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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. _____

To provide for certain reforms with respect to the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, the Food and Drug Administration, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

M____. _____ introduced the following bill; which was referred to the
Committee on _____

A BILL

To provide for certain reforms with respect to the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, the Food and Drug Administration, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Lower Costs, More
5 Cures Act of 2019”.

1 SEC. 2. TABLE OF CONTENTS.

2 The table of contents for this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.

TITLE I—MEDICARE PARTS B AND D

Subtitle A—Medicare Part B Provisions

- Sec. 101. Improvements to Medicare site-of-service transparency.
- Sec. 102. Requiring manufacturers of certain single-dose container or single-use package drugs payable under part B of the Medicare program to provide refunds with respect to discarded amounts of such drugs.
- Sec. 103. Providing for variation in payment for certain drugs covered under part B of the Medicare program.
- Sec. 104. Establishment of maximum add-on payment for drugs and biologicals.
- Sec. 105. Treatment of drug administration services furnished by certain excepted off-campus outpatient departments of a provider.

Subtitle B—Drug Price Transparency

- Sec. 111. Reporting on explanation for drug price increases.
- Sec. 112. Public disclosure of drug discounts.
- Sec. 113. Study of pharmaceutical supply chain intermediaries and merger activity.
- Sec. 114. Requiring certain manufacturers to report drug pricing information with respect to drugs under the Medicare program.
- Sec. 115. Making prescription drug marketing sample information reported by manufacturers available to certain individuals and entities.
- Sec. 116. Requiring prescription drug plan sponsors to include real-time benefit information as part of such sponsor's electronic prescription program under the Medicare program.
- Sec. 117. Sense of Congress regarding the need to expand commercially available drug pricing comparison platforms.
- Sec. 118. Technical corrections.

Subtitle C—Medicare Part D Benefit Redesign

- Sec. 121. Medicare Part D Benefit Redesign.

Subtitle D—Other Medicare Part D Provisions

- Sec. 131. Transitional coverage and retroactive Medicare Part D coverage for certain low-income beneficiaries.
- Sec. 132. Allowing the offering of additional prescription drug plans under Medicare part D.
- Sec. 133. Allowing certain enrollees of prescription drugs plans and MA-PD plans under Medicare program to spread out cost-sharing under certain circumstances.
- Sec. 134. Establishing a monthly cap on beneficiary incurred costs for insulin products and supplies under a prescription drug plan or MA-PD plan.
- Sec. 135. Growth rate of Medicare part D out-of-pocket cost threshold.

Subtitle E—MedPAC

- Sec. 141. Providing the Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission with access to certain drug payment information, including certain rebate information.

TITLE II—MEDICAID

- Sec. 201. Sunset of limit on maximum rebate amount for single source drugs and innovator multiple source drugs.
- Sec. 202. Medicaid pharmacy and therapeutics committee improvements.
- Sec. 203. GAO report on conflicts of interest in State Medicaid program drug use review boards and pharmacy and therapeutics (P&T) committees.
- Sec. 204. Ensuring the accuracy of manufacturer price and drug product information under the Medicaid drug rebate program.
- Sec. 205. Improving transparency and preventing the use of abusive spread pricing and related practices in Medicaid.
- Sec. 206. T-MSIS drug data analytics reports.
- Sec. 207. Risk-sharing value-based payment agreements for covered outpatient drugs under Medicaid.
- Sec. 208. Applying Medicaid drug rebate requirement to drugs provided as part of outpatient hospital services.

TITLE III—FOOD AND DRUG ADMINISTRATION

Subtitle A—CREATES Act

- Sec. 301. Actions for delays of generic drugs and biosimilar biological products.
- Sec. 302. Rems approval process for subsequent filers.
- Sec. 303. Rule of construction.

Subtitle B—Pay-for-Delay

- Sec. 311. Unlawful agreements.
- Sec. 312. Notice and certification of agreements.
- Sec. 313. Forfeiture of 180-day exclusivity period.
- Sec. 314. Commission litigation authority.
- Sec. 315. Statute of limitations.

Subtitle C—BLOCKING Act

- Sec. 321. Change conditions of first generic exclusivity to spur access and competition.

Subtitle D—Purple Book

- Sec. 331. Public Listing.
- Sec. 332. Review and report on types of Information To be listed.

Subtitle E—Orange Book

- Sec. 341. Orange Book.
- Sec. 342. GAO report to Congress.

Subtitle F—Advancing Education on Biosimilars

- Sec. 351. Education on biological products.

Subtitle G—Streamlining Transition of Biological Products

Sec. 361. Streamlining the transition of biological products.

Subtitle H—Over-the-Counter Monograph Safety, Innovation, and Reform

Sec. 370. Short title; references in subtitle.

PART 1—OTC DRUG REVIEW

Sec. 371. Regulation of certain nonprescription drugs that are marketed without an approved drug application.

Sec. 372. Misbranding.

Sec. 373. Drugs excluded from the over-the-counter drug review.

Sec. 374. Treatment of Sunscreen Innovation Act.

Sec. 375. Annual update to Congress on appropriate pediatric indication for certain OTC cough and cold drugs.

Sec. 376. Technical corrections.

PART 2—USER FEES

Sec. 381. Short title; finding.

Sec. 382. Fees relating to over-the-counter drugs.

Subtitle I—Other Provisions

Sec. 391. Protecting access to biological products.

Sec. 392. Orphan drug clarification.

Sec. 393. Conditions of use for biosimilar biological products.

Sec. 394. Clarifying the meaning of new chemical entity.

TITLE IV—REVENUE PROVISIONS

Sec. 401. Permanent extension of reduction in medical expense deduction floor.

Sec. 402. Safe harbor for high deductible health plans without deductible for insulin.

Sec. 403. Inclusion of certain over-the-counter medical products as qualified medical expenses.

TITLE V—MISCELLANEOUS

Sec. 501. Payment for biosimilar biological products during initial period.

Sec. 502. GAO study and report on average sales price.

Sec. 503. Requiring prescription drug plans and MA–PD plans to report potential fraud, waste, and abuse to the Secretary of HHS.

Sec. 504. Establishment of pharmacy quality measures under Medicare part D.

Sec. 505. Improving coordination between the Food and Drug Administration and the Centers for Medicare & Medicaid Services.

Sec. 506. Patient consultation in Medicare national and local coverage determinations in order to mitigate barriers to inclusion of such perspectives.

Sec. 507. MedPAC report on shifting coverage of certain Medicare part B drugs to Medicare part D.

Sec. 508. Requirement that direct-to-consumer advertisements for prescription drugs and biological products include truthful and non-misleading pricing information.

Sec. 509. Chief Pharmaceutical Negotiator at the Office of the United States Trade Representative.

Sec. 510. Waiving Medicare coinsurance for colorectal cancer screening tests.

1 **TITLE I—MEDICARE PARTS B**
2 **AND D**
3 **Subtitle A—Medicare Part B**
4 **Provisions**

5 **SEC. 101. IMPROVEMENTS TO MEDICARE SITE-OF-SERVICE**
6 **TRANSPARENCY.**

7 Section 1834(t) of the Social Security Act (42 U.S.C.
8 1395m(t)) is amended—

9 (1) in paragraph (1)—

10 (A) in the heading, by striking “IN GEN-
11 ERAL” and inserting “SITE PAYMENT”;

12 (B) in the matter preceding subparagraph
13 (A)—

14 (i) by striking “or to” and inserting “,
15 to”;

16 (ii) by inserting “, or to a physician
17 for services furnished in a physician’s of-
18 fice” and “surgical center”; and

19 (iii) by inserting “(or 2021 with re-
20 spect to a physician for services furnished
21 in a physician’s office)” after “2018”; and

22 (C) in subparagraph (A)—

23 (i) by striking “and the” and insert-
24 ing “, the”; and

1 (ii) by inserting “, and the physician
2 fee schedule under section 1848 (with re-
3 spect to the practice expense component of
4 such payment amount)” after “such sec-
5 tion”;

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

8 (3) by inserting after paragraph (1) the fol-
9 lowing new paragraph:

10 “(2) PHYSICIAN PAYMENT.—Beginning in
11 2021, the Secretary shall expand the information in-
12 cluded on the Internet website described in para-
13 graph (1) to include—

14 “(A) the amount paid to a physician under
15 section 1848 for an item or service for the set-
16 tings described in paragraph (1); and

17 “(B) the estimated amount of beneficiary
18 liability applicable to the item or service.”.

1 **SEC. 102. REQUIRING MANUFACTURERS OF CERTAIN SIN-**
2 **GLE-DOSE CONTAINER OR SINGLE-USE PACK-**
3 **AGE DRUGS PAYABLE UNDER PART B OF THE**
4 **MEDICARE PROGRAM TO PROVIDE REFUNDS**
5 **WITH RESPECT TO DISCARDED AMOUNTS OF**
6 **SUCH DRUGS.**

7 Section 1847A of the Social Security Act (42 U.S.C.
8 1395–3a) is amended by adding at the end the following
9 new subsection:

10 “(h) REFUND FOR CERTAIN DISCARDED SINGLE-
11 DOSE CONTAINER OR SINGLE-USE PACKAGE DRUGS.—

12 “(1) SECRETARIAL PROVISION OF INFORMA-
13 TION.—

14 “(A) IN GENERAL.—For each calendar
15 quarter beginning on or after July 1, 2021, the
16 Secretary shall, with respect to a refundable
17 single-dose container or single-use package drug
18 (as defined in paragraph (8)), report to each
19 manufacturer (as defined in subsection
20 (c)(6)(A)) of such refundable single-dose con-
21 tainer or single-use package drug the following
22 for the calendar quarter:

23 “(i) Subject to subparagraph (C), in-
24 formation on the total number of units of
25 the billing and payment code of such drug,
26 if any, that were discarded during such

1 quarter, as determined using a mechanism
2 such as the JW modifier used as of the
3 date of enactment of this subsection (or
4 any such successor modifier that includes
5 such data as determined appropriate by
6 the Secretary).

7 “(ii) The refund amount that the
8 manufacturer is liable for pursuant to
9 paragraph (3).

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

18 “(C) EXCLUSION OF UNITS OF PACKAGED
19 DRUGS.—The total number of units of the bill-
20 ing and payment code of a refundable single-
21 dose container or single-use package drug of a
22 manufacturer furnished during a calendar quar-
23 ter for purposes of subparagraph (A)(i), and
24 the determination of the estimated total allowed
25 charges for the drug in the quarter for purposes

1 of paragraph (3)(A)(ii), shall not include such
2 units that are packaged into the payment
3 amount for an item or service and are not sepa-
4 rately payable.

5 “(2) MANUFACTURER REQUIREMENT.—For
6 each calendar quarter beginning on or after July 1,
7 2021, the manufacturer of a refundable single-dose
8 container or single-use package drug shall, for such
9 drug, provide to the Secretary a refund that is equal
10 to the amount specified in paragraph (3) for such
11 drug for such quarter.

12 “(3) REFUND AMOUNT.—

13 “(A) IN GENERAL.—The amount of the re-
14 fund specified in this paragraph is, with respect
15 to a refundable single-dose container or single-
16 use package drug of a manufacturer assigned to
17 a billing and payment code for a calendar quar-
18 ter beginning on or after July 1, 2021, an
19 amount equal to the estimated amount (if any)
20 by which—

21 “(i) the product of—

22 “(I) the total number of units of
23 the billing and payment code for such
24 drug that were discarded during such

1 quarter (as determined under para-
2 graph (1)); and

3 “(II)(aa) in the case of a refund-
4 able single-dose container or single-
5 use package drug that is a single
6 source drug or biological, the amount
7 determined for such drug under sub-
8 section (b)(4); or

9 “(bb) in the case of a refundable
10 single-dose container or single-use
11 package drug that is a biosimilar bio-
12 logical product, the average sales price
13 determined under subsection
14 (b)(8)(A); exceeds

15 “(ii) an amount equal to the applica-
16 ble percentage (as defined in subparagraph
17 (B)) of the estimated total allowed charges
18 for such drug during the quarter.

19 “(B) APPLICABLE PERCENTAGE DE-
20 FINED.—

21 “(i) IN GENERAL.—For purposes of
22 subparagraph (A)(ii), the term ‘applicable
23 percentage’ means—

24 “(I) subject to subclause (II), 10
25 percent; and

1 “(II) if applicable, in the case of
2 a refundable single-dose container or
3 single-use package drug described in
4 clause (ii), a percentage specified by
5 the Secretary pursuant to such clause.

6 “(ii) TREATMENT OF DRUGS THAT
7 HAVE UNIQUE CIRCUMSTANCES.—In the
8 case of a refundable single-dose container
9 or single-use package drug that has unique
10 circumstances involving similar loss of
11 product as that described in paragraph
12 (8)(B), the Secretary, through notice and
13 comment rulemaking, may increase the ap-
14 plicable percentage otherwise applicable
15 under clause (i)(I) as determined appro-
16 priate by the Secretary.

17 “(4) FREQUENCY.—Amounts required to be re-
18 funded pursuant to paragraph (2) shall be paid in
19 regular intervals (as determined appropriate by the
20 Secretary).

21 “(5) REFUND DEPOSITS.—Amounts paid as re-
22 funds pursuant to paragraph (2) shall be deposited
23 into the Federal Supplementary Medical Insurance
24 Trust Fund established under section 1841.

25 “(6) ENFORCEMENT.—

1 “(A) AUDITS.—

2 “(i) MANUFACTURER AUDITS.—Each
3 manufacturer of a refundable single-dose
4 container or single-use package drug that
5 is required to provide a refund under this
6 subsection shall be subject to periodic
7 audit with respect to such drug and such
8 refunds by the Secretary.

9 “(ii) PROVIDER AUDITS.—The Sec-
10 retary shall conduct periodic audits of
11 claims submitted under this part with re-
12 spect to refundable single-dose container or
13 single-use package drugs in accordance
14 with the authority under section 1833(e) to
15 ensure compliance with the requirements
16 applicable under this subsection.

17 “(B) CIVIL MONEY PENALTY.—

18 “(i) IN GENERAL.—The Secretary
19 shall impose a civil money penalty on a
20 manufacturer of a refundable single-dose
21 container or single-use package drug who
22 has failed to comply with the requirement
23 under paragraph (2) for such drug for a
24 calendar quarter in an amount equal to the
25 sum of—

1 “(I) the amount that the manu-
2 facturer would have paid under such
3 paragraph with respect to such drug
4 for such quarter; and

5 “(II) 25 percent of such amount.

6 “(ii) APPLICATION.—The provisions
7 of section 1128A (other than subsections
8 (a) and (b)) shall apply to a civil money
9 penalty under this subparagraph in the
10 same manner as such provisions apply to a
11 penalty or proceeding under section
12 1128A(a).

13 “(7) IMPLEMENTATION.—The Secretary shall
14 implement this subsection through notice and com-
15 ment rulemaking.

16 “(8) DEFINITION OF REFUNDABLE SINGLE-
17 DOSE CONTAINER OR SINGLE-USE PACKAGE DRUG.—

18 “(A) IN GENERAL.—Except as provided in
19 subparagraph (B), in this subsection, the term
20 ‘refundable single-dose container or single-use
21 package drug’ means a single source drug or bi-
22 ological (as defined in section 1847A(c)(6)(D))
23 or a biosimilar biological product (as defined in
24 section 1847A(c)(6)(H)) for which payment is
25 established under this part and that is fur-

1 nished from a single-dose container or single-
2 use package.

3 “(B) EXCLUSIONS.—The term ‘refundable
4 single-dose container or single-use package
5 drug’ does not include—

6 “(i) a drug or biological that is either
7 a radiopharmaceutical or an imaging
8 agent;

9 “(ii) a drug or biological for which
10 dosage and administration instructions ap-
11 proved by the Commissioner of Food and
12 Drugs require filtration during the drug
13 preparation process, prior to dilution and
14 administration, and require that any un-
15 used portion of such drug after the filtra-
16 tion process be discarded after the comple-
17 tion of such filtration process; or

18 “(iii) a drug or biological approved by
19 the Food and Drug Administration on or
20 after the date of enactment of this sub-
21 section and with respect to which payment
22 has been made under this part for less
23 than 18 months.”.

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

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

6 (1) in paragraph (1)—

7 (A) in subparagraph (A), by inserting after
8 “or 106 percent” the following: “(or, for a mul-
9 tiple source drug (other than autologous cellular
10 immunotherapy) furnished on or after January
11 1, 2021, the applicable percent specified in
12 paragraph (9)(A) for the drug and quarter in-
13 volved)”; and

14 (B) in subparagraph (B) of paragraph (1),
15 by inserting after “106 percent” the following:
16 “(or, for a single source drug or biological
17 (other than autologous cellular immunotherapy)
18 furnished on or after January 1, 2021, the ap-
19 plicable percent specified in paragraph (9)(A)
20 for the drug or biological and quarter in-
21 volved)”; and

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

24 “(9) APPLICATION OF VARIABLE PERCENTAGES
25 BASED ON PERCENTILE RANKING OF PER BENE-
26 FICIARY ALLOWED CHARGES.—

1 “(A) APPLICABLE PERCENT TO BE AP-
2 PLIED.—

3 “(i) IN GENERAL.—Subject to clauses
4 (ii), with respect to a drug or biological
5 furnished in a calendar quarter beginning
6 on or after January 1, 2021, if the Sec-
7 retary determines that the percentile rank
8 of a drug or biological under subparagraph
9 (B)(i)(III), with respect to per beneficiary
10 allowed charges for all such drugs or
11 biologicals, is—

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

16 “(II) at least equal to the 70th
17 percentile, but less than the 85th per-
18 centile, such applicable percent is 106
19 percent;

20 “(III) at least equal to the 50th
21 percentile, but less than the 70th per-
22 centile, such applicable percent is 108
23 percent; or

1 “(IV) less than the 50th per-
2 centile, such applicable percent is 110
3 percent.

4 “(ii) CASES WHERE DATA NOT SUFFI-
5 CIENTLY AVAILABLE TO COMPUTE PER
6 BENEFICIARY ALLOWED CHARGES.—Sub-
7 ject to clause (iii), in the case of a drug or
8 biological furnished for which the amount
9 of payment is determined under subpara-
10 graph (A) or (B) of paragraph (1) and not
11 under subsection (c)(4), for calendar quar-
12 ters during a period in which data are not
13 sufficiently available to compute a per ben-
14 eficiary allowed charges for the drug or bi-
15 ological, the applicable percent is 106 per-
16 cent.

17 “(B) DETERMINATION OF PERCENTILE
18 RANK OF PER BENEFICIARY ALLOWED CHARGES
19 OF DRUGS.—

20 “(i) IN GENERAL.—With respect to a
21 calendar quarter beginning on or after
22 January 1, 2021, for drugs and biologicals
23 for which the amount of payment is deter-
24 mined under subparagraph (A) or (B) of
25 paragraph (1), except for drugs or

1 biologicals for which data are not suffi-
2 ciently available, the Secretary shall—

3 “(I) compute the per beneficiary
4 allowed charges (as defined in sub-
5 paragraph (C)) for each such drug or
6 biological;

7 “(II) adjust such per beneficiary
8 allowed charges for the quarter, to the
9 extent provided under subparagraph
10 (D); and

11 “(III) array such adjusted per
12 beneficiary allowed charges for all
13 such drugs or biologicals from high to
14 low and rank such drugs or biologicals
15 by percentile of such arrayed per ben-
16 eficiary allowed charges.

17 “(ii) FREQUENCY.—The Secretary
18 shall make the computations under clause
19 (i)(I) every 6 months (or, if necessary, as
20 determined by the Secretary, every 9 or 12
21 months) and such computations shall apply
22 to succeeding calendar quarters until a
23 new computation has been made.

24 “(iii) APPLICABLE DATA PERIOD.—
25 For purposes of this paragraph, the term

1 ‘applicable data period’ means the most re-
2 cent period for which the data necessary
3 for making the computations under clause
4 (i) are available, as determined by the Sec-
5 retary.

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

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

16 “(ii) the number of individuals for
17 whom any payment for the drug or biologi-
18 cal was made under paragraph (1) for the
19 applicable data period, as estimated by the
20 Secretary.

21 “(D) ADJUSTMENT TO REFLECT CHANGES
22 IN AVERAGE SALES PRICE.—In applying this
23 paragraph for a particular calendar quarter, the
24 Secretary shall adjust the per beneficiary al-
25 lowed charges for a drug or biological by multi-

1 plying such per beneficiary allowed charges
2 under subparagraph (C) for the applicable data
3 period by the ratio of—

4 “(i) the average sales price for the
5 drug or biological for the most recent cal-
6 endar quarter used under subsection
7 (c)(5)(B); to

8 “(ii) the average sales price for the
9 drug or biological for the calendar quarter
10 (or the weighted average for the quarters
11 involved) included in the applicable data
12 period.”.

13 (b) APPLICATION OF JUDICIAL REVIEW PROVI-
14 SIONS.—Section 1847A(g) of the Social Security Act is
15 amended—

16 (1) by striking “and” at the end of paragraph
17 (4);

18 (2) by striking the period at the end of para-
19 graph (5) and inserting “; and”; and

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

22 “(6) the determination of per beneficiary al-
23 lowed charges of drugs or biologicals and ranking of
24 such charges under subsection (b)(9).”.

1 **SEC. 104. ESTABLISHMENT OF MAXIMUM ADD-ON PAYMENT**
2 **FOR DRUGS AND BIOLOGICALS.**

3 (a) IN GENERAL.—Section 1847A of the Social Secu-
4 rity Act (42 U.S.C. 1395w–3a), as amended by section
5 103, is further amended—

6 (1) in subsection (b)—

7 (A) in paragraph (1), in the matter pre-
8 ceding subparagraph (A), by striking “para-
9 graph (7)” and inserting “paragraphs (7) and
10 (10)”; and

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

13 “(10) MAXIMUM ADD-ON PAYMENT AMOUNT.—

14 “(A) IN GENERAL.—In determining the
15 payment amount under the provisions of sub-
16 paragraph (A), (B), or (C) of paragraph (1) of
17 this subsection, subsection (c)(4)(A)(ii), or sub-
18 section (d)(3)(C) for a drug or biological fur-
19 nished on or after January 1, 2021, if the ap-
20 plicable add-on payment (as defined in subpara-
21 graph (B)) for each drug or biological on a
22 claim for a date of service exceeds the max-
23 imum add-on payment amount specified under
24 subparagraph (C) for the drug or biological,
25 then the payment amount otherwise determined
26 for the drug or biological under those provi-

1 sions, as applicable, shall be reduced by the
2 amount of such excess.

3 “(B) APPLICABLE ADD-ON PAYMENT DE-
4 FINED.—In this paragraph, the term ‘applicable
5 add-on payment’ means the following amounts,
6 determined without regard to the application of
7 subparagraph (A):

8 “(i) In the case of a multiple source
9 drug, an amount equal to the difference
10 between—

11 “(I) the amount that would oth-
12 erwise be applied under paragraph
13 (1)(A); and

14 “(II) the amount that would be
15 applied under such paragraph if ‘100
16 percent’ were substituted for the ap-
17 plicable percent (as defined in para-
18 graph (9)) for such drug.

19 “(ii) In the case of a single source
20 drug or biological, an amount equal to the
21 difference between—

22 “(I) the amount that would oth-
23 erwise be applied under paragraph
24 (1)(B); and

1 “(II) the amount that would be
2 applied under such paragraph if ‘100
3 percent’ were substituted for the ap-
4 plicable percent (as defined in para-
5 graph (9)) for such drug or biological.

6 “(iii) In the case of a biosimilar bio-
7 logical product, the amount otherwise de-
8 termined under paragraph (8)(B).

9 “(iv) In the case of a drug or biologi-
10 cal during the initial period described in
11 subsection (c)(4)(A), an amount equal to
12 the difference between—

13 “(I) the amount that would oth-
14 erwise be applied under subsection
15 (c)(4)(A)(ii); and

16 “(II) the amount that would be
17 applied under such subsection if ‘100
18 percent’ were substituted, as applica-
19 ble, for—

20 “(aa) ‘103 percent’ in sub-
21 clause (I) of such subsection; or

22 “(bb) any percent in excess
23 of 100 percent applied under
24 subclause (II) of such subsection.

1 “(v) In the case of a drug or biological
2 to which subsection (d)(3)(C) applies,
3 an amount equal to the difference between—
4 between—

5 “(I) the amount that would otherwise be applied under such subsection;
6 and
7 section; and

8 “(II) the amount that would be
9 applied under such subsection if ‘100
10 percent’ were substituted, as applicable, for—
11 ble, for—

12 “(aa) any percent in excess
13 of 100 percent applied under
14 clause (i) of such subsection; or

15 “(bb) ‘103 percent’ in clause
16 (ii) of such subsection.

17 “(C) MAXIMUM ADD-ON PAYMENT AMOUNT
18 SPECIFIED.—For purposes of subparagraph
19 (A), the maximum add-on payment amount
20 specified in this subparagraph is—

21 “(i) with respect to a drug or biological
22 cal (other than autologous cellular
23 immunotherapy)—

24 “(I) for each of 2021 through
25 2028, \$1,000; and

1 “(II) for a subsequent year, the
2 amount specified in this subparagraph
3 for the preceding year increased by
4 the percentage increase in the con-
5 sumer price index for all urban con-
6 sumers (all items; United States city
7 average) for the 12-month period end-
8 ing with June of the previous year; or
9 “(ii) with respect to a drug or biologi-
10 cal consisting of autologous cellular
11 immunotherapy—

12 “(I) for each of 2021 through
13 2028, \$2,000; and

14 “(II) for a subsequent year, the
15 amount specified in this subparagraph
16 for the preceding year increased by
17 the percentage increase in the con-
18 sumer price index for all urban con-
19 sumers (all items; United States city
20 average) for the 12-month period end-
21 ing with June of the previous year.

22 Any amount determined under this subpara-
23 graph that is not a multiple of \$10 shall be
24 rounded to the nearest multiple of \$10.”

1 (2) in subsection (c)(4)(A)(ii), by striking “in
2 the case” and inserting “subject to subsection
3 (b)(10), in the case”.

4 (b) CONFORMING AMENDMENTS RELATING TO SEPA-
5 RATELY PAYABLE DRUGS.—

6 (1) OPPS.—Section 1833(t)(14) of the Social
7 Security Act (42 U.S.C. 1395l(t)(14)) is amended—

8 (A) in subparagraph (A)(iii)(II), by insert-
9 ing “, subject to subparagraph (I)” after “are
10 not available”; and

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

13 “(I) APPLICATION OF MAXIMUM ADD-ON
14 PAYMENT FOR SEPARATELY PAYABLE DRUGS
15 AND BIOLOGICALS.—In establishing the amount
16 of payment under subparagraph (A) for a speci-
17 fied covered outpatient drug that is furnished
18 as part of a covered OPD service (or group of
19 services) on or after January 1, 2021, if such
20 payment is determined based on the average
21 price for the year established under section
22 1847A pursuant to clause (iii)(II) of such sub-
23 paragraph, the provisions of subsection (b)(10)
24 of section 1847A shall apply to the amount of
25 payment so established in the same manner as

1 such provisions apply to the amount of payment
2 under section 1847A.”.

3 (2) ASC.—Section 1833(i)(2)(D) of the Social
4 Security Act (42 U.S.C. 1395l(i)(2)(D)) is amend-
5 ed—

6 (A) by moving clause (v) 6 ems to the left;

7 (B) by redesignating clause (vi) as clause
8 (vii); and

9 (C) by inserting after clause (v) the fol-
10 lowing new clause:

11 “(vi) If there is a separate payment
12 under the system described in clause (i) for
13 a drug or biological furnished on or after
14 January 1, 2021, the provisions of sub-
15 section (t)(14)(I) shall apply to the estab-
16 lishment of the amount of payment for the
17 drug or biological under such system in the
18 same manner in which such provisions
19 apply to the establishment of the amount
20 of payment under subsection (t)(14)(A).”.

1 **SEC. 105. TREATMENT OF DRUG ADMINISTRATION SERV-**
2 **ICES FURNISHED BY CERTAIN EXCEPTED**
3 **OFF-CAMPUS OUTPATIENT DEPARTMENTS OF**
4 **A PROVIDER.**

5 Section 1833(t)(16) of the Social Security Act (42
6 12 U.S.C. 1395l(t)(16)) is amended by adding at the end
7 the following new subparagraph:

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

11 “(i) IN GENERAL.—In the case of a
12 covered OPD service that is a drug admin-
13 istration service (as defined by the Sec-
14 retary) furnished by a department of a
15 provider described in clause (ii) or (iv) of
16 paragraph (21)(B), the payment amount
17 for such service furnished on or after Jan-
18 uary 1, 2021, shall be the same payment
19 amount (as determined in paragraph
20 (21)(C)) that would apply if the drug ad-
21 ministration service was furnished by an
22 off-campus outpatient department of a pro-
23 vider (as defined in paragraph (21)(B)).

24 “(ii) APPLICATION WITHOUT REGARD
25 TO BUDGET NEUTRALITY.—The reductions
26 made under this subparagraph—

1 “(I) shall not be considered an
2 adjustment under paragraph (2)(E);
3 and

4 “(II) shall not be implemented in
5 a budget neutral manner.”.

6 **Subtitle B—Drug Price**
7 **Transparency**

8 **SEC. 111. REPORTING ON EXPLANATION FOR DRUG PRICE**
9 **INCREASES.**

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

13 **“PART W—DRUG PRICE REPORTING; DRUG**
14 **VALUE FUND**

15 **“SEC. 3990O. REPORTING ON EXPLANATION FOR DRUG**
16 **PRICE INCREASES.**

17 “(a) DEFINITIONS.—In this section:

18 “(1) MANUFACTURER.—The term ‘manufac-
19 turer’ means the person—

20 “(A) that holds the application for a drug
21 approved under section 505 of the Federal
22 Food, Drug, and Cosmetic Act or licensed
23 under section 351 of this Act; or

24 “(B) who is responsible for setting the
25 wholesale acquisition cost for the drug.

1 “(2) QUALIFYING DRUG.—The term ‘qualifying
2 drug’ means any drug that is approved under sub-
3 section (c) or (j) of section 505 of the Federal Food,
4 Drug, and Cosmetic Act or licensed under subsection
5 (a) or (k) of section 351 of this Act—

6 “(A) that has a wholesale acquisition cost
7 of \$100 or more, adjusted for inflation occur-
8 ring after the date of enactment of this section,
9 for a month’s supply or a typical course of
10 treatment that lasts less than a month, and
11 is—

12 “(i) subject to section 503(b)(1) of
13 the Federal Food, Drug, and Cosmetic
14 Act;

15 “(ii) administered or otherwise dis-
16 pensed to treat a disease or condition af-
17 fecting more than 200,000 persons in the
18 United States; and

19 “(iii) not a vaccine; and

20 “(B) for which, during the previous cal-
21 endar year, at least 1 dollar of the total amount
22 of sales were for individuals enrolled under the
23 Medicare program under title XVIII of the So-
24 cial Security Act (42 U.S.C. 1395 et seq.) or
25 under a State Medicaid plan under title XIX of

1 such Act (42 U.S.C. 1396 et seq.) or under a
2 waiver of such plan.

3 “(3) WHOLESALE ACQUISITION COST.—The
4 term ‘wholesale acquisition cost’ has the meaning
5 given that term in section 1847A(c)(6)(B) of the So-
6 cial Security Act (42 U.S.C. 1395w-3a(c)(6)(B)).

7 “(b) REPORT.—

8 “(1) REPORT REQUIRED.—The manufacturer of
9 a qualifying drug shall submit a report to the Sec-
10 retary—

11 “(A) for each increase in the price of a
12 qualifying drug that results in an increase in
13 the wholesale acquisition cost of that drug that
14 is equal to—

15 “(i) 10 percent or more within a sin-
16 gle calendar year beginning on or after
17 January 1, 2019; or

18 “(ii) 25 percent or more within three
19 consecutive calendar years for which the
20 first such calendar year begins on or after
21 January 1, 2019; and

22 “(B) in the case that the qualifying drug
23 is first covered under title XVIII with respect
24 to an applicable year, if the estimated cost or
25 spending under such title per individual or per

1 user of such drug (as estimated by the Sec-
2 retary) for such applicable year (or per course
3 of treatment in such applicable year, as defined
4 by the Secretary) is at least \$26,000.

5 “(2) REPORT DEADLINE.—Each report de-
6 scribed in paragraph (1) shall be submitted to the
7 Secretary—

8 “(A) in the case of a report with respect
9 to an increase in the price of a qualifying drug
10 that occurs during the period beginning on Jan-
11 uary 1, 2019, and ending on the day that is 60
12 days after the date of enactment of this section,
13 not later than 90 days after such date of enact-
14 ment;

15 “(B) in the case of a report with respect
16 to an increase in the price of a qualifying drug
17 that occurs after the period described in sub-
18 paragraph (A), not later than 30 days prior to
19 the planned effective date of such price increase
20 for such qualifying drug; and

21 “(C) in the case of a report with respect
22 to a qualifying drug that meets the criteria de-
23 scribed in paragraph (1)(B), not later than 30
24 days after such drug meets such criteria.

1 “(c) CONTENTS.—A report under subsection (b), con-
2 sistent with the standard for disclosures described in sec-
3 tion 213.3(d) of title 12, Code of Federal Regulations (as
4 in effect on the date of enactment of this section), shall,
5 at a minimum, include—

6 “(1) with respect to the qualifying drug—

7 “(A) the percentage by which the manufac-
8 turer will raise the wholesale acquisition cost of
9 the drug within the calendar year or three con-
10 secutive calendar years as described in sub-
11 section (b)(1)(A) or (b)(1)(B), if applicable, and
12 the effective date of such price increase;

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

19 “(C) if known and different from the man-
20 ufacturer of the qualifying drug, the identity
21 of—

22 “(i) the sponsor or sponsors of any in-
23 vestigational new drug applications under
24 section 505(i) of the Federal Food, Drug,
25 and Cosmetic Act for clinical investigations

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

4 “(I) for approval of the drug
5 under section 505 of such Act; or

6 “(II) for licensure of the drug
7 under section 351 of this Act; and

8 “(ii) the sponsor of an application for
9 the drug approved under such section 505
10 of the Federal Food, Drug, and Cosmetic
11 Act or licensed under section 351 of this
12 Act;

13 “(D) a description of the history of the
14 manufacturer’s price increases for the drug
15 since the approval of the application for the
16 drug under section 505 of the Federal Food,
17 Drug, and Cosmetic Act or the issuance of the
18 license for the drug under section 351 of this
19 Act, or since the manufacturer acquired such
20 approved application or license, if applicable;

21 “(E) the current wholesale acquisition cost
22 of the drug;

23 “(F) the total expenditures of the manu-
24 facturer on—

1 “(i) materials and manufacturing for
2 such drug; and

3 “(ii) acquiring patents and licensing
4 for such drug;

5 “(G) the percentage of total expenditures
6 of the manufacturer on research and develop-
7 ment for such drug that was derived from Fed-
8 eral funds;

9 “(H) the total expenditures of the manu-
10 facturer on research and development for such
11 drug that is necessary to demonstrate that it
12 meets applicable statutory standards for ap-
13 proval under section 505 of the Federal Food,
14 Drug, and Cosmetic Act or licensure under sec-
15 tion 351 of this Act, as applicable;

16 “(I) the total expenditures of the manufac-
17 turer on pursuing new or expanded indications
18 or dosage changes for such drug under section
19 505 of the Federal Food, Drug, and Cosmetic
20 Act or section 351 of this Act;

21 “(J) the total expenditures of the manufac-
22 turer on carrying out postmarket requirements
23 related to such drug, including under section
24 505(o)(3) of the Federal Food, Drug, and Cos-
25 metic Act;

1 “(K) the total revenue and the net profit
2 generated from the qualifying drug for each cal-
3 endar year since the approval of the application
4 for the drug under section 505 of the Federal
5 Food, Drug, and Cosmetic Act or the issuance
6 of the license for the drug under section 351,
7 or since the manufacturer acquired such ap-
8 proved application or license; and

9 “(L) the total costs associated with mar-
10 keting and advertising for the qualifying drug;
11 “(2) with respect to the manufacturer—

12 “(A) the total revenue and the net profit
13 of the manufacturer for each of the 1-year pe-
14 riod described in subsection (b)(1)(A) or the 3-
15 year period described in subsection (b)(1)(B),
16 as applicable;

17 “(B) all stock-based performance metrics
18 used by the manufacturer to determine execu-
19 tive compensation for each of the 1-year period
20 described in subsection (b)(1)(A) or the 3-year
21 period described in subsection (b)(1)(B), as ap-
22 plicable; and

23 “(C) any additional information the manu-
24 facturer chooses to provide related to drug pric-
25 ing decisions, such as total expenditures on—

1 “(i) drug research and development;

2 or

3 “(ii) clinical trials, including on drugs

4 that failed to receive approval by the Food

5 and Drug Administration; and

6 “(3) such other related information as the Sec-

7 retary considers appropriate and as specified by the

8 Secretary through notice-and-comment rulemaking.

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

15 “(e) CIVIL MONETARY PENALTY.—Any manufac-
16 turer of a qualifying drug that fails to submit a report
17 for the drug as required by this section, following notifica-
18 tion by the Secretary to the manufacturer that the manu-
19 facturer is not in compliance with this section, shall be
20 subject to a civil monetary penalty of \$75,000 for each
21 day on which the violation continues.

