clause (iv) of such subparagraph
15 shall not apply.

16 “(E) OVERSIGHT.—Information reported
17 under this paragraph may be used by the In-
18 spector General of the Department of Health
19 and Human Services for the statutorily author-
20 ized purposes of audit, investigation, and eval-
21 uations.

22 “(F) PENALTIES FOR FAILURE TO PRO-
23 VIDE TIMELY INFORMATION AND PROVISION OF
24 FALSE INFORMATION.—In the case of a PDP
25 sponsor—

1 “(i) that fails to provide information
2 required under subparagraph (B) on a
3 timely basis, the sponsor is subject to a
4 civil money penalty in the amount of
5 \$10,000 for each day in which such infor-
6 mation has not been provided; or

7 “(ii) that knowingly (as defined in
8 section 1128A(i)) provides false informa-
9 tion under such subparagraph, the sponsor
10 is subject to a civil money penalty in an
11 amount not to exceed \$100,000 for each
12 item of false information.

13 Such civil money penalties are in addition to
14 other penalties as may be prescribed by law.
15 The provisions of section 1128A (other than
16 subsections (a) and (b)) shall apply to a civil
17 money penalty under this subparagraph in the
18 same manner as such provisions apply to a pen-
19 alty or proceeding under section 1128A(a).”.

20 (2) APPLICATION TO MA ORGANIZATIONS.—Sec-
21 tion 1857(f)(3) of the Social Security Act (42
22 U.S.C. 1395w-27(f)(3)) is amended by adding at
23 the end the following:

24 “(D) REPORTING REQUIREMENT RELATED
25 TO REBATE FOR REBATE ELIGIBLE MEDICARE

1 DRUG PLAN ENROLLEES.—Section 1860D–
2 12(b)(7).”.

3 (c) DEPOSIT OF REBATES INTO MEDICARE PRE-
4 SCRIPTON DRUG ACCOUNT.—Section 1860D–16(c) of the
5 Social Security Act (42 U.S.C. 1395w–116(c)) is amended
6 by adding at the end the following new paragraph:

7 “(6) REBATE FOR REBATE ELIGIBLE MEDICARE
8 DRUG PLAN ENROLLEES.—Amounts paid under a re-
9 bate agreement under section 1860D–2(f) shall be
10 deposited into the Account.”.

11 (d) EXCLUSION FROM DETERMINATION OF BEST
12 PRICE AND AVERAGE MANUFACTURER PRICE UNDER
13 MEDICAID.—

14 (1) EXCLUSION FROM BEST PRICE DETERMINA-
15 TION.—Section 1927(c)(1)(C)(ii)(I) of the Social Se-
16 curity Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is
17 amended by inserting “and amounts paid under a
18 rebate agreement under section 1860D–2(f)” after
19 “this section”.

20 (2) EXCLUSION FROM AVERAGE MANUFAC-
21 Turer Price Determination.—Section
22 1927(k)(1)(B)(i) of the Social Security Act (42
23 U.S.C. 1396r–8(k)(1)(B)(i)) is amended—

24 (A) in subclause (IV), by striking “and”
25 after the semicolon;

1 (B) in subclause (V), by striking the period
2 at the end and inserting “; and”; and

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

4 “(VI) amounts paid under a re-
5 bate agreement under section 1860D-
6 2(f).”.

7 **SEC. 205. CAP ON PRESCRIPTION DRUG COST-SHARING.**

8 (a) **QUALIFIED HEALTH PLANS.**—Section 1302(c) of
9 the Patient Protection and Affordable Care Act (42
10 U.S.C. 18022(c)) is amended—

11 (1) in paragraph (3)(A)(i), by inserting “, in-
12 cluding cost-sharing with respect to prescription
13 drugs covered by the plan” after “charges”; and

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

15 “(5) **PRESCRIPTION DRUG COST-SHARING.**—

16 “(A) **2020.**—For plan years beginning in
17 2020, the cost-sharing incurred under a health
18 plan with respect to prescription drugs covered
19 by the plan shall not exceed \$250 per month for
20 each enrolled individual, or \$500 for each fam-
21 ily.

22 “(B) **2021 AND LATER.**—

23 “(i) **IN GENERAL.**—In the case of any
24 plan year beginning in a calendar year
25 after 2020, the limitation under this para-

1 graph shall be equal to the applicable dol-
2 lar amount under subparagraph (A) for
3 plan years beginning in 2020, increased by
4 an amount equal to the product of that
5 amount and the medical care component of
6 the consumer price index for all urban con-
7 sumers (as published by the Bureau of
8 Labor Statistics) for that year.

9 “(ii) ADJUSTMENT TO AMOUNT.—If
10 the amount of any increase under clause
11 (i) is not a multiple of \$5, such increase
12 shall be rounded to the next lowest mul-
13 tiple of \$5.”.

14 (b) GROUP HEALTH PLANS.—Section 2707(b) of the
15 Public Health Service Act (42 U.S.C. 300gg–6(b)) is
16 amended—

17 (1) by striking “annual”; and

18 (2) by striking “paragraph (1) of section
19 1302(e)” and inserting “paragraphs (1) and (5) of
20 section 1302(e) of the Patient Protection and Af-
21 fordable Care Act”.

22 (c) EFFECTIVE DATE.—The amendments made by
23 subsections (a) and (b) shall take effect with respect to
24 plans beginning after December 31, 2019.

1 **TITLE III—INNOVATION**

2 **SEC. 301. PRIZE FUND FOR NEW AND MORE EFFECTIVE**
3 **TREATMENTS OF BACTERIAL INFECTIONS.**

4 Part B of title IV of the Public Health Service Act
5 (42 U.S.C. 284 et seq.) is amended by adding at the end
6 the following:

7 **“SEC. 409K. PRIZE FUND FOR NEW AND MORE EFFECTIVE**
8 **TREATMENTS OF BACTERIAL INFECTIONS.**

9 “(a) ESTABLISHMENT OF FUND.—There is hereby
10 established in the Treasury of the United States a revolv-
11 ing fund to be known as the ‘Antibiotics Prize Fund’,
12 which shall consist of funds transferred under subsection
13 (b).

14 “(b) AMOUNTS CREDITED TO THE FUND.—There
15 are hereby authorized to be appropriated, and appro-
16 priated, to the Antibiotics Prize Fund, for fiscal year
17 2020, out of any monies in the Treasury not otherwise
18 appropriated, \$2,000,000,000. Such funds shall remain
19 available until expended.

20 “(c) AWARDS.—

21 “(1) IN GENERAL.—During the 10-year period
22 following the date of enactment of the Affordable
23 Medications Act, the Director of the NIH, in accord-
24 ance with the criteria under subsection (d) and the
25 goals under subsection (e), shall award—

1 “(A) up to 3 prizes for qualifying products
2 that provide added benefit for patients over ex-
3 isting therapies in the treatment of serious and
4 life-threatening bacterial infections dem-
5 onstrating in superiority trials; and

6 “(B) award open source dividend prizes for
7 contributions that significantly advance the
8 field of antibiotic research with openly sourced
9 materials, technology, data, and knowledge.

10 “(2) AWARD AMOUNT REQUIREMENTS.—No
11 more than 5 percent of the amount available in the
12 Antibiotics Prize Fund shall be dedicated to open
13 source dividend prizes.

14 “(d) CRITERIA AND STRUCTURE OF PRIZES.—

15 “(1) ESTABLISHMENT OF CRITERIA.—Not later
16 than 120 days after the date of enactment of the Af-
17 fordable Medications Act, the Director of NIH shall
18 establish criteria for the selection of recipients and
19 eligibility of persons for prizes under this section
20 and criteria for determining the amounts of such
21 prizes, through notice and comment rulemaking.

22 “(2) CONSIDERATIONS IN ESTABLISHING CRI-
23 TERIA FOR QUALIFYING PRODUCTS.—In establishing
24 the criteria for selection of recipients and amounts
25 of prizes under paragraph (1), the Director of NIH,

1 in consultation with other agencies as appropriate,
2 shall consider the following:

3 “(A) The number of patients in the United
4 States and in other countries who would benefit
5 from the qualifying product that treats a seri-
6 ous or life-threatening bacterial infection, and
7 the number of patients in the United States
8 and in other countries projected to benefit dur-
9 ing the upcoming 10-year period.

10 “(B) Whether the qualifying product
11 treats, or has the potential to treat, a serious
12 or life-threatening bacterial infection for which
13 no other treatment is currently available or for
14 which there is a high threat of resistance to ex-
15 isting treatments.

16 “(C) The incremental and additional thera-
17 peutic benefit to human in the United States
18 and other countries of the qualifying product as
19 compared to other treatments available to treat
20 the bacterial infection, evaluating the incre-
21 mental therapeutic benefit in comparison to
22 treatments that were not recently developed.

23 “(D) The transmissibility of the bacterial
24 infection the qualifying product would treat,
25 and barriers to prevention of that infection.

1 “(E) The extent to which knowledge, data,
2 materials, and technology that are openly
3 sourced have contributed to the successful de-
4 velopment of new treatments that provide an
5 added benefit to patients, such as decreasing
6 mortality or irreversible morbidity on patient-
7 centered outcomes, significantly advancing the
8 field of antibiotic research, or improving proc-
9 esses for manufacturing products used for the
10 treatment.

11 “(F) Other criteria that the Director of
12 NIH determines to be relevant and useful in
13 ensuring that the prizes provide appropriate in-
14 centives.

15 “(3) CRITERIA FOR OPEN SOURCE DIVIDEND
16 PRIZES.—An open source dividend prize under this
17 section shall reward persons that openly shared on
18 a royalty-free, not-for-profit and non-discriminatory
19 basis, materials, technology, data, and knowledge
20 that contribute in a significant way to the successful
21 development of a qualifying product or significantly
22 advanced the field of antibiotic research.

23 “(e) GOALS.—With respect to each year for which the
24 Director of NIH awards prizes under subsection (c), the
25 Director of NIH shall establish a framework of goals that

1 a qualifying product or contribution that significantly ad-
2 vances the field of antibiotic research is required to show
3 promise to help meet in order for a person to be eligible
4 to receive a prize with respect to such product or such
5 contribution. Such goals may include—

6 “(1) reduced hospital admissions or readmis-
7 sions;

8 “(2) use of diagnostics prior to prescribing of
9 drugs; and

10 “(3) use of innovative programs for antibiotic
11 stewardship.

12 “(f) CONDITION ON RECEIPT OF PRIZE.—

13 “(1) IN GENERAL.—Each prize for a qualifying
14 product offered under this section shall be condi-
15 tioned on the following:

16 “(A) The recipient shall agree to offer the
17 qualifying product at a reasonable price as de-
18 scribed in paragraph (3).

19 “(B) Subject to applicable patient privacy
20 protections, the recipient shall agree to publicly
21 disclose all pre-clinical and clinical trial data
22 with respect to the qualifying product.

23 “(C) The recipient shall agree to submit to
24 the Director of NIH, for review and approval
25 by such director, in collaboration with the Com-

1 missioner of Food and Drugs and the Director
2 of the Centers for Disease Control and Preven-
3 tion, all marketing, sales, and other promotional
4 and educational activities associated with the
5 qualifying product, to ensure that such activi-
6 ties align with, and advance the goals of, re-
7 source conserving stewardship, protecting the
8 utility of antibiotics, and encouraging and en-
9 suring the correct use of antibiotics.

10 “(D) The recipient shall irrevocably
11 waive—

12 “(i) all periods of exclusivity available
13 to the product under chapter V of the Fed-
14 eral Food, Drug, and Cosmetic Act or sec-
15 tion 351 of this Act; and

16 “(ii) all applicable patent rights under
17 title 35, United States Code.

18 “(E) Any other conditions the Director of
19 NIH determines appropriate.

20 “(2) APPLICABILITY.—All conditions described
21 in paragraph (1) shall apply to subsequent owners,
22 licensees, producers, and manufacturers, and assign-
23 ees of the product or any chemical component of the
24 qualifying product for which the prize was awarded.

25 “(3) REASONABLE PRICE.—

1 “(A) IN GENERAL.—A recipient may sat-
2 isfy the requirement to offer a qualifying prod-
3 uct or contribution at a ‘reasonable price’ for
4 purposes of paragraph (1)(A) by—

5 “(i)(I) providing open licensing of all
6 necessary rights to patents, manufacturing
7 processes, rights in data, and other intel-
8 lectual property rights needed to make and
9 sell the product to manufacturers of the
10 generic version of such product; or

11 “(II) selling such product at a price
12 that is no more than twice the price of an-
13 tibiotic drugs approved under section
14 505(j) of the Federal Food, Drug, and
15 Cosmetic Act with similar manufacturing
16 costs; and

17 “(ii) selling such product at a price
18 that is not higher than the median price
19 charged, at the time of such sale, in the
20 applicable 7 countries, as determined
21 under in subparagraph (B).

22 “(B) CRITERIA.—For purposes of subpara-
23 graph (A)(ii), the Director of NIH shall iden-
24 tify, on an annual basis, the countries that have
25 a per capita income that is not less than half

1 the per capita income of the United States, se-
2 lect the 7 of such countries that have the larg-
3 est gross domestic product, and determine the
4 median price charged for each qualifying prod-
5 uct for which an award has been granted under
6 subsection (c).

7 “(g) ENFORCEMENT.—If the prize recipient, or sub-
8 sequent owner, licensee, or assignee of the qualifying prod-
9 uct, does not fulfill the conditions described subsection
10 (f)(1), the Secretary, in collaboration with the Attorney
11 General, shall take all necessary action to clawback the
12 prize.

13 “(h) TRANSPARENCY.—With respect to each prize
14 awarded under this section, the Director of NIH shall
15 make public—

16 “(1) the methodology used and criteria analyzed
17 in determining the prize recipient; and

18 “(2) a complete analysis of the recipient’s ful-
19 fillment of award conditions under subsection (e)(1).

20 “(i) QUALIFYING PRODUCT.—For purposes of this
21 section, the term ‘qualifying product’ means a drug (as
22 defined in section 201(g) of the Federal Food, Drug, and
23 Cosmetic Act) subject to section 503(b)(1) of the Federal
24 Food, Drug, and Cosmetic Act.