22 “(f) FALSE INFORMATION.—Any manufacturer that
23 submits a report for a drug as required by this section
24 that knowingly provides false information in such report

1 is subject to a civil monetary penalty in an amount not
2 to exceed \$75,000 for each item of false information.

3 “(g) PUBLIC POSTING.—

4 “(1) IN GENERAL.—Subject to paragraph (3),
5 the Secretary shall post each report submitted under
6 subsection (b) on the public website of the Depart-
7 ment of Health and Human Services the day the
8 price increase of a qualifying drug is scheduled to go
9 into effect.

10 “(2) FORMAT.—In developing the format in
11 which reports will be publicly posted under para-
12 graph (1), the Secretary shall consult with stake-
13 holders, including beneficiary groups, and shall seek
14 feedback from consumer advocates and readability
15 experts on the format and presentation of the con-
16 tent of such reports to ensure that such reports
17 are—

18 “(A) user-friendly to the public; and

19 “(B) written in plain language that con-
20 sumers can readily understand.

21 “(3) PROTECTED INFORMATION.—Nothing in
22 this section shall be construed to authorize the pub-
23 lic disclosure of information submitted by a manu-
24 facturer that is prohibited from disclosure by appli-
25 cable laws concerning the protection of trade secrets,

1 commercial information, and other information cov-
2 ered under such laws.

3 **“SEC. 39900-1. ANNUAL REPORT TO CONGRESS.**

4 “(a) IN GENERAL.—Subject to subsection (b), the
5 Secretary shall submit to Congress, and post on the public
6 website of the Department of Health and Human Services
7 in a way that is user-friendly to the public and written
8 in plain language that consumers can readily understand,
9 an annual report—

10 “(1) summarizing the information reported pur-
11 suant to section 39900;

12 “(2) including copies of the reports and sup-
13 porting detailed economic analyses submitted pursu-
14 ant to such section;

15 “(3) detailing the costs and expenditures in-
16 curred by the Department of Health and Human
17 Services in carrying out section 39900; and

18 “(4) explaining how the Department of Health
19 and Human Services is improving consumer and
20 provider information about drug value and drug
21 price transparency.

22 “(b) PROTECTED INFORMATION.—Nothing in this
23 section shall be construed to authorize the public disclo-
24 sure of information submitted by a manufacturer that is
25 prohibited from disclosure by applicable laws concerning

1 the protection of trade secrets, commercial information,
2 and other information covered under such laws.”.

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

6 **SEC. 112. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.**

7 Section 1150A of the Social Security Act (42 U.S.C.
8 1320b–23) is amended—

9 (1) in subsection (c), in the matter preceding
10 paragraph (1), by inserting “(other than as per-
11 mitted under subsection (e))” after “disclosed by the
12 Secretary”; and

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

15 “(e) **PUBLIC AVAILABILITY OF CERTAIN INFORMA-**
16 **TION.**—

17 “(1) **IN GENERAL.**—In order to allow the com-
18 parison of PBMs’ ability to negotiate rebates, dis-
19 counts, direct and indirect remuneration fees, ad-
20 ministrative fees, and price concessions and the
21 amount of such rebates, discounts, direct and indi-
22 rect remuneration fees, administrative fees, and
23 price concessions that are passed through to plan
24 sponsors, beginning January 1, 2020, the Secretary
25 shall make available on the Internet website of the

1 Department of Health and Human Services the in-
2 formation with respect to the second preceding cal-
3 endar year provided to the Secretary on generic dis-
4 pensing rates (as described in paragraph (1) of sub-
5 section (b)) and information provided to the Sec-
6 retary under paragraphs (2) and (3) of such sub-
7 section that, as determined by the Secretary, is with
8 respect to each PBM.

9 “(2) AVAILABILITY OF DATA.—In carrying out
10 paragraph (1), the Secretary shall ensure the fol-
11 lowing:

12 “(A) CONFIDENTIALITY.—The information
13 described in such paragraph is displayed in a
14 manner that prevents the disclosure of informa-
15 tion, with respect to an individual drug or an
16 individual plan, on rebates, discounts, direct
17 and indirect remuneration fees, administrative
18 fees, and price concessions.

19 “(B) CLASS OF DRUG.—The information
20 described in such paragraph is made available
21 by class of drug, using an existing classification
22 system, but only if the class contains such num-
23 ber of drugs, as specified by the Secretary (but
24 not fewer than three drugs), to ensure confiden-
25 tiality of proprietary information or other infor-

1 mation that is prevented to be disclosed under
2 subparagraph (A).”.

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

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

9 (1) addresses at minimum—

10 (A) whether pharmacy benefit managers—

11 (i) charge payers a higher price than
12 the reimbursement rate at which the phar-
13 macy benefit managers reimburse com-
14 peting pharmacies;

15 (ii) steer patients for anticompetitive
16 purposes to any pharmacies, including re-
17 tail, mail-order, or any other type of phar-
18 macy, in which the pharmacy benefit man-
19 ager has an ownership interest;

20 (iii) audit or review proprietary data,
21 including acquisition costs, patient infor-
22 mation, or dispensing information, of com-
23 peting pharmacies that can be used for
24 anticompetitive purposes; or

1 (iv) use formulary designs to increase
2 the market share of higher cost prescrip-
3 tion drugs and depress the market share of
4 lower cost prescription drugs (each net of
5 rebates and discounts);

6 (B) how companies and payers assess the
7 benefits, costs, and risks of contracting with
8 intermediaries, including pharmacy services ad-
9 ministrative organizations, and whether more
10 information about the roles of intermediaries
11 should be available to consumers and payers;
12 and

13 (C) whether there are any specific legal or
14 regulatory obstacles the Commission currently
15 faces in ensuring a competitive and transparent
16 marketplace in the pharmaceutical supply
17 chain, including the pharmacy benefit manager
18 marketplace and pharmacy services administra-
19 tive organizations; and

20 (2) provides—

21 (A) observations or conclusions drawn
22 from the November 2017 roundtable entitled
23 “Understanding Competition in Prescription
24 Drug Markets: Entry and Supply Chain Dy-
25 namics”, and any similar efforts;

1 (B) specific actions the Commission in-
2 tends to take as a result of the November 2017
3 roundtable, and any similar efforts, including a
4 detailed description of relevant forthcoming ac-
5 tions, additional research or roundtable discus-
6 sions, consumer education efforts, or enforce-
7 ment actions; and

8 (C) policy or legislative recommendations
9 to—

10 (i) improve transparency and competi-
11 tion in the pharmaceutical supply chain;

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

15 (iii) best ensure that consumers ben-
16 efit from any cost savings or efficiencies
17 that may result from mergers and consoli-
18 dations.

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

25 (c) DEFINITIONS.—In this section:

1 (1) APPROPRIATE COMMITTEES OF CON-
2 GRESS.—The term “appropriate committees of Con-
3 gress” means—

4 (A) the Committee on Energy and Com-
5 merce of the House of Representatives;

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

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

10 (2) COMMISSION.—The term “Commission”
11 means the Federal Trade Commission.

12 **SEC. 114. REQUIRING CERTAIN MANUFACTURERS TO RE-**
13 **PORT DRUG PRICING INFORMATION WITH**
14 **RESPECT TO DRUGS UNDER THE MEDICARE**
15 **PROGRAM.**

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

18 (1) in subsection (b)—

19 (A) in paragraph (2)(A), by inserting “or
20 subsection (f)(2), as applicable” before the pe-
21 riod at the end;

22 (B) in paragraph (3), in the matter pre-
23 ceding subparagraph (A), by inserting “or sub-
24 section (f)(2), as applicable,” before “deter-
25 mined by”; and

1 (C) in paragraph (6)(A), in the matter
2 preceding clause (i), by inserting “or subsection
3 (f)(2), as applicable,” before “determined by”;
4 and
5 (2) in subsection (f)—

6 (A) by striking “For requirements” and
7 inserting the following:

8 “(1) IN GENERAL.—For requirements”; and

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

11 “(2) MANUFACTURERS WITHOUT A REBATE
12 AGREEMENT UNDER TITLE XIX.—

13 “(A) IN GENERAL.—If the manufacturer
14 of a drug or biological described in subpara-
15 graph (C), (E), or (G) of section 1842(o)(1) or
16 in section 1881(b)(14)(B) that is payable under
17 this part has not entered into and does not
18 have in effect a rebate agreement described in
19 subsection (b) of section 1927, for calendar
20 quarters beginning on or after January 1,
21 2020, such manufacturer shall report to the
22 Secretary the information described in sub-
23 section (b)(3)(A)(iii) of such section 1927 with
24 respect to such drug or biological in a time and
25 manner specified by the Secretary. For pur-

1 poses of applying this paragraph, a drug or bio-
2 logical described in the previous sentence in-
3 cludes items, services, supplies, and products
4 that are payable under this part as a drug or
5 biological.

6 “(B) AUDIT.—Information reported under
7 subparagraph (A) is subject to audit by the In-
8 specter General of the Department of Health
9 and Human Services.

10 “(C) VERIFICATION.—The Secretary may
11 survey wholesalers and manufacturers that di-
12 rectly distribute drugs described in subpara-
13 graph (A), when necessary, to verify manufac-
14 turer prices and manufacturer’s average sales
15 prices (including wholesale acquisition cost) if
16 required to make payment reported under sub-
17 paragraph (A). The Secretary may impose a
18 civil monetary penalty in an amount not to ex-
19 ceed \$100,000 on a wholesaler, manufacturer,
20 or direct seller, if the wholesaler, manufacturer,
21 or direct seller of such a drug refuses a request
22 for information about charges or prices by the
23 Secretary in connection with a survey under
24 this subparagraph or knowingly provides false
25 information. The provisions of section 1128A

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

7 “(D) CONFIDENTIALITY.—Notwith-
8 standing any other provision of law, information
9 disclosed by manufacturers or wholesalers
10 under this paragraph (other than the wholesale
11 acquisition cost for purposes of carrying out
12 this section) is confidential and shall not be dis-
13 closed by the Secretary in a form which dis-
14 closes the identity of a specific manufacturer or
15 wholesaler or prices charged for drugs by such
16 manufacturer or wholesaler, except—

17 “(i) as the Secretary determines to be
18 necessary to carry out this section (includ-
19 ing the determination and implementation
20 of the payment amount), or to carry out
21 section 1847B;

22 “(ii) to permit the Comptroller Gen-
23 eral of the United States to review the in-
24 formation provided; and

1 “(iii) to permit the Director of the
2 Congressional Budget Office to review the
3 information provided.”.

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

6 (1) in subsection (d)(4)—

7 (A) in subparagraph (A), by striking “IN
8 GENERAL” and inserting “MISREPRESENTA-
9 TION”;

10 (B) in subparagraph (B), by striking “sub-
11 paragraph (B)” and inserting “subparagraph
12 (A), (B), or (C)”;

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

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

17 “(B) FAILURE TO PROVIDE TIMELY INFOR-
18 MATION.—If the Secretary determines that a
19 manufacturer described in subsection (f)(2) has
20 failed to report on information described in sec-
21 tion 1927(b)(3)(A)(iii) with respect to a drug or
22 biological in accordance with such subsection,
23 the Secretary shall apply a civil money penalty
24 in an amount of \$10,000 for each day the man-

1 manufacturer has failed to report such information
2 and such amount shall be paid to the Treasury.

3 “(C) FALSE INFORMATION.—Any manu-
4 facturer required to submit information under
5 subsection (f)(2) that knowingly provides false
6 information is subject to a civil money penalty
7 in an amount not to exceed \$100,000 for each
8 item of false information. Such civil money pen-
9 alties are in addition to other penalties as may
10 be prescribed by law.”; and

11 (2) in subsection (c)(6)(A), by striking the pe-
12 riod at the end and inserting “, except that, for pur-
13 poses of subsection (f)(2), the Secretary may, if the
14 Secretary determines appropriate, exclude repack-
15 agers of a drug or biological from such term.”.

16 (c) MANUFACTURERS WITH A REBATE AGREE-
17 MENT.—

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

1 (2) TECHNICAL AMENDMENT.—Section
2 1927(b)(3)(A)(iii) of the Social Security Act (42
3 U.S.C. 1396r–8(b)(3)(A)(iii)) is amended by striking
4 “section 1881(b)(13)(A)(ii)” and inserting “section
5 1881(b)(14)(B)”.

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

14 **SEC. 115. MAKING PRESCRIPTION DRUG MARKETING SAM-**
15 **PLE INFORMATION REPORTED BY MANUFAC-**
16 **TURERS AVAILABLE TO CERTAIN INDIVID-**
17 **UALS AND ENTITIES.**

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

20 (1) by redesignating subsection (b) as sub-
21 section (e); and

22 (2) by inserting after subsection (a) the fol-
23 lowing new subsections:

24 “(b) DATA SHARING AGREEMENTS.—

1 “(1) IN GENERAL.—The Secretary shall enter
2 into agreements with the specified data sharing indi-
3 viduals and entities described in paragraph (2)
4 under which—

5 “(A) upon request of such an individual or
6 entity, as applicable, the Secretary makes avail-
7 able to such individual or entity the information
8 submitted under subsection (a) by manufactur-
9 ers and authorized distributors of record; and

10 “(B) such individual or entity agrees to
11 not disclose publicly or to another individual or
12 entity any information that identifies a par-
13 ticular practitioner or health care facility.

14 “(2) SPECIFIED DATA SHARING INDIVIDUALS
15 AND ENTITIES.—For purposes of paragraph (1), the
16 specified data sharing individuals and entities de-
17 scribed in this paragraph are the following:

18 “(A) OVERSIGHT AGENCIES.—Health over-
19 sight agencies (as defined in section 164.501 of
20 title 45, Code of Federal Regulations), includ-
21 ing the Centers for Medicare & Medicaid Serv-
22 ices, the Office of the Inspector General of the
23 Department of Health and Human Services, the
24 Government Accountability Office, the Congres-
25 sional Budget Office, the Medicare Payment

1 Advisory Commission, and the Medicaid and
2 CHIP Payment and Access Commission.

3 “(B) RESEARCHERS.—Individuals who
4 conduct scientific research (as defined in sec-
5 tion 164.501 of title 45, Code of Federal Regu-
6 lations) in relevant areas as determined by the
7 Secretary.

8 “(C) PAYERS.—Private and public health
9 care payers, including group health plans,
10 health insurance coverage offered by health in-
11 surance issuers, Federal health programs, and
12 State health programs.

13 “(3) EXEMPTION FROM FREEDOM OF INFORMA-
14 TION ACT.—Except as described in paragraph (1),
15 the Secretary may not be compelled to disclose the
16 information submitted under subsection (a) to any
17 individual or entity. For purposes of section 552 of
18 title 5, United States Code (commonly referred to as
19 the Freedom of Information Act), this paragraph
20 shall be considered a statute described in subsection
21 (b)(3)(B) of such section.

22 “(c) PENALTIES.—

23 “(1) DATA SHARING AGREEMENTS.—Subject to
24 paragraph (3), any specified data sharing individual
25 or entity described in subsection (b)(2) that violates

1 the terms of a data sharing agreement the individual
2 or entity has with the Secretary under subsection
3 (b)(1) shall be subject to a civil money penalty of
4 not less than \$1,000, but not more than \$10,000,
5 for each such violation. Such penalty shall be im-
6 posed and collected in the same manner as civil
7 money penalties under subsection (a) of section
8 1128A are imposed and collected under that section.

9 “(2) FAILURE TO REPORT.—Subject to para-
10 graph (3), any manufacturer or authorized dis-
11 tributor of record of an applicable drug under sub-
12 section (a) that fails to submit information required
13 under such subsection in a timely manner in accord-
14 ance with rules or regulations promulgated to carry
15 out such subsection shall be subject to a civil money
16 penalty of not less than \$1,000, but not more than
17 \$10,000, for each such failure. Such penalty shall be
18 imposed and collected in the same manner as civil
19 money penalties under subsection (a) of section
20 1128A are imposed and collected under that section.

21 “(3) LIMITATION.—The total amount of civil
22 money penalties imposed under paragraph (1) or (2)
23 with respect to a year and an individual or entity de-
24 scribed in paragraph (1) or a manufacturer or dis-

1 tributor described in paragraph (2), respectively,
2 shall not exceed \$150,000.

3 “(d) DRUG SAMPLE DISTRIBUTION INFORMATION.—

4 “(1) IN GENERAL.—Not later than January 1
5 of each year (beginning with 2021), the Secretary
6 shall maintain a list containing information related
7 to the distribution of samples of applicable drugs.
8 Such list shall provide the following information with
9 respect to the preceding year:

10 “(A) The name of the manufacturer or au-
11 thorized distributor of record of an applicable
12 drug for which samples were requested or dis-
13 tributed under this section.

14 “(B) The quantity and class of drug sam-
15 ples requested.

16 “(C) The quantity and class of drug sam-
17 ples distributed.

18 “(2) PUBLIC AVAILABILITY.—The Secretary
19 shall make the information in such list available to
20 the public on the Internet website of the Food and
21 Drug Administration.”.

22 (b) FDA MAINTENANCE OF INFORMATION.—The
23 Food and Drug Administration shall maintain information
24 available to affected reporting companies to ensure their

1 ability to fully comply with the requirements of section
2 1128H of the Social Security Act.

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

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

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

9 “(5) No person may distribute a drug sample of a
10 drug that is—

11 “(A) an applicable drug (as defined in section
12 1128H(e) of the Social Security Act);

13 “(B) a controlled substance (as defined in sec-
14 tion 102 of the Controlled Substances Act) for which
15 the findings required under section 202(b)(2) of
16 such Act have been made; and

17 “(C) approved under section 505 for use in the
18 management or treatment of pain (other than for
19 the management or treatment of a substance use
20 disorder).”.

21 (d) MEDPAC REPORT.—Not later than 3 years after
22 the date of the enactment of this Act, the Medicare Pay-
23 ment Advisory Commission shall conduct a study on the
24 impact of drug samples on provider prescribing practices

1 and health care costs and may, as the Commission deems
2 appropriate, make recommendations on such study.

3 **SEC. 116. REQUIRING PRESCRIPTION DRUG PLAN SPON-**
4 **SORS TO INCLUDE REAL-TIME BENEFIT IN-**
5 **FORMATION AS PART OF SUCH SPONSOR'S**
6 **ELECTRONIC PRESCRIPTION PROGRAM**
7 **UNDER THE MEDICARE PROGRAM.**

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

10 (1) in subparagraph (D), by striking “To the
11 extent” and inserting “Except as provided in sub-
12 paragraph (F), to the extent”; and

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

15 “(F) REAL-TIME BENEFIT INFORMA-
16 TION.—

17 “(i) IN GENERAL.—Not later than
18 January 1, 2021, the program shall imple-
19 ment real-time benefit tools that are capa-
20 ble of integrating with a prescribing health
21 care professional’s electronic prescribing or
22 electronic health record system for the
23 transmission of formulary and benefit in-
24 formation in real time to prescribing health
25 care professionals. With respect to a cov-

1 ered part D drug, such tools shall be capa-
2 ble of transmitting such information spe-
3 cific to an individual enrolled in a prescrip-
4 tion drug plan. Such information shall in-
5 clude the following:

6 “(I) A list of any clinically-appro-
7 priate alternatives to such drug in-
8 cluded in the formulary of such plan.

9 “(II) Cost-sharing information
10 for such drug and such alternatives,
11 including a description of any vari-
12 ance in cost-sharing based on the
13 pharmacy dispensing such drug or
14 such alternatives.

15 “(III) Information relating to
16 whether such drug is included in the
17 formulary of such plan and any prior
18 authorization or other utilization man-
19 agement requirements applicable to
20 such drug and such alternatives so in-
21 cluded.

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

1 clause (i) in the same manner as such pro-
2 visions apply with respect to an electronic
3 transmission described in clause (i) of such
4 subparagraph.

5 “(iii) SPECIAL RULE FOR 2021.—The
6 program shall be deemed to be in compli-
7 ance with clause (i) for 2021 if the pro-
8 gram complies with the provisions of sec-
9 tion 423.160(b)(7) of title 42, Code of
10 Federal Regulations (or a successor regula-
11 tion), for such year.

12 “(iv) RULE OF CONSTRUCTION.—
13 Nothing in this subparagraph shall be con-
14 strued as to allow a real-time benefits tool
15 to steer an individual, without the consent
16 of the individual, to a particular pharmacy
17 or pharmacy setting over their preferred
18 pharmacy setting nor prohibit the designa-
19 tion of a preferred pharmacy under such
20 tool.”.

21 **SEC. 117. SENSE OF CONGRESS REGARDING THE NEED TO**
22 **EXPAND COMMERCIALY AVAILABLE DRUG**
23 **PRICING COMPARISON PLATFORMS.**

24 It is the sense of Congress that—

1 (1) commercially available drug pricing com-
2 parison platforms can, at no cost, help patients find
3 the lowest price for their medications at their local
4 pharmacy;

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

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

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

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

16 **SEC. 118. TECHNICAL CORRECTIONS.**

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

20 “(4) APPLICATION OF AUTHORITIES UNDER IN-
21 SPECTOR GENERAL ACT OF 1978.—In carrying out
22 this subsection, the Inspector General shall have the
23 same authorities as provided under section 6 of the
24 Inspector General Act of 1978 (5 U.S.C. App.).”.

1 (b) EFFECTIVE DATE.—The amendment made by
2 subsection (a) shall take effect as if included in the enact-
3 ment of the 21st Century Cures Act (Public Law 114–
4 255).

5 **Subtitle C—Medicare Part D** 6 **Benefit Redesign**

7 **SEC. 121. MEDICARE PART D BENEFIT REDESIGN.**

8 (a) BENEFIT STRUCTURE REDESIGN.—Section
9 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
10 102(b)) is amended—

11 (1) in paragraph (2)—

12 (A) in subparagraph (A)—

13 (i) in the matter preceding clause (i),
14 by inserting “for a year preceding 2022
15 and for costs above the annual deductible
16 specified in paragraph (1) and up to the
17 annual out-of-pocket threshold specified in
18 paragraph (4)(B) for 2022 and each subse-
19 quent year” after “paragraph (3)”; and

20 (ii) in clause (i), by inserting after
21 “25 percent” the following: “(or, for 2022
22 and each subsequent year, 15 percent)”;
23

(B) in subparagraph (C)—

24 (i) in clause (i), in the matter pre-
25 ceding subclause (I), by inserting “for a

1 year preceding 2022,” after “paragraph
2 (4),”; and

3 (ii) in clause (ii)(III), by striking
4 “and each subsequent year” and inserting
5 “and 2021”; and

6 (C) in subparagraph (D)—

7 (i) in clause (i)—

8 (I) in the matter preceding sub-
9 clause (I), by inserting “for a year
10 preceding 2022,” after “paragraph
11 (4),”; and

12 (II) in subclause (I)(bb), by
13 striking “a year after 2018” and in-
14 serting “each of years 2018 through
15 2021”; and

16 (ii) in clause (ii)(V), by striking
17 “2019 and each subsequent year” and in-
18 serting “each of years 2019 through
19 2021”;

20 (2) in paragraph (3)(A)—

21 (A) in the matter preceding clause (i), by
22 inserting “for a year preceding 2022,” after
23 “and (4),”; and

1 (B) in clause (ii), by striking “for a subse-
2 quent year” and inserting “for each of years
3 2007 through 2021”;

4 (3) in paragraph (4)—

5 (A) in subparagraph (A)—

6 (i) in clause (i)—

7 (I) by redesignating subclauses
8 (I) and (II) as items (aa) and (bb),
9 respectively, and indenting appro-
10 priately;

11 (II) in the matter preceding item
12 (aa), as redesignated by subclause (I),
13 by striking “is equal to the greater
14 of—” and inserting “is equal to—

15 “(I) for a year preceding 2022,
16 the greater of—”.

17 (III) by striking the period at the
18 end of item (bb), as redesignated by
19 subclause (I), and inserting “; and”;
20 and

21 (IV) by adding at the end the fol-
22 lowing:

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

25 (ii) in clause (ii)—

1 (I) by striking “clause (i)(I)” and
2 inserting “clause (i)(I)(aa)”; and

3 (II) by adding at the end the fol-
4 lowing new sentence: “The Secretary
5 shall continue to calculate the dollar
6 amounts specified in clause (i)(I)(aa),
7 including with the adjustment under
8 this clause, after 2021 for purposes of
9 section 1860D–14(a)(1)(D)(iii).”;

10 (B) in subparagraph (B)—

11 (i) in clause (i)—

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

14 (II) in subclause (VI)—

15 (aa) by striking “for a sub-
16 sequent year” and inserting “for
17 2021”; and

18 (bb) by striking the period
19 at the end and inserting a semi-
20 colon; and

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

23 “(VII) for 2022, is equal to
24 \$3,100; or

1 “(VIII) for a subsequent year, is
2 equal to the amount specified in this
3 subparagraph for the previous year,
4 increased by the annual percentage in-
5 crease described in paragraph (6) for
6 the year involved.”; and

7 (ii) in clause (ii), by striking “clause
8 (i)(II)” and inserting “clause (i)”;

9 (C) in subparagraph (C)(i), by striking
10 “and for amounts” and inserting “and for a
11 year preceding 2022 for amounts”; and

12 (D) in subparagraph (E), by striking “In
13 applying” and inserting “For each of 2011
14 through 2021, in applying”.

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

18 (1) by striking “equal to 80 percent” and in-
19 serting “equal to—

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

22 (2) in subparagraph (A), as added by para-
23 graph (1), by striking the period at the end and in-
24 serting “; and”; and

1 (3) by adding at the end the following new sub-
2 paragraph:

3 “(B) for 2022 and each subsequent year,
4 the sum of—

5 “(i) an amount equal to 20 percent of
6 the allowable reinsurance costs (as speci-
7 fied in paragraph (2)) attributable to that
8 portion of gross covered prescription drug
9 costs as specified in paragraph (3) in-
10 curred in the coverage year after such indi-
11 vidual has incurred costs that exceed the
12 annual out-of-pocket threshold specified in
13 section 1860D–2(b)(4)(B) with respect to
14 applicable drugs (as defined in section
15 1860D–14B(g)(2)); and

16 “(ii) an amount equal to 30 percent of
17 the allowable reinsurance costs (as speci-
18 fied in paragraph (2)) attributable to that
19 portion of gross covered prescription drug
20 costs as specified in paragraph (3) in-
21 curred in the coverage year after such indi-
22 vidual has incurred costs that exceed the
23 annual out-of-pocket threshold specified in
24 section 1860D–2(b)(4)(B) with respect to

1 covered part D drugs that are not applica-
2 ble drugs (as so defined).”.

3 (c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

9 “(a) ESTABLISHMENT.—The Secretary shall estab-
10 lish a manufacturer discount program (in this section re-
11 ferred to as the ‘program’). Under the program, the Sec-
12 retary shall enter into agreements described in subsection
13 (b) with manufacturers and provide for the performance
14 of the duties described in subsection (c). The Secretary
15 shall establish a model agreement for use under the pro-
16 gram by not later than January 1, 2021, in consultation
17 with manufacturers, and allow for comment on such model
18 agreement.

19 “(b) TERMS OF AGREEMENT.—

20 “(1) IN GENERAL.—

21 “(A) AGREEMENT.—An agreement under
22 this section shall require the manufacturer to
23 provide applicable beneficiaries access to dis-
24 counted prices for applicable drugs of the man-

1 manufacturer that are dispensed on or after Janu-
2 ary 1, 2022.

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

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

15 “(3) COMPLIANCE WITH REQUIREMENTS FOR
16 ADMINISTRATION OF PROGRAM.—Each manufac-
17 turer with an agreement in effect under this section
18 shall comply with requirements imposed by the Sec-
19 retary or a third party with a contract under sub-
20 section (d)(3), as applicable, for purposes of admin-
21 istering the program, including any determination
22 under subparagraph (A) of subsection (c)(1) or pro-
23 cedures established under such subsection (c)(1).

24 “(4) LENGTH OF AGREEMENT.—

1 “(A) IN GENERAL.—An agreement under
2 this section shall be effective for an initial pe-
3 riod of not less than 12 months and shall be
4 automatically renewed for a period of not less
5 than 1 year unless terminated under subpara-
6 graph (B).

7 “(B) TERMINATION.—

8 “(i) BY THE SECRETARY.—The Sec-
9 retary may provide for termination of an
10 agreement under this section for a knowing
11 and willful violation of the requirements of
12 the agreement or other good cause shown.
13 Such termination shall not be effective ear-
14 lier than 30 days after the date of notice
15 to the manufacturer of such termination.
16 The Secretary shall provide, upon request,
17 a manufacturer with a hearing concerning
18 such a termination, and such hearing shall
19 take place prior to the effective date of the
20 termination with sufficient time for such
21 effective date to be repealed if the Sec-
22 retary determines appropriate.

23 “(ii) BY A MANUFACTURER.—A man-
24 ufacturer may terminate an agreement
25 under this section for any reason. Any

1 such termination shall be effective, with re-
2 spect to a plan year—

3 “(I) if the termination occurs be-
4 fore January 30 of a plan year, as of
5 the day after the end of the plan year;
6 and

7 “(II) if the termination occurs on
8 or after January 30 of a plan year, as
9 of the day after the end of the suc-
10 ceeding plan year.

11 “(iii) EFFECTIVENESS OF TERMI-
12 NATION.—Any termination under this sub-
13 paragraph shall not affect discounts for
14 applicable drugs of the manufacturer that
15 are due under the agreement before the ef-
16 fective date of its termination.

17 “(iv) NOTICE TO THIRD PARTY.—The
18 Secretary shall provide notice of such ter-
19 mination to a third party with a contract
20 under subsection (d)(3) within not less
21 than 30 days before the effective date of
22 such termination.

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

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

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

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

7 “(A) the determination of the amount of
8 the discounted price of an applicable drug of a
9 manufacturer;

10 “(B) the establishment of procedures
11 under which discounted prices are provided to
12 applicable beneficiaries at pharmacies or by
13 mail order service at the point-of-sale of an ap-
14 plicable drug;

15 “(C) the establishment of procedures to
16 ensure that, not later than the applicable num-
17 ber of calendar days after the dispensing of an
18 applicable drug by a pharmacy or mail order
19 service, the pharmacy or mail order service is
20 reimbursed for an amount equal to the dif-
21 ference between—

22 “(i) the negotiated price of the appli-
23 cable drug; and

24 “(ii) the discounted price of the appli-
25 cable drug;

1 “(D) the establishment of procedures to
2 ensure that the discounted price for an applica-
3 ble drug under this section is applied before any
4 coverage or financial assistance under other
5 health benefit plans or programs that provide
6 coverage or financial assistance for the pur-
7 chase or provision of prescription drug coverage
8 on behalf of applicable beneficiaries as the Sec-
9 retary may specify; and

10 “(E) providing a reasonable dispute resolu-
11 tion mechanism to resolve disagreements be-
12 tween manufacturers, applicable beneficiaries,
13 and the third party with a contract under sub-
14 section (d)(3).

15 “(2) MONITORING COMPLIANCE.—

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

19 “(B) NOTIFICATION.—If a third party
20 with a contract under subsection (d)(3) deter-
21 mines that the manufacturer is not in compli-
22 ance with such agreement, the third party shall
23 notify the Secretary of such noncompliance for
24 appropriate enforcement under subsection (e).

1 “(3) COLLECTION OF DATA FROM PRESCRIP-
2 TION DRUG PLANS AND MA-PD PLANS.—The Sec-
3 retary may collect appropriate data from prescrip-
4 tion drug plans and MA-PD plans in a timeframe
5 that allows for discounted prices to be provided for
6 applicable drugs under this section.

7 “(d) ADMINISTRATION.—

8 “(1) IN GENERAL.—Subject to paragraph (2),
9 the Secretary shall provide for the implementation of
10 this section, including the performance of the duties
11 described in subsection (e).

12 “(2) LIMITATION.—In providing for the imple-
13 mentation of this section, the Secretary shall not re-
14 ceive or distribute any funds of a manufacturer
15 under the program.

16 “(3) CONTRACT WITH THIRD PARTIES.—The
17 Secretary shall enter into a contract with 1 or more
18 third parties to administer the requirements estab-
19 lished by the Secretary in order to carry out this
20 section. At a minimum, the contract with a third
21 party under the preceding sentence shall require
22 that the third party—

23 “(A) receive and transmit information be-
24 tween the Secretary, manufacturers, and other

1 individuals or entities the Secretary determines
2 appropriate;

3 “(B) receive, distribute, or facilitate the
4 distribution of funds of manufacturers to ap-
5 propriate individuals or entities in order to
6 meet the obligations of manufacturers under
7 agreements under this section;

8 “(C) provide adequate and timely informa-
9 tion to manufacturers, consistent with the
10 agreement with the manufacturer under this
11 section, as necessary for the manufacturer to
12 fulfill its obligations under this section; and

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

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

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

4 “(e) ENFORCEMENT.—

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

8 “(2) CIVIL MONEY PENALTY.—

9 “(A) IN GENERAL.—The Secretary shall
10 impose a civil money penalty on a manufacturer
11 that fails to provide applicable beneficiaries dis-
12 counts for applicable drugs of the manufacturer
13 in accordance with such agreement for each
14 such failure in an amount the Secretary deter-
15 mines is commensurate with the sum of—

16 “(i) the amount that the manufac-
17 turer would have paid with respect to such
18 discounts under the agreement, which will
19 then be used to pay the discounts which
20 the manufacturer had failed to provide;
21 and

22 “(ii) 25 percent of such amount.

23 “(B) APPLICATION.—The provisions of
24 section 1128A (other than subsections (a) and
25 (b)) shall apply to a civil money penalty under

1 this paragraph in the same manner as such
2 provisions apply to a penalty or proceeding
3 under section 1128A(a).

4 “(f) CLARIFICATION REGARDING AVAILABILITY OF
5 OTHER COVERED PART D DRUGS.—Nothing in this sec-
6 tion shall prevent an applicable beneficiary from pur-
7 chasing a covered part D drug that is not on the formulary
8 of the prescription drug plan or MA–PD plan that the
9 applicable beneficiary is enrolled in.

10 “(g) DEFINITIONS.—In this section:

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

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

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

18 “(C) has incurred costs for covered part D
19 drugs in the year that are equal to or exceed
20 the annual deductible specified in section
21 1860D–2(b)(1) for such year.

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

1 “(A) approved under a new drug applica-
2 tion under section 505(c) of the Federal Food,
3 Drug, and Cosmetic Act or, in the case of a bio-
4 logic product, licensed under section 351 of the
5 Public Health Service Act (including a product
6 licensed under subsection (k) of such section);
7 and

8 “(B)(i) if the PDP sponsor of the prescrip-
9 tion drug plan or the MA organization offering
10 the MA–PD plan uses a formulary, which is on
11 the formulary of the prescription drug plan or
12 MA–PD plan that the applicable beneficiary is
13 enrolled in;

14 “(ii) if the PDP sponsor of the prescrip-
15 tion drug plan or the MA organization offering
16 the MA–PD plan does not use a formulary, for
17 which benefits are available under the prescrip-
18 tion drug plan or MA–PD plan that the appli-
19 cable beneficiary is enrolled in; or

20 “(iii) is provided through an exception or
21 appeal.

22 “(3) APPLICABLE NUMBER OF CALENDAR
23 DAYS.—The term ‘applicable number of calendar
24 days’ means—

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

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

5 “(4) DISCOUNTED PRICE.—

6 “(A) IN GENERAL.—The term ‘discounted
7 price’ means, with respect to an applicable drug
8 of a manufacturer furnished during a year to
9 an applicable beneficiary, 90 percent of the ne-
10 gotiated price of such drug.

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

15 “(C) SPECIAL CASE FOR CLAIMS SPANNING
16 DEDUCTIBLE.—In the case where the entire
17 amount of the negotiated price of an individual
18 claim for an applicable drug with respect to an
19 applicable beneficiary does not fall at or above
20 the annual deductible specified in section
21 1860D–2(b)(1) for the year, the manufacturer
22 of the applicable drug shall provide the dis-
23 counted price under this section on only the
24 portion of the negotiated price of the applicable

1 drug that falls at or above such annual deduct-
2 ible.

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

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

18 “(7) QUALIFIED RETIREE PRESCRIPTION DRUG
19 PLAN.—The term ‘qualified retiree prescription drug
20 plan’ has the meaning given such term in section
21 11860D–22(a)(2).”.

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

1 (A) in subsection (a), in the first sentence,
2 by striking “The Secretary” and inserting
3 “Subject to subsection (h), the Secretary”; and

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

6 “(h) SUNSET OF PROGRAM.—

7 “(1) IN GENERAL.—The program shall not
8 apply to applicable drugs dispensed on or after Jan-
9 uary 1, 2022, and, subject to paragraph (2), agree-
10 ments under this section shall be terminated as of
11 such date.