25 “(j) STUDY.—

1 “(1) IN GENERAL.—The Director of NIH shall
2 seek to enter into an agreement with the National
3 Academies of Sciences, Engineering, and Medicine to
4 conduct a study to examine—

5 “(A) the use of innovation inducement
6 prize funds and push financing mechanisms as
7 ways to stimulate investments in biomedical re-
8 search and development that de-links costs from
9 product prices;

10 “(B) models of different possible means of
11 de-linking research and development costs from
12 drug prices, including the replacement of the
13 monopoly on new products as an incentive, with
14 innovation inducement prize funds and push fi-
15 nancing mechanisms as new incentives to stim-
16 ulate the development of drugs, including drugs
17 to treat bacterial infections, rare diseases, HIV/
18 AIDS, and cancer; and

19 “(C) the size of prizes awarded under this
20 section and the effectiveness of such prizes in
21 stimulating innovation.

22 “(2) AUTHORIZATION OF APPROPRIATIONS.—
23 For the purpose of carrying out this subsection,
24 there are authorized to be appropriated, and there

1 are appropriated, \$3,000,000 for fiscal year 2020.
2 Such funds shall remain available until expended.”.

3 **SEC. 302. PUBLIC FUNDING FOR CLINICAL TRIALS.**

4 (a) IN GENERAL.—Part E of title IV of the Public
5 Health Service Act (42 U.S.C. 287 et seq.) is amended
6 by adding at the end the following:

7 **“Subpart 6—Center for Clinical Research**

8 **“SEC. 485E. CENTER FOR CLINICAL RESEARCH.**

9 “(a) IN GENERAL.—There is established within the
10 National Institutes of Health the Center for Clinical Re-
11 search, for the purpose of conducting clinical trials on
12 drugs, as described in subsection (b), with the intention
13 of obtaining approval of such drug under section 505 of
14 the Federal Food, Drug, and Cosmetic Act or section 351
15 of this Act. The Director of NIH shall appoint a Director
16 of the Center for Clinical Research referred to in this sec-
17 tion as the ‘Director’) not later than 90 days after the
18 date of enactment of the Affordable Medications Act.

19 “(b) CLINICAL TRIALS.—

20 “(1) IN GENERAL.—Each year, beginning not
21 later than 1 year after the date of enactment of the
22 Affordable Medications Act, the Director shall select
23 at least 2 molecules, compounds, drugs, or biological
24 products and conduct clinical trials on such mol-
25 ecules, compounds, drugs, or biological products, or

1 enter into contracts with other entities to conduct
2 such clinical trials.

3 “(2) SELECTION OF DRUGS.—

4 “(A) CRITERIA.—The Director shall estab-
5 lish criteria, which shall be made public, for ac-
6 quiring the patent rights for, and selecting,
7 drugs under paragraph (1) to ensure that the
8 drugs selected for clinical trials through the
9 Center—

10 “(i) have the potential to address an
11 existing or emerging need, including drugs
12 that can be repurposed to treat a new con-
13 dition in the case of a national emergency;
14 and

15 “(ii) are not solely drugs that private
16 sector researchers with access to all avail-
17 able information on such drugs chose not
18 to develop.

19 “(B) PROCESS.—The Director shall secure
20 all patent rights to each drug selected under
21 paragraph (1), as applicable, and perform the
22 clinical trials at NIH or subcontract with an-
23 other entity to conduct the clinical trials.

24 “(c) TREATMENT OF APPROVED DRUGS.—If a drug
25 for which clinical trials have been conducted by the Center

1 for Clinical Research is approved by the Food and Drug
2 Administration under section 505 of the Federal Food,
3 Drug, and Cosmetic Act or section 351 of this Act, the
4 Director shall—

5 “(1) execute non-exclusive licenses to allow
6 drug manufacturers to manufacture and sell the
7 drug; or

8 “(2) in collaboration with other Federal agen-
9 cies as appropriate, enter into purchasing contracts.

10 “(d) PUBLIC INFORMATION.—

11 “(1) RESEARCH DATA AND FINDINGS.—Subject
12 to applicable patient privacy protections, the Sec-
13 retary shall—

14 “(A)(i) submit all completed studies (and
15 terminated studies, if terminated for safety or
16 ethical reasons) for publication in a peer-re-
17 viewed publication within 180 days of comple-
18 tion or termination; and

19 “(ii) if a study submitted as described in
20 clause (i) is not selected for publication, pub-
21 licly disclose all de-identified primary clinical
22 data not later than 180 days after the Sec-
23 retary’s final decision not to pursue further
24 submissions for publication; and

1 “(B) publicly disclose all de-identified pri-
2 mary clinical data upon publication of a study
3 as described in subparagraph (A)(i).

4 “(2) FINANCIAL INFORMATION.—The Director
5 shall make public all costs to the Federal Govern-
6 ment associated with carrying out clinical trials by
7 the Center for Clinical Research and with sub-
8 contract agreements under this section.

9 “(e) DEFINITION.—In this section, the term ‘drug’
10 has the meaning given such term in section 201(g) of the
11 Federal Food, Drug, and Cosmetic Act.

12 “(f) APPROPRIATIONS.—For the purpose of carrying
13 out this section, in addition to any other funds available
14 for such purpose, there are authorized to be appropriated,
15 and there are appropriated, \$1,000,000,000 for each of
16 fiscal years 2019 through 2029, to remain available until
17 expended.”.

18 (b) CLERICAL AMENDMENT.—Section 401(b) of the
19 Public Health Service Act (42 U.S.C. 281(b)) is amend-
20 ed—

21 (1) by redesignating paragraph (25) as para-
22 graph (26); and

23 (2) by inserting after paragraph (24) the fol-
24 lowing:

25 “(25) The Center for Clinical Research.”.

1 **SEC. 303. REWARDING INNOVATIVE DRUG DEVELOPMENT.**

2 (a) DRUG EXCLUSIVITY.—

3 (1) NEW CHEMICAL ENTITY EXCLUSIVITY.—

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

7 (i) in subparagraph (B)—

8 (I) in clause (i), by inserting “ex-
9 cept that such approval may not be
10 made effective before the date that is
11 5 years after the date on which the
12 drug to which the application refers
13 was approved under subsection (c)”
14 before the period; and

15 (II) in clause (ii), by inserting
16 “except that such approval may not
17 be made effective before the date that
18 is 5 years after the date on which the
19 drug to which the application refers
20 was approved under subsection (c)”
21 before the period; and

22 (ii) in subparagraph (F)(ii)—

23 (I) by striking “expiration of five
24 years” and inserting “expiration of 3
25 years”;

1 (II) by striking “, except that
2 such an application may be submitted
3 under this subsection after the expira-
4 tion of four years from the date of the
5 approval of the subsection (b) applica-
6 tion if it contains a certification of
7 patent invalidity or noninfringement
8 described in subclause (IV) of para-
9 graph (2)(A)(vii)”; and

10 (III) by striking “seven and one-
11 half years” and inserting “6 and one-
12 half years”.