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

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

22 (A) in subsection (b)(2)(C)(iii)—

23 (i) by striking “assumptions regarding
24 the reinsurance” and inserting “assump-
25 tions regarding—

1 “(I) the reinsurance”; and

2 (ii) by adding at the end the fol-
3 lowing:

4 “(II) for 2022 and each subse-
5 quent year, the manufacturer dis-
6 counts provided under section 1860D-
7 14B subtracted from the actuarial
8 value to produce such bid; and”;

9 (B) in subsection (c)(1)(C)—

10 (i) by striking “an actuarial valuation
11 of the reinsurance” and inserting “an ac-
12 tuarial valuation of—

13 “(i) the reinsurance”;

14 (ii) in clause (i), as added by clause
15 (i) of this subparagraph, by adding “and”
16 at the end; and

17 (iii) by adding at the end the fol-
18 lowing:

19 “(ii) for 2022 and each subsequent
20 year, the manufacturer discounts provided
21 under section 1860D-14B;”.

22 (d) DETERMINATION OF ALLOWABLE REINSURANCE
23 COSTS.—Section 1860D-15(b) of the Social Security Act
24 (42 U.S.C. 1395w-115(b)) is amended—

25 (1) in paragraph (2)—

1 (A) by striking “COSTS.—For purposes”
2 and inserting “COSTS.—

3 “(A) IN GENERAL.—Subject to subpara-
4 graph (B), for purposes”.

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

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

17 (2) in paragraph (3)—

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

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

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

6 “(3) UPDATING RISK ADJUSTMENT METH-
7 ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA-
8 TION REDESIGN.—The Secretary shall update the
9 risk adjustment model used to adjust bid amounts
10 pursuant to this subsection as appropriate to take
11 into account changes in benefits under this part pur-
12 suant to the amendments made by section 121 of
13 the Lower Costs, More Cures Act of 2019.”.

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

17 (1) in subsection (a)—

18 (A) in paragraph (2), by striking “and” at
19 the end;

20 (B) in paragraph (3), by striking the pe-
21 riod at the end and inserting a semicolon; and

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

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

1 “(5) have entered into and have in effect an
2 agreement described in subsection (b) of such sec-
3 tion 1860D–14B with the Secretary; and

4 “(6) have entered into and have in effect, under
5 terms and conditions specified by the Secretary, a
6 contract with a third party that the Secretary has
7 entered into a contract with under subsection (d)(3)
8 of such section 1860D–14B.”;

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

11 “(b) EFFECTIVE DATE.—Paragraphs (1) through (3)
12 of subsection (a) shall apply to covered part D drugs dis-
13 pensed under this part on or after January 1, 2011, and
14 before January 1, 2022, and paragraphs (4) through (6)
15 of such subsection shall apply to covered part D drugs
16 dispensed on or after January 1, 2022.”; and

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

19 “(2) the Secretary determines that in the period
20 beginning on January 1, 2011, and ending on De-
21 cember 31, 2011 (with respect to paragraphs (1)
22 through (3) of subsection (a)) or the period begin-
23 ning on January 1, 2022, and ending December 31,
24 2022 (with respect to paragraphs (4) through (6) of

1 such subsection), there were extenuating cir-
2 cumstances.”.

3 (g) CONFORMING AMENDMENTS.—

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

6 (A) in subsection (a)(2)(A)(i)(I), by strik-
7 ing “, or an increase in the initial” and insert-
8 ing “or for a year preceding 2022 an increase
9 in the initial”;

10 (B) in subsection (c)(1)(C)—

11 (i) in the subparagraph heading, by
12 striking “AT INITIAL COVERAGE LIMIT”;
13 and

14 (ii) by inserting “for a year preceding
15 2022 or the annual out-of-pocket threshold
16 specified in subsection (b)(4)(B) for the
17 year for 2022 and each subsequent year”
18 after “subsection (b)(3) for the year” each
19 place it appears; and

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

23 (2) Section 1860D–4(a)(4)(B)(i) of the Social
24 Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is

1 amended by striking “the initial” and inserting “for
2 a year preceding 2022, the initial”.

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

5 (A) in paragraph (1)—

6 (i) in subparagraph (C), by striking
7 “The continuation” and inserting “For a
8 year preceding 2022, the continuation”;

9 (ii) in subparagraph (D)(iii), by strik-
10 ing “1860D–2(b)(4)(A)(i)(I)” and insert-
11 ing “1860D–2(b)(4)(A)(i)(I)(aa)”; and

12 (iii) in subparagraph (E), by striking
13 “The elimination” and inserting “For a
14 year preceding 2022, the elimination”; and

15 (B) in paragraph (2)—

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

19 and

20 (ii) in subparagraph (E)—

21 (I) by inserting “for a year pre-
22 ceding 2022,” after “subsection (c)”;
23 and

1 (II) by striking “1860D–
2 2(b)(4)(A)(i)(I)” and inserting
3 “1860D–2(b)(4)(A)(i)(I)(aa)”.

4 (4) Section 1860D–21(d)(7) of the Social Secu-
5 rity Act (42 U.S.C. 1395w–131(d)(7)) is amended
6 by striking “section 1860D–2(b)(4)(B)(i)” and in-
7 serting “section 1860D–2(b)(4)(C)(i)”.

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

11 (A) by striking “the value of any discount”
12 and inserting the following: “the value of—

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

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

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

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

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

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

3 (B) by inserting “for such year” before the
4 period.

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

8 **Subtitle D—Other Medicare Part D** 9 **Provisions**

10 **SEC. 131. TRANSITIONAL COVERAGE AND RETROACTIVE** 11 **MEDICARE PART D COVERAGE FOR CERTAIN** 12 **LOW-INCOME BENEFICIARIES.**

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

15 (1) by redesignating subsection (e) as sub-
16 section (f); and

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

19 “(e) LIMITED INCOME NEWLY ELIGIBLE TRANSI-
20 TION PROGRAM.—

21 “(1) IN GENERAL.—Beginning not later than
22 January 1, 2021, the Secretary shall carry out a
23 program to provide transitional coverage for covered
24 part D drugs for LI NET eligible individuals in ac-
25 cordance with this subsection.

1 “(2) LI NET ELIGIBLE INDIVIDUAL DEFINED.—
2 For purposes of this subsection, the term ‘LI NET
3 eligible individual’ means a part D eligible individual
4 who—

5 “(A) meets the requirements of clauses (ii)
6 and (iii) of subsection (a)(3)(A); and

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

11 “(3) TRANSITIONAL COVERAGE.—For purposes
12 of this subsection, the term ‘transitional coverage’
13 means, with respect to an LI NET eligible indi-
14 vidual—

15 “(A) immediate access to covered part D
16 drugs at the point-of-sale during the period that
17 begins on the first day of the month such indi-
18 vidual is determined to meet the requirements
19 of clauses (ii) and (iii) of subsection (a)(3)(A)
20 and ends on the date that coverage under a pre-
21 scription drug plan or MA–PD plan takes effect
22 with respect to such individual; and

23 “(B) in the case of an LI NET eligible in-
24 dividual who is a full-benefit dual eligible indi-
25 vidual (as defined in section 1935(c)(6)) or a

1 recipient of supplemental security income bene-
2 fits under title XVI, retroactive coverage (in the
3 form of reimbursement of the amounts that
4 would have been paid under this part had such
5 individual been enrolled in a prescription drug
6 plan or MA-PD plan) of covered part D drugs
7 purchased by such individual during the period
8 that begins on the date that is the later of—

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

12 “(ii) the date that is 36 months prior
13 to the date such individual enrolls in a pre-
14 scription drug plan or MA-PD plan, and
15 ends on the date that coverage under such
16 plan takes effect.

17 “(4) PROGRAM ADMINISTRATION.—

18 “(A) SINGLE POINT OF CONTACT.—The
19 Secretary shall, to the extent feasible, admin-
20 ister the program under this subsection through
21 a contract with a single program administrator.

22 “(B) BENEFIT DESIGN.—The Secretary
23 shall ensure that the transitional coverage pro-
24 vided to LI NET eligible individuals under this
25 subsection—

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

3 “(ii) permits all pharmacies deter-
4 mined by the Secretary to be in good
5 standing to process claims under the pro-
6 gram;

7 “(iii) is consistent with such require-
8 ments as the Secretary considers necessary
9 to improve patient safety and ensure ap-
10 propriate dispensing of medication; and

11 “(iv) meets such other requirements
12 as the Secretary may establish.

13 “(5) RELATIONSHIP TO OTHER PROVISIONS OF
14 THIS TITLE; WAIVER AUTHORITY.—

15 “(A) IN GENERAL.—The following provi-
16 sions shall not apply with respect to the pro-
17 gram under this subsection:

18 “(i) Paragraphs (1) and (3)(B) of sec-
19 tion 1860D–4(a) (relating to dissemination
20 of general information; availability of infor-
21 mation on changes in formulary through
22 the internet).

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

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

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

6 “(B) WAIVER AUTHORITY.—The Secretary
7 may waive such other requirements of title XI
8 and this title as may be necessary to carry out
9 the purposes of the program established under
10 this subsection.”.

11 **SEC. 132. ALLOWING THE OFFERING OF ADDITIONAL PRE-**
12 **SCRIPTION DRUG PLANS UNDER MEDICARE**
13 **PART D.**

14 (a) RESCINDING AND ISSUANCE OF NEW GUID-
15 ANCE.—Not later than one year after the date of the en-
16 actment of this Act, the Secretary of Health and Human
17 Services (in this section referred to as the “Secretary”)
18 shall—

19 (1) rescind sections of any sub-regulatory guid-
20 ance that limit the number of prescription drug
21 plans in each PDP region that may be offered by a
22 PDP sponsor under part D of title XVIII of the So-
23 cial Security Act (42 U.S.C. 1395w–101 et seq.);
24 and

1 (2) issue new guidance specifying that a PDP
2 sponsor may offer up to 4 (or a greater number if
3 determined appropriate by the Secretary) prescrip-
4 tion drug plans in each PDP region, except in cases
5 where the PDP sponsor may offer up to 2 additional
6 plans in a PDP region pursuant to section 1860D–
7 11(d)(4) of the Social Security Act (42 U.S.C.
8 1395w–111(d)(4)), as added by subsection (b).

9 (b) OFFERING OF ADDITIONAL PLANS.—Section
10 1860D–11(d) of the Social Security Act (42 U.S.C.
11 1395w–111(d)) is amended by adding at the end the fol-
12 lowing new paragraph:

13 “(4) OFFERING OF ADDITIONAL PLANS.—

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

22 “(B) REQUIREMENTS.—In order to be eli-
23 gible to offer up to 2 additional plans in a PDP
24 region pursuant to subparagraph (A), a PDP
25 sponsor must ensure that, with respect to at

1 least one such prescription drug plan, the spon-
2 sor or any entity that provides pharmacy bene-
3 fits management services under a contract with
4 any such sponsor or plan does not receive direct
5 or indirect remuneration, as defined in section
6 423.308 of title 42, Code of Federal Regula-
7 tions (or any successor regulation), unless at
8 least 25 percent of the aggregate reductions in
9 price or other remuneration received by the
10 PDP sponsor or entity from drug manufactur-
11 ers with respect to the plan and plan year—

12 “(i) are reflected at the point-of-sale
13 to the enrollee; or

14 “(ii) are used to reduce total bene-
15 ficiary cost-sharing estimated by the PDP
16 sponsor for prescription drug coverage
17 under the plan in the annual bid submitted
18 by the PDP sponsor under section 1860D-
19 11(b).

20 “(C) DEFINITION OF REDUCTIONS IN
21 PRICE.—For purposes of subparagraph (B), the
22 term ‘reductions in price’ refers only to collect-
23 ible amounts, as determined by the Secretary,
24 which excludes amounts which after adjudica-
25 tion and reconciliation with pharmacies and

1 manufacturers are duplicate in nature, contrary
2 to other contractual clauses, or otherwise ineli-
3 gible (such as due to beneficiary disenrollment
4 or coordination of benefits).”.

5 (c) **RULE OF CONSTRUCTION.**—Nothing in the provi-
6 sions of, or amendments made by, this section shall be
7 construed as limiting the ability of the Secretary to in-
8 crease any limit otherwise applicable on the number of
9 prescription drug plans that a PDP sponsor may offer,
10 at the discretion of the PDP sponsor, in a PDP region
11 under part D of title XVIII of the Social Security Act (42
12 U.S.C. 1395w–101 et seq.).

13 **SEC. 133. ALLOWING CERTAIN ENROLLEES OF PRESCRIP-**
14 **TION DRUGS PLANS AND MA-PD PLANS**
15 **UNDER MEDICARE PROGRAM TO SPREAD**
16 **OUT COST-SHARING UNDER CERTAIN CIR-**
17 **CUMSTANCES.**

18 (a) **STANDARD PRESCRIPTION DRUG COVERAGE.**—
19 Section 1860D–2(b)(2) of the Social Security Act (42
20 U.S.C. 1395w–102(b)(2)), as amended by section 121, is
21 further amended—

22 (1) in subparagraph (A), by striking “Subject
23 to subparagraphs (C) and (D)” and inserting “Sub-
24 ject to subparagraphs (C), (D), and (E)”; and

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

3 “(E) ENROLLEE OPTION REGARDING
4 SPREADING COST-SHARING.—

5 “(i) IN GENERAL.—The Secretary
6 shall establish by regulation a process
7 under which, with respect to plan year
8 2022 and subsequent plan years, a pre-
9 scription drug plan or an MA–PD plan
10 shall, in the case of a part D eligible indi-
11 vidual enrolled with such plan for such
12 plan year with respect to whom the plan
13 projects that the dispensing of a covered
14 part D drug to such individual will result
15 in the individual incurring costs within a
16 30-day period that are equal to a signifi-
17 cant percentage (as specified by the Sec-
18 retary pursuant to such regulation) of the
19 annual out-of-pocket threshold specified in
20 paragraph (4)(B) for such plan year, pro-
21 vide such individual with the option to
22 make the coinsurance payment required
23 under subparagraph (A) for such costs in
24 the form of equal monthly installments
25 over the remainder of such plan year.

1 “(ii) SIGNIFICANT PERCENTAGE LIM-
2 TATIONS.—In specifying a significant per-
3 centage pursuant to the regulation estab-
4 lished by the Secretary under clause (i),
5 the Secretary may not specify a percentage
6 that is less than 30 percent or greater
7 than 100 percent.”.

8 (b) ALTERNATIVE PRESCRIPTION DRUG COV-
9 ERAGE.—Section 1860D–2(c) of the Social Security Act
10 (42 U.S.C. 1395w–102(c)) is amended by adding at the
11 end the following new paragraph:

12 “(4) SAME ENROLLEE OPTION REGARDING
13 SPREADING COST-SHARING.—For plan year 2022
14 and subsequent plan years, the coverage provides the
15 enrollee option regarding spreading cost-sharing de-
16 scribed in and required under subsection
17 (b)(2)(E).”.

18 **SEC. 134. ESTABLISHING A MONTHLY CAP ON BENEFICIARY**
19 **INCURRED COSTS FOR INSULIN PRODUCTS**
20 **AND SUPPLIES UNDER A PRESCRIPTION**
21 **DRUG PLAN OR MA-PD PLAN.**

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

25 (1) in subsection (b)(2)—

1 (A) in subparagraph (A), by striking “and
2 (E)” and inserting “(E), and (F)”;

3 (B) in subparagraph (B), by striking “and
4 (D)” and inserting “(D), and (F)”;

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

7 “(F) CAP ON INCURRED COSTS FOR INSU-
8 LIN PRODUCTS AND SUPPLIES.—

9 “(i) IN GENERAL.—The coverage pro-
10 vides benefits, for costs above the annual
11 deductible specified in paragraph (1) and
12 up to the annual out-of-pocket threshold
13 described in paragraph (4)(B) and with re-
14 spect to a month (beginning with January
15 of 2022), with cost sharing that is equal to
16 \$0 for a specified covered part D drug (as
17 defined in clause (iii)) furnished to an indi-
18 vidual who has incurred costs during such
19 month with respect to specified covered
20 part D drugs equal to—

21 “(I) for months occurring in
22 2022, \$50; or

23 “(II) for months occurring in a
24 subsequent year, the amount applica-
25 ble under this clause for months oc-

1 curring in the year preceding such
2 subsequent year, increased by the an-
3 nual percentage increase specified in
4 paragraph (6) for such subsequent
5 year and rounded to the nearest dol-
6 lar.

7 “(ii) APPLICATION.—The provisions
8 of clauses (i) through (iii) of paragraph
9 (4)(C) shall apply with respect to the de-
10 termination of the incurred costs for speci-
11 fied covered part D drugs for purposes of
12 clause (i) in the same manner as such pro-
13 visions apply with respect to the deter-
14 mination of incurred costs for covered part
15 D drugs for purposes of paragraph (4)(A).

16 “(iii) SPECIFIED COVERED PART D
17 DRUG.—For purposes of this subpara-
18 graph, the term ‘specified covered part D
19 drug’ means a covered part D drug that
20 is—

21 “(I) insulin; or

22 “(II) a medical supply associated
23 with the injection of insulin (as de-
24 fined in regulations of the Secretary

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

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

5 “(5) SAME PROTECTION WITH RESPECT TO EX-
6 PENDITURES FOR INSULIN AND CERTAIN MEDICAL
7 SUPPLIES.—The coverage provides the coverage re-
8 quired under subsection (b)(2)(F).”.

9 (b) CONFORMING AMENDMENTS.—

10 (1) IN GENERAL.—Section 1860D–14(a)(1)(D)
11 of the Social Security Act (42 U.S.C. 1395w–
12 114(a)(1)(D)), as amended by section 121, is fur-
13 ther amended—

14 (A) in clause (ii), by striking “section
15 1860D–2(b)(2)” and inserting “section 1860D–
16 2(b)(2)(A)”; and

17 (B) in clause (iii), by striking “section
18 1860D–2(b)(2)” and inserting “section 1860D–
19 2(b)(2)(A)”.

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

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

3 (a) PROVIDING MEDICARE PART D BENEFICIARIES
4 WITH CERTAIN 2020 OFFSET PAYMENTS.—Section
5 1860D–2(b)(4) of the Social Security Act (42 U.S.C.
6 1395w–102(b)(4)) is amended by adding at the end the
7 following new subparagraph:

8 “(F) 2020 OFFSET PAYMENTS.—

9 “(i) IN GENERAL.—Subject to clause
10 (iv), the Secretary shall provide for pay-
11 ment from the Medicare Prescription Drug
12 Account as follows:

13 “(I) In the case of a specified in-
14 dividual (as defined in clause (ii)(I))
15 who as of the last day of a calendar
16 quarter in 2020 has incurred costs for
17 covered part D drugs so that the indi-
18 vidual has exceeded the annual out-of-
19 pocket threshold applied under sub-
20 paragraph (B)(i)(V) for 2020, pay-
21 ment to the individual by not later
22 than 15th day of the third month fol-
23 lowing the end of such quarter of the
24 amount by which such threshold so
25 applied exceeded the target threshold
26 for 2020.

1 “(II) In the case of a specified
2 individual who is not described in sub-
3 clause (I) and who as of the last day
4 of 2020 has incurred costs for covered
5 part D drugs so that the individual
6 has exceeded the target threshold for
7 2020, payment to the individual by
8 not later than December 31, 2021 of
9 the amount by which such incurred
10 costs exceeded the target threshold for
11 2020.

12 “(ii) DEFINITIONS.—For purposes of
13 this subparagraph:

14 “(I) SPECIFIED INDIVIDUAL.—
15 The term ‘specified individual’ means
16 an individual who—

17 “(aa) is enrolled in a pre-
18 scription drug plan or an MA-
19 PD plan;

20 “(bb) is not enrolled in a
21 qualified retiree prescription drug
22 plan; and

23 “(cc) is not entitled to an in-
24 come-related subsidy under sec-
25 tion 1860D–14(a).

1 “(II) TARGET THRESHOLD FOR
2 2020.—the term ‘target threshold for
3 2020’ means the annual out-of-pocket
4 threshold that would have been ap-
5 plied under subparagraph (B)(i) for
6 2020 if such threshold had been de-
7 termined in accordance with subclause
8 (IV) of such subparagraph instead of
9 subclause (V) of such subparagraph.

10 “(iii) NOTIFICATION.—In the case of
11 any specified individual who during 2020
12 has incurred costs for covered part D
13 drugs so that the individual has exceeded
14 the target threshold for 2020, the Sec-
15 retary shall, not later than September 30,
16 2021, provide to such individual a notifica-
17 tion informing such individual of such indi-
18 vidual’s right to a payment described in
19 clause (i) and the estimated timing of such
20 payment.

21 “(iv) CLARIFICATION.—The Secretary
22 shall provide only 1 payment under this
23 subparagraph with respect to any indi-
24 vidual.

1 “(v) IMPLEMENTATION.—The Sec-
2 retary may implement this subparagraph
3 by program instruction or otherwise.”.

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

8 (1) in subclause (V), by striking at the end
9 “or”;

10 (2) by redesignating subclause (VI) as sub-
11 clause (VIII); and

12 (3) by inserting after subclause (V) the fol-
13 lowing new subclauses:

14 “(VI) for 2021, is equal to the
15 amount that would have been applied
16 under this subparagraph for 2020 if
17 such amount had been determined in
18 accordance with subclause (IV) in-
19 stead of subclause (V), increased by
20 the lesser of—

21 “(aa) the annual percentage
22 increase described in paragraph
23 (7) for 2021, plus 2 percentage
24 points; or

1 “(bb) the annual percentage
2 increase described in paragraph
3 (6) for 2021;

4 “(VII) for 2022, is equal to the
5 amount that would have been applied
6 under this subparagraph for 2022 if
7 the amendments made by section
8 1101(d)(1) of the Health Care and
9 Education Reconciliation Act of 2010
10 and by section 135 of the Lower
11 Costs, More Cures Act of 2019 had
12 not been enacted; or”.

13 **Subtitle E—MedPAC**

14 **SEC. 141. PROVIDING THE MEDICARE PAYMENT ADVISORY** 15 **COMMISSION AND MEDICAID AND CHIP PAY-** 16 **MENT AND ACCESS COMMISSION WITH AC-** 17 **CESS TO CERTAIN DRUG PAYMENT INFORMA-** 18 **TION, INCLUDING CERTAIN REBATE INFOR-** 19 **MATION.**

20 (a) ACCESS TO CERTAIN PART D PAYMENT DATA.—

21 Section 1860D–15(f) of the Social Security Act (42
22 U.S.C. 1395w–115(f)) is amended—

23 (1) in paragraph (2)—

24 (A) in subparagraph (A)(ii), by striking

25 “and” at the end;

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

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

5 “(C) by the Executive Director of the
6 Medicare Payment Advisory Commission for
7 purposes of monitoring, making recommenda-
8 tions, and analysis of the program under this
9 title and by the Executive Director of the Med-
10 icaid and CHIP Payment and Access Commis-
11 sion for purposes of monitoring, making rec-
12 ommendations, and analysis of the Medicaid
13 program established under title XIX and the
14 Children’s Health Insurance Program under
15 title XXI.”; and

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

18 “(3) ADDITIONAL RESTRICTIONS ON DISCLO-
19 SURE OF INFORMATION.—The Executive Directors
20 described in paragraph (2)(C) shall not disclose any
21 of the following information disclosed to such Execu-
22 tive Directors or obtained by such Executive Direc-
23 tors pursuant to such paragraph, with respect to a
24 prescription drug plan offered by a PDP sponsor:

1 “(A) The specific amounts or the identity
2 of the source of any rebates, price concessions,
3 or other forms of direct or indirect remunera-
4 tion under such prescription drug plan.

5 “(B) Information submitted with the bid
6 submitted under section 1860D–11 by such
7 PDP sponsor.

8 “(C) In the case of such information from
9 prescription drug event records, in a form that
10 would not be permitted under section
11 423.505(m) of title 42, Code of Federal Regula-
12 tions, or any successor regulation, if made by
13 the Centers for Medicare & Medicaid Services.”.

14 (b) ACCESS TO CERTAIN REBATE AND PAYMENT
15 DATA UNDER MEDICARE AND MEDICAID.—Section
16 1927(b)(3)(D) of the Social Security Act (42 U.S.C.
17 1396r–8(b)(3)(D)) is amended—

18 (1) in the matter before clause (i), by striking
19 “subsection (a)(6)(A)(ii)” and inserting “subsection
20 (a)(6)(A)”;

21 (2) in clause (v), by striking “and” at the end;

22 (3) in clause (vi), by striking the period at the
23 end and inserting “, and”;

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

1 “(vii) to permit the Executive Direc-
2 tor of the Medicare Payment Advisory
3 Commission and the Executive Director of
4 the Medicaid and CHIP Payment and Ac-
5 cess Commission to review the information
6 provided.”;

7 (5) in the matter at the end, by striking
8 “1860D–4(c)(2)(E)” and inserting “1860D–
9 4(c)(2)(G)”; and

10 (6) by adding at the end the following new sen-
11 tence: “Any information disclosed to the Executive
12 Director of the Medicare Payment Advisory Commis-
13 sion or the Executive Director of the Medicaid and
14 CHIP Payment and Access Commission pursuant to
15 this subparagraph shall not be disclosed by either
16 such Executive Director in a form which discloses
17 the identity of a specific manufacturer or wholesaler
18 or prices charged for drugs by such manufacturer or
19 wholesaler.”.

20 **TITLE II—MEDICAID**

21 **SEC. 201. SUNSET OF LIMIT ON MAXIMUM REBATE AMOUNT** 22 **FOR SINGLE SOURCE DRUGS AND INNO-** 23 **VATOR MULTIPLE SOURCE DRUGS.**

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

1 “December 31, 2009,” the following: “and before January
2 1, 2023,”.

3 **SEC. 202. MEDICAID PHARMACY AND THERAPEUTICS COM-**
4 **MITTEE IMPROVEMENTS.**

5 (a) IN GENERAL.—Subparagraph (A) of section
6 1927(d)(4) of the Social Security Act (42 U.S.C. 1396r–
7 8(d)(4)) is amended to read as follows:

8 “(A)(i) The formulary is developed and re-
9 viewed by a pharmacy and therapeutics com-
10 mittee consisting of physicians, pharmacists,
11 and other appropriate individuals appointed by
12 the Governor of the State.

13 “(ii) Subject to clause (vi), the State estab-
14 lishes and implements a conflict of interest pol-
15 icy for the pharmacy and therapeutics com-
16 mittee that—

17 “(I) is publicly accessible;

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

24 “(III) contains clear processes, such
25 as recusal from voting or discussion, for

1 those members who report a conflict of in-
2 terest, along with appropriate processes to
3 address any instance where a member fails
4 to report a conflict of interest.

5 “(iii) The membership of the pharmacy
6 and therapeutics committee—

7 “(I) includes at least 1 actively prac-
8 ticing physician and at least 1 actively
9 practicing pharmacist, each of whom—

10 “(aa) is independent and free of
11 conflict with respect to manufacturers
12 and Medicaid participating plans or
13 subcontractors, including pharmacy
14 benefit managers; and

15 “(bb) has expertise in the care of
16 1 or more Medicaid-specific popu-
17 lations such as elderly or disabled in-
18 dividuals, children with complex med-
19 ical needs, or low-income individuals
20 with chronic illnesses; and

21 “(II) is made publicly available.

22 “(iv) At the option of the State, the
23 State’s drug use review board established under
24 subsection (g)(3) may serve as the pharmacy
25 and therapeutics committee provided the State

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

3 “(v) The State reviews and has final ap-
4 proval of the formulary established by the phar-
5 macy and therapeutics committee.

6 “(vi) If the Secretary determines it appro-
7 priate or necessary based on the findings and
8 recommendations of the Comptroller General of
9 the United States in the report submitted to
10 Congress under section 203 of the Lower Costs,
11 More Cures Act of 2019, the Secretary shall
12 issue guidance that States must follow for es-
13 tablishing conflict of interest policies for the
14 pharmacy and therapeutics committee in ac-
15 cordance with the requirements of clause (ii),
16 including appropriate standards and require-
17 ments for identifying, addressing, and reporting
18 on conflicts of interest.”.

19 (b) APPLICATION TO MEDICAID MANAGED CARE OR-
20 GANIZATIONS.—Clause (xiii) of section 1903(m)(2)(A) of
21 the Social Security Act (42 U.S.C. 1396b(m)(2)(A)) is
22 amended—

23 (1) by striking “and (III)” and inserting
24 “(III)”;

1 (2) by striking the period at the end and insert-
2 ing “, and (IV) any formulary used by the entity for
3 covered outpatient drugs dispensed to individuals eli-
4 gible for medical assistance who are enrolled with
5 the entity is developed and reviewed by a pharmacy
6 and therapeutics committee that meets the require-
7 ments of clauses (ii) and (iii) of section
8 1927(d)(4)(A).”; and

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

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

13 **SEC. 203. GAO REPORT ON CONFLICTS OF INTEREST IN**
14 **STATE MEDICAID PROGRAM DRUG USE RE-**
15 **VIEW BOARDS AND PHARMACY AND THERA-**
16 **PEUTICS (P&T) COMMITTEES.**

17 (a) INVESTIGATION.—The Comptroller General of the
18 United States shall conduct an investigation of potential
19 or existing conflicts of interest among members of State
20 Medicaid program State drug use review boards (in this
21 section referred to as “DUR Boards”) and pharmacy and
22 therapeutics committees (in this section referred to as
23 “P&T Committees”).

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

1 shall submit to Congress a report on the investigation con-
2 ducted under subsection (a) that includes the following:

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

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

8 (B) States that operate separate P&T
9 Committees for their fee-for-service Medicaid
10 program and their Medicaid managed care or-
11 ganizations or other Medicaid managed care ar-
12 rangements (collectively referred to in this sec-
13 tion as “Medicaid MCOs”); and

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

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

22 (3) A description outlining the tools P&T Com-
23 mittees may use to determine Medicaid drug cov-
24 erage and utilization management policies.

1 (4) An analysis of whether and how States or
2 P&T Committees establish participation and inde-
3 pendence requirements for DUR Boards and P&T
4 Committees, including with respect to entities with
5 connections with drug manufacturers, State Med-
6 icaid programs, managed care organizations, and
7 other entities or individuals in the pharmaceutical
8 industry.

9 (5) A description outlining how States, DUR
10 Boards, or P&T Committees define conflicts of inter-
11 est.

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

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

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

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

1 the requirements of titles XI and XIX of the Social
2 Security Act (42 U.S.C. 1301 et seq., 1396 et seq.)
3 and access to effective, clinically appropriate, and
4 medically necessary drug treatments for Medicaid
5 beneficiaries, including recommendations for such
6 legislative and administrative actions as the Comp-
7 troller General determines appropriate.

8 **SEC. 204. ENSURING THE ACCURACY OF MANUFACTURER**
9 **PRICE AND DRUG PRODUCT INFORMATION**
10 **UNDER THE MEDICAID DRUG REBATE PRO-**
11 **GRAM.**

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

14 (1) IN GENERAL.—Subparagraph (B) of section
15 1927(b)(3) of the Social Security Act (42 U.S.C.
16 1396r-8(b)(3)) is amended to read as follows:

17 “(B) AUDITS AND SURVEYS OF MANUFAC-
18 Turer PRICE AND DRUG PRODUCT INFORMA-
19 TION.—

20 “(i) AUDITS.—The Secretary shall
21 conduct ongoing audits of the price and
22 drug product information reported by man-
23 ufacturers under subparagraph (A) for the
24 most recently ended rebate period to en-
25 sure the accuracy and timeliness of such

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

5 “(ii) VERIFICATIONS SURVEYS OF AV-
6 ERAGE MANUFACTURER PRICE AND MANU-
7 FACTURER’S AVERAGE SALES PRICE.—In
8 addition to the audits required under
9 clause (i), the Secretary may survey whole-
10 salers and manufacturers (including manu-
11 facturers that directly distribute their cov-
12 ered outpatient drugs (in this subpara-
13 graph referred to as ‘direct sellers’)), when
14 necessary, to verify manufacturer prices
15 and manufacturer’s average sales prices
16 (including wholesale acquisition cost) to
17 make payment reported under subpara-
18 graph (A).

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

1 er, if the wholesaler, manufacturer, or di-
2 rect seller of a covered outpatient drug re-
3 fuses a request for information about
4 charges or prices by the Secretary in con-
5 nection with an audit or survey under this
6 subparagraph or knowingly provides false
7 information. The provisions of section
8 1128A (other than subsections (a) (with
9 respect to amounts of penalties or addi-
10 tional assessments) and (b)) shall apply to
11 a civil money penalty under this clause in
12 the same manner as such provisions apply
13 to a penalty or proceeding under section
14 1128A(a).

15 “(iv) REPORTS.—

16 “(I) REPORT TO CONGRESS.—

17 The Secretary shall, not later than 18
18 months after date of enactment of
19 this subparagraph, submit a report to
20 the Committee on Energy and Com-
21 merce of the House of Representatives
22 and the Committee on Finance of the
23 Senate regarding additional regulatory
24 or statutory changes that may be re-
25 quired in order to ensure accurate and

1 timely reporting and oversight of
2 manufacturer price and drug product
3 information, including whether
4 changes should be made to reasonable
5 assumption requirements to ensure
6 such assumptions are reasonable and
7 accurate or whether another method-
8 ology for ensuring accurate and timely
9 reporting of price and drug product
10 information should be considered to
11 ensure the integrity of the drug rebate
12 program under this section.

13 “(II) ANNUAL REPORTS.—The
14 Secretary shall, on at least an annual
15 basis, submit a report to the Com-
16 mittee on Energy and Commerce of
17 the House of Representatives and the
18 Committee on Finance of the Senate
19 summarizing the results of the audits
20 and surveys conducted under this sub-
21 paragraph during the period that is
22 the subject of the report.

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

1 subject of the report, include sum-
2 maries of—

3 “(aa) error rates in the
4 price, drug product, and other
5 relevant information supplied by
6 manufacturers under subpara-
7 graph (A);

8 “(bb) the timeliness with
9 which manufacturers, whole-
10 salers, and direct sellers provide
11 information required under sub-
12 paragraph (A) or under clause (i)
13 or (ii) of this subparagraph;

14 “(cc) the number of manu-
15 facturers, wholesalers, and direct
16 sellers and drug products audited
17 under this subparagraph;

18 “(dd) the types of price and
19 drug product information re-
20 viewed under the audits con-
21 ducted under this subparagraph;

22 “(ee) the tools and meth-
23 odologies employed in such au-
24 dits;

1 “(ff) the findings of such
2 audits, including which manufac-
3 turers, if any, were penalized
4 under this subparagraph; and

5 “(gg) such other relevant in-
6 formation as the Secretary shall
7 deem appropriate.

8 “(IV) PROTECTION OF INFORMA-
9 TION.—In preparing a report required
10 under subclause (II), the Secretary
11 shall redact such proprietary informa-
12 tion as the Secretary determines ap-
13 propriate to prevent disclosure of, and
14 to safeguard, such information.

15 “(v) APPROPRIATIONS.—Out of any
16 funds in the Treasury not otherwise appro-
17 priated, there is appropriated to the Sec-
18 retary \$2,000,000 for fiscal year 2020 and
19 each fiscal year thereafter to carry out this
20 subparagraph.”.

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

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

3 (1) INCREASED PENALTY FOR LATE REPORTING
4 OF INFORMATION.—Section 1927(b)(3)(C)(i) of the
5 Social Security Act (42 U.S.C. 1396r–8(b)(3)(C)(i))
6 is amended by striking “increased by \$10,000 for
7 each day in which such information has not been
8 provided and such amount shall be paid to the
9 Treasury” and inserting “, for each covered out-
10 patient drug with respect to which such information
11 is not provided, \$50,000 for the first day that such
12 information is not provided on a timely basis and
13 \$19,000 for each subsequent day that such informa-
14 tion is not provided”.

15 (2) INCREASED PENALTY FOR KNOWINGLY RE-
16 PORTING FALSE INFORMATION.—Section
17 1927(b)(3)(C)(ii) of the Social Security Act (42
18 U.S.C. 1396r–8(b)(3)(C)(ii)) is amended by striking
19 “\$100,000” and inserting “\$500,000”.

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

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

4 (a) PASS-THROUGH PRICING REQUIRED.—

5 (1) IN GENERAL.—Section 1927(e) of the So-
6 cial Security Act (42 U.S.C. 1396r-8(e)) is amended
7 by adding at the end the following:

8 “(6) PASS-THROUGH PRICING REQUIRED.—A
9 contract between the State and a pharmacy benefit
10 manager (referred to in this paragraph as a ‘PBM’),
11 or a contract between the State and a managed care
12 entity or other specified entity (as such terms are
13 defined in section 1903(m)(9)(D)) that includes pro-
14 visions making the entity responsible for coverage of
15 covered outpatient drugs dispensed to individuals en-
16 rolled with the entity, shall require that payment for
17 such drugs and related administrative services (as
18 applicable), including payments made by a PBM on
19 behalf of the State or entity, is based on a pass-
20 through pricing model under which—

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

23 “(i) is limited to—

24 “(I) ingredient cost; and

25 “(II) a professional dispensing
26 fee that is not less than the profes-

1 sional dispensing fee that the State
2 plan or waiver would pay if the plan
3 or waiver was making the payment di-
4 rectly;

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

8 “(iii) is made in a manner that is con-
9 sistent with section 1902(a)(30)(A) and
10 sections 447.512, 447.514, and 447.518 of
11 title 42, Code of Federal Regulations (or
12 any successor regulation) as if such re-
13 quirements applied directly to the entity or
14 the PBM;

15 “(B) payment to the entity or the PBM
16 (as applicable) for administrative services per-
17 formed by the entity or PBM is limited to a
18 reasonable administrative fee that covers the
19 reasonable cost of providing such services;

20 “(C) the entity or the PBM (as applicable)
21 shall make available to the State, and the Sec-
22 retary upon request, all costs and payments re-
23 lated to covered outpatient drugs and accom-
24 panying administrative services incurred, re-
25 ceived, or made by the entity or the PBM, in-

1 including ingredient costs, professional dispensing
2 fees, administrative fees, post-sale and post-in-
3 voice fees. Discounts, or related adjustments
4 such as direct and indirect remuneration fees,
5 and any and all remuneration; and

6 “(D) any form of spread pricing whereby
7 any amount charged or claimed by the entity or
8 the PBM (as applicable) is in excess of the
9 amount paid to the pharmacies on behalf of the
10 entity, including any post-sale or post-invoice
11 fees, discounts, or related adjustments such as
12 direct and indirect remuneration fees or assess-
13 ments (after allowing for a reasonable adminis-
14 trative fee as described in subparagraph (B)) is
15 not allowable for purposes of claiming Federal
16 matching payments under this title.”.

17 (2) CONFORMING AMENDMENT.—Clause (xiii)
18 of section 1903(m)(2)(A) of such Act (42 U.S.C.
19 1396b(m)(2)(A)), as amended by section 202, is fur-
20 ther amended—

21 (A) by striking “and (IV)” and inserting
22 “(IV)”; and

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

1 provided by a pharmacy benefit manager on be-
2 half of the entity under a contract or other ar-
3 rangement between the entity and the phar-
4 macy benefit manager, shall comply with the re-
5 quirements of section 1927(e)(6)”.

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

12 (b) SURVEY OF RETAIL PRICES.—

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

15 (A) by striking “and” after the semicolon
16 at the end of paragraph (1)(A)(i) and all that
17 precedes it through “(1)” and inserting the fol-
18 lowing:

19 “(1) SURVEY OF RETAIL PRICES.—The Sec-
20 retary shall conduct a survey of retail community
21 drug prices, to include at least the national average
22 drug acquisition cost, as follows:

23 “(A) USE OF VENDOR.—The Secretary
24 may contract services for—

1 “(i) with respect to retail community
2 pharmacies, the determination on a month-
3 ly basis of retail survey prices of the na-
4 tional average drug acquisition cost for
5 covered outpatient drugs for such phar-
6 macies, net of all discounts and rebates (to
7 the extent any information with respect to
8 such discounts and rebates is available),
9 the average reimbursement received for
10 such drugs by such pharmacies from all
11 sources of payment, including third par-
12 ties, and, to the extent available, the usual
13 and customary charges to consumers for
14 such drugs; and”;

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

17 “(F) SURVEY REPORTING.—In order to
18 meet the requirement of section 1902(a)(54), a
19 State shall require that any retail community
20 pharmacy in the State that receives any pay-
21 ment, administrative fee, discount, or rebate re-
22 lated to the dispensing of covered outpatient
23 drugs to individuals receiving benefits under
24 this title, regardless of whether such payment,
25 fee, discount, or rebate is received from the

1 State or a managed care entity directly or from
2 a pharmacy benefit manager or another entity
3 that has a contract with the State or a man-
4 aged care entity, shall respond to surveys of re-
5 tail prices conducted under this subsection.

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

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

13 “(ii) The sampling frame and number
14 of pharmacies sampled monthly.

15 “(iii) Characteristics of reporting
16 pharmacies, including type (such as inde-
17 pendent or chain), geographic or regional
18 location, and dispensing volume.

19 “(iv) Reporting of a separate national
20 average drug acquisition cost for each drug
21 for independent retail pharmacies and
22 chain operated pharmacies.

23 “(v) Information on price concessions
24 including on and off invoice discounts, re-
25 bates, and other price concessions.

1 “(vi) Information on average profes-
2 sional dispensing fees paid.

3 “(H) PENALTIES.—

4 “(i) FAILURE TO PROVIDE TIMELY IN-
5 FORMATION.—A retail community phar-
6 macy that fails to respond to a survey con-
7 ducted under this subsection on a timely
8 basis may be subject to a civil monetary
9 penalty in the amount of \$10,000 for each
10 day in which such information has not
11 been provided.

12 “(ii) FALSE INFORMATION.—A retail
13 community pharmacy that knowingly pro-
14 vides false information in response to a
15 survey conducted under this subsection
16 may be subject to a civil money penalty in
17 an amount not to exceed \$100,000 for
18 each item of false information.

19 “(iii) OTHER PENALTIES.—Any civil
20 money penalties imposed under this sub-
21 paragraph shall be in addition to other
22 penalties as may be prescribed by law. The
23 provisions of section 1128A (other than
24 subsections (a) and (b)) shall apply to a
25 civil money penalty under this subpara-

1 graph in the same manner as such provi-
2 sions apply to a penalty or proceedings
3 under section 1128A(a).

4 “(I) REPORT ON SPECIALTY PHAR-
5 MACIES.—

6 “(i) IN GENERAL.—Not later than 1
7 year after the effective date of this sub-
8 paragraph, the Secretary shall submit a re-
9 port to Congress examining specialty drug
10 coverage and reimbursement under this
11 title.

12 “(ii) CONTENT OF REPORT.—Such re-
13 port shall include a description of how
14 State Medicaid programs define specialty
15 drugs, how much State Medicaid programs
16 pay for specialty drugs, how States and
17 managed care plans determine payment for
18 specialty drugs, the settings in which spe-
19 cialty drugs are dispensed (such as retail
20 community pharmacies or specialty phar-
21 macies), whether acquisition costs for spe-
22 cialty drugs are captured in the national
23 average drug acquisition cost survey, and
24 recommendations as to whether specialty
25 pharmacies should be included in the sur-

1 vey of retail prices to ensure national aver-
2 age drug acquisition costs capture drugs
3 sold at specialty pharmacies and how such
4 specialty pharmacies should be defined.”;

5 (C) in paragraph (2)—

6 (i) in subparagraph (A), by inserting
7 “, including payments rates under Med-
8 icaid managed care plans,” after “under
9 this title”; and

10 (ii) in subparagraph (B), by inserting
11 “and the basis for such dispensing fees”
12 before the semicolon; and

13 (D) in paragraph (4), by inserting “, and
14 \$5,000,000 for fiscal year 2020 and each fiscal
15 year thereafter,” after “2010”.

16 (2) EFFECTIVE DATE.—The amendments made
17 by this subsection take effect on the 1st day of the
18 1st quarter that begins on or after the date that is
19 18 months after the date of enactment of this Act.

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

24 (1) in subparagraph (A)(i)—

1 (A) in subclause (I), by striking “and”
2 after the semicolon;

3 (B) in subclause (II), by adding “and”
4 after the semicolon;

5 (C) by moving the left margins of sub-
6 clause (I) and (II) 2 ems to the right; and

7 (D) by adding at the end the following:

8 “(III) in the case of rebate peri-
9 ods that begin on or after the date of
10 enactment of this subclause, on the
11 wholesale acquisition cost (as defined
12 in section 1847A(c)(6)(B)) for cov-
13 ered outpatient drugs for the rebate
14 period under the agreement (including
15 for all such drugs that are sold under
16 a new drug application approved
17 under section 505(c) of the Federal
18 Food, Drug, and Cosmetic Act);”;

19 (2) in subparagraph (D)—

20 (A) in the matter preceding clause (i), by
21 inserting “and clause (vii) of this subpara-
22 graph” after “1847A”;

23 (B) in clause (vi), by striking “and” after
24 the comma;

1 (C) in clause (vii), by striking the period
2 and inserting “, and”; and

3 (D) by inserting after clause (vii) the fol-
4 lowing:

5 “(viii) to the Secretary to disclose
6 (through a website accessible to the public)
7 the most recently reported wholesale acqui-
8 sition cost (as defined in section
9 1847A(c)(6)(B)) for each covered out-
10 patient drug (including for all such drugs
11 that are sold under a new drug application
12 approved under section 505(c) of the Fed-
13 eral Food, Drug, and Cosmetic Act), as re-
14 ported under subparagraph (A)(i)(III).”.

15 **SEC. 206. T-MSIS DRUG DATA ANALYTICS REPORTS.**

16 (a) IN GENERAL.—Not later than May 1 of each cal-
17 endar year beginning with calendar year 2021, the Sec-
18 retary of Health and Human Services (in this section re-
19 ferred to as the “Secretary”) shall publish on a website
20 of the Centers for Medicare & Medicaid Services that is
21 accessible to the public a report of the most recently avail-
22 able data on provider prescribing patterns under the Med-
23 icaid program.

24 (b) CONTENT OF REPORT.—

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

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

16 (i) across all forms or models of reim-
17 bursement used under the plan or waiver;

18 (ii) within specialties and subspecial-
19 ties, as defined by the Secretary;

20 (iii) by episodes of care for—

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

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

3 (II) procedural groupings; and

4 (III) rare disease diagnosis codes;

5 (iv) by patient demographic character-
6 istics, including race (to the extent that
7 the Secretary determines that there is suf-
8 ficient data available with respect to such
9 characteristic in a majority of States), gen-
10 der, and age;

11 (v) by patient high-utilizer or risk sta-
12 tus; and

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

16 (B) In the case of medical assistance for
17 covered outpatient drugs (as so defined) pro-
18 vided under a State Medicaid plan or waiver of
19 such plan in a managed care setting, an anal-
20 ysis of the differences in managed care pre-
21 scribing patterns when a covered outpatient
22 drug is prescribed in a managed care setting as
23 compared to when the drug is prescribed in a
24 fee-for-service setting.

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

6 (A) a description of prescription utilization
7 management tools under State programs to pro-
8 vide long-term services and supports under a
9 State Medicaid plan or a waiver of such plan;

10 (B) a comparison of prescription utilization
11 management tools applicable to populations cov-
12 ered under a State Medicaid plan waiver under
13 section 1115 of the Social Security Act (42
14 U.S.C. 1315) and the models applicable to pop-
15 ulations that are not covered under the waiver;

16 (C) a comparison of the prescription utili-
17 zation management tools employed by different
18 Medicaid managed care organizations, phar-
19 macy benefit managers, and related entities
20 within the State;

21 (D) a comparison of the prescription utili-
22 zation management tools applicable to each en-
23 rollment category under a State Medicaid plan
24 or waiver; and

1 (E) a comparison of the prescription utili-
2 zation management tools applicable under the
3 State Medicaid plan or waiver by patient high-
4 utilizer or risk status.

5 (3) ADDITIONAL ANALYSIS.—To the extent
6 practicable, the Secretary shall include in each re-
7 port published under subsection (a)—

8 (A) analyses of national, State, and local
9 patterns of Medicaid population-based pre-
10 scribing behaviors; and

11 (B) recommendations for administrative or
12 legislative action to improve the effectiveness of,
13 and reduce costs for, covered outpatient drugs
14 under Medicaid while ensuring timely bene-
15 ficiary access to medically necessary covered
16 outpatient drugs.

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

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

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

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

5 “(2) SECRETARIAL APPROVAL.—

6 “(A) IN GENERAL.—A State shall submit a
7 request to the Secretary to enter into a risk-
8 sharing value based payment agreement, and
9 the Secretary shall not approve a proposed risk-
10 sharing value-based payment agreement be-
11 tween a State and a manufacturer for payment
12 for a covered outpatient drug of the manufac-
13 turer unless the following requirements are met:

14 “(i) MANUFACTURER IS PARTY TO RE-
15 BATE AGREEMENT AND IN COMPLIANCE
16 WITH REQUIREMENTS.—The manufacturer
17 has a rebate agreement in effect as re-
18 quired under subsection (a) and (b) of this
19 section and is in compliance with all appli-
20 cable requirements under this title.

21 “(ii) NO INCREASE TO PROJECTED
22 NET FEDERAL SPENDING.—

23 “(I) IN GENERAL.—The Chief
24 Actuary certifies that the projected
25 payments for each covered outpatient

1 drug under such proposed agreement
2 would not result in greater estimated
3 Federal spending under this title than
4 the net Federal spending that would
5 result in the absence of the agree-
6 ment.

7 “(II) NET FEDERAL SPENDING
8 DEFINED.—For purposes of this sub-
9 section, the term ‘net Federal spend-
10 ing’ means the amount of Federal
11 payments the Chief Actuary estimates
12 would be made under this title for ad-
13 ministering a covered outpatient drug
14 to an individual eligible for medical
15 assistance under a State plan or a
16 waiver of such plan, reduced by the
17 amount of all rebates the Chief Actu-
18 ary estimates would be paid with re-
19 spect to the administering of such
20 drug, including all rebates under this
21 title and any supplemental or other
22 additional rebates, in the absence of
23 such an agreement.

24 “(III) INFORMATION.—The Chief
25 Actuary shall make the certifications

1 required under this clause based on
2 the most recently available and reli-
3 able drug pricing and product infor-
4 mation. The State and manufacturer
5 shall provide the Secretary and the
6 Chief Actuary with all necessary infor-
7 mation required to make the estimates
8 needed for such certifications.

9 “(iii) LAUNCH AND LIST PRICE JUS-
10 TIFICATIONS.—The manufacturer submits
11 all relevant information and supporting
12 documentation necessary for pricing deci-
13 sions as deemed appropriate by the Sec-
14 retary, which shall be truthful and non-
15 misleading, including manufacturer infor-
16 mation and supporting documentation for
17 launch price or list price increases, and
18 any applicable justification required under
19 section 1128L.

20 “(iv) CONFIDENTIALITY OF INFORMA-
21 TION; PENALTIES.—The provisions of sub-
22 paragraphs (C) and (D) of subsection
23 (b)(3) shall apply to a manufacturer that
24 fails to submit the information and docu-
25 mentation required under clauses (ii) and

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

6 “(B) CONSIDERATION OF STATE REQUEST
7 FOR APPROVAL.—

8 “(i) IN GENERAL.—The Secretary
9 shall treat a State request for approval of
10 a risk-sharing value-based payment agree-
11 ment in the same manner that the Sec-
12 retary treats a State plan amendment, and
13 subpart B of part 430 of title 42, Code of
14 Federal Regulations, including, subject to
15 clause (ii), the timing requirements of sec-
16 tion 430.16 of such title (as in effect on
17 the date of enactment of this subsection),
18 shall apply to a request for approval of a
19 risk-sharing value-based payment agree-
20 ment in the same manner as such subpart
21 applies to a State plan amendment.

22 “(ii) TIMING.—The Secretary shall
23 consult with the Commissioner of Food
24 and Drugs as required under subpara-
25 graph (C) and make a determination on

1 whether to approve a request from a State
2 for approval of a proposed risk-sharing
3 value-based payment agreement (or request
4 additional information necessary to allow
5 the Secretary to make a determination
6 with respect to such request for approval)
7 within the time period, to the extent prac-
8 ticable, specified in section 430.16 of title
9 42, Code of Federal Regulations (as in ef-
10 fect on the date of enactment of this sub-
11 section), but in no case shall the Secretary
12 take more than 180 days after the receipt
13 of such request for approval or response to
14 such request for additional information to
15 make such a determination (or request ad-
16 ditional information).

17 “(C) CONSULTATION WITH THE COMMIS-
18 SIONER OF FOOD AND DRUGS.—In considering
19 whether to approve a risk-sharing value-based
20 payment agreement, the Secretary, to the ex-
21 tent necessary, shall consult with the Commis-
22 sioner of Food and Drugs to determine whether
23 the relevant clinical parameters specified in
24 such agreement are appropriate.

1 “(3) INSTALLMENT-BASED PAYMENT STRUC-
2 TURE.—

3 “(A) IN GENERAL.—A risk-sharing value-
4 based payment agreement shall provide for a
5 payment structure under which, for every in-
6 stallment year of the agreement (subject to sub-
7 paragraph (B)), the State shall pay the total in-
8 stallment year amount in equal installments to
9 be paid at regular intervals over a period of
10 time that shall be specified in the agreement.

11 “(B) REQUIREMENTS FOR INSTALLMENT
12 PAYMENTS.—

13 “(i) TIMING OF FIRST PAYMENT.—
14 The State shall make the first of the in-
15 stallment payments described in subpara-
16 graph (A) for an installment year not later
17 than 30 days after the end of such year.

18 “(ii) LENGTH OF INSTALLMENT PE-
19 RIOD.—The period of time over which the
20 State shall make the installment payments
21 described in subparagraph (A) for an in-
22 stallment year shall not be longer than 5
23 years.

24 “(iii) NONPAYMENT OR REDUCED
25 PAYMENT OF INSTALLMENTS FOLLOWING

1 A FAILURE TO MEET CLINICAL PARAM-
2 ETER.—If, prior to the payment date (as
3 specified in the agreement) of any install-
4 ment payment described in subparagraph
5 (A) or any other alternative date or time
6 frame (as otherwise specified in the agree-
7 ment), the covered outpatient drug which
8 is subject to the agreement fails to meet a
9 relevant clinical parameter of the agree-
10 ment, the agreement shall provide that—

11 “(I) the installment payment
12 shall not be made; or

13 “(II) the installment payment
14 shall be reduced by a percentage spec-
15 ified in the agreement that is based
16 on the outcome achieved by the drug
17 relative to the relevant clinical param-
18 eter.

19 “(4) NOTICE OF INTENT.—

20 “(A) IN GENERAL.—Subject to subpara-
21 graph (B), a manufacturer of a covered out-
22 patient drug shall not be eligible to enter into
23 a risk-sharing value-based payment agreement
24 under this subsection with respect to such drug
25 unless the manufacturer notifies the Secretary

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

9 “(B) TREATMENT OF SUBSEQUENTLY AP-
10 PROVED DRUGS.—

11 “(i) IN GENERAL.—In the case of a
12 manufacturer of a covered outpatient drug
13 approved under section 505 of the Federal
14 Food, Drug, and Cosmetic Act or licensed
15 under section 351 of the Public Health
16 Service Act after the date of enactment of
17 this subsection, not more than 90 days
18 after meeting with the Food and Drug Ad-
19 ministration following phase II clinical
20 trials for such drug (or, in the case of a
21 drug described in clause (ii), not later than
22 March 31, 2022), the manufacturer must
23 notify the Secretary of the manufacturer’s
24 intent to enter into a risk-sharing value-
25 based payment agreement under this sub-

1 section with respect to such drug. If no
2 such meeting has occurred, the Secretary
3 may use discretion as to whether a poten-
4 tially curative treatment intended for one-
5 time use may qualify for a risk-sharing
6 value-based payment agreement under this
7 section. A manufacturer notification of in-
8 terest shall not have any influence on a de-
9 cision for approval by the Food and Drug
10 Administration.

11 “(ii) APPLICATION TO CERTAIN SUB-
12 SEQUENTLY APPROVED DRUGS.—A drug
13 described in this clause is a covered out-
14 patient drug of a manufacturer—

15 “(I) that is approved under sec-
16 tion 505 of the Federal Food, Drug,
17 and Cosmetic Act or licensed under
18 section 351 of the Public Health Serv-
19 ice Act after the date of enactment of
20 this subsection; and

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

1 ministration following phase II clinical
2 trials for such drug.

3 “(iii) PARALLEL APPROVAL.—The
4 Secretary, in coordination with the Admin-
5 istrator of the Centers for Medicare &
6 Medicaid Services and the Commissioner of
7 Food and Drugs, shall, to the extent prac-
8 ticable, approve a State’s request to enter
9 into a proposed risk-sharing value-based
10 payment agreement that otherwise meets
11 the requirements of this subsection at the
12 time that such a drug is approved by the
13 Food and Drug Administration to help
14 provide that no State that wishes to enter
15 into such an agreement is required to pay
16 for the drug in full at one time if the State
17 is seeking to pay over a period of time as
18 outlined in the proposed agreement.

19 “(iv) RULE OF CONSTRUCTION.—
20 Nothing in this paragraph shall be applied
21 or construed to modify or affect the time-
22 frames or factors involved in the Sec-
23 retary’s determination of whether to ap-
24 prove or license a drug under section 505
25 of the Federal Food, Drug, and Cosmetic

1 Act or section 351 of the Public Health
2 Service Act.

3 “(5) SPECIAL PAYMENT RULES.—

4 “(A) IN GENERAL.—Except as otherwise
5 provided in this paragraph, with respect to an
6 individual who is administered a unit of a cov-
7 ered outpatient drug that is purchased under a
8 State plan by a State Medicaid agency under a
9 risk-sharing value-based payment agreement in
10 an installment year, the State shall remain lia-
11 ble to the manufacturer of such drug for pay-
12 ment for such unit without regard to whether
13 the individual remains enrolled in the State
14 plan under this title (or a waiver of such plan)
15 for each installment year for which the State is
16 to make installment payments for covered out-
17 patient drugs purchased under the agreement
18 in such year.

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

1 owed under the agreement described in such
2 subparagraph.

3 “(C) WITHDRAWAL OF APPROVAL.—In the
4 case of a covered outpatient drug that is the
5 subject of a risk-sharing value-based agreement
6 between a State and a manufacturer under this
7 subsection, including a drug approved in ac-
8 cordance with section 506(c) of the Federal
9 Food, Drug, and Cosmetic Act, and such drug
10 is the subject of an application that has been
11 withdrawn by the Secretary, the State plan
12 shall not be liable for any remaining payment
13 that is owed under the agreement.

14 “(D) ALTERNATIVE ARRANGEMENT UNDER
15 AGREEMENT.—Subject to approval by the Sec-
16 retary, the terms of a proposed risk-sharing
17 value-based payment agreement submitted for
18 approval by a State may provide that subpara-
19 graph (A) shall not apply.

20 “(E) GUIDANCE.—Not later than January
21 1, 2022, the Secretary shall issue guidance to
22 States establishing a process for States to no-
23 tify the Secretary when an individual who is ad-
24 ministered a unit of a covered outpatient drug
25 that is purchased by a State plan under a risk-

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

6 “(6) TREATMENT OF PAYMENTS UNDER RISK-
7 SHARING VALUE-BASED AGREEMENTS FOR PUR-
8 POSES OF AVERAGE MANUFACTURER PRICE; BEST
9 PRICE.—The Secretary shall treat any payments
10 made to the manufacturer of a covered outpatient
11 drug under a risk-sharing value-based payment
12 agreement under this subsection during a rebate pe-
13 riod in the same manner that the Secretary treats
14 payments made under a State supplemental rebate
15 agreement under sections 447.504(c)(19) and
16 447.505(c)(7) of title 42, Code of Federal Regula-
17 tions (or any successor regulations) for purposes of
18 determining average manufacturer price and best
19 price under this section with respect to the covered
20 outpatient drug and a rebate period and for pur-
21 poses of offsets required under subsection (b)(1)(B).

22 “(7) ASSESSMENTS AND REPORT TO CON-
23 GRESS.—

24 “(A) ASSESSMENTS.—

1 “(i) IN GENERAL.—Not later than
2 180 days after the end of each assessment
3 period of any risk-sharing value-based pay-
4 ment agreement for a State approved
5 under this subsection, the Secretary shall
6 conduct an evaluation of such agreement
7 which shall include an evaluation by the
8 Chief Actuary to determine whether pro-
9 gram spending under the risk-sharing
10 value-based payment agreement aligned
11 with the projections for the agreement
12 made under paragraph (2)(A)(ii), including
13 an assessment of whether actual Federal
14 spending under this title under the agree-
15 ment was less or more than net Federal
16 spending would have been in the absence
17 of the agreement.

18 “(ii) ASSESSMENT PERIOD.—For pur-
19 poses of clause (i)—

20 “(I) the first assessment period
21 for a risk-sharing value-based pay-
22 ment agreement shall be the period of
23 time over which payments are sched-
24 uled to be made under the agreement
25 for the first 10 individuals who are

1 administered covered outpatient drugs
2 under the agreement except that such
3 period shall not exceed the 5-year pe-
4 riod after the date on which the Sec-
5 retary approves the agreement; and

6 “(II) each subsequent assessment
7 period for a risk-sharing value-based
8 payment agreement shall be the 5-
9 year period following the end of the
10 previous assessment period.

11 “(B) RESULTS OF ASSESSMENTS.—

12 “(i) TERMINATION OPTION.—If the
13 Secretary determines as a result of the as-
14 sessment by the Chief Actuary under sub-
15 paragraph (A) that the actual Federal
16 spending under this title for any covered
17 outpatient drug that was the subject of the
18 State’s risk-sharing value-based payment
19 agreement was greater than the net Fed-
20 eral spending that would have resulted in
21 the absence of the agreement, the Sec-
22 retary may terminate approval of such
23 agreement and shall immediately conduct
24 an assessment under this paragraph of any
25 other ongoing risk-sharing value-based

1 payment agreement to which the same
2 manufacturer is a party.

3 “(ii) REPAYMENT REQUIRED.—

4 “(I) IN GENERAL.—If the Sec-
5 retary determines as a result of the
6 assessment by the Chief Actuary
7 under subparagraph (A) that the Fed-
8 eral spending under the risk-sharing
9 value-based agreement for a covered
10 outpatient drug that was subject to
11 such agreement was greater than the
12 net Federal spending that would have
13 resulted in the absence of the agree-
14 ment, the manufacturer shall repay
15 the difference to the State and Fed-
16 eral governments in a timely manner
17 as determined by the Secretary.

18 “(II) TERMINATION FOR FAIL-
19 URE TO PAY.—The failure of a manu-
20 facturer to make repayments required
21 under subclause (I) in a timely man-
22 ner shall result in immediate termi-
23 nation of all risk-sharing value-based
24 agreements to which the manufacturer
25 is a party.

1 “(III) ADDITIONAL PEN-
2 ALTIES.—In the case of a manufac-
3 turer that fails to make repayments
4 required under subclause (I), the Sec-
5 retary may treat such manufacturer
6 in the same manner as a manufac-
7 turer that fails to pay required re-
8 bates under this section, and the Sec-
9 retary may—

10 “(aa) suspend or terminate
11 the manufacturer’s rebate agree-
12 ment under this section; and

13 “(bb) pursue any other rem-
14 edy that would be available if the
15 manufacturer had failed to pay
16 required rebates under this sec-
17 tion.

18 “(C) REPORT TO CONGRESS.—Not later
19 than 5 years after the first risk-sharing value-
20 based payment agreement is approved under
21 this subsection, the Secretary shall submit to
22 Congress and make available to the public a re-
23 port that includes—

24 “(i) an assessment of the impact of
25 risk-sharing value-based payment agree-

1 ments on access for individuals who are eli-
2 gible for benefits under a State plan or
3 waiver under this title to medically nec-
4 essary covered outpatient drugs and re-
5 lated treatments;

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

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

12 “(iv) such recommendations to Con-
13 gress as the Secretary deems appropriate.

14 “(8) GUIDANCE AND REGULATIONS.—

15 “(A) IN GENERAL.—Not later than Janu-
16 ary 1, 2022, the Secretary shall issue guidance
17 to States seeking to enter into risk-sharing
18 value-based payment agreements under this
19 subsection that includes a model template for
20 such agreements. The Secretary may issue any
21 additional guidance or promulgate regulations
22 as necessary to implement and enforce the pro-
23 visions of this subsection.

24 “(B) MODEL AGREEMENTS.—

1 “(i) IN GENERAL.—If a State ex-
2 presses an interest in pursuing a risk-shar-
3 ing value-based payment agreement under
4 this subsection with a manufacturer for
5 the purchase of a covered outpatient drug,
6 the Secretary may share with such State
7 any risk-sharing value-based agreement be-
8 tween a State and the manufacturer for
9 the purchase of such drug that has been
10 approved under this subsection. While such
11 shared agreement may serve as a template
12 for a State that wishes to propose, the use
13 of a previously approved agreement shall
14 not affect the submission and approval
15 process for approval of a proposed risk-
16 sharing value-based payment agreement
17 under this subsection, including the re-
18 quirements under paragraph (2)(A).

19 “(ii) CONFIDENTIALITY.—In the case
20 of a risk-sharing value-based payment
21 agreement that is disclosed to a State by
22 the Secretary under this subparagraph and
23 that is only in effect with respect to a sin-
24 gle State, the confidentiality of information

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

3 “(C) **OIG CONSULTATION.**—

4 “(i) **IN GENERAL.**—The Secretary
5 shall consult with the Office of the Inspec-
6 tor General of the Department of Health
7 and Human Services to determine whether
8 there are potential program integrity con-
9 cerns with agreement approvals or tem-
10 plates and address accordingly.

11 “(ii) **OIG POLICY UPDATES AS NEC-**
12 **CESSARY.**—The Inspector General of the
13 Department of Health and Human Serv-
14 ices shall review and update, as necessary,
15 any policies or guidelines of the Office of
16 the Inspector General of the Department
17 of Human Services (including policies re-
18 lated to the enforcement of section 1128B)
19 to accommodate the use of risk-sharing
20 value-based payment agreements in accord-
21 ance with this section.

22 “(9) **RULES OF CONSTRUCTION.**—

23 “(A) **MODIFICATIONS.**—Nothing in this
24 subsection or any regulations promulgated
25 under this subsection shall prohibit a State

1 from requesting a modification from the Sec-
2 retary to the terms of a risk-sharing value-
3 based payment agreement. A modification that
4 is expected to result in any increase to pro-
5 jected net State or Federal spending under the
6 agreement shall be subject to recertification by
7 the Chief Actuary as described in paragraph
8 (2)(A)(ii) before the modification may be ap-
9 proved.

10 “(B) REBATE AGREEMENTS.—Nothing in
11 this subsection shall be construed as requiring
12 a State to enter into a risk-sharing value-based
13 payment agreement or as limiting or super-
14 seding the ability of a State to enter into a sup-
15 plemental rebate agreement for a covered out-
16 patient drug.

17 “(C) FFP FOR PAYMENTS UNDER RISK-
18 SHARING VALUE-BASED PAYMENT AGREE-
19 MENTS.—Federal financial participation shall
20 be available under this title for any payment
21 made by a State to a manufacturer for a cov-
22 ered outpatient drug under a risk-sharing
23 value-based payment agreement in accordance
24 with this subsection, except that no Federal fi-
25 nancial participation shall be available for any

1 payment made by a State to a manufacturer
2 under such an agreement on and after the ef-
3 fective date of a disapproval of such agreement
4 by the Secretary.

5 “(D) CONTINUED APPLICATION OF OTHER
6 PROVISIONS.—Except as expressly provided in
7 this subsection, nothing in this subsection or in
8 any regulations promulgated under this sub-
9 section shall affect the application of any other
10 provision of this Act.

11 “(10) APPROPRIATIONS.—For fiscal year 2020
12 and each fiscal year thereafter, there are appro-
13 priated to the Secretary \$5,000,000 for the purpose
14 of carrying out this subsection.

15 “(11) DEFINITIONS.—In this subsection:

16 “(A) CHIEF ACTUARY.—The term ‘Chief
17 Actuary’ means the Chief Actuary of the Cen-
18 ters for Medicare & Medicaid Services.

19 “(B) INSTALLMENT YEAR.—The term ‘in-
20 stallment year’ means, with respect to a risk-
21 sharing value-based payment agreement, a 12-
22 month period during which a covered outpatient
23 drug is administered under the agreement.

24 “(C) POTENTIALLY CURATIVE TREATMENT
25 INTENDED FOR ONE-TIME USE.—The term ‘po-

1 tentially curative treatment intended for one-
2 time use’ means a treatment that consists of
3 the administration of a covered outpatient drug
4 that—

5 “(i) is a form of gene therapy for a
6 rare disease, as defined by the Commis-
7 sioner of Food and Drugs, designated
8 under section 526 of the Federal Food,
9 Drug, and Cosmetics Act, and approved
10 under section 505 of such Act or licensed
11 under subsection (a) or (k) of section 351
12 of the Public Health Service Act to treat
13 a serious or life-threatening disease or con-
14 dition;

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

18 “(I) the cure of such disease or
19 condition; or

20 “(II) a reduction in the symp-
21 toms of such disease or condition to
22 the extent that such disease or condi-
23 tion is not expected to lead to early
24 mortality; and

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

5 “(D) RELEVANT CLINICAL PARAMETER.—
6 The term ‘relevant clinical parameter’ means,
7 with respect to a covered outpatient drug that
8 is the subject of a risk-sharing value-based pay-
9 ment agreement—

10 “(i) a clinical endpoint specified in the
11 drug’s labeling or supported by one or
12 more of the compendia described in section
13 1861(t)(2)(B)(ii)(I) that—

14 “(I) is able to be measured or
15 evaluated on an annual basis for each
16 year of the agreement on an inde-
17 pendent basis by a provider or other
18 entity; and

19 “(II) is required to be achieved
20 (based on observed metrics in patient
21 populations) under the terms of the
22 agreement; or

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

1 developed by patient-focused drug develop-
2 ment tools, that—

3 “(I) is able to be measured or
4 evaluated on an annual basis for each
5 year of the agreement on an inde-
6 pendent basis by a provider or other
7 entity; and

8 “(II) has been qualified by the
9 Food and Drug Administration.

10 “(E) RISK-SHARING VALUE-BASED PAY-
11 MENT AGREEMENT.—The term ‘risk-sharing
12 value-based payment agreement’ means an
13 agreement between a State plan and a manu-
14 facturer—

15 “(i) for the purchase of a covered out-
16 patient drug of the manufacturer that is a
17 potentially curative treatment intended for
18 one-time use;

19 “(ii) under which payment for such
20 drug shall be made pursuant to an install-
21 ment-based payment structure that meets
22 the requirements of paragraph (3);

23 “(iii) which conditions payment on the
24 achievement of at least 2 relevant clinical

1 parameters (as defined in subparagraph
2 (C));

3 “(iv) which provides that—

4 “(I) the State plan will directly
5 reimburse the manufacturer for the
6 drug; or

7 “(II) a third party will reimburse
8 the manufacture in a manner ap-
9 proved by the Secretary; and

10 “(v) is approved by the Secretary in
11 accordance with paragraph (2).

12 “(F) TOTAL INSTALLMENT YEAR
13 AMOUNT.—The term ‘total installment year
14 amount’ means, with respect to a risk-sharing
15 value-based payment agreement for the pur-
16 chase of a covered outpatient drug and an in-
17 stallment year, an amount equal to the product
18 of—

19 “(i) the unit price of the drug charged
20 under the agreement; and

21 “(ii) the number of units of such drug
22 administered under the agreement during
23 such installment year.”.

24 (b) CONFORMING AMENDMENTS.—

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

8 (2) Section 1927(b) of the Social Security Act
9 (42 U.S.C. 1396r-8(b)) is amended—

10 (A) in paragraph (1)(A), by inserting “(ex-
11 cept for drugs for which payment is made by a
12 State under a risk-sharing value-based payment
13 agreement under subsection (l))” after “under
14 the State plan for such period”; and

15 (B) in paragraph (3)—

16 (i) in subparagraph (C)(i), by insert-
17 ing “or subsection (l)(2)(A)” after “sub-
18 paragraph (A)”; and

19 (ii) in subparagraph (D), in the mat-
20 ter preceding clause (i), by inserting “,
21 under subsection (l)(2)(A),” after “under
22 this paragraph”.

1 **SEC. 208. APPLYING MEDICAID DRUG REBATE REQUIRE-**
2 **MENT TO DRUGS PROVIDED AS PART OF OUT-**
3 **PATIENT HOSPITAL SERVICES.**

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

7 “(3) LIMITING DEFINITION.—

8 “(A) IN GENERAL.—The term ‘covered
9 outpatient drug’ does not include any drug, bio-
10 logical product, or insulin provided as part of,
11 or as incident to and in the same setting as,
12 any of the following (and for which payment
13 may be made under this title as part of pay-
14 ment for the following and not as direct reim-
15 bursement for the drug):

16 “(i) Inpatient hospital services.

17 “(ii) Hospice services.

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

22 “(iv) Physicians’ services.

23 “(v) Outpatient hospital services.

24 “(vi) Nursing facility services and
25 services provided by an intermediate care
26 facility for the mentally retarded.

1 “(vii) Other laboratory and x-ray serv-
2 ices.

3 “(viii) Renal dialysis.

4 “(B) OTHER EXCLUSIONS.—Such term
5 also does not include any such drug or product
6 for which a National Drug Code number is not
7 required by the Food and Drug Administration
8 or a drug or biological used for a medical indi-
9 cation which is not a medically accepted indica-
10 tion.

11 “(C) STATE OPTION.—At the option of a
12 State, such term may include any drug, biologi-
13 cal product, or insulin for which the State is
14 the primary payer under this title or a dem-
15 onstration project concerning this title, and that
16 is provided on an outpatient basis as part of, or
17 as incident to and in the same setting as, de-
18 scribed in clause (iv) or (v) of subparagraph (A)
19 and for which payment is made as part of pay-
20 ment for such services.

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

1 best price (as defined in subsection (e)(1)(C))
2 for such drug, biological product, or insulin.”.

3 (b) EFFECTIVE DATE; IMPLEMENTATION GUID-
4 ANCE.—

5 (1) IN GENERAL.—The amendment made by
6 subsection (a) shall take effect on the date that is
7 1 year after the date of enactment of this Act.