13 (B) CONFORMING AMENDMENTS.—Chapter
14 V of the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 351 et seq.) is amended—

16 (i) in subsection (v)(2)(A)(i)(II) of
17 section 505, by inserting “the 3-year exclu-
18 sivity period referred to” before “under
19 clause (ii) of subsection (j)(5)(F)”;

20 (ii) in subsections (b)(1)(A)(i)(I) and
21 (c)(1)(A)(i)(I) of section 505A—

22 (I) by striking “five years” each
23 place such term appears and inserting
24 “3 years”;

1 (II) by striking “seven and one-
2 half years” each place such term ap-
3 pears and inserting “6 and one-half
4 years”; and

5 (III) by striking “eight years”
6 each place such term appears and in-
7 serting “7 years”; and

8 (iii) in section 505E, by striking “the
9 4- and 5-year periods described in sub-
10 sections (c)(3)(E)(ii) and (j)(5)(F)(ii) of
11 section 505, the 3-year periods described
12 in clauses (iii) and (iv) of subsection
13 (c)(3)(E) and clauses (iii) and (iv) of sub-
14 section (j)(5)(F)” and inserting “the 4-
15 and 5-year periods described in subsection
16 (c)(3)(E)(ii) of section 505, the 3-year pe-
17 riods described in clauses (iii) and (iv) of
18 subsection (c)(3)(E) and clauses (ii), (iii),
19 and (iv) of subsection (j)(5)(F)”;

20 (2) NEW CLINICAL INVESTIGATION EXCLU-
21 SIVITY.—Section 505(c)(3)(E)(iv) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C.
23 355(c)(3)(E)(iv)) is amended by inserting “, and the
24 supplement shows a significant clinical benefit over
25 existing therapies manufactured by the applicant in

1 the 5-year period preceding the submission of the
2 application,” before “the Secretary”.

3 (3) BIOLOGICAL PRODUCT EXCLUSIVITY.—

4 (A) IN GENERAL.—Section 351(k)(7)(A) of
5 the Public Health Service Act (42 U.S.C.
6 262(k)(7)(A)) is amended by striking “12
7 years” and inserting “7 years”.

8 (B) CONFORMING AMENDMENTS.—Para-
9 graphs (2)(A) and (3)(A) of section 351(m) of
10 the Public Health Service Act (42 U.S.C.
11 262(m)) is amended by striking “12 years”
12 each place it appears and inserting “7 years”.

13 (b) APPLICABILITY.—The amendments made by sub-
14 section (a) apply only with respect to a drug or biological
15 product for which the listed drug (as described in section
16 505(j)(7) of the Federal Food, Drug, and Cosmetic Act
17 (21 U.S.C. 355(j)(7)) or reference product (as such term
18 is used in section 351 of the Public Health Service Act
19 (42 U.S.C. 262)) is approved under section 505(c) of the
20 Federal Food, Drug, and Cosmetic Act or licensed under
21 section 351(a) of the Public Health Service Act, as appli-
22 cable, on or after the date of enactment of this Act.

23 (c) GAO STUDY.—Not later than 1 year after the
24 date of enactment of this Act, the Comptroller General

1 of the United States shall conduct a study and submit to
2 Congress a report that includes—

3 (1)(A) the number of requests for designation
4 as a drug for a rare disease or condition under sec-
5 tion 526 of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 360bb) the Food and Drug Adminis-
7 tration receives each year in the previous 10-year pe-
8 riod;

9 (B) the number of such requests granted, de-
10 nied, and pending;

11 (C) the names of all drugs receiving such des-
12 ignation during such period, including the date of
13 approval and indication for which market exclusivity
14 was granted; and

15 (D) any drugs for which such designation has
16 been revoked or amended during such period;

17 (2) for each drug so designated as a drug for
18 a rare disease or condition in the previous 10-year
19 period, the total annual expenditures for such drugs
20 under the Medicare program under title XVIII of
21 the Social Security Act (42 U.S.C. 1395 et seq.) and
22 the Medicaid program under title XIX of the Social
23 Security Act (42 U.S.C. 1396 et seq.), the number
24 of Medicare and Medicaid beneficiaries who used
25 each such drug each year during such time period,

1 and any changes in price per unit during such time
2 period; and

3 (3) for a sample of drugs (selected by the
4 Comptroller General) so designated in the previous
5 10-year period, to the extent feasible—

6 (A) gross revenues of the manufacturers
7 with respect to each such drug, and manufac-
8 turer spending for marketing and patient as-
9 sistance programs;

10 (B) the average price per drug and how
11 those prices changed over time for the selected
12 drugs based on industry drug pricing bench-
13 marks; and

14 (C) the indications that were the basis of
15 such designation and other approved indications
16 for the drugs, and the indications for which
17 each drug has most commonly been used, in-
18 cluding non-approved indications for which the
19 drug may be recommended by external organi-
20 zations such as physician or patient organiza-
21 tions.

22 **SEC. 304. IMPROVING PROGRAM INTEGRITY.**

23 (a) IN GENERAL.—Subchapter E of chapter V of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb
25 et seq.) is amended by adding at the end the following:

1 **“SEC. 569D. CONDITIONS ON AWARD OF DRUG EXCLU-**
2 **SIVITY.**

3 “(a) **TERMINATION OF EXCLUSIVITY.**—Notwith-
4 standing any other provision of this Act, any period of
5 exclusivity described in subsection (b) granted to a person
6 or assigned to a person on or after the date of enactment
7 of this section with respect to a drug shall be terminated
8 if the person to which such exclusivity was granted or any
9 person to which such exclusivity is assigned commits a vio-
10 lation described in subsection (c)(1) with respect to such
11 drug.

12 “(b) **EXCLUSIVITIES AFFECTED.**—The periods of ex-
13 clusivity described in this subsection are those periods of
14 exclusivity granted under any of the following sections:

15 “(1) Clause (ii), (iii), or (iv) of section
16 505(c)(3)(E).

17 “(2) Clause (iv) of section 505(j)(5)(B).

18 “(3) Clause (ii), (iii), or (iv) of section
19 505(j)(5)(F).

20 “(4) Section 505A.

21 “(5) Section 505E.

22 “(6) Section 527.

23 “(7) Section 351(k)(7) of the Public Health
24 Service Act.

1 “(8) Any other provision of this Act that pro-
2 vides for market exclusivity (or extension of market
3 exclusivity) with respect to a drug.

4 “(c) VIOLATIONS.—

5 “(1) IN GENERAL.—A violation described in
6 this subsection is a violation of a law described in
7 paragraph (2), enforced by a Federal or State gov-
8 ernmental entity that results in—

9 “(A) a criminal conviction of a person de-
10 scribed in subsection (a);

11 “(B) a civil judgment against a person de-
12 scribed in subsection (a); or

13 “(C) a settlement agreement in which a
14 person described in subsection (a) admits to
15 fault.

16 “(2) LAWS DESCRIBED.—The laws described in
17 this paragraph are the following:

18 “(A) The provisions of this Act that pro-
19 hibit—

20 “(i) the adulteration or misbranding
21 of a drug;

22 “(ii) the making of false statements to
23 the Secretary or committing fraud; or

24 “(iii) the illegal marketing of a drug.

1 “(B) Section 3729 of title 31, United
2 States Code.

3 “(C) Section 286 or 287 of title 18, United
4 States Code.

5 “(D) The Medicare and Medicaid Patient
6 Protection and Program Act of 1987 (com-
7 monly known as the ‘Antikickback Statute’).

8 “(E) Section 1927 of the Social Security
9 Act.

10 “(F) A State law against fraud comparable
11 to a law described in subparagraphs (A)
12 through (E).

13 “(d) DATE OF EXCLUSIVITY TERMINATION.—The
14 date on which the exclusivity shall be terminated as de-
15 scribed in subsection (a) is the date on which, as applica-
16 ble—

17 “(1) a final judgment is entered relating to a
18 violation described in subparagraph (A) or (B) of
19 subsection (c)(1); or

20 “(2)(A) a settlement agreement described in
21 subsection (c)(1)(C) is approved by a court order
22 that is or becomes final and nonappealable; or

23 “(B) if there is no court order approving a set-
24 tlement agreement described in subsection (c)(1)(C),
25 a court order dismissing the applicable case, issued

1 after the settlement agreement, is or becomes final
2 and nonappealable.

3 “(e) REPORTING OF INFORMATION.—

4 “(1) IN GENERAL.—A person described in sub-
5 section (a) that commits a violation described in
6 subsection (c)(1) shall report such violation to the
7 Secretary no later than 30 days after the date
8 that—

9 “(A) a final judgment is entered relating
10 to a violation described in subparagraph (A) or
11 (B) of subsection (c)(1); or

12 “(B)(i) a settlement agreement described
13 in subsection (c)(1)(C) is approved by a court
14 order that is or becomes final and nonappeal-
15 able; or

16 “(ii) if there is no court order approving a
17 settlement agreement described in subsection
18 (c)(1)(C), a court order dismissing the applica-
19 ble case, issued after the settlement agreement,
20 is or becomes final and nonappealable.

21 “(2) CIVIL PENALTY.—A person who fails to re-
22 port a violation as required under paragraph (1)
23 shall be subject to a civil penalty in the amount of
24 \$200,000 for each day the failure to report con-
25 tinues, beginning with the day after the date on

1 which such report is due as described in paragraph
2 (1).”.

3 (b) FTC.—There are authorized to be appropriated
4 to the Federal Trade Commission such sums as may be
5 necessary for the purpose of carrying out activities related
6 to addressing criminal activity and anticompetitive prac-
7 tices by pharmaceutical companies.

8 **TITLE IV—CHOICE AND** 9 **COMPETITION**

10 **SEC. 401. PRESERVING ACCESS TO AFFORDABLE** 11 **GENERICS.**

12 (a) IN GENERAL.—The Federal Trade Commission
13 Act (15 U.S.C. 44 et seq.) is amended by inserting after
14 section 26 (15 U.S.C. 57c–2) the following:

15 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE** 16 **GENERICS.**

17 “(a) IN GENERAL.—

18 “(1) ENFORCEMENT PROCEEDING.—The Com-
19 mission may initiate a proceeding to enforce the pro-
20 visions of this section against the parties to any
21 agreement resolving or settling, on a final or interim
22 basis, a patent infringement claim, in connection
23 with the sale of a drug product.

24 “(2) PRESUMPTION AND VIOLATION.—

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

5 “(i) an ANDA filer receives anything
6 of value, including an exclusive license; and

7 “(ii) the ANDA filer agrees to limit or
8 forego research, development, manufac-
9 turing, marketing, or sales of the ANDA
10 product for any period of time.

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

15 “(i) the value described in subpara-
16 graph (A)(i) is compensation solely for
17 other goods or services that the ANDA
18 filer has promised to provide; or

19 “(ii) the procompetitive benefits of the
20 agreement outweigh the anticompetitive ef-
21 fects of the agreement.

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

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

4 “(2) that the agreement’s provision for entry of
5 the ANDA product prior to the expiration of the rel-
6 evant patent or statutory exclusivity means that the
7 agreement is procompetitive.

8 “(c) EXCLUSIONS.—Nothing in this section shall pro-
9 hibit a resolution or settlement of a patent infringement
10 claim in which the consideration granted by the NDA
11 holder to the ANDA filer as part of the resolution or set-
12 tlement includes only one or more of the following:

13 “(1) The right to market the ANDA product in
14 the United States prior to the expiration of—

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

17 “(B) any patent right or other statutory
18 exclusivity that would prevent the marketing of
19 such drug.

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 infringes a United States patent.

24 “(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 is incorporated as of the
18 date that the NDA is filed with the Com-
19 missioner of Food and Drugs; or

20 “(iii) the United States Court of Ap-
21 peals for the circuit in which the ultimate
22 parent entity of the ANDA filer is incor-
23 porated as of the date that the ANDA is
24 filed with the Commissioner of Food and
25 Drugs.

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

6 “(e) ANTITRUST LAWS.—Nothing in this section
7 shall be construed to modify, impair, or supersede the ap-
8 plicability of the antitrust laws as defined in subsection
9 (a) of the first section of the Clayton Act (15 U.S.C.
10 12(a)), and of section 5 of this Act to the extent that sec-
11 tion 5 applies to unfair methods of competition. Nothing
12 in this section shall modify, impair, limit, or supersede the
13 right of an ANDA filer to assert claims or counterclaims
14 against any person, under the antitrust laws or other laws
15 relating to unfair competition.

16 “(f) PENALTIES.—

17 “(1) FORFEITURE.—Each party that violates or
18 assists in the violation of this section shall forfeit
19 and pay to the United States a civil penalty suffi-
20 cient to deter violations of this section, but in no
21 event greater than 3 times the value received by the
22 party that is reasonably attributable to the violation
23 of this section. If no such value has been received by
24 the NDA holder, the penalty to the NDA holder
25 shall be sufficient to deter violations, but in no event

1 greater than 3 times the value given to the ANDA
2 filer reasonably attributable to the violation of this
3 section. Such penalty shall accrue to the United
4 States and may be recovered in a civil action
5 brought by the Commission, in its own name by any
6 of its attorneys designated by it for such purpose, in
7 a district court of the United States against any
8 party that violates this section. In such actions, the
9 United States district courts are empowered to grant
10 mandatory injunctions and such other and further
11 equitable relief as they deem appropriate.

12 “(2) CEASE AND DESIST.—

13 “(A) IN GENERAL.—If the Commission has
14 issued a cease and desist order with respect to
15 a party in an administrative adjudicative pro-
16 ceeding under the authority of subsection
17 (a)(1), an action brought pursuant to para-
18 graph (1) may be commenced against such
19 party at any time before the expiration of 1
20 year after such order becomes final pursuant to
21 section 5(g).

22 “(B) EXCEPTION.—In an action under
23 subparagraph (A), the findings of the Commis-
24 sion as to the material facts in the administra-
25 tive adjudicative proceeding with respect to the

1 violation of this section by a party shall be con-
2 clusive unless—

3 “(i) the terms of such cease and de-
4 sist order expressly provide that the Com-
5 mission’s findings shall not be conclusive;
6 or

7 “(ii) the order became final by reason
8 of section 5(g)(1), in which case such find-
9 ing shall be conclusive if supported by evi-
10 dence.

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

14 “(A) the nature, circumstances, extent,
15 and gravity of the violation;

16 “(B) with respect to the violator, the de-
17 gree of culpability, any history of violations, the
18 ability to pay, any effect on the ability to con-
19 tinue doing business, profits earned by the
20 NDA holder, compensation received by the
21 ANDA filer, and the amount of commerce af-
22 fected; and

23 “(C) other matters that justice requires.

24 “(4) REMEDIES IN ADDITION.—Remedies pro-
25 vided in this subsection are in addition to, and not

1 in lieu of, any other remedy provided by Federal
2 law. Nothing in this paragraph shall be construed to
3 affect any authority of the Commission under any
4 other provision of law.