8 (2) IMPLEMENTATION AND GUIDANCE.—Not
9 later than 1 year after the date of enactment of this
10 Act, the Secretary of Health and Human Services
11 shall issue guidance and relevant informational bul-
12 letins for States, manufacturers (as defined in sec-
13 tion 1927(k)(5) of the Social Security Act (42
14 U.S.C. 1396r–8(k)(5)), and other relevant stake-
15 holders, including health care providers, regarding
16 implementation of the amendment made by sub-
17 section (a).

18 **TITLE III—FOOD AND DRUG**
19 **ADMINISTRATION**
20 **Subtitle A—CREATES Act**

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

23 (a) DEFINITIONS.—In this section—

24 (1) the term “commercially reasonable, market-
25 based terms” means—

1 (A) a nondiscriminatory price for the sale
2 of the covered product at or below, but not
3 greater than, the most recent wholesale acquisition
4 cost for the drug, as defined in section
5 1847A(c)(6)(B) of the Social Security Act (42
6 U.S.C. 1395w-3a(c)(6)(B));

7 (B) a schedule for delivery that results in
8 the transfer of the covered product to the eligi-
9 ble product developer consistent with the timing
10 under subsection (b)(2)(A)(iv); and

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

13 (2) the term “covered product”—

14 (A) means—

15 (i) any drug approved under sub-
16 section (c) or (j) of section 505 of the Fed-
17 eral Food, Drug, and Cosmetic Act (21
18 U.S.C. 355) or biological product licensed
19 under subsection (a) or (k) of section 351
20 of the Public Health Service Act (42
21 U.S.C. 262);

22 (ii) any combination of a drug or bio-
23 logical product described in clause (i); or

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

1 section 505 of the Federal Food, Drug,
2 and Cosmetic Act (21 U.S.C. 355), or sec-
3 tion 351 of the Public Health Service Act
4 (42 U.S.C. 262), as applicable, or other-
5 wise meet the requirements for approval
6 under either such section, any product, in-
7 cluding any device, that is marketed or in-
8 tended for use with such a drug or biologi-
9 cal product; and

10 (B) does not include any drug or biological
11 product that appears on the drug shortage list
12 in effect under section 506E of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C.
14 356e), unless—

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

19 (ii) the Secretary determines that in-
20 clusion of the drug or biological product as
21 a covered product is likely to contribute to
22 alleviating or preventing a shortage;

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

1 (4) the term “eligible product developer” means
2 a person that seeks to develop a product for ap-
3 proval pursuant to an application for approval under
4 subsection (b)(2) or (j) of section 505 of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or
6 for licensing pursuant to an application under sec-
7 tion 351(k) of the Public Health Service Act (42
8 U.S.C. 262(k));

9 (5) the term “license holder” means the holder
10 of an application approved under subsection (c) or
11 (j) of section 505 of the Federal Food, Drug, and
12 Cosmetic Act (21 U.S.C. 355) or the holder of a li-
13 cense under subsection (a) or (k) of section 351 of
14 the Public Health Service Act (42 U.S.C. 262) for
15 a covered product;

16 (6) the term “REMS” means a risk evaluation
17 and mitigation strategy under section 505–1 of the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 355–1);

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

24 (8) the term “Secretary” means the Secretary
25 of Health and Human Services;

1 (9) the term “single, shared system of elements
2 to assure safe use” means a single, shared system
3 of elements to assure safe use under section 505–
4 1(f) of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 355–1(f)); and

6 (10) the term “sufficient quantities” means an
7 amount of a covered product that the eligible prod-
8 uct developer determines allows it to—

9 (A) conduct testing to support an applica-
10 tion under—

11 (i) subsection (b)(2) or (j) of section
12 505 of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 355); or

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

17 (B) fulfill any regulatory requirements re-
18 lating to approval of such an application.

19 (b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFI-
20 CIENT QUANTITIES OF A COVERED PRODUCT.—

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

1 to provide sufficient quantities of the covered prod-
2 uct to the eligible product developer on commercially
3 reasonable, market-based terms.

4 (2) ELEMENTS.—

5 (A) IN GENERAL.—To prevail in a civil ac-
6 tion brought under paragraph (1), an eligible
7 product developer shall prove, by a preponder-
8 ance of the evidence—

9 (i) that—

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

12 (II) if the covered product is sub-
13 ject to a REMS with ETASU—

14 (aa) the eligible product de-
15 veloper has obtained a covered
16 product authorization from the
17 Secretary in accordance with sub-
18 paragraph (B); and

19 (bb) the eligible product de-
20 veloper has provided a copy of
21 the covered product authorization
22 to the license holder;

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

1 the covered product on commercially rea-
2 sonable, market-based terms;

3 (iii) that the eligible product developer
4 has submitted a written request to pur-
5 chase sufficient quantities of the covered
6 product to the license holder and such re-
7 quest—

8 (I) was sent to a named cor-
9 porate officer of the license holder;

10 (II) was made by certified or reg-
11 istered mail with return receipt re-
12 quested;

13 (III) specified an individual as
14 the point of contact for the license
15 holder to direct communications re-
16 lated to the sale of the covered prod-
17 uct to the eligible product developer
18 and a means for electronic and writ-
19 ten communications with that indi-
20 vidual; and

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

1 (iv) that the license holder has not de-
2 livered to the eligible product developer
3 sufficient quantities of the covered product
4 on commercially reasonable, market-based
5 terms—

6 (I) for a covered product that is
7 not subject to a REMS with ETASU,
8 by the date that is 31 days after the
9 date on which the license holder re-
10 ceived the request for the covered
11 product; and

12 (II) for a covered product that is
13 subject to a REMS with ETASU, by
14 31 days after the later of—

15 (aa) the date on which the
16 license holder received the re-
17 quest for the covered product; or

18 (bb) the date on which the
19 license holder received a copy of
20 the covered product authorization
21 issued by the Secretary in ac-
22 cordance with subparagraph (B).

23 (B) AUTHORIZATION FOR COVERED PROD-
24 UCT SUBJECT TO A REMS WITH ETASU.—

1 (i) REQUEST.—An eligible product de-
2 veloper may submit to the Secretary a
3 written request for the eligible product de-
4 veloper to be authorized to obtain suffi-
5 cient quantities of an individual covered
6 product subject to a REMS with ETASU.

7 (ii) AUTHORIZATION.—Not later than
8 120 days after the date on which a request
9 under clause (i) is received, the Secretary
10 shall, by written notice, authorize the eligi-
11 ble product developer to obtain sufficient
12 quantities of an individual covered product
13 subject to a REMS with ETASU for pur-
14 poses of—

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

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

23 (aa)(AA) submitted proto-
24 cols, informed consent docu-
25 ments, and informational mate-

1 rials for testing that include pro-
2 tections that provide safety pro-
3 tections comparable to those pro-
4 vided by the REMS for the cov-
5 ered product; or

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

9 (bb) met any other require-
10 ments the Secretary may estab-
11 lish.

12 (iii) NOTICE.—A covered product au-
13 thorization issued under this subparagraph
14 shall state that the provision of the covered
15 product by the license holder under the
16 terms of the authorization will not be a
17 violation of the REMS for the covered
18 product.

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

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

1 sufficient quantities of the covered product from the
2 license holder—

3 (i) neither the license holder nor any
4 of its agents, wholesalers, or distributors
5 was engaged in the manufacturing or com-
6 mercial marketing of the covered product;
7 and

8 (ii) neither the license holder nor any
9 of its agents, wholesalers, or distributors
10 otherwise had access to inventory of the
11 covered product to supply to the eligible
12 product developer on commercially reason-
13 able, market-based terms;

14 (B) that—

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

18 (ii) the license holder has placed no
19 restrictions, explicit or implicit, on its
20 agents, distributors, or wholesalers to sell
21 covered products to eligible product devel-
22 opers; and

23 (iii) the covered product can be pur-
24 chased by the eligible product developer in
25 sufficient quantities on commercially rea-

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

4 (C) that the license holder made an offer
5 to the individual specified pursuant to para-
6 graph (2)(A)(iii)(III), by a means of commu-
7 nication (electronic, written, or both) specified
8 pursuant to such paragraph, to sell sufficient
9 quantities of the covered product to the eligible
10 product developer at commercially reasonable
11 market-based terms—

12 (i) for a covered product that is not
13 subject to a REMS with ETASU, by the
14 date that is 14 days after the date on
15 which the license holder received the re-
16 quest for the covered product, and the eli-
17 gible product developer did not accept such
18 offer by the date that is 7 days after the
19 date on which the eligible product devel-
20 oper received such offer from the license
21 holder; or

22 (ii) for a covered product that is sub-
23 ject to a REMS with ETASU, by the date
24 that is 20 days after the date on which the
25 license holder received the request for the

1 covered product, and the eligible product
2 developer did not accept such offer by the
3 date that is 10 days after the date on
4 which the eligible product developer re-
5 ceived such offer from the license holder.

6 (4) REMEDIES.—

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

10 (i) order the license holder to provide
11 to the eligible product developer without
12 delay sufficient quantities of the covered
13 product on commercially reasonable, mar-
14 ket-based terms;

15 (ii) award to the eligible product de-
16 veloper reasonable attorney's fees and costs
17 of the civil action; and

18 (iii) award to the eligible product de-
19 veloper a monetary amount sufficient to
20 deter the license holder from failing to pro-
21 vide eligible product developers with suffi-
22 cient quantities of a covered product on
23 commercially reasonable, market-based
24 terms, if the court finds, by a preponder-
25 ance of the evidence—

1 (I) that the license holder delayed
2 providing sufficient quantities of the
3 covered product to the eligible product
4 developer without a legitimate busi-
5 ness justification; or

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

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

14 (i) beginning on—

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

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

1 (aa) the date on which the
2 license holder received the re-
3 quest; or

4 (bb) the date on which the
5 license holder received a copy of
6 the covered product authorization
7 issued by the Secretary in ac-
8 cordance with paragraph (2)(B);
9 and

10 (ii) ending on the date on which the
11 eligible product developer received suffi-
12 cient quantities of the covered product.

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

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

1 ing transportation, handling, use, or disposal of the cov-
2 ered product by the eligible product developer.

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

7 “(1) PROVISION OF SAMPLES NOT A VIOLATION OF
8 STRATEGY.—The provision of samples of a covered prod-
9 uct to an eligible product developer (as those terms are
10 defined in section 301(a) of the Lower Costs, More Cures
11 Act of 2019) shall not be considered a violation of the
12 requirements of any risk evaluation and mitigation strat-
13 egy that may be in place under this section for such
14 drug.”.

15 (e) RULE OF CONSTRUCTION.—

16 (1) DEFINITION.—In this subsection, the term
17 “antitrust laws”—

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

21 (B) includes section 5 of the Federal
22 Trade Commission Act (15 U.S.C. 45) to the
23 extent that such section applies to unfair meth-
24 ods of competition.

1 (2) ANTITRUST LAWS.—Nothing in this section
2 shall be construed to limit the operation of any pro-
3 vision of the antitrust laws.

4 **SEC. 302. REMS APPROVAL PROCESS FOR SUBSEQUENT**
5 **FILERS.**

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

9 (1) in subsection (g)(4)(B)—

10 (A) in clause (i) by striking “or” after the
11 semicolon;

12 (B) in clause (ii) by striking the period at
13 the end and inserting “; or”; and

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

15 “(iii) accommodate different, com-
16 parable aspects of the elements to assure
17 safe use for a drug that is the subject of
18 an application under section 505(j), and
19 the applicable listed drug.”;

20 (2) in subsection (i)(1), by striking subpara-
21 graph (C) and inserting the following:

22 “(C)(i) Elements to assure safe use, if re-
23 quired under subsection (f) for the listed drug,
24 which, subject to clause (ii), for a drug that is

1 the subject of an application under section
2 505(j) may use—

3 “(I) a single, shared system with
4 the listed drug under subsection (f);
5 or

6 “(II) a different, comparable as-
7 pect of the elements to assure safe use
8 under subsection (f).

9 “(ii) The Secretary may require a
10 drug that is the subject of an application
11 under section 505(j) and the listed drug to
12 use a single, shared system under sub-
13 section (f), if the Secretary determines
14 that no different, comparable aspect of the
15 elements to assure safe use could satisfy
16 the requirements of subsection (f).”;

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

19 “(3) SHARED REMS.—If the Secretary ap-
20 proves, in accordance with paragraph (1)(C)(i)(II), a
21 different, comparable aspect of the elements to as-
22 sure safe use under subsection (f) for a drug that
23 is the subject of an abbreviated new drug application
24 under section 505(j), the Secretary may require that
25 such different comparable aspect of the elements to

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

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

6 “(m) SEPARATE REMS.—When used in this section,
7 the terms ‘different, comparable aspect of the elements to
8 assure safe use’ or ‘different, comparable approved risk
9 evaluation and mitigation strategies’ means a risk evalua-
10 tion and mitigation strategy for a drug that is the subject
11 of an application under section 505(j) that uses different
12 methods or operational means than the strategy required
13 under subsection (a) for the applicable listed drug, or
14 other application under section 505(j) with the same such
15 listed drug, but achieves the same level of safety as such
16 strategy.”.

17 **SEC. 303. RULE OF CONSTRUCTION.**

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

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

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

5 (b) DEFINITIONS.—In this section, the terms “cov-
6 ered product”, “eligible product developer”, “license hold-
7 er”, and “REMS with ETASU” have the meanings given
8 such terms in section 301(a).

9 **Subtitle B—Pay-for-Delay**

10 **SEC. 311. UNLAWFUL AGREEMENTS.**

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

17 (1) a subsequent filer directly or indirectly re-
18 ceives from such holder (or in the case of such an
19 agreement between two subsequent filers, the other
20 subsequent filer) anything of value, including a li-
21 cense; and

22 (2) the subsequent filer agrees to limit or fore-
23 go research on, or development, manufacturing,
24 marketing, or sales, for any period of time, of the
25 covered product that is the subject of the application

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

3 (b) EXCLUSION.—It shall not be unlawful under sub-
4 section (a) if a party to an agreement described in such
5 subsection demonstrates by clear and convincing evidence
6 that the value described in subsection (a)(1) is compensa-
7 tion solely for other goods or services that the subsequent
8 filer has promised to provide.

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

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

19 (A) any patent that is the basis of the cov-
20 ered patent infringement claim; or

21 (B) any patent right or other statutory ex-
22 clusivity that would prevent the marketing of
23 such covered product.

24 (2) A payment for reasonable litigation ex-
25 penses not to exceed \$7,500,000 in the aggregate.

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

3 (d) ENFORCEMENT BY FEDERAL TRADE COMMIS-
4 SION.—

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

8 (A) a person, partnership, or corporation
9 over which the Commission has authority pur-
10 suant to section 5(a)(2) of the Federal Trade
11 Commission Act (15 U.S.C. 45(a)(2)); or

12 (B) a person, partnership, or corporation
13 over which the Commission would have author-
14 ity pursuant to such section but for the fact
15 that such person, partnership, or corporation is
16 not organized to carry on business for its own
17 profit or that of its members.

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

20 (A) IN GENERAL.—A violation of this sec-
21 tion shall be treated as an unfair or deceptive
22 act or practice in violation of section 5(a)(1) of
23 the Federal Trade Commission Act (15 U.S.C.
24 45(a)(1)).

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

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

12 (ii) any NDA or BLA holder or subse-
13 quent filer that violates this section shall
14 be subject to the penalties and entitled to
15 the privileges and immunities provided in
16 the Federal Trade Commission Act.

17 (C) JUDICIAL REVIEW.—In the case of a
18 cease and desist order issued by the Commis-
19 sion under section 5 of the Federal Trade Com-
20 mission Act (15 U.S.C. 45) for violation of this
21 section, a party to such order may obtain judi-
22 cial review of such order as provided in such
23 section 5, except that—

24 (i) such review may only be obtained
25 in—

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

4 (II) the United States Court of
5 Appeals for the circuit in which the
6 ultimate parent entity, as defined in
7 section 801.1(a)(3) of title 16, Code
8 of Federal Regulations, or any suc-
9 cessor thereto, of the NDA or BLA
10 holder (if any such holder is a party
11 to such order) is incorporated as of
12 the date that the application described
13 in subparagraph (A) or (B) of sub-
14 section (g)(8) or an approved applica-
15 tion that is deemed to be a license for
16 a biological product under section
17 351(k) of the Public Health Service
18 Act (42 U.S.C. 262(k)) pursuant to
19 section 7002(e)(4) of the Biologics
20 Price Competition and Innovation Act
21 of 2009 (Public Law 111–148; 124
22 Stat. 817) is submitted to the Com-
23 missioner of Food and Drugs; or

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

1 ultimate parent entity, as so defined,
2 of any subsequent filer that is a party
3 to such order is incorporated as of the
4 date that the application described in
5 subparagraph (A) or (B) of subsection
6 (g)(8) is submitted to the Commis-
7 sioner of Food and Drugs; and

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

12 (3) ADDITIONAL ENFORCEMENT AUTHORITY.—

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

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

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

1 (I) the Commission may com-
2 mence a civil action under subpara-
3 graph (A) to recover a civil penalty
4 against any party to such order at
5 any time before the expiration of the
6 1-year period beginning on the date
7 on which such order becomes final
8 under section 5(g) of such Act (15
9 U.S.C. 45(g)); and

10 (II) in such civil action, the find-
11 ings of the Commission as to the ma-
12 terial facts in such proceeding shall be
13 conclusive, unless—

14 (aa) the terms of such order
15 expressly provide that the Com-
16 mission's findings shall not be
17 conclusive; or

18 (bb) such order became final
19 by reason of section 5(g)(1) of
20 such Act (15 U.S.C. 45(g)(1)), in
21 which case such findings shall be
22 conclusive if supported by evi-
23 dence.

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

1 provided in clause (i) for violation of this
2 section is separate from and in addition to
3 any penalty that may be incurred for viola-
4 tion of an order of the Commission under
5 section 5(l) of the Federal Trade Commis-
6 sion Act (15 U.S.C. 45(l)).

7 (C) AMOUNT OF PENALTY.—

8 (i) IN GENERAL.—The amount of a
9 civil penalty imposed in a civil action under
10 subparagraph (A) on a party to an agree-
11 ment described in subsection (a) shall be
12 sufficient to deter violations of this section,
13 but in no event greater than—

14 (I) if such party is the NDA or
15 BLA holder (or, in the case of an
16 agreement between two subsequent fil-
17 ers, the subsequent filer who gave the
18 value described in subsection (a)(1)),
19 the greater of—

20 (aa) 3 times the value re-
21 ceived by such NDA or BLA
22 holder (or by such subsequent
23 filer) that is reasonably attrib-
24 utable to the violation of this sec-
25 tion; or

1 (bb) 3 times the value given
2 to the subsequent filer (or to the
3 other subsequent filer) reason-
4 ably attributable to the violation
5 of this section; and

6 (II) if such party is the subse-
7 quent filer (or, in the case of an
8 agreement between two subsequent fil-
9 ers, the subsequent filer who received
10 the value described in subsection
11 (a)(1)), 3 times the value received by
12 such subsequent filer that is reason-
13 ably attributable to the violation of
14 this section.

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

18 (I) the nature, circumstances, ex-
19 tent, and gravity of the violation;

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

1 agreement between two subsequent fil-
2 ers, the subsequent filer who gave the
3 value described in subsection (a)(1)),
4 compensation received by the subse-
5 quent filer (or, in the case of an
6 agreement between two subsequent fil-
7 ers, the subsequent filer who received
8 the value described in subsection
9 (a)(1)), and the amount of commerce
10 affected; and

11 (III) other matters that justice
12 requires.

13 (D) INJUNCTIONS AND OTHER EQUITABLE
14 RELIEF.—In a civil action under subparagraph
15 (A), the United States district courts are em-
16 powered to grant mandatory injunctions and
17 such other and further equitable relief as they
18 deem appropriate.

19 (4) REMEDIES IN ADDITION.—Remedies pro-
20 vided in this subsection are in addition to, and not
21 in lieu of, any other remedy provided by Federal
22 law.

23 (5) PRESERVATION OF AUTHORITY OF COMMIS-
24 SION.—Nothing in this section shall be construed to

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

3 (e) FEDERAL TRADE COMMISSION RULEMAKING.—

4 The Commission may, in its discretion, by rule promul-
5 gated under section 553 of title 5, United States Code,
6 exempt from this section certain agreements described in
7 subsection (a) if the Commission finds such agreements
8 to be in furtherance of market competition and for the
9 benefit of consumers.

10 (f) ANTITRUST LAWS.—Nothing in this section shall
11 modify, impair, limit, or supersede the applicability of the
12 antitrust laws as defined in subsection (a) of the first sec-
13 tion of the Clayton Act (15 U.S.C. 12(a)), and of section
14 5 of the Federal Trade Commission Act (15 U.S.C. 45)
15 to the extent that such section 5 applies to unfair methods
16 of competition. Nothing in this section shall modify, im-
17 pair, limit, or supersede the right of a subsequent filer
18 to assert claims or counterclaims against any person,
19 under the antitrust laws or other laws relating to unfair
20 competition.

21 (g) DEFINITIONS.—In this section:

22 (1) AGREEMENT RESOLVING OR SETTling A
23 COVERED PATENT INFRINGEMENT CLAIM.—The
24 term “agreement resolving or settling a covered pat-

1 ent infringement claim” means any agreement
2 that—

3 (A) resolves or settles a covered patent in-
4 fringement claim; or

5 (B) is contingent upon, provides for a con-
6 tingent condition for, or is otherwise related to
7 the resolution or settlement of a covered patent
8 infringement claim.

9 (2) COMMISSION.—The term “Commission”
10 means the Federal Trade Commission.

11 (3) COVERED PATENT INFRINGEMENT CLAIM.—
12 The term “covered patent infringement claim”
13 means an allegation made by the NDA or BLA hold-
14 er to a subsequent filer (or, in the case of an agree-
15 ment between two subsequent filers, by one subse-
16 quent filer to another), whether or not included in
17 a complaint filed with a court of law, that—

18 (A) the submission of the application de-
19 scribed in subparagraph (A) or (B) of para-
20 graph (9), or the manufacture, use, offering for
21 sale, sale, or importation into the United States
22 of a covered product that is the subject of such
23 an application—

24 (i) in the case of an agreement be-
25 tween an NDA or BLA holder and a sub-

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

4 (ii) in the case of an agreement be-
5 tween two subsequent filers, infringes any
6 patent owned by the subsequent filer; or

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

12 (4) COVERED PRODUCT.—The term “covered
13 product” means a drug (as defined in section 201(g)
14 of the Federal Food, Drug, and Cosmetic Act (21
15 U.S.C. 321(g))), including a biological product (as
16 defined in section 351(i) of the Public Health Serv-
17 ice Act (42 U.S.C. 262(i)).

18 (5) NDA OR BLA HOLDER.—The term “NDA
19 or BLA holder” means—

20 (A) the holder of—

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

1 (ii) a biologics license application filed
2 under section 351(a) of the Public Health
3 Service Act (42 U.S.C. 262(a)) with re-
4 spect to a biological product;

5 (B) a person owning or controlling enforce-
6 ment of the patent on—

7 (i) the list published under section
8 505(j)(7) of the Federal Food, Drug, and
9 Cosmetic Act (21 U.S.C. 355(j)(7)) in con-
10 nection with the application described in
11 subparagraph (A)(i); or

12 (ii) any list published under section
13 351 of the Public Health Service Act (42
14 U.S.C. 262) comprised of patents associ-
15 ated with biologics license applications filed
16 under section 351(a) of such Act (42
17 U.S.C. 262(a)); or

18 (C) the predecessors, subsidiaries, divi-
19 sions, groups, and affiliates controlled by, con-
20 trolling, or under common control with any en-
21 tity described in subparagraph (A) or (B) (such
22 control to be presumed by direct or indirect
23 share ownership of 50 percent or greater), as
24 well as the licensees, licensors, successors, and
25 assigns of each of the entities.

1 (6) PATENT.—The term “patent” means a pat-
2 ent issued by the United States Patent and Trade-
3 mark Office.

4 (7) STATUTORY EXCLUSIVITY.—The term
5 “statutory exclusivity” means those prohibitions on
6 the submission or approval of drug applications
7 under clauses (ii) through (iv) of section
8 505(c)(3)(E) (5- and 3-year exclusivity), clauses (ii)
9 through (iv) of section 505(j)(5)(F) (5-year and 3-
10 year exclusivity), section 505(j)(5)(B)(iv) (180-day
11 exclusivity), section 527 (orphan drug exclusivity),
12 section 505A (pediatric exclusivity), or section 505E
13 (qualified infectious disease product exclusivity) of
14 the Federal Food, Drug, and Cosmetic Act (21
15 U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 355(j)(5)(F),
16 360cc, 355a, 355f), or prohibitions on the submis-
17 sion or licensing of biologics license applications
18 under section 351(k)(6) (interchangeable biological
19 product exclusivity) or section 351(k)(7) (biological
20 product reference product exclusivity) of the Public
21 Health Service Act (42 U.S.C. 262(k)(6), (7)).

22 (8) SUBSEQUENT FILER.—The term “subse-
23 quent filer” means—

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

1 cation submitted pursuant to section 505(j) of
2 the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 355(j)) or a new drug application sub-
4 mitted pursuant to section 505(b)(2) of the
5 Federal Food, Drug, and Cosmetic Act
6 (21U.S.C. 355(b)(2)) and filed under section
7 505(b)(1) of such Act (21 U.S.C. 355(b)(1)) or
8 has the exclusive rights to distribute the cov-
9 ered product that is the subject of such applica-
10 tion; or

11 (B) in the case of a biological product, a
12 party that owns or controls an application filed
13 with the Food and Drug Administration under
14 section 351(k) of the Public Health Service Act
15 (42 U.S.C. 262(k)) or has the exclusive rights
16 to distribute the biological product that is the
17 subject of such application.

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

21 **SEC. 312. NOTICE AND CERTIFICATION OF AGREEMENTS.**

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

1 a claim of infringement could reasonably be asserted
2 against any person for making, using, offering to sell, sell-
3 ing, or importing into the United States a biological prod-
4 uct that is the subject of a biosimilar biological product
5 application” before the period at the end.

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

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

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

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

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

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

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

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

14 **SEC. 314. COMMISSION LITIGATION AUTHORITY.**

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

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

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

21 (3) by inserting after subparagraph (E) the fol-
22 lowing:

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

1 **SEC. 315. STATUTE OF LIMITATIONS.**

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

10 (b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND
11 DESIST ORDER.—If the Commission has issued a cease
12 and desist order under section 5 of the Federal Trade
13 Commission Act (15 U.S.C. 45) for violation of section
14 311 of this Act and the proceeding for the issuance of
15 such order was commenced within the period required by
16 subsection (a) of this section, such subsection does not
17 prohibit the commencement, after such period, of a civil
18 action under section 311(d)(3)(A) against a party to such
19 order or a civil action under subsection (l) of such section
20 5 for violation of such order.

21 **Subtitle C—BLOCKING Act**

22 **SEC. 321. CHANGE CONDITIONS OF FIRST GENERIC EXCLU-**
23 **SIVITY TO SPUR ACCESS AND COMPETITION.**

24 (a) IN GENERAL.—Section 505(j)(5)(B)(iv) of the
25 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
26 355(j)(5)(B)(iv)) is amended—

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

5 “(aa) the date of the first com-
6 mercial marketing of the drug (includ-
7 ing the commercial marketing of the
8 listed drug) by any first applicant; or

9 “(bb) the applicable date speci-
10 fied in subclause (III).”; and

11 (2) by adding at the end the following new sub-
12 clause:

13 “(III) APPLICABLE DATE.—The appli-
14 cable date specified in this subclause, with
15 respect to an application for a drug de-
16 scribed in subclause (I), is the date on
17 which each of the following conditions is
18 first met:

19 “(aa) The approval of such an
20 application could be made effective,
21 but for the eligibility of a first appli-
22 cant for 180-day exclusivity under
23 this clause.

24 “(bb) At least 30 months have
25 passed since the date of submission of

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

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

7 “(dd) No application for the drug
8 submitted by any first applicant is ap-
9 proved at the time the conditions
10 under items (aa), (bb), and (cc) are
11 all met, regardless of whether such an
12 application is subsequently ap-
13 proved.”.

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

16 (1) not later than 120 days after the date of
17 enactment of this Act, publish, as appropriate and
18 available, information sufficient to allow applicants
19 to assess whether the conditions described in section
20 505(j)(5)(B)(iv)(III) of the Federal Food, Drug, and
21 Cosmetic Act (as added by subsection (a)) are satis-
22 fied for all applications where the exclusivity period
23 under clause (iv)(I) of section 505(j)(5)(B) of the
24 Federal Food, Drug, and Cosmetic Act (as amended
25 by such subsection) has not expired; and

1 (2) publish updates to such information to re-
2 flect the most recent information available to the
3 Secretary.

4 **Subtitle D—Purple Book**

5 **SEC. 331. PUBLIC LISTING.**

6 Section 351(k) of the Public Health Service Act (42
7 U.S.C. 262(k)) is amended by adding at the end the fol-
8 lowing:

9 “(9) PUBLIC LISTING.—

10 “(A) IN GENERAL.—

11 “(i) INITIAL PUBLICATION.—Not later
12 than 180 days after the date of enactment
13 of the Lower Costs, More Cures Act of
14 2019, the Secretary shall publish and
15 make available to the public in a search-
16 able, electronic format—

17 “(I) a list in alphabetical order of
18 the nonproprietary or proper name of
19 each biological product for which a
20 biologics license under subsection (a)
21 or this subsection is in effect, or that
22 has been deemed to be licensed under
23 this section pursuant to section
24 7002(e)(4) of the Biologics Price

1 Competition and Innovation Act of
2 2009, as of such date of enactment;

3 “(II) the date of approval of the
4 marketing application and the applica-
5 tion number; and

6 “(III) the marketing or licensure
7 status of the biological product for
8 which a biologics license under sub-
9 section (a) or this subsection is in ef-
10 fect or that has been deemed to be li-
11 censed under this section pursuant to
12 section 7002(e)(4) of the Biologics
13 Price Competition and Innovation Act
14 of 2009.

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

21 “(iii) PATENT INFORMATION.—Not
22 later than 30 days after a list of patents
23 under subsection (l)(3)(A), or a supple-
24 ment to such list under subsection (l)(7),
25 has been provided by the reference product

1 sponsor to the subsection (k) applicant re-
2 specting a biological product included on
3 the list published under this subparagraph,
4 the reference product sponsor shall provide
5 such list of patents (or supplement there-
6 to) and their corresponding expiry dates to
7 the Secretary, and the Secretary shall, in
8 revisions made under clause (ii), include
9 such information for such biological prod-
10 uct. Within 30 days of providing any sub-
11 sequent or supplemental list of patents to
12 any subsequent subsection (k) applicant
13 under subsection (1)(3)(A) or (1)(7), the
14 reference product sponsor shall update the
15 information provided to the Secretary
16 under this clause with any additional pat-
17 ents from such subsequent or supplemental
18 list and their corresponding expiry dates.

19 “(iv) LISTING OF EXCLUSIVITIES.—
20 For each biological product included on the
21 list published under this subparagraph, the
22 Secretary shall specify each exclusivity pe-
23 riod that is applicable and has not con-
24 cluded under paragraph (6) or paragraph
25 (7).

1 “(B) WITHDRAWAL OR SUSPENSION OF LI-
2 CENSURE.—If the licensing of a biological prod-
3 uct was withdrawn or suspended for safety, pu-
4 rity, or potency reasons, it may not be pub-
5 lished in the list under subparagraph (A). If the
6 withdrawal or suspension occurred after its
7 publication in such list, the reference product
8 sponsor shall notify the Secretary that—

9 “(i) the biological product shall be im-
10 mediately removed from such list—

11 “(I) for the same period as the
12 withdrawal or suspension; or

13 “(II) if the biological product has
14 been withdrawn from sale, for the pe-
15 riod of withdrawal from sale or, if ear-
16 lier, the period ending on the date the
17 Secretary determines that the with-
18 drawal from sale is not for safety, pu-
19 rity, or potency reasons; and

20 “(ii) a notice of the removal shall be
21 published in the Federal Register.”.

1 **SEC. 332. REVIEW AND REPORT ON TYPES OF INFORMA-**
2 **TION TO BE LISTED.**

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

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

11 (2) transmit to Congress an evaluation of such
12 comments, including any recommendations about the
13 types of information that should be added to or re-
14 moved from the list.

15 **Subtitle E—Orange Book**

16 **SEC. 341. ORANGE BOOK.**

17 (a) SUBMISSION OF PATENT INFORMATION FOR
18 BRAND NAME DRUGS.—Paragraph (1) of section 505(b)
19 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 355(b)) is amended to read as follows:

21 “(b)(1) Any person may file with the Secretary an
22 application with respect to any drug subject to the provi-
23 sions of subsection (a). Such persons shall submit to the
24 Secretary as part of the application—

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

4 “(B) a full list of the articles used as compo-
5 nents of such drug;

6 “(C) a full statement of the composition of such
7 drug;

8 “(D) a full description of the methods used in,
9 and the facilities and controls used for, the manufac-
10 ture, processing, and packing of such drug;

11 “(E) such samples of such drug and of the arti-
12 cles used as components thereof as the Secretary
13 may require;

14 “(F) specimens of the labeling proposed to be
15 used for such drug;

16 “(G) any assessments required under section
17 505B; and

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

1 “(i) The applicant shall file with the appli-
2 cation the patent number and the expiration
3 date of—

4 “(I) any patent which claims the drug
5 for which the applicant submitted the ap-
6 plication and is a drug substance (includ-
7 ing active ingredient) patent or a drug
8 product (including formulation and com-
9 position) patent; and

10 “(II) any patent which claims the
11 method of using such drug.

12 “(ii) If an application is filed under this
13 subsection for a drug and a patent of the type
14 described in clause (i) which claims such drug
15 or a method of using such drug is issued after
16 the filing date but before approval of the appli-
17 cation, the applicant shall amend the applica-
18 tion to include such patent information.

19 Upon approval of the application, the Secretary shall pub-
20 lish the information submitted under subparagraph (H).
21 The Secretary shall, in consultation with the Director of
22 the National Institutes of Health and with representatives
23 of the drug manufacturing industry, review and develop
24 guidance, as appropriate, on the inclusion of women and

1 minorities in clinical trials required by subparagraph
2 (A).”.

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

7 (1) by inserting after “the patent number and
8 the expiration date of any patent which” the fol-
9 lowing: “fulfills the criteria in subsection (b) and”;

10 (2) by inserting after the first sentence the fol-
11 lowing: “Patent information that is not the type of
12 patent information required by subsection (b) shall
13 not be submitted.”; and

14 (3) by inserting after “could not file patent in-
15 formation under subsection (b) because no patent”
16 the following: “of the type required to be submitted
17 in subsection (b)”.

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

22 “(iv) For each drug included on the list, the Sec-
23 retary shall specify each exclusivity period that is applica-
24 ble and has not concluded under—

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

3 “(II) clause (iv) or (v) of paragraph (5)(B) of
4 this subsection;

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

7 “(IV) section 505A;

8 “(V) section 505E; or

9 “(VI) section 527(a).”.

10 (d) REMOVAL OF INVALID PATENTS.—

11 (1) IN GENERAL.—Section 505(j)(7) of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 355(j)(7)) is amended by adding at the end the fol-
14 lowing:

15 “(D)(i) The holder of an application approved under
16 subsection (c) for a drug on the list shall notify within
17 14 days the Secretary in writing if either of the following
18 occurs:

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

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

1 “(ii) The holder of an approved application shall in-
2 clude in any notification under clause (i) a copy of the
3 decision described in subclause (I) or (II) of clause (i).

4 “(iii) The Secretary shall remove from the list any
5 patent that is determined to be invalid in a decision de-
6 scribed in subclause (I) or (II) of clause (i)—

7 “(I) promptly; but

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

12 (2) APPLICABILITY.—Subparagraph (D) of sec-
13 tion 505(j)(7) of the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 355(j)(7)), as added by para-
15 graph (1), applies only with respect to a decision de-
16 scribed in such subparagraph that is issued on or
17 after the date of enactment of this Act.

18 (e) REVIEW AND REPORT.—Not later than one year
19 after the date of enactment of this Act, the Secretary of
20 Health and Human Services, acting through the Commis-
21 sioner of Food and Drugs, shall—

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

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

5 **SEC. 342. GAO REPORT TO CONGRESS.**

6 (a) IN GENERAL.—Not later than one year after the
7 date of enactment of this Act, the Comptroller General
8 of the United States (referred to in this section as the
9 “Comptroller General”) shall submit to the Committee on
10 Energy and Commerce of the House of Representatives
11 a report on the patents included in the list published under
12 section 505(j)(7) of the Federal Food, Drug and Cosmetic
13 Act (21 U.S.C. 355(j)(7)), including an analysis and eval-
14 uation of the types of patents included in such list and
15 the claims such patents make about the products they
16 claim.