5 “(g) DEFINITIONS.—In this section:

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

10 “(2) AGREEMENT RESOLVING OR SETTling A
11 PATENT INFRINGEMENT CLAIM.—The term ‘agree-
12 ment resolving or settling a patent infringement
13 claim’ includes any agreement that is entered into
14 within 30 days of the resolution or the settlement of
15 the claim, or any other agreement that is contingent
16 upon, provides a contingent condition for, or is oth-
17 erwise related to the resolution or settlement of the
18 claim.

19 “(3) ANDA.—The term ‘ANDA’ means an ab-
20 breviated new drug application filed under section
21 505(j) of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 355(j)) or a new drug application filed
23 under section 505(b)(2) of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 355(b)(2)).

1 “(4) ANDA FILER.—The term ‘ANDA filer’
2 means a party that owns or controls an ANDA filed
3 with the Commission of Food and Drugs or has the
4 exclusive rights under such ANDA to distribute the
5 ANDA product.

6 “(5) ANDA PRODUCT.—The term ‘ANDA
7 product’ means the product to be manufactured
8 under the ANDA that is the subject of the patent
9 infringement claim.

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

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

18 “(8) NDA HOLDER.—The term ‘NDA holder’
19 means—

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

22 “(B) a person owning or controlling en-
23 forcement of the patent listed in the Approved
24 Drug Products With Therapeutic Equivalence

1 Evaluations (commonly known as the ‘FDA Or-
2 ange Book’) in connection with the NDA; or

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

11 “(9) PARTY.—The term ‘party’ means any per-
12 son, partnership, corporation, or other legal entity.

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

19 “(11) PATENT INFRINGEMENT CLAIM.—The
20 term ‘patent infringement claim’ means any allega-
21 tion made to an ANDA filer, whether or not in-
22 cluded in a complaint filed with a court of law, that
23 its ANDA or ANDA product may infringe any pat-
24 ent held by, or exclusively licensed to, the NDA
25 holder of the drug product.

1 (ii) by redesignating items (cc) and
2 (dd) as items (bb) and (cc), respectively;
3 and

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

5 “(v) FIRST APPLICANT DEFINED.—As used in
6 this subsection, the term ‘first applicant’ means an
7 applicant—

8 “(I)(aa) that, on the first day on which a
9 substantially complete application containing a
10 certification described in paragraph
11 (2)(A)(vii)(IV) is submitted for approval of a
12 drug, submits a substantially complete applica-
13 tion that contains and lawfully maintains a cer-
14 tification described in paragraph (2)(A)(vii)(IV)
15 for the drug; and

16 “(bb) that has not entered into a disquali-
17 fying agreement described under clause
18 (vii)(II); or

19 “(II)(aa) for the drug that is not described
20 in subclause (I) and that, with respect to the
21 applicant and drug, each requirement described
22 in clause (vi) is satisfied; and

23 “(bb) that has not entered into a disquali-
24 fying agreement described under clause
25 (vii)(II).

1 “(vi) REQUIREMENT.—The requirements de-
2 scribed in this clause are the following:

3 “(I) The applicant described in clause
4 (v)(II) submitted and lawfully maintains a cer-
5 tification described in paragraph (2)(A)(vii)(IV)
6 or a statement described in paragraph
7 (2)(A)(viii) for each unexpired patent for which
8 a first applicant described in clause (v)(I) had
9 submitted a certification described in paragraph
10 (2)(A)(vii)(IV) on the first day on which a sub-
11 stantially complete application containing such
12 a certification was submitted.

13 “(II) With regard to each such unexpired
14 patent for which the applicant described in
15 clause (v)(II) submitted a certification de-
16 scribed in paragraph (2)(A)(vii)(IV), no action
17 for patent infringement was brought against
18 such applicant within the 45-day period speci-
19 fied in paragraph (5)(B)(iii); or if an action
20 was brought within such time period, such an
21 action was withdrawn or dismissed by a court
22 (including a district court) without a decision
23 that the patent was valid and infringed; or if an
24 action was brought within such time period and
25 was not withdrawn or so dismissed, such appli-

1 cant has obtained the decision of a court (in-
2 cluding a district court) that the patent is in-
3 valid or not infringed (including any substantive
4 determination that there is no cause of action
5 for patent infringement or invalidity, and in-
6 cluding a settlement order or consent decree
7 signed and entered by the court stating that the
8 patent is invalid or not infringed).

9 “(III) If an applicant described in clause
10 (v)(I) has begun commercial marketing of such
11 drug, the applicant described in clause (v)(II)
12 does not begin commercial marketing of such
13 drug until the date that is 30 days after the
14 date on which the applicant described in clause
15 (v)(I) began such commercial marketing.”.

16 (2) CONFORMING AMENDMENT.—Section
17 505(j)(5)(D)(i)(IV) of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(IV)) is
19 amended by striking “The first applicant” and in-
20 serting “The first applicant, as defined in subpara-
21 graph (B)(v)(I),”.

22 (b) APPLICABILITY.—The amendments made by sub-
23 section (a) shall apply only with respect to an application
24 filed under section 505(j) of the Federal Food, Drug, and
25 Cosmetic Act (21 U.S.C. 355(j)) to which the amendments

1 made by section 1102(a) of the Medicare Prescription
2 Drug, Improvement, and Modernization Act of 2003 (Pub-
3 lic Law 108–173) apply.

4 **SEC. 403. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS RE-**
5 **GARDING AGREEMENTS TO DEFER COMMER-**
6 **CIAL MARKETING.**

7 (a) AMENDMENTS TO FEDERAL FOOD, DRUG, AND
8 COSMETIC ACT.—

9 (1) LIMITATIONS ON AGREEMENTS TO DEFER
10 COMMERCIAL MARKETING DATE.—Section
11 505(j)(5)(B) of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 355(j)(5)(B)), as amended by
13 section 402, is further amended by adding at the
14 end the following:

15 “(vii) AGREEMENT BY FIRST APPLICANT TO
16 DEFER COMMERCIAL MARKETING; LIMITATION ON
17 ACCELERATION OF DEFERRED COMMERCIAL MAR-
18 KETING DATE.—

19 “(I) AGREEMENT TO DEFER APPROVAL OR
20 COMMERCIAL MARKETING DATE.—An agree-
21 ment described in this subclause is an agree-
22 ment between a first applicant and the holder
23 of the application for the listed drug or an
24 owner of one or more of the patents as to which
25 any applicant submitted a certification quali-

1 fying such applicant for the 180-day exclusivity
2 period whereby that applicant agrees, directly
3 or indirectly, (aa) not to seek an approval of its
4 application that is made effective on the earliest
5 possible date under this subparagraph, subpara-
6 graph (F) of this paragraph, section 505A, or
7 section 527, (bb) not to begin the commercial
8 marketing of its drug on the earliest possible
9 date after receiving an approval of its applica-
10 tion that is made effective under this subpara-
11 graph, subparagraph (F) of this paragraph, sec-
12 tion 505A, or section 527, or (cc) to both items
13 (aa) and (bb).