17 (b) CONTENTS.—The Comptroller General shall in-
18 clude in the report under subsection (a)—

19 (1) data on the number of—

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

1 gether comprising the finished dosage form of
2 the drug; and

3 (B) claims in each patent that claim a de-
4 vice that is used for the delivery of the drug,
5 but do not claim such device in combination
6 with an active ingredient or formulation of a
7 drug;

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

13 (3) an analysis regarding the impact of includ-
14 ing on the list under paragraph (7) of such section
15 505(j) certain types of patent information for drug
16 product applicants and approved application holders,
17 including an analysis of whether—

18 (A) the listing of the patents described in
19 paragraph (1)(A) delayed the market entry of
20 one or more drugs approved under such section
21 505(j); and

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

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

8 **Subtitle F—Advancing Education**
9 **on Biosimilars**

10 **SEC. 351. EDUCATION ON BIOLOGICAL PRODUCTS.**

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

15 **“SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.**

16 “(a) INTERNET WEBSITE.—

17 “(1) IN GENERAL.—The Secretary shall main-
18 tain and operate an internet website to provide edu-
19 cational materials for health care providers, patients,
20 and caregivers, regarding the meaning of the terms,
21 and the standards for review and licensing of, bio-
22 logical products, including biosimilar biological prod-
23 ucts and interchangeable biosimilar biological prod-
24 ucts.

1 “(2) CONTENT.—Educational materials pro-
2 vided under paragraph (1) may include—

3 “(A) explanations of key statutory and
4 regulatory terms, including ‘biosimilar’ and
5 ‘interchangeable’, and clarification regarding
6 the use of interchangeable biosimilar biological
7 products;

8 “(B) information related to development
9 programs for biological products, including bio-
10 similar biological products and interchangeable
11 biosimilar biological products and relevant clin-
12 ical considerations for prescribers, which may
13 include, as appropriate and applicable, informa-
14 tion related to the comparability of such biologi-
15 cal products;

16 “(C) an explanation of the process for re-
17 porting adverse events for biological products,
18 including biosimilar biological products and
19 interchangeable biosimilar biological products;
20 and

21 “(D) an explanation of the relationship be-
22 tween biosimilar biological products and inter-
23 changeable biosimilar biological products li-
24 censed under section 351(k) and reference
25 products (as defined in section 351(i)), includ-

1 ing the standards for review and licensing of
2 each such type of biological product.

3 “(3) FORMAT.—The educational materials pro-
4 vided under paragraph (1) may be—

5 “(A) in formats such as webinars, con-
6 tinuing medical education modules, videos, fact
7 sheets, infographics, stakeholder toolkits, or
8 other formats as appropriate and applicable;
9 and

10 “(B) tailored for the unique needs of
11 health care providers, patients, caregivers, and
12 other audiences, as the Secretary determines
13 appropriate.

14 “(4) OTHER INFORMATION.—In addition to the
15 information described in paragraph (2), the Sec-
16 retary shall continue to publish the following infor-
17 mation:

18 “(A) The action package of each biological
19 product licensed under subsection (a) or (k).

20 “(B) The summary review of each biologi-
21 cal product licensed under subsection (a) or (k).

22 “(5) CONFIDENTIAL AND TRADE SECRET IN-
23 FORMATION.—This subsection does not authorize
24 the disclosure of any trade secret, confidential com-

1 the highest potential score for the perform-
2 ance category described in paragraph
3 (2)(A)(iii) for such performance period. A
4 MIPS eligible professional may only count
5 the completion of such a program for pur-
6 poses of such category one time during the
7 eligible professional’s lifetime.”.

8 **Subtitle G—Streamlining**
9 **Transition of Biological Products**

10 **SEC. 361. STREAMLINING THE TRANSITION OF BIOLOGICAL**
11 **PRODUCTS.**

12 Section 7002(e)(4) of the Biologics Price Competition
13 and Innovation Act of 2009 (Public Law 111–148) is
14 amended—

15 (1) by striking “An approved application” and
16 inserting the following:

17 “(A) IN GENERAL.—An approved applica-
18 tion”;

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

20 “(B) TREATMENT OF CERTAIN APPLICA-
21 TIONS.—

22 “(i) IN GENERAL.—With respect to an
23 application for a biological product sub-
24 mitted under subsection (b) or (j) of sec-
25 tion 505 of the Federal Food, Drug, and

1 Cosmetic Act (21 U.S.C. 355) that is filed
2 not later than March 23, 2019, the Sec-
3 retary shall continue to review such appli-
4 cation under such section 505, even if such
5 review continues after March 23, 2020.

6 “(ii) EFFECT ON LISTED DRUGS.—
7 Only for purposes of carrying out clause
8 (i), with respect to any applicable listed
9 drug with respect to such application, the
10 following shall apply:

11 “(I) Any drug that is a biological
12 product that has been deemed licensed
13 under section 351 of the Public
14 Health Service Act (42 U.S.C. 262)
15 pursuant to subparagraph (A) and
16 that is referenced in an application
17 described in clause (i), shall continue
18 to be identified as a listed drug on the
19 list published pursuant to section
20 505(j)(7) of the Federal Food, Drug,
21 and Cosmetic Act, and the informa-
22 tion for such drug on such list shall
23 not be revised after March 20, 2020,
24 until—

1 “(aa) such drug is removed
2 from such list in accordance with
3 subclause (III) or subparagraph
4 (C) of such section 505(j)(7); or

5 “(bb) this subparagraph no
6 longer has force or effect.

7 “(II) Any drug that is a biologi-
8 cal product that has been deemed li-
9 censed under section 351 of the Pub-
10 lic Health Service Act (42 U.S.C.
11 262) pursuant to subparagraph (A)
12 and that is referenced in an applica-
13 tion described in clause (i) shall be
14 subject only to requirements applica-
15 ble to biological products licensed
16 under such section.

17 “(III) Upon approval under sub-
18 section (c) or (j) of section 505 of the
19 Federal Food, Drug, and Cosmetic
20 Act of an application described in
21 clause (i), the Secretary shall remove
22 from the list published pursuant to
23 section 505(j)(7) of the Federal Food,
24 Drug, and Cosmetic Act any listed
25 drug that is a biological product that

1 has been deemed licensed under sec-
2 tion 351 of the Public Health Service
3 Act pursuant to subparagraph (A)
4 and that is referenced in such ap-
5 proved application, unless such listed
6 drug is referenced in one or more ad-
7 ditional applications described in
8 clause (i).

9 “(iii) DEEMED LICENSURE.—Upon
10 approval of an application described in
11 clause (i), such approved application shall
12 be deemed to be a license for the biological
13 product under section 351 of the Public
14 Health Service Act, pursuant to subpara-
15 graph (A), and any period of exclusivity, as
16 applicable, shall be determined in accord-
17 ance with such section.

18 “(iv) RULE OF CONSTRUCTION.—

19 “(I) APPLICATION OF CERTAIN
20 PROVISIONS.—

21 “(aa) PATENT CERTIFI-
22 CATION OR STATEMENT.—An ap-
23 plication described in clause (i)
24 shall contain a patent certifi-
25 cation or statement described in,

1 as applicable, section 505(b)(2)
2 of the Federal Food, Drug, and
3 Cosmetic Act or clauses (vii) and
4 (viii) of section 505(j)(2)(A) of
5 such Act and, with respect to any
6 listed drug referenced in such ap-
7 plication, comply with related re-
8 quirements concerning any timely
9 filed patent information listed
10 pursuant to section 505(j)(7).

11 “(bb) DATE OF AP-
12 PROVAL.—The earliest possible
13 date on which any pending appli-
14 cation described in clause (i) may
15 be approved shall be determined
16 based on—

17 “(AA) the last expira-
18 tion date of any applicable
19 period of exclusivity that
20 would prevent such approval
21 and that is described in sec-
22 tion 505(c)(3)(E),
23 505(j)(5)(B)(iv),
24 505(j)(5)(F), 505A, 505E,
25 or 527 of the Federal Food,

1 Drug, and Cosmetic Act;
2 and

3 “(BB) if the application
4 was submitted under section
5 505(b)(2) of the Federal
6 Food, Drug, and Cosmetic
7 Act and references any list-
8 ed drug, the last applicable
9 date determined under sub-
10 paragraph (A), (B), or (C)
11 of section 505(c)(3) of such
12 Act, or, if the application
13 was submitted under section
14 505(j) of such Act, the last
15 applicable date determined
16 under clause (i), (ii), or (iii)
17 of section 505(j)(5)(B).

18 “(II) RULE OF CON-
19 STRUCTION WITH RESPECT
20 TO EXCLUSIVITY.—Nothing
21 in this subparagraph shall
22 be construed to affect sec-
23 tion 351(k)(7)(D) of the
24 Public Health Service Act.

1 “(v) AUTHORIZED DISCLOSURE.—The
2 Secretary may continue to review an appli-
3 cation after March 23, 2020, pursuant to
4 clause (i), and continue to identify any ap-
5 plicable listed drug pursuant to clause (ii)
6 on the list published pursuant to section
7 505(j)(7) of the Federal Food, Drug, and
8 Cosmetic Act, even if such review or listing
9 may reveal the existence of such applica-
10 tion and the identity of any listed drug for
11 which the investigations described in sec-
12 tion 505(b)(1)(A) of the Federal Food,
13 Drug, and Cosmetic Act are relied upon by
14 the applicant for approval of the pending
15 application. Nothing in this subparagraph
16 shall be construed as authorizing the Sec-
17 retary to disclose any other information
18 that is a trade secret or confidential infor-
19 mation described in section 552(b)(4) of
20 title 5, United States Code.

21 “(vi) SUNSET.—Beginning on October
22 1, 2022, this subparagraph shall have no
23 force or effect and any applications de-
24 scribed in clause (i) that have not been ap-
25 proved shall be deemed withdrawn.”.

1 **Subtitle H—Over-the-Counter**
2 **Monograph Safety, Innovation,**
3 **and Reform**

4 **SEC. 370. SHORT TITLE; REFERENCES IN SUBTITLE.**

5 (a) **SHORT TITLE.**—This subtitle may be cited as the
6 “Over-the-Counter Monograph Safety, Innovation, and
7 Reform Act of 2019”.

8 (b) **REFERENCES.**—Except as otherwise specified,
9 any reference to “this Act” contained in this subtitle shall
10 be treated as referring only to the provisions of this sub-
11 title.

12 **PART 1—OTC DRUG REVIEW**

13 **SEC. 371. REGULATION OF CERTAIN NONPRESCRIPTION**
14 **DRUGS THAT ARE MARKETED WITHOUT AN**
15 **APPROVED DRUG APPLICATION.**

16 (a) **IN GENERAL.**—Chapter V of the Federal Food,
17 Drug, and Cosmetic Act is amended by inserting after sec-
18 tion 505F of such Act (21 U.S.C. 355g) the following:

19 **“SEC. 505G. REGULATION OF CERTAIN NONPRESCRIPTION**
20 **DRUGS THAT ARE MARKETED WITHOUT AN**
21 **APPROVED DRUG APPLICATION.**

22 “(a) **NONPRESCRIPTION DRUGS MARKETED WITH-**
23 **OUT AN APPROVED APPLICATION.**—Nonprescription
24 drugs marketed without an approved drug application
25 under section 505, as of the date of the enactment of this

1 section, shall be treated in accordance with this sub-
2 section.

3 “(1) DRUGS SUBJECT TO A FINAL MONOGRAPH;
4 CATEGORY I DRUGS SUBJECT TO A TENTATIVE
5 FINAL MONOGRAPH.—A drug is deemed to be gen-
6 erally recognized as safe and effective under section
7 201(p)(1), not a new drug under section 201(p), and
8 not subject to section 503(b)(1), if—

9 “(A) the drug is—

10 “(i) in conformity with the require-
11 ments for nonprescription use of a final
12 monograph issued under part 330 of title
13 21, Code of Federal Regulations (except as
14 provided in paragraph (2)), the general re-
15 quirements for nonprescription drugs, and
16 conditions or requirements under sub-
17 sections (b), (c), and (k); and

18 “(ii) except as permitted by an order
19 issued under subsection (b) or, in the case
20 of a minor change in the drug, in con-
21 formity with an order issued under sub-
22 section (c), in a dosage form that, imme-
23 diately prior to the date of the enactment
24 of this section, has been used to a material

1 extent and for a material time under sec-
2 tion 201(p)(2); or

3 “(B) the drug is—

4 “(i) classified in category I for safety
5 and effectiveness under a tentative final
6 monograph that is the most recently appli-
7 cable proposal or determination issued
8 under part 330 of title 21, Code of Federal
9 Regulations;

10 “(ii) in conformity with the proposed
11 requirements for nonprescription use of
12 such tentative final monograph, any appli-
13 cable subsequent determination by the Sec-
14 retary, the general requirements for non-
15 prescription drugs, and conditions or re-
16 quirements under subsections (b), (c), and
17 (k); and

18 “(iii) except as permitted by an order
19 issued under subsection (b) or, in the case
20 of a minor change in the drug, in con-
21 formity with an order issued under sub-
22 section (c), in a dosage form that, imme-
23 diately prior to the date of the enactment
24 of this section, has been used to a material

1 extent and for a material time under sec-
2 tion 201(p)(2).

3 “(2) TREATMENT OF SUNSCREEN DRUGS.—

4 With respect to sunscreen drugs subject to this sec-
5 tion, the applicable requirements in terms of con-
6 formity with a final monograph, for purposes of
7 paragraph (1)(A)(i), shall be the requirements speci-
8 fied in part 352 of title 21, Code of Federal Regula-
9 tions, as published on May 21, 1999, beginning on
10 page 27687 of volume 64 of the Federal Register,
11 except that the applicable requirements governing ef-
12 fectiveness and labeling shall be those specified in
13 section 201.327 of title 21, Code of Federal Regula-
14 tions.

15 “(3) CATEGORY III DRUGS SUBJECT TO A TEN-
16 TATIVE FINAL MONOGRAPH; CATEGORY I DRUGS
17 SUBJECT TO PROPOSED MONOGRAPH OR ADVANCE
18 NOTICE OF PROPOSED RULEMAKING.—A drug that
19 is not described in paragraph (1), (2), or (4) is not
20 required to be the subject of an application approved
21 under section 505, and is not subject to section
22 503(b)(1), if—

23 “(A) the drug is—

24 “(i) classified in category III for safe-
25 ty or effectiveness in the preamble of a

1 proposed rule establishing a tentative final
2 monograph that is the most recently appli-
3 cable proposal or determination for such
4 drug issued under part 330 of title 21,
5 Code of Federal Regulations;

6 “(ii) in conformity with—

7 “(I) the conditions of use, includ-
8 ing indication and dosage strength, if
9 any, described for such category III
10 drug in such preamble or in an appli-
11 cable subsequent proposed rule;

12 “(II) the proposed requirements
13 for drugs classified in such tentative
14 final monograph in category I in the
15 most recently proposed rule estab-
16 lishing requirements related to such
17 tentative final monograph and in any
18 final rule establishing requirements
19 that are applicable to the drug; and

20 “(III) the general requirements
21 for nonprescription drugs and condi-
22 tions or requirements under sub-
23 section (b) or (k); and

24 “(iii) in a dosage form that, imme-
25 diately prior to the date of the enactment

1 of this section, had been used to a material
2 extent and for a material time under sec-
3 tion 201(p)(2); or
4 “(B) the drug is—
5 “(i) classified in category I for safety
6 and effectiveness under a proposed mono-
7 graph or advance notice of proposed rule-
8 making that is the most recently applicable
9 proposal or determination for such drug
10 issued under part 330 of title 21, Code of
11 Federal Regulations;
12 “(ii) in conformity with the require-
13 ments for nonprescription use of such pro-
14 posed monograph or advance notice of pro-
15 posed rulemaking, any applicable subse-
16 quent determination by the Secretary, the
17 general requirements for nonprescription
18 drugs, and conditions or requirements
19 under subsection (b) or (k); and
20 “(iii) in a dosage form that, imme-
21 diately prior to the date of the enactment
22 of this section, has been used to a material
23 extent and for a material time under sec-
24 tion 201(p)(2).

1 “(4) CATEGORY II DRUGS DEEMED NEW
2 DRUGS.—A drug that is classified in category II for
3 safety or effectiveness under a tentative final mono-
4 graph or that is subject to a determination to be not
5 generally recognized as safe and effective in a pro-
6 posed rule that is the most recently applicable pro-
7 posal issued under part 330 of title 21, Code of Fed-
8 eral Regulations, shall be deemed to be a new drug
9 under section 201(p), misbranded under section
10 502(ee), and subject to the requirement for an ap-
11 proved new drug application under section 505 be-
12 ginning on the day that is 180 calendar days after
13 the date of the enactment of this section, unless, be-
14 fore such day, the Secretary determines that it is in
15 the interest of public health to extend the period
16 during which the drug may be marketed without
17 such an approved new drug application.

18 “(5) DRUGS NOT GRASE DEEMED NEW
19 DRUGS.—A drug that the Secretary has determined
20 not to be generally recognized as safe and effective
21 under section 201(p)(1) under a final determination
22 issued under part 330 of title 21, Code of Federal
23 Regulations, shall be deemed to be a new drug under
24 section 201(p), misbranded under section 502(ee),

1 and subject to the requirement for an approved new
2 drug application under section 505.

3 “(6) OTHER DRUGS DEEMED NEW DRUGS.—
4 Except as provided in subsection (m), a drug is
5 deemed to be a new drug under section 201(p) and
6 misbranded under section 502(ee) if the drug—

7 “(A) is not subject to section 503(b)(1);
8 and

9 “(B) is not described in paragraph (1),
10 (2), (3), (4), or (5), or subsection (b)(1)(B).

11 “(b) ADMINISTRATIVE ORDERS.—

12 “(1) IN GENERAL.—

13 “(A) DETERMINATION.—The Secretary
14 may, on the initiative of the Secretary or at the
15 request of one or more requestors, issue an ad-
16 ministrative order determining whether there
17 are conditions under which a specific drug, a
18 class of drugs, or a combination of drugs, is de-
19 termined to be—

20 “(i) not subject to section 503(b)(1);
21 and

22 “(ii) generally recognized as safe and
23 effective under section 201(p)(1).

24 “(B) EFFECT.—A drug or combination of
25 drugs shall be deemed to not require approval

1 under section 505 if such drug or combination
2 of drugs—

3 “(i) is determined by the Secretary to
4 meet the conditions specified in clauses (i)
5 and (ii) of subparagraph (A);

6 “(ii) is marketed in conformity with
7 an administrative order under this sub-
8 section;

9 “(iii) meets the general requirements
10 for nonprescription drugs; and

11 “(iv) meets the requirements under
12 subsections (c) and (k).

13 “(C) STANDARD.—The Secretary shall find
14 that a drug is not generally recognized as safe
15 and effective under section 201(p)(1) if—

16 “(i) the evidence shows that the drug
17 is not generally recognized as safe and ef-
18 fective under section 201(p)(1); or

19 “(ii) the evidence is inadequate to
20 show that the drug is generally recognized
21 as safe and effective under section
22 201(p)(1).

23 “(2) ADMINISTRATIVE ORDERS INITIATED BY
24 THE SECRETARY.—

1 “(A) IN GENERAL.—In issuing an adminis-
2 trative order under paragraph (1) upon the
3 Secretary’s initiative, the Secretary shall—

4 “(i) make reasonable efforts to notify
5 informally, not later than 2 business days
6 before the issuance of the proposed order,
7 the sponsors of drugs who have a listing in
8 effect under section 510(j) for the drugs or
9 combination of drugs that will be subject
10 to the administrative order;

11 “(ii) after any such reasonable efforts
12 of notification—

13 “(I) issue a proposed administra-
14 tive order by publishing it on the
15 website of the Food and Drug Admin-
16 istration and include in such order the
17 reasons for the issuance of such order;
18 and

19 “(II) publish a notice of avail-
20 ability of such proposed order in the
21 Federal Register;

22 “(iii) except as provided in subpara-
23 graph (B), provide for a public comment
24 period with respect to such proposed order
25 of not less than 45 calendar days; and

1 “(iv) if, after completion of the pro-
2 ceedings specified in clauses (i) through
3 (iii), the Secretary determines that it is ap-
4 propriate to issue a final administrative
5 order—

6 “(I) issue the final administrative
7 order, together with a detailed state-
8 ment of reasons, which order shall not
9 take effect until the time for request-
10 ing judicial review under paragraph
11 (3)(D)(ii) has expired;

12 “(II) publish a notice of such
13 final administrative order in the Fed-
14 eral Register;

15 “(III) afford requestors of drugs
16 that will be subject to such order the
17 opportunity for formal dispute resolu-
18 tion up to the level of the Director of
19 the Center for Drug Evaluation and
20 Research, which initially must be re-
21 quested within 45 calendar days of
22 the issuance of the order, and, for
23 subsequent levels of appeal, within 30
24 calendar days of the prior decision;
25 and

1 “(IV) except with respect to
2 drugs described in paragraph (3)(B),
3 upon completion of the formal dispute
4 resolution procedure, inform the per-
5 sons which sought such dispute reso-
6 lution of their right to request a hear-
7 ing.

8 “(B) EXCEPTIONS.—When issuing an ad-
9 ministrative order under paragraph (1) on the
10 Secretary’s initiative proposing to determine
11 that a drug described in subsection (a)(3) is not
12 generally recognized as safe and effective under
13 section 201(p)(1), the Secretary shall follow the
14 procedures in subparagraph (A), except that—

15 “(i) the proposed order shall include
16 notice of—

17 “(I) the general categories of
18 data the Secretary has determined
19 necessary to establish that the drug is
20 generally recognized as safe and effec-
21 tive under section 201(p)(1); and

22 “(II) the format for submissions
23 by interested persons;

24 “(ii) the Secretary shall provide for a
25 public comment period of no less than 180

1 calendar days with respect to such pro-
2 posed order, except when the Secretary de-
3 termines, for good cause, that a shorter pe-
4 riod is in the interest of public health; and

5 “(iii) any person who submits data in
6 such comment period shall include a cer-
7 tification that the person has submitted all
8 evidence created, obtained, or received by
9 that person that is both within the cat-
10 egories of data identified in the proposed
11 order and relevant to a determination as to
12 whether the drug is generally recognized as
13 safe and effective under section 201(p)(1).

14 “(3) HEARINGS; JUDICIAL REVIEW.—

15 “(A) IN GENERAL.—Only a person who
16 participated in each stage of formal dispute res-
17 olution under subclause (III) of paragraph
18 (2)(A)(iv) of an administrative order with re-
19 spect to a drug may request a hearing con-
20 cerning a final administrative order issued
21 under such paragraph with respect to such
22 drug. If a hearing is sought, such person must
23 submit a request for a hearing, which shall be
24 based solely on information in the administra-
25 tive record, to the Secretary not later than 30

1 calendar days after receiving notice of the final
2 decision of the formal dispute resolution proce-
3 dure.

4 “(B) NO HEARING REQUIRED WITH RE-
5 SPECT TO ORDERS RELATING TO CERTAIN
6 DRUGS.—

7 “(i) IN GENERAL.—The Secretary
8 shall not be required to provide notice and
9 an opportunity for a hearing pursuant to
10 paragraph (2)(A)(iv) if the final adminis-
11 trative order involved relates to a drug—

12 “(I) that is described in sub-
13 section (a)(3)(A); and

14 “(II) with respect to which no
15 human or non-human data studies rel-
16 evant to the safety or effectiveness of
17 such drug have been submitted to the
18 administrative record since the
19 issuance of the most recent tentative
20 final monograph relating to such
21 drug.

22 “(ii) HUMAN DATA STUDIES AND
23 NON-HUMAN DATA DEFINED.—In this sub-
24 paragraph:

1 “(I) The term ‘human data stud-
2 ies’ means clinical trials of safety or
3 effectiveness (including actual use
4 studies), pharmacokinetics studies, or
5 bioavailability studies.

6 “(II) The term ‘non-human data’
7 means data from testing other than
8 with human subjects which provides
9 information concerning safety or ef-
10 fectiveness.

11 “(C) HEARING PROCEDURES.—

12 “(i) DENIAL OF REQUEST FOR HEAR-
13 ING.—If the Secretary determines that in-
14 formation submitted in a request for a
15 hearing under subparagraph (A) with re-
16 spect to a final administrative order issued
17 under paragraph (2)(A)(iv) does not iden-
18 tify the existence of a genuine and sub-
19 stantial question of material fact, the Sec-
20 retary may deny such request. In making
21 such a determination, the Secretary may
22 consider only information and data that
23 are based on relevant and reliable scientific
24 principles and methodologies.

1 “(ii) SINGLE HEARING FOR MULTIPLE
2 RELATED REQUESTS.—If more than one
3 request for a hearing is submitted with re-
4 spect to the same administrative order
5 under subparagraph (A), the Secretary
6 may direct that a single hearing be con-
7 ducted in which all persons whose hearing
8 requests were granted may participate.

9 “(iii) PRESIDING OFFICER.—The pre-
10 siding officer of a hearing requested under
11 subparagraph (A) shall—

12 “(I) be designated by the Sec-
13 retary;

14 “(II) not be an employee of the
15 Center for Drug Evaluation and Re-
16 search; and

17 “(III) not have been previously
18 involved in the development of the ad-
19 ministrative order involved or pro-
20 ceedings relating to that administra-
21 tive order.

22 “(iv) RIGHTS OF PARTIES TO HEAR-
23 ING.—The parties to a hearing requested
24 under subparagraph (A) shall have the
25 right to present testimony, including testi-

1 mony of expert witnesses, and to cross-ex-
2 amine witnesses presented by other parties.
3 Where appropriate, the presiding officer
4 may require that cross-examination by par-
5 ties representing substantially the same in-
6 terests be consolidated to promote effi-
7 ciency and avoid duplication.

8 “(v) FINAL DECISION.—

9 “(I) At the conclusion of a hear-
10 ing requested under subparagraph
11 (A), the presiding officer of the hear-
12 ing shall issue a decision containing
13 findings of fact and conclusions of
14 law. The decision of the presiding offi-
15 cer shall be final.

16 “(II) The final decision may not
17 take effect until the period under sub-
18 paragraph (D)(ii) for submitting a re-
19 quest for judicial review of such deci-
20 sion expires.

21 “(D) JUDICIAL REVIEW OF FINAL ADMIN-
22 ISTRATIVE ORDER.—

23 “(i) IN GENERAL.—The procedures
24 described in section 505(h) shall apply
25 with respect to judicial review of final ad-

1 ministrative orders issued under this sub-
2 section in the same manner and to the
3 same extent as such section applies to an
4 order described in such section except that
5 the judicial review shall be taken by filing
6 in an appropriate district court of the
7 United States in lieu of the appellate
8 courts specified in such section.

9 “(ii) PERIOD TO SUBMIT A REQUEST
10 FOR JUDICIAL REVIEW.—A person eligible
11 to request a hearing under this paragraph
12 and seeking judicial review of a final ad-
13 ministrative order issued under this sub-
14 section shall file such request for judicial
15 review not later than 60 calendar days
16 after the latest of—

17 “(I) the date on which notice of
18 such order is published;

19 “(II) the date on which a hearing
20 with respect to such order is denied
21 under subparagraph (B) or (C)(i);

22 “(III) the date on which a final
23 decision is made following a hearing
24 under subparagraph (C)(v); or

1 “(IV) if no hearing is requested,
2 the date on which the time for re-
3 questing a hearing expires.

4 “(4) EXPEDITED PROCEDURE WITH RESPECT
5 TO ADMINISTRATIVE ORDERS INITIATED BY THE
6 SECRETARY.—

7 “(A) IMMINENT HAZARD TO THE PUBLIC
8 HEALTH.—

9 “(i) IN GENERAL.—In the case of a
10 determination by the Secretary that a
11 drug, class of drugs, or combination of
12 drugs subject to this section poses an im-
13 minent hazard to the public health, the
14 Secretary, after first making reasonable ef-
15 forts to notify, not later than 48 hours be-
16 fore issuance of such order under this sub-
17 paragraph, sponsors who have a listing in
18 effect under section 510(j) for such drug
19 or combination of drugs—

20 “(I) may issue an interim final
21 administrative order for such drug,
22 class of drugs, or combination of
23 drugs under paragraph (1), together
24 with a detailed statement of the rea-
25 sons for such order;

1 “(II) shall publish in the Federal
2 Register a notice of availability of any
3 such order; and

4 “(III) shall provide for a public
5 comment period of at least 45 cal-
6 endar days with respect to such in-
7 terim final order.

8 “(ii) NONDELEGATION.—The Sec-
9 retary may not delegate the authority to
10 issue an interim final administrative order
11 under this subparagraph.

12 “(B) SAFETY LABELING CHANGES.—

13 “(i) IN GENERAL.—In the case of a
14 determination by the Secretary that a
15 change in the labeling of a drug, class of
16 drugs, or combination of drugs subject to
17 this section is reasonably expected to miti-
18 gate a significant or unreasonable risk of
19 a serious adverse event associated with use
20 of the drug, the Secretary may—

21 “(I) make reasonable efforts to
22 notify informally, not later than 48
23 hours before the issuance of the in-
24 terim final order, the sponsors of
25 drugs who have a listing in effect

1 under section 510(j) for such drug or
2 combination of drugs;

3 “(II) after reasonable efforts of
4 notification, issue an interim final ad-
5 ministrative order in accordance with
6 paragraph (1) to require such change,
7 together with a detailed statement of
8 the reasons for such order;

9 “(III) publish in the Federal
10 Register a notice of availability of
11 such order; and

12 “(IV) provide for a public com-
13 ment period of at least 45 calendar
14 days with respect to such interim final
15 order.

16 “(ii) CONTENT OF ORDER.—An in-
17 terim final order issued under this sub-
18 paragraph with respect to the labeling of a
19 drug may provide for new warnings and
20 other information required for safe use of
21 the drug.

22 “(C) EFFECTIVE DATE.—An order under
23 subparagraph (A) or (B) shall take effect on a
24 date specified by the Secretary.

1 “(D) FINAL ORDER.—After the completion
2 of the proceedings in subparagraph (A) or (B),
3 the Secretary shall—

4 “(i) issue a final order in accordance
5 with paragraph (1);

6 “(ii) publish a notice of availability of
7 such final administrative order in the Fed-
8 eral Register; and

9 “(iii) afford sponsors of such drugs
10 that will be subject to such an order the
11 opportunity for formal dispute resolution
12 up to the level of the Director of the Cen-
13 ter for Drug Evaluation and Research,
14 which must initially be within 45 calendar
15 days of the issuance of the order, and for
16 subsequent levels of appeal, within 30 cal-
17 endar days of the prior decision.

18 “(E) HEARINGS.—A sponsor of a drug
19 subject to a final order issued under subpara-
20 graph (D) and that participated in each stage
21 of formal dispute resolution under clause (iii) of
22 such subparagraph may request a hearing on
23 such order. The provisions of subparagraphs
24 (A), (B), and (C) of paragraph (3), other than
25 paragraph (3)(C)(v)(II), shall apply with re-

1 spect to a hearing on such order in the same
2 manner and to the same extent as such provi-
3 sions apply with respect to a hearing on an ad-
4 ministrative order issued under paragraph
5 (2)(A)(iv).

6 “(F) TIMING.—

7 “(i) FINAL ORDER AND HEARING.—

8 The Secretary shall—

9 “(I) not later than 6 months
10 after the date on which the comment
11 period closes under subparagraph (A)
12 or (B), issue a final order in accord-
13 ance with paragraph (1); and

14 “(II) not later than 12 months
15 after the date on which such final
16 order is issued, complete any hearing
17 under subparagraph (E).

18 “(ii) DISPUTE RESOLUTION RE-
19 QUEST.—The Secretary shall specify in an
20 interim final order issued under subpara-
21 graph (A) or (B) such shorter periods for
22 requesting dispute resolution under sub-
23 paragraph (D)(iii) as are necessary to
24 meet the requirements of this subpara-
25 graph.

1 “(G) JUDICIAL REVIEW.—A final order
2 issued pursuant to subparagraph (F) shall be
3 subject to judicial review in accordance with
4 paragraph (3)(D).

5 “(5) ADMINISTRATIVE ORDER INITIATED AT
6 THE REQUEST OF A REQUESTOR.—

7 “(A) IN GENERAL.—In issuing an adminis-
8 trative order under paragraph (1) at the re-
9 quest of a requestor with respect to certain
10 drugs, classes of drugs, or combinations of
11 drugs—

12 “(i) the Secretary shall, after receiv-
13 ing a request under this subparagraph, de-
14 termine whether the request is sufficiently
15 complete and formatted to permit a sub-
16 stantive review;

17 “(ii) if the Secretary determines that
18 the request is sufficiently complete and for-
19 matted to permit a substantive review, the
20 Secretary shall—

21 “(I) file the request; and

22 “(II) initiate proceedings with re-
23 spect to issuing an administrative
24 order in accordance with paragraphs
25 (2) and (3); and

1 “(iii) except as provided in paragraph
2 (6), if the Secretary determines that a re-
3 quest does not meet the requirements for
4 filing or is not sufficiently complete and
5 formatted to permit a substantive review,
6 the requestor may demand that the request
7 be filed over protest, and the Secretary
8 shall initiate proceedings to review the re-
9 quest in accordance with paragraph (2)(A).

10 “(B) REQUEST TO INITIATE PRO-
11 CEEDINGS.—

12 “(i) IN GENERAL.—A requestor seek-
13 ing an administrative order under para-
14 graph (1) with respect to certain drugs,
15 classes of drugs, or combinations of drugs,
16 shall submit to the Secretary a request to
17 initiate proceedings for such order in the
18 form and manner as specified by the Sec-
19 retary. Such requestor may submit a re-
20 quest under this subparagraph for the
21 issuance of an administrative order—

22 “(I) determining whether a drug
23 is generally recognized as safe and ef-
24 fective under section 201(p)(1), ex-
25 empt from section 503(b)(1), and not

1 required to be the subject of an ap-
2 proved application under section 505;
3 or

4 “(II) determining whether a
5 change to a condition of use of a drug
6 is generally recognized as safe and ef-
7 fective under section 201(p)(1), ex-
8 empt from section 503(b)(1), and not
9 required to be the subject of an ap-
10 proved application under section 505,
11 if, absent such a changed condition of
12 use, such drug is—

13 “(aa) generally recognized
14 as safe and effective under sec-
15 tion 201(p)(1) in accordance with
16 subsection (a)(1), (a)(2), or an
17 order under this subsection; or

18 “(bb) subject to subsection
19 (a)(3), but only if such requestor
20 initiates such request in conjunc-
21 tion with a request for the Sec-
22 retary to determine whether such
23 drug is generally recognized as
24 safe and effective under section
25 201(p)(1), which is filed by the

1 Secretary under subparagraph
2 (A)(ii).

3 “(ii) EXCEPTION.—The Secretary is
4 not required to complete review of a re-
5 quest for a change described in clause
6 (i)(II) if the Secretary determines that
7 there is an inadequate basis to find the
8 drug is generally recognized as safe and ef-
9 fective under section 201(p)(1) under para-
10 graph (1) and issues a final order an-
11 nouncing that determination.

12 “(iii) WITHDRAWAL.—The requestor
13 may withdraw a request under this para-
14 graph, according to the procedures set
15 forth pursuant to subsection (d)(2)(B).
16 Notwithstanding any other provision of
17 this section, if such request is withdrawn,
18 the Secretary may cease proceedings under
19 this subparagraph.

20 “(C) EXCLUSIVITY.—

21 “(i) IN GENERAL.—A final adminis-
22 trative order issued in response to a re-
23 quest under this section shall have the ef-
24 fect of authorizing solely the order re-
25 questor (or the licensees, assignees, or suc-

1 cessors in interest of such requestor with
2 respect to the subject of such order), for a
3 period of 18 months following the effective
4 date of such final order and beginning on
5 the date the requestor may lawfully market
6 such drugs pursuant to the order, to mar-
7 ket drugs—

8 “(I) incorporating changes de-
9 scribed in clause (ii); and

10 “(II) subject to the limitations
11 under clause (iv).

12 “(ii) CHANGES DESCRIBED.—A
13 change described in this clause is a change
14 subject to an order specified in clause (i),
15 which—

16 “(I) provides for a drug to con-
17 tain an active ingredient (including
18 any ester or salt of the active ingre-
19 dient) not previously incorporated in a
20 drug described in clause (iii); or

21 “(II) provides for a change in the
22 conditions of use of a drug, for which
23 new human data studies conducted or
24 sponsored by the requestor (or for
25 which the requestor has an exclusive

1 right of reference) were essential to
2 the issuance of such order.

3 “(iii) DRUGS DESCRIBED.—The drugs
4 described in this clause are drugs—

5 “(I) specified in subsection
6 (a)(1), (a)(2), or (a)(3);

7 “(II) subject to a final order
8 issued under this section;

9 “(III) subject to a final sun-
10 screen order (as defined in section
11 586(2)(A)); or

12 “(IV) described in subsection
13 (m)(1), other than drugs subject to an
14 active enforcement action under chap-
15 ter III of this Act.

16 “(iv) LIMITATIONS ON EXCLU-
17 SIVITY.—

18 “(I) IN GENERAL.—Only one 18-
19 month period under this subpara-
20 graph shall be granted, under each
21 order described in clause (i), with re-
22 spect to changes (to the drug subject
23 to such order) which are either—

1 “(aa) changes described in
2 clause (ii)(I), relating to active
3 ingredients; or

4 “(bb) changes described in
5 clause (ii)(II), relating to condi-
6 tions of use.

7 “(II) NO EXCLUSIVITY AL-
8 LOWED.—No exclusivity shall apply to
9 changes to a drug which are—

10 “(aa) the subject of a Tier 2
11 OTC monograph order request
12 (as defined in section 744L);

13 “(bb) safety-related changes,
14 as defined by the Secretary, or
15 any other changes the Secretary
16 considers necessary to assure
17 safe use; or

18 “(cc) changes related to
19 methods of testing safety or effi-
20 cacy.

21 “(v) NEW HUMAN DATA STUDIES DE-
22 FINED.—In this subparagraph, the term
23 ‘new human data studies’ means clinical
24 trials of safety or effectiveness (including
25 actual use studies), pharmacokinetics stud-

1 ies, or bioavailability studies, the results of
2 which—

3 “(I) have not been relied on by
4 the Secretary to support—

5 “(aa) a proposed or final de-
6 termination that a drug described
7 in subclause (I), (II), or (III) of
8 clause (iii) is generally recognized
9 as safe and effective under sec-
10 tion 201(p)(1); or

11 “(bb) approval of a drug
12 that was approved under section
13 505; and

14 “(II) do not duplicate the results
15 of another study that was relied on by
16 the Secretary to support—

17 “(aa) a proposed or final de-
18 termination that a drug described
19 in subclause (I), (II), or (III) of
20 clause (iii) is generally recognized
21 as safe and effective under sec-
22 tion 201(p)(1); or

23 “(bb) approval of a drug
24 that was approved under section
25 505.

1 “(6) INFORMATION REGARDING SAFE NON-
2 PRESCRIPTION MARKETING AND USE AS CONDITION
3 FOR FILING A GENERALLY RECOGNIZED AS SAFE
4 AND EFFECTIVE REQUEST.—

5 “(A) IN GENERAL.—In response to a re-
6 quest under this section that a drug described
7 in subparagraph (B) be generally recognized as
8 safe and effective, the Secretary—

9 “(i) may file such request, if the re-
10 quest includes information specified under
11 subparagraph (C) with respect to safe non-
12 prescription marketing and use of such
13 drug; or

14 “(ii) if the request fails to include in-
15 formation specified under subparagraph
16 (C), shall refuse to file such request and
17 require that nonprescription marketing of
18 the drug be pursuant to a new drug appli-
19 cation as described in subparagraph (D).

20 “(B) DRUG DESCRIBED.—A drug de-
21 scribed in this subparagraph is a nonprescrip-
22 tion drug which contains an active ingredient
23 not previously incorporated in a drug—

24 “(i) specified in subsection (a)(1),
25 (a)(2), or (a)(3);

1 “(ii) subject to a final order under
2 this section; or

3 “(iii) subject to a final sunscreen
4 order (as defined in section 586(2)(A)).

5 “(C) INFORMATION DEMONSTRATING
6 PRIMA FACIE SAFE NONPRESCRIPTION MAR-
7 KETING AND USE.—Information specified in
8 this subparagraph, with respect to a request de-
9 scribed in subparagraph (A)(i), is—

10 “(i) information sufficient for a prima
11 facie demonstration that the drug subject
12 to such request has a verifiable history of
13 being marketed and safely used by con-
14 sumers in the United States as a non-
15 prescription drug under comparable condi-
16 tions of use;

17 “(ii) if the drug has not been pre-
18 viously marketed in the United States as a
19 nonprescription drug, information suffi-
20 cient for a prima facie demonstration that
21 the drug was marketed and safely used
22 under comparable conditions of marketing
23 and use in a country listed in section
24 802(b)(1)(A) or designated by the Sec-

1 retary in accordance with section
2 802(b)(1)(B)—

3 “(I) for such period as needed to
4 provide reasonable assurances con-
5 cerning the safe nonprescription use
6 of the drug; and

7 “(II) during such time was sub-
8 ject to sufficient monitoring by a reg-
9 ulatory body considered acceptable by
10 the Secretary for such monitoring
11 purposes, including for adverse events
12 associated with nonprescription use of
13 the drug; or

14 “(iii) if the Secretary determines that
15 information described in clause (i) or (ii) is
16 not needed to provide a prima facie dem-
17 onstration that the drug can be safely mar-
18 keted and used as a nonprescription drug,
19 such other information the Secretary deter-
20 mines is sufficient for such purposes.

21 “(D) MARKETING PURSUANT TO NEW
22 DRUG APPLICATION.—In the case of a request
23 described in subparagraph (A)(ii), the drug
24 subject to such request may be resubmitted for
25 filing only if—

1 “(i) the drug is marketed as a non-
2 prescription drug, under conditions of use
3 comparable to the conditions specified in
4 the request, for such period as the Sec-
5 retary determines appropriate (not to ex-
6 ceed 5 consecutive years) pursuant to an
7 application approved under section 505;
8 and

9 “(ii) during such period, 1,000,000
10 retail packages of the drug, or an equiva-
11 lent quantity as determined by the Sec-
12 retary, were distributed for retail sale, as
13 determined in such manner as the Sec-
14 retary finds appropriate.

15 “(E) RULE OF APPLICATION.—Except in
16 the case of a request involving a drug described
17 in section 586(9), as in effect on January 1,
18 2017, if the Secretary refuses to file a request
19 under this paragraph, the requestor may not
20 file such request over protest under paragraph
21 (5)(A)(iii).

22 “(7) PACKAGING.—An administrative order
23 issued under paragraph (2), (4)(A), or (5) may in-
24 clude requirements for the packaging of a drug to
25 encourage use in accordance with labeling. Such re-

1 requirements may include unit dose packaging, re-
2 quirements for products intended for use by pedi-
3 atric populations, requirements to reduce risk of
4 harm from unsupervised ingestion, and other appro-
5 priate requirements. This paragraph does not au-
6 thorize the Food and Drug Administration to re-
7 quire standards or testing procedures as described in
8 part 1700 of title 16, Code of Federal Regulations.

9 “(8) FINAL AND TENTATIVE FINAL MONO-
10 GRAPHS FOR CATEGORY I DRUGS DEEMED FINAL
11 ADMINISTRATIVE ORDERS.—

12 “(A) IN GENERAL.—A final monograph or
13 tentative final monograph described in subpara-
14 graph (B) shall be deemed to be a final admin-
15 istrative order under this subsection and may
16 be amended, revoked, or otherwise modified in
17 accordance with the procedures of this sub-
18 section.

19 “(B) MONOGRAPHS DESCRIBED.—For pur-
20 poses of subparagraph (A), a final monograph
21 or tentative final monograph is described in this
22 subparagraph if it—

23 “(i) establishes conditions of use for a
24 drug described in paragraph (1) or (2) of
25 subsection (a); and

1 “(ii) represents the most recently pro-
2 mulgated version of such conditions, in-
3 cluding as modified, in whole or in part, by
4 any proposed or final rule.

5 “(C) DEEMED ORDERS INCLUDE HARMO-
6 NIZING TECHNICAL AMENDMENTS.—The
7 deemed establishment of a final administrative
8 order under subparagraph (A) shall be con-
9 strued to include any technical amendments to
10 such order as the Secretary determines nec-
11 essary to ensure that such order is appro-
12 priately harmonized, in terms of terminology or
13 cross-references, with the applicable provisions
14 of this Act (and regulations thereunder) and
15 any other orders issued under this section.

16 “(c) PROCEDURE FOR MINOR CHANGES.—

17 “(1) IN GENERAL.—Minor changes in the dos-
18 age form of a drug that is described in paragraph
19 (1) or (2) of subsection (a) or the subject of an
20 order issued under subsection (b) may be made by
21 a requestor without the issuance of an order under
22 subsection (b) if—

23 “(A) the requestor maintains such infor-
24 mation as is necessary to demonstrate that the
25 change—

1 “(i) will not affect the safety or effec-
2 tiveness of the drug; and

3 “(ii) will not materially affect the ex-
4 tent of absorption or other exposure to the
5 active ingredient in comparison to a suit-
6 able reference product; and

7 “(B) the change is in conformity with the
8 requirements of an applicable administrative
9 order issued by the Secretary under paragraph
10 (3).

11 “(2) ADDITIONAL INFORMATION.—

12 “(A) ACCESS TO RECORDS.—A sponsor
13 shall submit records requested by the Secretary
14 relating to such a minor change under section
15 704(a)(4), within 15 business days of receiving
16 such a request, or such longer period as the
17 Secretary may provide.

18 “(B) INSUFFICIENT INFORMATION.—If the
19 Secretary determines that the information con-
20 tained in such records is not sufficient to dem-
21 onstrate that the change does not affect the
22 safety or effectiveness of the drug or materially
23 affect the extent of absorption or other expo-
24 sure to the active ingredient, the Secretary—

1 “(i) may so inform the sponsor of the
2 drug in writing; and

3 “(ii) if the Secretary so informs the
4 sponsor, shall provide the sponsor of the
5 drug with a reasonable opportunity to pro-
6 vide additional information.

7 “(C) FAILURE TO SUBMIT SUFFICIENT IN-
8 FORMATION.—If the sponsor fails to provide
9 such additional information within a time pre-
10 scribed by the Secretary, or if the Secretary de-
11 termines that such additional information does
12 not demonstrate that the change does not—

13 “(i) affect the safety or effectiveness
14 of the drug; or

15 “(ii) materially affect the extent of
16 absorption or other exposure to the active
17 ingredient in comparison to a suitable ref-
18 erence product,

19 the drug as modified is a new drug under sec-
20 tion 201(p) and shall be deemed to be mis-
21 branded under section 502(ee).

22 “(3) DETERMINING WHETHER A CHANGE WILL
23 AFFECT SAFETY OR EFFECTIVENESS.—

24 “(A) IN GENERAL.—The Secretary shall
25 issue one or more administrative orders speci-

1 fying requirements for determining whether a
2 minor change made by a sponsor pursuant to
3 this subsection will affect the safety or effective-
4 ness of a drug or materially affect the extent of
5 absorption or other exposure to an active ingre-
6 dient in the drug in comparison to a suitable
7 reference product, together with guidance for
8 applying those orders to specific dosage forms.

9 “(B) STANDARD PRACTICES.—The orders
10 and guidance issued by the Secretary under
11 subparagraph (A) shall take into account rel-
12 evant public standards and standard practices
13 for evaluating the quality of drugs, and may
14 take into account the special needs of popu-
15 lations, including children.

16 “(d) CONFIDENTIALITY OF INFORMATION SUB-
17 MITTED TO THE SECRETARY.—

18 “(1) IN GENERAL.—Subject to paragraph (2),
19 any information, including reports of testing con-
20 ducted on the drug or drugs involved, that is sub-
21 mitted by a requestor in connection with proceedings
22 on an order under this section (including any minor
23 change under subsection (c)) and is a trade secret
24 or confidential information subject to section
25 552(b)(4) of title 5, United States Code, or section

1 1905 of title 18, United States Code, shall not be
2 disclosed to the public unless the requestor consents
3 to that disclosure.

4 “(2) PUBLIC AVAILABILITY.—

5 “(A) IN GENERAL.—Except as provided in
6 subparagraph (B), the Secretary shall—

7 “(i) make any information submitted
8 by a requestor in support of a request
9 under subsection (b)(5)(A) available to the
10 public not later than the date on which the
11 proposed order is issued; and

12 “(ii) make any information submitted
13 by any other person with respect to an
14 order requested (or initiated by the Sec-
15 retary) under subsection (b), available to
16 the public upon such submission.

17 “(B) LIMITATIONS ON PUBLIC AVAIL-
18 ABILITY.—Information described in subpara-
19 graph (A) shall not be made public if—

20 “(i) the information pertains to phar-
21 maceutical quality information, unless such
22 information is necessary to establish stand-
23 ards under which a drug is generally rec-
24 ognized as safe and effective under section
25 201(p)(1);

1 “(ii) the information is submitted in a
2 requestor-initiated request, but the re-
3 questor withdraws such request, in accord-
4 ance with withdrawal procedures estab-
5 lished by the Secretary, before the Sec-
6 retary issues the proposed order;

7 “(iii) the Secretary requests and ob-
8 tains the information under subsection (c)
9 and such information is not submitted in
10 relation to an order under subsection (b);
11 or

12 “(iv) the information is of the type
13 contained in raw datasets.

14 “(e) UPDATES TO DRUG LISTING INFORMATION.—
15 A sponsor who makes a change to a drug subject to this
16 section shall submit updated drug listing information for
17 the drug in accordance with section 510(j) within 30 cal-
18 endar days of the date when the drug is first commercially
19 marketed, except that a sponsor who was the order re-
20 questor with respect to an order subject to subsection
21 (b)(5)(C) (or a licensee, assignee, or successor in interest
22 of such requestor) shall submit updated drug listing infor-
23 mation on or before the date when the drug is first com-
24 mercially marketed.

1 “(f) APPROVALS UNDER SECTION 505.—The provi-
2 sions of this section shall not be construed to preclude a
3 person from seeking or maintaining the approval of an ap-
4 plication for a drug under sections 505(b)(1), 505(b)(2),
5 and 505(j). A determination under this section that a drug
6 is not subject to section 503(b)(1), is generally recognized
7 as safe and effective under section 201(p)(1), and is not
8 a new drug under section 201(p) shall constitute a finding
9 that the drug is safe and effective that may be relied upon
10 for purposes of an application under section 505(b)(2), so
11 that the applicant shall be required to submit for purposes
12 of such application only information needed to support any
13 modification of the drug that is not covered by such deter-
14 mination under this section.

15 “(g) PUBLIC AVAILABILITY OF ADMINISTRATIVE OR-
16 DERS.—The Secretary shall establish, maintain, update
17 (as determined necessary by the Secretary but no less fre-
18 quently than annually), and make publicly available, with
19 respect to orders issued under this section—

20 “(1) a repository of each final order and in-
21 terim final order in effect, including the complete
22 text of the order; and

23 “(2) a listing of all orders proposed and under
24 development under subsection (b)(2), including—

1 “(A) a brief description of each such order;

2 and

3 “(B) the Secretary’s expectations, if re-

4 sources permit, for issuance of proposed orders

5 over a 3-year period.

6 “(h) DEVELOPMENT ADVICE TO SPONSORS OR RE-

7 QUESTORS.—The Secretary shall establish procedures

8 under which sponsors or requestors may meet with appro-

9 priate officials of the Food and Drug Administration to

10 obtain advice on the studies and other information nec-

11 essary to support submissions under this section and other

12 matters relevant to the regulation of nonprescription

13 drugs and the development of new nonprescription drugs

14 under this section.

15 “(i) PARTICIPATION OF MULTIPLE SPONSORS OR RE-

16 QUESTORS.—The Secretary shall establish procedures to

17 facilitate efficient participation by multiple sponsors or re-

18 questors in proceedings under this section, including provi-

19 sion for joint meetings with multiple sponsors or reques-

20 tors or with organizations nominated by sponsors or re-

21 questors to represent their interests in a proceeding.

22 “(j) ELECTRONIC FORMAT.—All submissions under

23 this section shall be in electronic format.

24 “(k) EFFECT ON EXISTING REGULATIONS GOV-

25 ERNING NONPRESCRIPTION DRUGS.—

1 “(1) REGULATIONS OF GENERAL APPLICA-
2 BILITY TO NONPRESCRIPTION DRUGS.—Except as
3 provided in this subsection, nothing in this section
4 supersedes regulations establishing general require-
5 ments for nonprescription drugs, including regula-
6 tions of general applicability contained in parts 201,
7 250, and 330 of title 21, Code of Federal Regula-
8 tions, or any successor regulations. The Secretary
9 shall establish or modify such regulations by means
10 of rulemaking in accordance with section 553 of title
11 5, United States Code.

12 “(2) REGULATIONS ESTABLISHING REQUIRE-
13 MENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

14 “(A) The provisions of section 310.545 of
15 title 21, Code of Federal Regulations, as in ef-
16 fect on the day before the date of the enact-
17 ment of this section, shall be deemed to be a
18 final order under subsection (b).

19 “(B) Regulations in effect on the day be-
20 fore the date of the enactment of this section,
21 establishing requirements for specific non-
22 prescription drugs marketed pursuant to this
23 section (including such requirements in parts
24 201 and 250 of title 21, Code of Federal Regu-
25 lations), shall be deemed to be final orders

1 under subsection (b), only as they apply to
2 drugs—

3 “(i) subject to paragraph (1), (2), (3),
4 or (4) of subsection (a); or

5 “(ii) otherwise subject to an order
6 under this section.

7 “(3) WITHDRAWAL OF REGULATIONS.—The
8 Secretary shall withdraw regulations establishing
9 final monographs and the procedures governing the
10 over-the-counter drug review under part 330 and
11 other relevant parts of title 21, Code of Federal
12 Regulations (as in effect on the day before the date
13 of the enactment of this section), or make technical
14 changes to such regulations to ensure conformity
15 with appropriate terminology and cross references.
16 Notwithstanding subchapter II of chapter 5 of title
17 5, United States Code, any such withdrawal or tech-
18 nical changes shall be made without public notice
19 and comment and shall be effective upon publication
20 through notice in the Federal Register (or upon such
21 date as specified in such notice).

22 “(l) GUIDANCE.—The Secretary shall issue guidance
23 that specifies—

1 “(1) the procedures and principles for formal
2 meetings between the Secretary and sponsors or re-
3 questors for drugs subject to this section;

4 “(2) the format and content of data submis-
5 sions to the Secretary under this section;

6 “(3) the format of electronic submissions to the
7 Secretary under this section;

8 “(4) consolidated proceedings for appeal and
9 the procedures for such proceedings where appro-
10 priate; and

11 “(5) for minor changes in drugs, recommenda-
12 tions on how to comply with the requirements in or-
13 ders issued under subsection (c)(3).

14 “(m) RULE OF CONSTRUCTION.—

15 “(1) IN GENERAL.—This section shall not af-
16 fect the treatment or status of a nonprescription
17 drug—

18 “(A) that is marketed without an applica-
19 tion approved under section 505 as of the date
20 of the enactment of this section;

21 “(B) that is not subject to an order issued
22 under this section; and

23 “(C) to which paragraphs (1), (2), (3), (4),
24 or (5) of subsection (a) do not apply.

1 “(2) TREATMENT OF PRODUCTS PREVIOUSLY
2 FOUND TO BE SUBJECT TO TIME AND EXTENT RE-
3 QUIREMENTS.—

4 “(A) Notwithstanding subsection (a), a
5 drug described in subparagraph (B) may only
6 be lawfully marketed, without an application
7 approved under section 505, pursuant to an
8 order issued under this section.

9 “(B) A drug described in this subpara-
10 graph is a drug which, prior to the date of the
11 enactment of this section, the Secretary deter-
12 mined in a proposed or final rule to be ineligible
13 for review under the OTC drug review (as such
14 phrase ‘OTC drug review’ was used in section
15 330.14 of title 21, Code of Federal Regulations,
16 as in effect on the day before the date of the
17 enactment of this section).

18 “(3) PRESERVATION OF AUTHORITY.—

19 “(A) Nothing in paragraph (1) shall be
20 construed to preclude or limit the applicability
21 of any provision of this Act other than this sec-
22 tion.

23 “(B) Nothing in subsection (a) shall be
24 construed to prohibit the Secretary from issuing
25 an order under this section finding a drug to be

1 not generally recognized as safe and effective
2 under section 201(p)(1), as the Secretary deter-
3 mines appropriate.

4 “(n) INVESTIGATIONAL NEW DRUGS.—A drug is not
5 subject to this section if an exemption for investigational
6 use under section 505(i) is in effect for such drug.

7 “(o) INAPPLICABILITY OF PAPERWORK REDUCTION
8 ACT.—Chapter 35 of title 44, United States Code, shall
9 not apply to collections of information made under this
10 section.

11 “(p) INAPPLICABILITY OF NOTICE AND COMMENT
12 RULEMAKING AND OTHER REQUIREMENTS.—The re-
13 quirements of subsection (b) shall apply with respect to
14 orders issued under this section instead of the require-
15 ments of subchapter II of chapter 5 of title 5, United
16 States Code.

17 “(q) DEFINITIONS.—In this section:

18 “(1) The term ‘nonprescription drug’ refers to
19 a drug not subject to the requirements of section
20 503(b)(1).

21 “(2) The term ‘sponsor’ refers to any person
22 marketing, manufacturing, or processing a drug
23 that—

24 “(A) is listed pursuant to section 510(j);

25 and

1 “(B) is or will be subject to an administra-
2 tive order under this section of the Food and
3 Drug Administration.

4 “(3) The term ‘requestor’ refers to any person
5 or group of persons marketing, manufacturing, proc-
6 essing, or developing a drug.”.

7 (b) GAO STUDY.—Not later than 4 years after the
8 date of enactment of this Act, the Comptroller General
9 of the United States shall submit a study to the Com-
10 mittee on Energy and Commerce of the House of Rep-
11 resentatives and the Committee on Health, Education,
12 Labor, and Pensions of the Senate addressing the effec-
13 tiveness and overall impact of exclusivity under section
14 505G of the Federal Food, Drug, and Cosmetic Act, as
15 added by subsection (a), and section 586C of such Act
16 (21 U.S.C. 360fff–3), including the impact of such exclu-
17 sivity on consumer access. Such study shall include—

18 (1) an analysis of the impact of exclusivity
19 under such section 505G for nonprescription drug
20 products, including—

21 (A) the number of nonprescription drug
22 products that were granted exclusivity and the
23 indication for which the nonprescription drug
24 products were determined to be generally recog-
25 nized as safe and effective;

1 (B) whether the exclusivity for such drug
2 products was granted for—

3 (i) a new active ingredient (including
4 any ester or salt of the active ingredient);

5 or

6 (ii) changes in the conditions of use of
7 a drug, for which new human data studies
8 conducted or sponsored by the requestor
9 were essential;

10 (C) whether, and to what extent, the exclu-
11 sivity impacted the requestor's or sponsor's de-
12 cision to develop the drug product;

13 (D) an analysis of the implementation of
14 the exclusivity provision in such section 505G,
15 including—

16 (i) the resources used by the Food
17 and Drug Administration;

18 (ii) the impact of such provision on
19 innovation, as well as research and devel-
20 opment in the nonprescription drug mar-
21 ket;

22 (iii) the impact of such provision on
23 competition in the nonprescription drug
24 market;

1 (iv) the impact of such provision on
2 consumer access to nonprescription drug
3 products;

4 (v) the impact of such provision on
5 the prices of nonprescription drug prod-
6 ucts; and

7 (vi) whether the administrative orders
8 initiated by requestors under such section
9 505G have been sufficient to encourage the
10 development of nonprescription drug prod-
11 ucts that would likely not be otherwise de-
12 veloped, or developed in as timely a man-
13 ner; and

14 (E) whether the administrative orders ini-
15 tiated by requestors under such section 505G
16 have been sufficient incentive to encourage in-
17 novation in the nonprescription drug market;
18 and

19 (2) an analysis of the impact of exclusivity
20 under such section 586C for sunscreen ingredients,
21 including—

22 (A) the number of sunscreen ingredients
23 that were granted exclusivity and the specific
24 ingredient that was determined to be generally
25 recognized as safe and effective;

1 (B) whether, and to what extent, the exclu-
2 sivity impacted the requestor's or sponsor's de-
3 cision to develop the sunscreen ingredient;

4 (C) whether, and to what extent, the sun-
5 screen ingredient granted exclusivity had pre-
6 viously been available outside of the United
7 States;

8 (D) an analysis of the implementation of
9 the exclusivity provision in such section 586C,
10 including—

11 (i) the resources used by the Food
12 and Drug Administration;

13 (ii) the impact of such provision on
14 innovation, as well as research and devel-
15 opment in the sunscreen market;

16 (iii) the impact of such provision on
17 competition in the sunscreen market;

18 (iv) the impact of such provision on
19 consumer access to sunscreen products;

20 (v) the impact of such provision on
21 the prices of sunscreen products; and

22 (vi) whether the administrative orders
23 initiated by requestors under such section
24 505G have been utilized by sunscreen in-
25 gredient sponsors and whether such proc-

1 ess has been sufficient to encourage the
2 development of sunscreen ingredients that
3 would likely not be otherwise developed, or
4 developed in as timely a manner; and

5 (E) whether the administrative orders ini-
6 tiated by requestors under such section 586C
7 have been sufficient incentive to encourage in-
8 novation in the sunscreen market.

9 (c) CONFORMING AMENDMENT.—Section 751(d)(1)
10 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 379r(d)(1)) is amended—

12 (1) in the matter preceding subparagraph (A)—

13 (A) by striking “final regulation promul-
14 gated” and inserting “final order under section
15 505G”; and

16 (B) by striking “and not misbranded”; and

17 (2) in subparagraph (A), by striking “regula-
18 tion in effect” and inserting “regulation or order in
19 effect”.

20 **SEC. 372. MISBRANDING.**

21 Section 502 of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 352) is amended by adding at the end the
23 following:

24 “(ee) If it is a nonprescription drug that is subject
25 to section 505G, is not the subject of an application ap-

1 proved under section 505, and does not comply with the
2 requirements under section 505G.

3 “(ff) If it is a drug and it was manufactured, pre-
4 pared, propagated, compounded, or processed in a facility
5 for which fees have not been paid as required by section
6 744M.”.

7 **SEC. 373. DRUGS EXCLUDED FROM THE OVER-THE-**
8 **COUNTER DRUG REVIEW.**

9 (a) IN GENERAL.—Nothing in this Act (or the
10 amendments made by this Act) shall apply to any non-
11 prescription drug (as defined in section 505G(q) of the
12 Federal Food, Drug, and Cosmetic Act, as added by sec-
13 tion 1001 of this Act) which was excluded by the Food
14 and Drug Administration from the Over-the-Counter
15 Drug Review in accordance with the paragraph numbered
16 25 on page 9466 of volume 37 of the Federal Register,
17 published on May 11, 1972.

18 (b) RULE OF CONSTRUCTION.—Nothing in this sec-
19 tion shall be construed to preclude or limit the applica-
20 bility of any other provision of the Federal Food, Drug,
21 and Cosmetic Act (21 U.S.C. 301 et seq.).

22 **SEC. 374. TREATMENT OF SUNSCREEN INNOVATION ACT.**

23 (a) REVIEW OF NONPRESCRIPTION SUNSCREEN AC-
24 TIVE INGREDIENTS.—

1 (1) APPLICABILITY OF SECTION 505G FOR
2 PENDING SUBMISSIONS.—

3 (A) IN GENERAL.—A sponsor of a non-
4 prescription sunscreen active ingredient or com-
5 bination of nonprescription sunscreen active in-
6 gredients that, as of the date of enactment of
7 this Act, is subject to a proposed sunscreen
8 order under section 586C of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 360fff–3)
10 may elect, by means of giving written notifica-
11 tion to the Secretary of Health and Human
12 Services within 180 calendar days of the enact-
13 ment of this Act, to transition into the review
14 of such ingredient or combination of ingredients
15 pursuant to the process set out in section 505G
16 of the Federal Food, Drug, and Cosmetic Act,
17 as added by section 1001 of this Act.

18 (B) ELECTION EXERCISED.—Upon receipt
19 by the Secretary of Health and Human Services
20 of a timely notification under subparagraph
21 (A)—

22 (i) the proposed sunscreen order in-
23 volved is deemed to be a request for an
24 order under subsection (b) of section 505G
25 of the Federal Food, Drug, and Cosmetic

1 Act, as added by section 1001 of this Act;
2 and

3 (ii) such order is deemed to have been
4 accepted for filing under subsection
5 (b)(6)(A)(i) of such section 505G.

6 (C) ELECTION NOT EXERCISED.—If a noti-
7 fication under subparagraph (A) is not received
8 by the Secretary of Health and Human Services
9 within 180 calendar days of the date of enact-
10 ment of this Act, the review of the proposed
11 sunscreen order described in subparagraph
12 (A)—

13 (i) shall continue under section 586C
14 of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 360fff–3); and

16 (ii) shall not be eligible for review
17 under section 505G, added by section 1001
18 of this Act.

19 (2) DEFINITIONS.—In this subsection, the
20 terms “sponsor”, “nonprescription”, “sunscreen ac-
21 tive ingredient”, and “proposed sunscreen order”
22 have the meanings given to those terms in section
23 586 of the Federal Food, Drug, and Cosmetic Act
24 (21 U.S.C. 360fff).

25 (b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

1 (1) FINAL SUNSCREEN ORDERS.—Paragraph
2 (3) of section 586C(e) of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 360fff–3(e)) is amend-
4 ed to read as follows:

5 “(3) RELATIONSHIP TO ORDERS UNDER SEC-
6 TION 505G.—A final sunscreen order shall be deemed
7 to be a final order under section 505G.”.

8 (2) MEETINGS.—Paragraph (7) of section
9 586C(b) of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 360fff–3(b)) is amended—

11 (A) by striking “A sponsor may request”
12 and inserting the following:

13 “(A) IN GENERAL.—A sponsor may re-
14 quest”; and

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

16 “(B) CONFIDENTIAL MEETINGS.—A spon-
17 sor may request one or more confidential meet-
18 ings with respect to a proposed sunscreen order,
19 including a letter deemed to be a proposed sun-
20 screen order under paragraph (3), to discuss
21 matters relating to data requirements to sup-
22 port a general recognition of safety and effec-
23 tiveness involving confidential information and
24 public information related to such proposed
25 sunscreen order, as appropriate. The Secretary

1 shall convene a confidential meeting with such
2 sponsor in a reasonable time period. If a spon-
3 sor requests more than one confidential meeting
4 for the same proposed sunscreen order, the Sec-
5 retary may refuse to grant an additional con-
6 fidential meeting request if the Secretary deter-
7 mines that such additional confidential meeting
8 is not reasonably necessary for the sponsor to
9 advance its proposed sunscreen order, or if the
10 request for a confidential meeting fails to in-
11 clude sufficient information upon which to base
12 a substantive discussion. The Secretary shall
13 publish a post-meeting summary of each con-
14 fidential meeting under this subparagraph that
15 does not disclose confidential commercial infor-
16 mation or trade secrets. This subparagraph
17 does not authorize the disclosure of confidential
18 commercial information or trade secrets subject
19 to 552(b)(4) of title 5, United States Code, or
20 section 1905 of title 18, United States Code.”.

21 (3) EXCLUSIVITY.—Section 586C of the Fed-
22 eral Food, Drug, and Cosmetic Act (21 U.S.C.
23 360fff–3) is amended by adding at the end the fol-
24 lowing:

25 “(f) EXCLUSIVITY.—

1 “(1) IN GENERAL.—A final sunscreen order
2 shall have the effect of authorizing solely the order
3 requestor (or the licensees, assignees, or successors
4 in interest of such requestor with respect to the sub-
5 ject of such request and listed under paragraph (5))
6 for a period of 18 months, to market a sunscreen in-
7 gredient under this section incorporating changes
8 described in paragraph (2) subject to the limitations
9 under paragraph (4), beginning on the date the re-
10 questor (or any licensees, assignees, or successors in
11 interest of such requestor with respect to the subject
12 of such request and listed under paragraph (5)) may
13 lawfully market such sunscreen ingredient pursuant
14 to the order.

15 “(2) CHANGES DESCRIBED.—A change de-
16 scribed in this paragraph is a change subject to an
17 order specified in paragraph (1) that permits a sun-
18 screen to contain an active sunscreen ingredient not
19 previously incorporated in a marketed sunscreen list-
20 ed in paragraph (3).

21 “(3) MARKETED SUNSCREEN.—The marketed
22 sunscreen ingredients described in this paragraph
23 are sunscreen ingredients—

24 “(A) marketed in accordance with a final
25 monograph for sunscreen drug products set

1 forth at part 352 of title 21, Code of Federal
2 Regulations (as published at 64 Fed. Reg.
3 27687); or

4 “(B) marketed in accordance with a final
5 order issued under this section.

6 “(4) LIMITATIONS ON EXCLUSIVITY.—Only one
7 18-month period may be granted per ingredient
8 under paragraph (1).

9 “(5) LISTING OF LICENSEES, ASSIGNEES, OR
10 SUCCESSORS IN INTEREST.—Requestors shall submit
11 to the Secretary at the time when a drug subject to
12 such request is introduced or delivered for introduc-
13 tion into interstate commerce, a list of licensees, as-
14 signees, or successors in interest under paragraph
15 (1).”.

16 (4) SUNSET PROVISION.—Subchapter I of chap-
17 ter V of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 360fff et seq.) is amended by adding at
19 the end the following:

20 **“SEC. 586H. SUNSET.**

21 “‘This subchapter shall cease to be effective at the end
22 of fiscal year 2022.’”.

23 (5) TREATMENT OF FINAL SUNSCREEN
24 ORDER.—The Federal Food, Drug, and Cosmetic

1 Act is amended by striking section 586E of such Act
2 (21 U.S.C. 360fff-5).

3 (c) TREATMENT OF AUTHORITY REGARDING FINAL-
4 IZATION OF SUNSCREEN MONOGRAPH.—

5 (1) IN GENERAL.—

6 (A) REVISION OF FINAL SUNSCREEN
7 ORDER.—Not later than November 26, 2019,
8 the Secretary of Health and Human Services
9 (referred to in this subsection as the “Sec-
10 retary”) shall amend and revise the final ad-
11 ministrative order concerning nonprescription
12 sunscreen (referred to in this subsection as the
13 “sunscreen order”) for which the content, prior
14 to the date of enactment of this Act, was rep-
15 resented by the final monograph for sunscreen
16 drug products set forth in part 352 of title 21,
17 Code of Federal Regulations (as in effect on
18 May 21, 1999).

19 (B) ISSUANCE OF REVISED SUNSCREEN
20 ORDER; EFFECTIVE DATE.—A revised sunscreen
21 order described in subparagraph (A) shall be—

22 (i) issued in accordance with the pro-
23 cedures described in section 505G(c)(2) of
24 the Federal Food, Drug, and Cosmetic
25 Act;

1 (ii) issued in proposed form not later
2 than May 28, 2019;

3 (iii) effective not later than November
4 26, 2020; and

5 (iv) issued by the Secretary at least 1
6 year prior to the effective date of the re-
7 vised order.

8 (2) REPORTS.—If a revised sunscreen order
9 issued under paragraph (1) does not include provi-
10 sions related to the effectiveness of various sun pro-
11 tection factor levels, and does not address all dosage
12 forms known to the Secretary to be used in sun-
13 screens marketed in the United States without a
14 new drug application approved under section 505 of
15 the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 355), the Secretary shall submit a report to
17 the Committee on Energy and Commerce of the
18 House of Representatives and the Committee on
19 Health, Education, Labor, and Pensions of the Sen-
20 ate on the rationale for omission of such provisions
21 from such order, and a plan and timeline to compile
22 any information necessary to address such provisions
23 through such order.

24 (d) TREATMENT OF NON-SUNSCREEN TIME AND EX-
25 TENT APPLICATIONS.—

1 (1) IN GENERAL.—Any application described in
2 section 586F of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 360fff–6) that was submitted
4 to the Secretary pursuant to section 330.14 of title
5 21, Code of Federal Regulations, as such provisions
6 were in effect immediately prior to the date of enact-
7 ment date of this Act, shall be extinguished as of
8 such date of enactment, subject to paragraph (2).

9 (2) ORDER REQUEST.—Nothing in paragraph
10 (1) precludes the submission of an order request
11 under section 505G(b) of the Federal Food, Drug,
12 and Cosmetic Act, as added by section 1001 of this
13 Act, with respect to a drug that was the subject of
14 an application extinguished under paragraph (1).

15 **SEC. 375. ANNUAL UPDATE TO CONGRESS ON APPRO-**
16 **PRIATE PEDIATRIC INDICATION FOR CER-**
17 **TAIN OTC COUGH AND COLD DRUGS.**

18 (a) IN GENERAL.—Subject to subsection (c), the Sec-
19 retary of Health and Human Services shall, beginning not
20 later than 1 year after the date of enactment of this Act,
21 annually submit to the Committee on Energy and Com-
22 merce of the House of Representatives and the Committee
23 on Health, Education, Labor, and Pensions of the Senate
24 a letter describing the progress of the Food and Drug Ad-
25 ministration—

1 (1) in evaluating the cough and cold monograph
2 described in subsection (b) with respect to children
3 under age 6; and

4 (2) as appropriate, revising such cough and cold
5 monograph to address such children through the
6 order process under section 505G(b) of the Federal
7 Food, Drug, and Cosmetic Act, as added by section
8 1001 of this Act.

9 (b) COUGH AND COLD MONOGRAPH DESCRIBED.—

10 The cough and cold monograph described in this sub-
11 section consists of the conditions under which nonprescrip-
12 tion drugs containing antitussive, expectorant, nasal de-
13 congestant, or antihistamine active ingredients (or com-
14 binations thereof) are generally recognized as safe and ef-
15 fective, as specified in part 341 of title 21, Code of Federal
16 Regulations (as in effect immediately prior to the date of
17 enactment of this Act), and included in an order deemed
18 to be established under section 505G(b) of the Federal
19 Food, Drug, and Cosmetic Act, as added by section 1001
20 of this Act.

21 (c) DURATION OF AUTHORITY.—The requirement
22 under subsection (a) shall terminate as of the date of a
23 letter submitted by the Secretary of Health and Human
24 Services pursuant to such subsection in which the Sec-
25 retary indicates that the Food and Drug Administration

1 has completed its evaluation and revised, in a final order,
2 as applicable, the cough and cold monograph as described
3 in subsection (a)(2).