14 “(II) AGREEMENT THAT DISQUALIFIES AP-
15 PLICANT FROM FIRST APPLICANT STATUS.—An
16 agreement described in this subclause is an
17 agreement between an applicant and the holder
18 of the application for the listed drug or an
19 owner of one or more of the patents as to which
20 any applicant submitted a certification quali-
21 fying such applicant for the 180-day exclusivity
22 period whereby that applicant agrees, directly
23 or indirectly, not to seek an approval of its ap-
24 plication or not to begin the commercial mar-
25 keting of its drug until a date that is after the

1 expiration of the 180-day exclusivity period
2 awarded to another applicant with respect to
3 such drug (without regard to whether such 180-
4 day exclusivity period is awarded before or after
5 the date of the agreement).

6 “(viii) LIMITATION ON ACCELERATION.—If an
7 agreement described in clause (vii)(I) includes more
8 than 1 possible date when an applicant may seek an
9 approval of its application or begin the commercial
10 marketing of its drug—

11 “(I) the applicant may seek an approval of
12 its application or begin such commercial mar-
13 keting on the date that is the earlier of—

14 “(aa) the latest date set forth in the
15 agreement on which that applicant can re-
16 ceive an approval that is made effective
17 under this subparagraph, subparagraph
18 (F) of this paragraph, section 505A, or
19 section 527, or begin the commercial mar-
20 keting of such drug, without regard to any
21 other provision of such agreement pursu-
22 ant to which the commercial marketing
23 could begin on an earlier date; or

1 “(bb) 180 days after another first ap-
2 plicant begins commercial marketing of
3 such drug; and

4 “(II) the latest date set forth in the agree-
5 ment on which that applicant can receive an ap-
6 proval that is made effective under this sub-
7 paragraph, subparagraph (F) of this paragraph,
8 section 505A, or section 527, or begin the com-
9 mercial marketing of such drug, without regard
10 to any other provision of such agreement pursu-
11 ant to which commercial marketing could begin
12 on an earlier date, shall be the date used to de-
13 termine whether an applicant is disqualified
14 from first applicant status pursuant to clause
15 (vii)(II).”.

16 (2) NOTIFICATION OF FDA.—Section 505(j) of
17 the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 355(j)) is amended by adding at the end the
19 following:

20 “(11)(A) The holder of an abbreviated application
21 under this subsection shall submit to the Secretary a noti-
22 fication that includes—

23 “(i)(I) the text of any agreement entered into
24 by such holder described under paragraph
25 (5)(B)(vii)(I); or

1 “(II) if such an agreement has not been re-
2 duced to text, a written detailed description of such
3 agreement that is sufficient to disclose all the terms
4 and conditions of the agreement; and

5 “(ii) the text, or a written detailed description
6 in the event of an agreement that has not been re-
7 duced to text, of any other agreements that are con-
8 tingent upon, provide a contingent condition for, or
9 are otherwise related to an agreement described in
10 clause (i).

11 “(B) The notification described under subparagraph
12 (A) shall be submitted not later than 10 business days
13 after execution of the agreement described in subpara-
14 graph (A)(i). Such notification is in addition to any notifi-
15 cation required under section 1112 of the Medicare Pre-
16 scription Drug, Improvement, and Modernization Act of
17 2003.

18 “(C) Any information or documentary material filed
19 with the Secretary pursuant to this paragraph shall be ex-
20 empt from disclosure under section 552 of title 5, United
21 States Code, and no such information or documentary ma-
22 terial may be made public, except as may be relevant to
23 any administrative or judicial action or proceeding. Noth-
24 ing in this paragraph is intended to prevent disclosure to

1 either body of the Congress or to any duly authorized com-
2 mittee or subcommittee of the Congress.”.

3 (3) PROHIBITED ACTS.—Section 301(e) of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 331(e)) is amended by striking “505 (i) or (k)” and
6 inserting “505 (i), (j)(11), or (k)”.

7 (b) INFRINGEMENT OF PATENT.—Section 271(e) of
8 title 35, United States Code, is amended by adding at the
9 end the following:

10 “(7) The exclusive remedy under this section for an
11 infringement of a patent for which the Secretary of Health
12 and Human Services has published information pursuant
13 to subsection (b)(1) or (c)(2) of section 505 of the Federal
14 Food, Drug, and Cosmetic Act shall be an action brought
15 under this subsection within the 45-day period described
16 in subsection (j)(5)(B)(iii) or (c)(3)(C) of section 505 of
17 the Federal Food, Drug, and Cosmetic Act.”.

18 (c) APPLICABILITY.—

19 (1) LIMITATIONS ON ACCELERATION OF DE-
20 FERRED COMMERCIAL MARKETING DATE.—The
21 amendment made by subsection (a)(1) shall apply
22 only with respect to—

23 (A) an application filed under section
24 505(j) of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 355(j)) to which the

1 amendments made by section 1102(a) of the
2 Medicare Prescription Drug, Improvement, and
3 Modernization Act of 2003 (Public Law 108–
4 173) apply; and

5 (B) an agreement described under section
6 505(j)(5)(B)(vii)(I) of the Federal Food, Drug,
7 and Cosmetic Act (as added by subsection
8 (a)(1)) executed after the date of enactment of
9 this Act.

10 (2) NOTIFICATION OF FDA.—The amendments
11 made by paragraphs (2) and (3) of subsection (a)
12 shall apply only with respect to an agreement de-
13 scribed under section 505(j)(5)(B)(vii)(I) of the
14 Federal Food, Drug, and Cosmetic Act (as added by
15 subsection (a)(1)) executed after the date of enact-
16 ment of this Act.

17 **SEC. 404. INCREASING DRUG COMPETITION AND PRE-**
18 **VENTING DRUG SHORTAGES.**

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

22 “(D)(i) The Commissioner shall—

23 “(I) not later than 9 months after the date of
24 enactment of the Affordable Medications Act, pub-
25 lish a complete, up-to-date list on the internet

1 website of the Food and Drug Administration of all
2 drugs, including authorized generics, together with,
3 with respect to the drug, as applicable—

4 “(aa) the drug trade name;

5 “(bb) the established name;

6 “(cc) each active pharmaceutical ingredient
7 facility (as defined in section 744B(a)(4)(a)(ii));

8 “(dd) each generic drug facility;

9 “(ee) each contract manufacturing organi-
10 zation facility (as defined in section 744A(5));

11 “(ff) the date any authorized generic drug
12 entered the market;

13 “(gg) the marketing status; and

14 “(hh) any other information the Secretary
15 may require to mitigate or prevent drug short-
16 ages;

17 “(II) designate each drug on the list that is a
18 sole-source generic drug;

19 “(III) designate each drug on the list that is an
20 essential medicine, as identified by the World Health
21 Organization, or another entity designated by the
22 Secretary that meets evidence-based standards as re-
23 quired by the Secretary; and

24 “(IV) maintain a confidential list of the identity
25 and address of each facility described in subclause

1 (I), and publicly report on the website only the city
2 and State or country of each such facility.

3 “(ii) The Commissioner may choose not to make in-
4 formation collected under clause (i) publicly available if
5 the Secretary determines that disclosure of such informa-
6 tion would adversely affect the public health (such as by
7 increasing the possibility of hoarding or other disruption
8 of the availability of drug products to patients).

9 “(iii) The Commissioner shall notify relevant Federal
10 agencies, including the Centers for Medicare & Medicaid
11 Services and the Federal Trade Commission, when the
12 Commissioner first publishes the information under clause
13 (i) that the information has been published and will be
14 updated regularly.

15 “(iv) In this subparagraph, the term ‘sole-source’
16 means, with respect to a drug, there is not more than one
17 approved drug on the list of drugs under subparagraph
18 (A), not including drugs on the discontinued section of
19 such list.”.

20 **SEC. 405. DISALLOWANCE OF DEDUCTION FOR ADVER-**
21 **TISING FOR PRESCRIPTION DRUGS.**

22 (a) IN GENERAL.—Part IX of subchapter B of chap-
23 ter 1 of subtitle A of the Internal Revenue Code of 1986
24 (relating to items not deductible) is amended by adding
25 at the end the following new section:

1 **“SEC. 280I. DISALLOWANCE OF DEDUCTION FOR DIRECT-**
2 **TO-CONSUMER ADVERTISING OF PRESCRIP-**
3 **TION DRUGS.**

4 “(a) IN GENERAL.—No deduction shall be allowed
5 under this chapter for expenses relating to direct-to-con-
6 sumer advertising of prescription drugs for any taxable
7 year.

8 “(b) DIRECT-TO-CONSUMER ADVERTISING.—For
9 purposes of this section, the term ‘direct-to-consumer ad-
10 vertising’ means any dissemination, by or on behalf of a
11 sponsor of a prescription drug product (as such term is
12 defined in section 735(3) of the Federal Food, Drug, and
13 Cosmetic Act), of an advertisement which—

14 “(1) is in regard to such prescription drug
15 product, and

16 “(2) primarily targeted to the general public,
17 including through—

18 “(A) publication in journals, magazines,
19 other periodicals, and newspapers,

20 “(B) broadcasting through media such as
21 radio, television, telephone communication sys-
22 tems, direct mail, and billboards,

23 “(C) dissemination on the Internet (includ-
24 ing social media), and

1 “(D) manufacturer patient assistance pro-
2 grams, as defined in section 399V-7 of the
3 Public Health Service Act.”.

4 (b) CONFORMING AMENDMENT.—The table of sec-
5 tions for such part IX of the Internal Revenue Code of
6 1986 is amended by adding after the item relating to sec-
7 tion 280H the following new item:

 “Sec. 280I. Disallowance of deduction for direct-to-consumer advertising of pre-
 scription drugs.”.

8 (c) EFFECTIVE DATE.—The amendments made by
9 subsections (a) and (b) shall apply to amounts paid or in-
10 curred after the date of the enactment of this Act, in tax-
11 able years ending after such date.

12 (d) OVERSIGHT OF PRESCRIPTION DRUGS.—

13 (1) IN GENERAL.—The Secretary of Health and
14 Human Services (referred to in this subsection as
15 the “Secretary”), acting through the Commissioner
16 of Food and Drugs and in coordination with other
17 Federal agencies, shall conduct oversight of the risks
18 and benefits of drugs that are on the market and
19 how such risks are presented in drug advertisements
20 for the purpose of correcting false or misleading in-
21 formation published in direct-to-consumer advertise-
22 ments and to disseminate corrective information to
23 health care providers and the general public regard-

1 ing the risks and benefits of a drug on an quarterly
2 basis.

3 (2) PREREVIEW OF TELEVISION ADVERTISE-
4 MENTS.—The Secretary, acting through the Com-
5 missioner of Food and Drugs and in consultation
6 with relevant stakeholders, shall issue new, or up-
7 date current, guidance issued under section 503C of
8 the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 353c). In carrying out this paragraph, the
10 Secretary shall focus on drugs that present the
11 greatest risk to consumers, drugs that represent the
12 greatest proportion of total spending in Federal pro-
13 grams, drugs with high unit price increases over the
14 preceding year, drugs with high launch prices, or
15 any other priority drugs identified by the Secretary.

16 (3) FUNDING.—There is authorized to be ap-
17 propriated to the Secretary an amount equal to the
18 increase in revenue resulting from the enactment of
19 section 280I of the Internal Revenue Code of 1986,
20 as added by subsection (a).

21 **SEC. 406. DRUG MANUFACTURER DUTY TO DISCLOSE DRUG**
22 **PRICES TO PRACTITIONERS.**

23 (a) DUTY TO DISCLOSE.—Whenever a drug manu-
24 facturer, including any representative of the manufac-
25 turer, communicates with a health care practitioner about

1 a drug manufactured by the drug manufacturer, including
2 through promotional, educational, or marketing commu-
3 nications, meetings or paid events, and the provision of
4 goods, gifts, and samples, the drug manufacturer shall dis-
5 close to the practitioner the wholesale acquisition cost (as
6 defined in section 1847A(c)(6)(B) of the Social Security
7 Act (42 U.S.C. 1395w-3a(c)(6)(B))) for a 30-day supply
8 of the drug, which may include a brief qualitative expla-
9 nation of reduced cost availability for certain consumers.

10 (b) ENFORCEMENT BY FEDERAL TRADE COMMIS-
11 SION.—

12 (1) UNFAIR OR DECEPTIVE ACTS OR PRAC-
13 TICES.—A violation of subsection (a) by a person
14 with respect to whom the Commission is empowered
15 under section 5(a)(2) of the Federal Trade Commis-
16 sion Act (15 U.S.C. 45(a)(2)) shall be treated as a
17 violation of a rule defining an unfair or deceptive act
18 or practice prescribed under section 18(a)(1)(B) of
19 the Federal Trade Commission Act (15 U.S.C.
20 57a(a)(1)(B)).

21 (2) POWERS OF FEDERAL TRADE COMMIS-
22 SION.—

23 (A) IN GENERAL.—The Federal Trade
24 Commission shall enforce this section in the
25 same manner, by the same means, and with the

1 same jurisdiction, powers, and duties as though
2 all applicable terms and provisions of the Fed-
3 eral Trade Commission Act (15 U.S.C. 41 et
4 seq.) were incorporated into and made a part of
5 this Act.

6 (B) PRIVILEGES AND IMMUNITIES.—Any
7 person who violates this section shall be subject
8 to the penalties and entitled to the privileges
9 and immunities provided in the Federal Trade
10 Commission Act (15 U.S.C. 41 et seq.).

11 (c) RULEMAKING.—The Federal Trade Commission
12 shall promulgate in accordance with section 553 of title
13 5, United States Code, such rules as may be necessary
14 to carry out this section.

15 (d) SAVINGS PROVISION.—Nothing in this section
16 shall be construed to limit, impair, or supersede the oper-
17 ation of the Federal Trade Commission Act or any other
18 provision of Federal law.

19 **SEC. 407. EXCLUDING AUTHORIZED GENERIC DRUGS FROM**
20 **CALCULATION OF AVERAGE MANUFACTURER**
21 **PRICE UNDER THE MEDICAID DRUG REBATE**
22 **PROGRAM.**

23 (a) IN GENERAL.—Subparagraph (C) of section
24 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r-
25 8(k)(1)) is amended—

1 (1) in the subparagraph heading, by striking
2 “INCLUSION” and inserting “EXCLUSION”;

3 (2) by striking “a new drug application” and
4 inserting “the manufacturer’s new drug applica-
5 tion”; and

6 (3) by striking “inclusive” and inserting “exclu-
7 sive”.

8 (b) **EFFECTIVE DATE.**—The amendments made by
9 this section shall take effect on October 1, 2019.

○