4 **SEC. 376. TECHNICAL CORRECTIONS.**

5 (a) IMPORTS AND EXPORTS.—Section
6 801(e)(4)(E)(iii) of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 381(e)(4)(E)(iii)) is amended by striking
8 “subparagraph” each place such term appears and insert-
9 ing “paragraph”.

10 (b) FDA REAUTHORIZATION ACT OF 2017.—

11 (1) IN GENERAL.—Section 905(b)(4) of the
12 FDA Reauthorization Act of 2017 (Public Law 115–
13 52) is amended by striking “Section 744H(e)(2)(B)”
14 and inserting “Section 744H(f)(2)(B)”.

15 (2) EFFECTIVE DATE.—The amendment made
16 by paragraph (1) shall take effect as of the enact-
17 ment of the FDA Reauthorization Act of 2017
18 (Public Law 115–52).

19 **PART 2—USER FEES**

20 **SEC. 381. SHORT TITLE; FINDING.**

21 (a) SHORT TITLE.—This part may be cited as the
22 “Over-the-Counter Monograph User Fee Act of 2019”.

23 (b) FINDING.—The Congress finds that the fees au-
24 thorized by the amendments made in this part will be dedi-
25 cated to OTC monograph drug activities, as set forth in

1 the goals identified for purposes of part 10 of subchapter
2 C of chapter VII of the Federal Food, Drug, and Cosmetic
3 Act, in the letters from the Secretary of Health and
4 Human Services to the Chairman of the Committee on
5 Health, Education, Labor, and Pensions of the Senate and
6 the Chairman of the Committee on Energy and Commerce
7 of the House of Representatives, as set forth in the Con-
8 gressional Record.

9 **SEC. 382. FEES RELATING TO OVER-THE-COUNTER DRUGS.**

10 Subchapter C of chapter VII of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is
12 amended by inserting after part 9 the following:

13 **“PART 10—FEES RELATING TO OVER-THE-**
14 **COUNTER DRUGS**

15 **“SEC. 744L. DEFINITIONS.**

16 “In this part:

17 “(1) The term ‘affiliate’ means a business enti-
18 ty that has a relationship with a second business en-
19 tity if, directly or indirectly—

20 “(A) one business entity controls, or has
21 the power to control, the other business entity;

22 or

23 “(B) a third party controls, or has power
24 to control, both of the business entities.

1 “(2) The term ‘contract manufacturing organi-
2 zation facility’ means an OTC monograph drug facil-
3 ity where neither the owner of such manufacturing
4 facility nor any affiliate of such owner or facility
5 sells the OTC monograph drug produced at such fa-
6 cility directly to wholesalers, retailers, or consumers
7 in the United States.

8 “(3) The term ‘costs of resources allocated for
9 OTC monograph drug activities’ means the expenses
10 in connection with OTC monograph drug activities
11 for—

12 “(A) officers and employees of the Food
13 and Drug Administration, contractors of the
14 Food and Drug Administration, advisory com-
15 mittees, and costs related to such officers, em-
16 ployees, and committees and costs related to
17 contracts with such contractors;

18 “(B) management of information, and the
19 acquisition, maintenance, and repair of com-
20 puter resources;

21 “(C) leasing, maintenance, renovation, and
22 repair of facilities and acquisition, maintenance,
23 and repair of fixtures, furniture, scientific
24 equipment, and other necessary materials and
25 supplies; and

1 “(D) collecting fees under section 744M
2 and accounting for resources allocated for OTC
3 monograph drug activities.

4 “(4) The term ‘FDA establishment identifier’ is
5 the unique number automatically generated by Food
6 and Drug Administration’s Field Accomplishments
7 and Compliance Tracking System (FACTS) (or any
8 successor system).

9 “(5) The term ‘OTC monograph drug’ means a
10 nonprescription drug without an approved new drug
11 application which is governed by the provisions of
12 section 505G.

13 “(6) The term ‘OTC monograph drug activities’
14 means activities of the Secretary associated with
15 OTC monograph drugs and inspection of facilities
16 associated with such products, including the fol-
17 lowing activities:

18 “(A) The activities necessary for review
19 and evaluation of OTC monographs and OTC
20 monograph order requests, including—

21 “(i) orders proposing or finalizing ap-
22 plicable conditions of use for OTC mono-
23 graph drugs;

24 “(ii) orders affecting status regarding
25 general recognition of safety and effective-

1 ness of an OTC monograph ingredient or
2 combination of ingredients under specified
3 conditions of use;

4 “(iii) all OTC monograph drug devel-
5 opment and review activities, including
6 intra-agency collaboration;

7 “(iv) regulation and policy develop-
8 ment activities related to OTC monograph
9 drugs;

10 “(v) development of product standards
11 for products subject to review and evalua-
12 tion;

13 “(vi) meetings referred to in section
14 505G(i);

15 “(vii) review of labeling prior to
16 issuance of orders related to OTC mono-
17 graph drugs or conditions of use; and

18 “(viii) regulatory science activities re-
19 lated to OTC monograph drugs.

20 “(B) Inspections related to OTC mono-
21 graph drugs.

22 “(C) Monitoring of clinical and other re-
23 search conducted in connection with OTC
24 monograph drugs.

1 “(D) Safety activities with respect to OTC
2 monograph drugs, including—

3 “(i) collecting, developing, and review-
4 ing safety information on OTC monograph
5 drugs, including adverse event reports;

6 “(ii) developing and using improved
7 adverse event data-collection systems, in-
8 cluding information technology systems;
9 and

10 “(iii) developing and using improved
11 analytical tools to assess potential safety
12 risks, including access to external data-
13 bases.

14 “(E) Other activities necessary for imple-
15 mentation of section 505G.

16 “(7) The term ‘OTC monograph order request’
17 means a request for an order submitted under sec-
18 tion 505G(b)(5).

19 “(8) The term ‘Tier 1 OTC monograph order
20 request’ means any OTC monograph order request
21 not determined to be a Tier 2 OTC monograph
22 order request.

23 “(9)(A) The term ‘Tier 2 OTC monograph
24 order request’ means, subject to subparagraph (B),
25 an OTC monograph order request for—

1 “(i) the reordering of existing information
2 in the drug facts label of an OTC monograph
3 drug;

4 “(ii) the addition of information to the
5 other information section of the drug facts label
6 of an OTC monograph drug, as limited by sec-
7 tion 201.66(c)(7) of title 21, Code of Federal
8 Regulations (or any successor regulations);

9 “(iii) modification to the directions for use
10 section of the drug facts label of an OTC mono-
11 graph drug, if such changes conform to changes
12 made pursuant to section 505G(c)(3)(A);

13 “(iv) the standardization of the concentra-
14 tion or dose of a specific finalized ingredient
15 within a particular finalized monograph;

16 “(v) a change to ingredient nomenclature
17 to align with nomenclature of a standards-set-
18 ting organization; or

19 “(vi) addition of an interchangeable term
20 in accordance with section 330.1 of title 21,
21 Code of Federal Regulations (or any successor
22 regulations).

23 “(B) The Secretary may, based on program im-
24 plementation experience or other factors found ap-
25 propriate by the Secretary, characterize any OTC

1 monograph order request as a Tier 2 OTC mono-
2 graph order request (including recharacterizing a re-
3 quest from Tier 1 to Tier 2) and publish such deter-
4 mination in a proposed order issued pursuant to sec-
5 tion 505G.

6 “(10)(A) The term ‘OTC monograph drug facil-
7 ity’ means a foreign or domestic business or other
8 entity that—

9 “(i) is—

10 “(I) under one management, either di-
11 rect or indirect; and

12 “(II) at one geographic location or ad-
13 dress engaged in manufacturing or proc-
14 essing the finished dosage form of an OTC
15 monograph drug;

16 “(ii) includes a finished dosage form man-
17 ufacturer facility in a contractual relationship
18 with the sponsor of one or more OTC mono-
19 graph drugs to manufacture or process such
20 drugs; and

21 “(iii) does not include a business or other
22 entity whose only manufacturing or processing
23 activities are one or more of the following: pro-
24 duction of clinical research supplies, testing, or
25 placement of outer packaging on packages con-

1 taining multiple products, for such purposes as
2 creating multipacks, when each monograph
3 drug product contained within the overpack-
4 aging is already in a final packaged form prior
5 to placement in the outer overpackaging.

6 “(B) For purposes of subparagraph (A)(i)(II),
7 separate buildings or locations within close proximity
8 are considered to be at one geographic location or
9 address if the activities conducted in such buildings
10 or locations are—

11 “(i) closely related to the same business
12 enterprise;

13 “(ii) under the supervision of the same
14 local management; and

15 “(iii) under a single FDA establishment
16 identifier and capable of being inspected by the
17 Food and Drug Administration during a single
18 inspection.

19 “(C) If a business or other entity would meet
20 criteria specified in subparagraph (A), but for being
21 under multiple management, the business or other
22 entity is deemed to constitute multiple facilities, one
23 per management entity, for purposes of this para-
24 graph.

1 “(11) The term ‘OTC monograph drug meet-
2 ing’ means any meeting regarding the content of a
3 proposed OTC monograph order request.

4 “(12) The term ‘person’ includes an affiliate of
5 a person.

6 “(13) The terms ‘requestor’ and ‘sponsor’ have
7 the meanings given such terms in section 505G.

8 **“SEC. 744M. AUTHORITY TO ASSESS AND USE OTC MONO-
9 GRAPH FEES.**

10 “(a) TYPES OF FEES.—Beginning with fiscal year
11 2019, the Secretary shall assess and collect fees in accord-
12 ance with this section as follows:

13 “(1) FACILITY FEE.—

14 “(A) IN GENERAL.—Each person that
15 owns a facility identified as an OTC monograph
16 drug facility on December 31 of the fiscal year
17 or at any time during the preceding 12-month
18 period shall be assessed an annual fee for each
19 such facility as determined under subsection
20 (c).

21 “(B) EXCEPTIONS.—

22 “(i) A fee shall not be assessed under
23 subparagraph (A) if the identified OTC
24 monograph drug facility—

1 “(I) has ceased all activities re-
2 lated to OTC monograph drugs prior
3 to January 31, 2019, for the first pro-
4 gram year, and December 31 of the
5 fiscal year for subsequent fiscal years;
6 and

7 “(II) has updated its registration
8 to reflect such change under the re-
9 quirements for drug establishment
10 registration set forth in section 510.

11 “(ii) The amount of the fee for a con-
12 tract manufacturing organization facility
13 shall be equal to two-thirds of the amount
14 of the fee for an OTC monograph drug fa-
15 cility that is not a contract manufacturing
16 organization facility.

17 “(C) AMOUNT.—The amount of fees estab-
18 lished under subparagraph (A) shall be estab-
19 lished under subsection (c).

20 “(D) DUE DATE.—

21 “(i) FOR FIRST PROGRAM YEAR.—For
22 fiscal year 2019, the facility fees required
23 under subparagraph (A) shall be due 45
24 calendar days after publication of the Fed-

1 eral Register notice provided for under
2 subsection (c)(4)(A).

3 “(ii) SUBSEQUENT FISCAL YEARS.—
4 For each fiscal year after fiscal year 2019,
5 the facility fees required under subpara-
6 graph (A) shall be due on the later of—

7 “(I) the first business day of
8 June of such year; or

9 “(II) the first business day after
10 the enactment of an appropriations
11 Act providing for the collection and
12 obligation of fees under this section
13 for such year.

14 “(2) OTC MONOGRAPH ORDER REQUEST
15 FEE.—

16 “(A) IN GENERAL.—Each person that sub-
17 mits an OTC monograph order request shall be
18 subject to a fee for an OTC monograph order
19 request. The amount of such fee shall be—

20 “(i) for a Tier 1 OTC monograph
21 order request, \$500,000, adjusted for in-
22 flation for the fiscal year (as determined
23 under subsection (c)(1)(B)); and

24 “(ii) for a Tier 2 OTC monograph
25 order request, \$100,000 adjusted for infla-

1 tion for the fiscal year (as determined
2 under subsection (c)(1)(B)).

3 “(B) DUE DATE.—The OTC monograph
4 order request fees required under subparagraph
5 (A) shall be due on the date of submission of
6 the OTC monograph order request.

7 “(C) EXCEPTION FOR CERTAIN SAFETY
8 CHANGES.—A person who is named as the re-
9 questor in an OTC monograph order shall not
10 be subject to a fee under subparagraph (A) if
11 the Secretary finds that the OTC monograph
12 order request seeks to change the drug facts la-
13 beling of an OTC monograph drug in a way
14 that would add to or strengthen—

15 “(i) a contraindication, warning, or
16 precaution;

17 “(ii) a statement about risk associated
18 with misuse or abuse; or

19 “(iii) an instruction about dosage and
20 administration that is intended to increase
21 the safe use of the OTC monograph drug.

22 “(D) REFUND OF FEE IF ORDER REQUEST
23 IS RECATEGORIZED AS A TIER 2 OTC MONO-
24 GRAPH ORDER REQUEST.—If the Secretary de-
25 termines that an OTC monograph request ini-

1 tially characterized as Tier 1 shall be re-charac-
2 terized as a Tier 2 OTC monograph order re-
3 quest, and the requestor has paid a Tier 1 fee
4 in accordance with subparagraph (A)(i), the
5 Secretary shall refund the requestor the dif-
6 ference between the Tier 1 and Tier 2 fees de-
7 termined under subparagraphs (A)(i) and
8 (A)(ii), respectively.

9 “(E) REFUND OF FEE IF ORDER REQUEST
10 REFUSED FOR FILING OR WITHDRAWN BEFORE
11 FILING.—The Secretary shall refund 75 percent
12 of the fee paid under subparagraph (B) for any
13 order request which is refused for filing or was
14 withdrawn before being accepted or refused for
15 filing.

16 “(F) FEES FOR ORDER REQUESTS PRE-
17 VIOUSLY REFUSED FOR FILING OR WITHDRAWN
18 BEFORE FILING.—An OTC monograph order
19 request that was submitted but was refused for
20 filing, or was withdrawn before being accepted
21 or refused for filing, shall be subject to the full
22 fee under subparagraph (A) upon being resub-
23 mitted or filed over protest.

24 “(G) REFUND OF FEE IF ORDER REQUEST
25 WITHDRAWN.—If an order request is withdrawn

1 after the order request was filed, the Secretary
2 may refund the fee or a portion of the fee if no
3 substantial work was performed on the order
4 request after the application was filed. The Sec-
5 retary shall have the sole discretion to refund a
6 fee or a portion of the fee under this subpara-
7 graph. A determination by the Secretary con-
8 cerning a refund under this subparagraph shall
9 not be reviewable.

10 “(3) REFUNDS.—

11 “(A) IN GENERAL.—Other than refunds
12 provided pursuant to any of subparagraphs (D)
13 through (G) of paragraph (2), the Secretary
14 shall not refund any fee paid under paragraph
15 (1) except as provided in subparagraph (B).

16 “(B) DISPUTES CONCERNING FEES.—To
17 qualify for the return of a fee claimed to have
18 been paid in error under paragraph (1) or (2),
19 a person shall submit to the Secretary a written
20 request justifying such return within 180 cal-
21 endar days after such fee was paid.

22 “(4) NOTICE.—Within the timeframe specified
23 in subsection (c), the Secretary shall publish in the
24 Federal Register the amount of the fees under para-
25 graph (1) for such fiscal year.

1 “(b) FEE REVENUE AMOUNTS.—

2 “(1) FISCAL YEAR 2019.—For fiscal year 2019,
3 fees under subsection (a)(1) shall be established to
4 generate a total facility fee revenue amount equal to
5 the sum of—

6 “(A) the annual base revenue for fiscal
7 year 2019 (as determined under paragraph
8 (3));

9 “(B) the dollar amount equal to the oper-
10 ating reserve adjustment for the fiscal year, if
11 applicable (as determined under subsection
12 (c)(2)); and

13 “(C) additional direct cost adjustments (as
14 determined under subsection (c)(3)).

15 “(2) SUBSEQUENT FISCAL YEARS.—For each of
16 the fiscal years 2020 through 2023, fees under sub-
17 section (a)(1) shall be established to generate a total
18 facility fee revenue amount equal to the sum of—

19 “(A) the annual base revenue for the fiscal
20 year (as determined under paragraph (3));

21 “(B) the dollar amount equal to the infla-
22 tion adjustment for the fiscal year (as deter-
23 mined under subsection (c)(1));

24 “(C) the dollar amount equal to the oper-
25 ating reserve adjustment for the fiscal year, if

1 applicable (as determined under subsection
2 (c)(2));

3 “(D) additional direct cost adjustments (as
4 determined under subsection (c)(3)); and

5 “(E) additional dollar amounts for each
6 fiscal year as follows:

7 “(i) \$7,000,000 for fiscal year 2020.

8 “(ii) \$6,000,000 for fiscal year 2021.

9 “(iii) \$7,000,000 for fiscal year 2022.

10 “(iv) \$3,000,000 for fiscal year 2023.

11 “(3) ANNUAL BASE REVENUE.—For purposes
12 of paragraphs (1)(A) and (2)(A), the dollar amount
13 of the annual base revenue for a fiscal year shall
14 be—

15 “(A) for fiscal year 2019, \$8,000,000; and

16 “(B) for fiscal years 2020 through 2023,
17 the dollar amount of the total revenue amount
18 established under this subsection for the pre-
19 vious fiscal year, not including any adjustments
20 made under subsection (c)(2) or (c)(3).

21 “(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

22 “(1) INFLATION ADJUSTMENT.—

23 “(A) IN GENERAL.—For purposes of sub-
24 section (b)(2)(B), the dollar amount of the in-
25 flation adjustment to the annual base revenue

1 for fiscal year 2020 and each subsequent fiscal
2 year shall be equal to the product of—

3 “(i) such annual base revenue for the
4 fiscal year under subsection (b)(2); and

5 “(ii) the inflation adjustment percent-
6 age under subparagraph (C).

7 “(B) OTC MONOGRAPH ORDER REQUEST
8 FEES.—For purposes of subsection (a)(2), the
9 dollar amount of the inflation adjustment to the
10 fee for OTC monograph order requests for fis-
11 cal year 2020 and each subsequent fiscal year
12 shall be equal to the product of—

13 “(i) the applicable fee under sub-
14 section (a)(2) for the preceding fiscal year;
15 and

16 “(ii) the inflation adjustment percent-
17 age under subparagraph (C).

18 “(C) INFLATION ADJUSTMENT PERCENT-
19 AGE.—The inflation adjustment percentage
20 under this subparagraph for a fiscal year is
21 equal to—

22 “(i) for each of fiscal years 2020 and
23 2021, the average annual percent change
24 that occurred in the Consumer Price Index
25 for urban consumers (Washington-Balti-

1 more, DC–MD–VA–WV; Not Seasonally
2 Adjusted; All items; Annual Index) for the
3 first 3 years of the preceding 4 years of
4 available data; and

5 “(ii) for each of fiscal years 2022 and
6 2023, the sum of—

7 “(I) the average annual percent
8 change in the cost, per full-time equiv-
9 alent position of the Food and Drug
10 Administration, of all personnel com-
11 pensation and benefits paid with re-
12 spect to such positions for the first 3
13 years of the preceding 4 fiscal years,
14 multiplied by the proportion of per-
15 sonnel compensation and benefits
16 costs to total costs of OTC mono-
17 graph drug activities for the first 3
18 years of the preceding 4 fiscal years;
19 and

20 “(II) the average annual percent
21 change that occurred in the Consumer
22 Price Index for urban consumers
23 (Washington-Baltimore, DC–MD–VA–
24 WV; Not Seasonally Adjusted; All
25 items; Annual Index) for the first 3

1 years of the preceding 4 years of
2 available data multiplied by the pro-
3 portion of all costs other than per-
4 sonnel compensation and benefits
5 costs to total costs of OTC mono-
6 graph drug activities for the first 3
7 years of the preceding 4 fiscal years.

8 “(2) OPERATING RESERVE ADJUSTMENT.—

9 “(A) IN GENERAL.—For fiscal year 2019
10 and subsequent fiscal years, for purposes of
11 subsections (b)(1)(B) and (b)(2)(C), the Sec-
12 retary may, in addition to adjustments under
13 paragraph (1), further increase the fee revenue
14 and fees if such an adjustment is necessary to
15 provide operating reserves of carryover user
16 fees for OTC monograph drug activities for not
17 more than the number of weeks specified in
18 subparagraph (B).

19 “(B) NUMBER OF WEEKS.—The number of
20 weeks specified in this subparagraph is—

21 “(i) 3 weeks for fiscal year 2019;

22 “(ii) 7 weeks for fiscal year 2020;

23 “(iii) 10 weeks for fiscal year 2021;

24 “(iv) 10 weeks for fiscal year 2022;

25 and

1 “(v) 10 weeks for fiscal year 2023.

2 “(C) DECREASE.—If the Secretary has
3 carryover balances for such process in excess of
4 10 weeks of the operating reserves referred to
5 in subparagraph (A), the Secretary shall de-
6 crease the fee revenue and fees referred to in
7 such subparagraph to provide for not more than
8 10 weeks of such operating reserves.

9 “(D) RATIONALE FOR ADJUSTMENT.—If
10 an adjustment under this paragraph is made,
11 the rationale for the amount of the increase or
12 decrease (as applicable) in fee revenue and fees
13 shall be contained in the annual Federal Reg-
14 ister notice under paragraph (4) establishing
15 fee revenue and fees for the fiscal year involved.

16 “(3) ADDITIONAL DIRECT COST ADJUST-
17 MENT.—The Secretary shall, in addition to adjust-
18 ments under paragraphs (1) and (2), further in-
19 crease the fee revenue and fees for purposes of sub-
20 section (b)(2)(D) by an amount equal to—

21 “(A) \$14,000,000 for fiscal year 2019;

22 “(B) \$7,000,000 for fiscal year 2020;

23 “(C) \$4,000,000 for fiscal year 2021;

24 “(D) \$3,000,000 for fiscal year 2022; and

25 “(E) \$3,000,000 for fiscal year 2023.

1 “(4) ANNUAL FEE SETTING.—

2 “(A) FISCAL YEAR 2019.—The Secretary
3 shall, not later than the second Monday in
4 March of 2019—

5 “(i) establish OTC monograph drug
6 facility fees for fiscal year 2019 under sub-
7 section (a), based on the revenue amount
8 for such year under subsection (b) and the
9 adjustments provided under this sub-
10 section; and

11 “(ii) publish fee revenue, facility fees,
12 and OTC monograph order requests in the
13 Federal Register.

14 “(B) SUBSEQUENT FISCAL YEARS.—The
15 Secretary shall, not later than the second Mon-
16 day in March of each fiscal year that begins
17 after September 30, 2019—

18 “(i) establish for each such fiscal
19 year, based on the revenue amounts under
20 subsection (b) and the adjustments pro-
21 vided under this subsection—

22 “(I) OTC monograph drug facil-
23 ity fees under subsection (a)(1); and

1 “(II) OTC monograph order re-
2 quest fees under subsection (a)(2);
3 and

4 “(ii) publish such fee revenue
5 amounts, facility fees, and OTC mono-
6 graph order request fees in the Federal
7 Register.

8 “(d) IDENTIFICATION OF FACILITIES.—Each person
9 that owns an OTC monograph drug facility shall submit
10 to the Secretary the information required under this sub-
11 section each year. Such information shall, for each fiscal
12 year—

13 “(1) be submitted as part of the requirements
14 for drug establishment registration set forth in sec-
15 tion 510; and

16 “(2) include for each such facility, at a min-
17 imum, identification of the facility’s business oper-
18 ation as that of an OTC monograph drug facility.

19 “(e) EFFECT OF FAILURE TO PAY FEES.—

20 “(1) OTC MONOGRAPH DRUG FACILITY FEE.—

21 “(A) IN GENERAL.—Failure to pay the fee
22 under subsection (a)(1) within 20 calendar days
23 of the due date as specified in subparagraph
24 (D) of such subsection shall result in the fol-
25 lowing:

1 “(i) The Secretary shall place the fa-
2 cility on a publicly available arrears list.

3 “(ii) All OTC monograph drugs man-
4 ufactured in such a facility or containing
5 an ingredient manufactured in such a facil-
6 ity shall be deemed misbranded under sec-
7 tion 502(ff).

8 “(B) APPLICATION OF PENALTIES.—The
9 penalties under this paragraph shall apply until
10 the fee established by subsection (a)(1) is paid.

11 “(2) ORDER REQUESTS.—An OTC monograph
12 order request submitted by a person subject to fees
13 under subsection (a) shall be considered incomplete
14 and shall not be accepted for filing by the Secretary
15 until all fees owed by such person under this section
16 have been paid.

17 “(3) MEETINGS.—A person subject to fees
18 under this section shall be considered ineligible for
19 OTC monograph drug meetings until all such fees
20 owed by such person have been paid.

21 “(f) CREDITING AND AVAILABILITY OF FEES.—

22 “(1) IN GENERAL.—Fees authorized under sub-
23 section (a) shall be collected and available for obliga-
24 tion only to the extent and in the amount provided
25 in advance in appropriations Acts. Such fees are au-

1 thorized to remain available until expended. Such
2 sums as may be necessary may be transferred from
3 the Food and Drug Administration salaries and ex-
4 penses appropriation account without fiscal year lim-
5 itation to such appropriation account for salaries
6 and expenses with such fiscal year limitation. The
7 sums transferred shall be available solely for OTC
8 monograph drug activities.

9 “(2) COLLECTIONS AND APPROPRIATION
10 ACTS.—

11 “(A) IN GENERAL.—Subject to subpara-
12 graph (C), the fees authorized by this section
13 shall be collected and available in each fiscal
14 year in an amount not to exceed the amount
15 specified in appropriation Acts, or otherwise
16 made available for obligation, for such fiscal
17 year.

18 “(B) USE OF FEES AND LIMITATION.—
19 The fees authorized by this section shall be
20 available to defray increases in the costs of the
21 resources allocated for OTC monograph drug
22 activities (including increases in such costs for
23 an additional number of full-time equivalent po-
24 sitions in the Department of Health and
25 Human Services to be engaged in such activi-

1 ties), only if the Secretary allocates for such
2 purpose an amount for such fiscal year (exclud-
3 ing amounts from fees collected under this sec-
4 tion) no less than \$12,000,000, multiplied by
5 the adjustment factor applicable to the fiscal
6 year involved under subsection (c)(1).

7 “(C) COMPLIANCE.—The Secretary shall
8 be considered to have met the requirements of
9 subparagraph (B) in any fiscal year if the costs
10 funded by appropriations and allocated for OTC
11 monograph drug activities are not more than 15
12 percent below the level specified in such sub-
13 paragraph.

14 “(D) PROVISION FOR EARLY PAYMENTS IN
15 SUBSEQUENT YEARS.—Payment of fees author-
16 ized under this section for a fiscal year (after
17 fiscal year 2019), prior to the due date for such
18 fees, may be accepted by the Secretary in ac-
19 cordance with authority provided in advance in
20 a prior year appropriations Act.

21 “(3) AUTHORIZATION OF APPROPRIATIONS.—
22 For each of the fiscal years 2019 through 2023,
23 there is authorized to be appropriated for fees under
24 this section an amount equal to the total amount of
25 fees assessed for such fiscal year under this section.

1 “(g) COLLECTION OF UNPAID FEES.—In any case
2 where the Secretary does not receive payment of a fee as-
3 sessed under subsection (a) within 30 calendar days after
4 it is due, such fee shall be treated as a claim of the United
5 States Government subject to subchapter II of chapter 37
6 of title 31, United States Code.

7 “(h) CONSTRUCTION.—This section may not be con-
8 strued to require that the number of full-time equivalent
9 positions in the Department of Health and Human Serv-
10 ices, for officers, employers, and advisory committees not
11 engaged in OTC monograph drug activities, be reduced
12 to offset the number of officers, employees, and advisory
13 committees so engaged.

14 **“SEC. 744N. REAUTHORIZATION; REPORTING REQUIRE-**
15 **MENTS.**

16 “(a) PERFORMANCE REPORT.—Beginning with fiscal
17 year 2019, and not later than 120 calendar days after the
18 end of each fiscal year thereafter for which fees are col-
19 lected under this part, the Secretary shall prepare and
20 submit to the Committee on Energy and Commerce of the
21 House of Representatives and the Committee on Health,
22 Education, Labor, and Pensions of the Senate a report
23 concerning the progress of the Food and Drug Adminis-
24 tration in achieving the goals identified in the letters de-
25 scribed in section 2001(b) of the Over-the-Counter Mono-

1 graph Safety, Innovation, and Reform Act of 2019 during
2 such fiscal year and the future plans of the Food and
3 Drug Administration for meeting such goals.

4 “(b) FISCAL REPORT.—Not later than 120 calendar
5 days after the end of fiscal year 2019 and each subsequent
6 fiscal year for which fees are collected under this part,
7 the Secretary shall prepare and submit to the Committee
8 on Energy and Commerce of the House of Representatives
9 and the Committee on Health, Education, Labor, and
10 Pensions of the Senate a report on the implementation
11 of the authority for such fees during such fiscal year and
12 the use, by the Food and Drug Administration, of the fees
13 collected for such fiscal year.

14 “(c) PUBLIC AVAILABILITY.—The Secretary shall
15 make the reports required under subsections (a) and (b)
16 available to the public on the internet website of the Food
17 and Drug Administration.

18 “(d) REAUTHORIZATION.—

19 “(1) CONSULTATION.—In developing rec-
20 ommendations to present to the Congress with re-
21 spect to the goals described in subsection (a), and
22 plans for meeting the goals, for OTC monograph
23 drug activities for the first 5 fiscal years after fiscal
24 year 2023, and for the reauthorization of this part

1 for such fiscal years, the Secretary shall consult
2 with—

3 “(A) the Committee on Energy and Com-
4 merce of the House of Representatives;

5 “(B) the Committee on Health, Education,
6 Labor, and Pensions of the Senate;

7 “(C) scientific and academic experts;

8 “(D) health care professionals;

9 “(E) representatives of patient and con-
10 sumer advocacy groups; and

11 “(F) the regulated industry.

12 “(2) PUBLIC REVIEW OF RECOMMENDA-
13 TIONS.—After negotiations with the regulated indus-
14 try, the Secretary shall—

15 “(A) present the recommendations devel-
16 oped under paragraph (1) to the congressional
17 committees specified in such paragraph;

18 “(B) publish such recommendations in the
19 Federal Register;

20 “(C) provide for a period of 30 calendar
21 days for the public to provide written comments
22 on such recommendations;

23 “(D) hold a meeting at which the public
24 may present its views on such recommenda-
25 tions; and

1 “(E) after consideration of such public
2 views and comments, revise such recommenda-
3 tions as necessary.

4 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
5 Not later than January 15, 2023, the Secretary
6 shall transmit to the Congress the revised rec-
7 ommendations under paragraph (2), a summary of
8 the views and comments received under such para-
9 graph, and any changes made to the recommenda-
10 tions in response to such views and comments.”.

11 **Subtitle I—Other Provisions**

12 **SEC. 391. PROTECTING ACCESS TO BIOLOGICAL PRODUCTS.**

13 Section 351(k)(7) of the Public Health Service Act
14 (42 U.S.C. 262(k)(7)) is amended by adding at the end
15 the following:

16 “(D) DEEMED LICENSES.—

17 “(i) NO ADDITIONAL EXCLUSIVITY
18 THROUGH DEEMING.—An approved appli-
19 cation that is deemed to be a license for a
20 biological product under this section pursu-
21 ant to section 7002(e)(4) of the Biologics
22 Price Competition and Innovation Act of
23 2009 shall not be treated as having been
24 first licensed under subsection (a) for pur-
25 poses of subparagraphs (A) and (B).

1 “(ii) APPLICATION OF LIMITATIONS
2 ON EXCLUSIVITY.—Subparagraph (C) shall
3 apply with respect to a reference product
4 referred to in such subparagraph that was
5 the subject of an approved application that
6 was deemed to be a license pursuant to
7 section 7002(e)(4) of the Biologics Price
8 Competition and Innovation Act of 2009.

9 “(iii) APPLICABILITY.—The exclu-
10 sivity periods described in section 527, sec-
11 tion 505A(b)(1)(A)(ii), and section
12 505A(c)(1)(A)(ii) of the Federal Food,
13 Drug, and Cosmetic Act shall continue to
14 apply to a biological product after an ap-
15 proved application for the biological prod-
16 uct is deemed to be a license for the bio-
17 logical product under subsection (a) pursu-
18 ant to section 7002(e)(4) of the Biologics
19 Price Competition and Innovation Act of
20 2009.”.

21 **SEC. 392. ORPHAN DRUG CLARIFICATION.**

22 Section 527(c) of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 360cc(c)) is amended by adding at
24 the end the following:

1 “(3) APPLICABILITY.—This subsection applies
2 to any drug designated under section 526 for which
3 an application was approved under section 505 of
4 this Act or licensed under section 351 of the Public
5 Health Service Act after the date of enactment of
6 the FDA Reauthorization Act of 2017, regardless of
7 the date on which such drug was designated under
8 section 526.”.

9 **SEC. 393. CONDITIONS OF USE FOR BIOSIMILAR BIOLOGI-**
10 **CAL PRODUCTS.**

11 Section 351(k)(2)(A)(iii) of the Public Health Service
12 Act (42 U.S.C. 262(k)(2)(A)(iii) is amended—

13 (1) in subclause (I), by striking “; and” and in-
14 serting a semicolon;

15 (2) in subclause (II), by striking the period and
16 inserting “; and” ; and

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

18 “(III) may include information to
19 show that the conditions of use pre-
20 scribed, recommended, or suggested in
21 the labeling proposed for the biological
22 product have been previously approved
23 for the reference product.”.

1 **SEC. 394. CLARIFYING THE MEANING OF NEW CHEMICAL**
2 **ENTITY.**

3 Chapter V of the Federal Food, Drug, and Cosmetic
4 Act is amended—

5 (1) in section 505 (21 U.S.C. 355)—

6 (A) in subsection (c)(3)(E)—

7 (i) in clause (ii), by striking “active
8 ingredient (including any ester or salt of
9 the active ingredient)” and inserting “ac-
10 tive moiety (as defined by the Secretary in
11 section 314.3 of title 21, Code of Federal
12 Regulations (or any successor regula-
13 tions))”; and

14 (ii) in clause (iii), by striking “active
15 ingredient (including any ester or salt of
16 the active ingredient)” and inserting “ac-
17 tive moiety (as defined by the Secretary in
18 section 314.3 of title 21, Code of Federal
19 Regulations (or any successor regula-
20 tions))”;

21 (B) in subsection (j)(5)(F)—

22 (i) in clause (ii), by striking “active
23 ingredient (including any ester or salt of
24 the active ingredient)” and inserting “ac-
25 tive moiety (as defined by the Secretary in
26 section 314.3 of title 21, Code of Federal

1 Regulations (or any successor regula-
2 tions))”; and

3 (ii) in clause (iii), by striking “active
4 ingredient (including any ester or salt of
5 the active ingredient)” and inserting “ac-
6 tive moiety (as defined by the Secretary in
7 section 314.3 of title 21, Code of Federal
8 Regulations (or any successor regula-
9 tions))”;

10 (C) in subsection (l)(2)(A)(i), by striking
11 “active ingredient (including any ester or salt of
12 the active ingredient)” and inserting “active
13 moiety (as defined by the Secretary in section
14 314.3 of title 21, Code of Federal Regulations
15 (or any successor regulations))”;

16 (D) in subsection (s), in the matter pre-
17 ceding paragraph (1), by striking “active ingre-
18 dient (including any ester or salt of the active
19 ingredient)” and inserting “active moiety (as
20 defined by the Secretary in section 314.3 of
21 title 21, Code of Federal Regulations (or any
22 successor regulations))”; and

23 (E) in subsection (u)(1), in the matter pre-
24 ceding subparagraph (A)—

1 (i) by striking “active ingredient (in-
2 cluding any ester or salt of the active in-
3 gredient)” and inserting “active moiety (as
4 defined by the Secretary in section 314.3
5 of title 21, Code of Federal Regulations (or
6 any successor regulations))”; and

7 (ii) by striking “same active ingre-
8 dient” and inserting “same active moiety”;

9 (2) in section 512(c)(2)(F) (21 U.S.C.
10 360b(c)(2)(F))—

11 (A) in clause (i), by striking “active ingre-
12 dient (including any ester or salt of the active
13 ingredient)” and inserting “active moiety (as
14 defined by the Secretary in section 314.3 of
15 title 21, Code of Federal Regulations (or any
16 successor regulations))”;

17 (B) in clause (ii), by striking “active ingre-
18 dient (including any ester or salt of the active
19 ingredient)” and inserting “active moiety (as
20 defined by the Secretary in section 314.3 of
21 title 21, Code of Federal Regulations (or any
22 successor regulations))”; and

23 (C) in clause (v), by striking “active ingre-
24 dient (including any ester or salt of the active
25 ingredient)” and inserting “active moiety (as

1 defined by the Secretary in section 314.3 of
2 title 21, Code of Federal Regulations (or any
3 successor regulations))”;

4 (3) in section 524(a)(4)(C) (21 U.S.C.
5 360n(a)(4)(C)), by striking “active ingredient (in-
6 cluding any ester or salt of the active ingredient)”
7 and inserting “active moiety (as defined by the Sec-
8 retary in section 314.3 of title 21, Code of Federal
9 Regulations (or any successor regulations))”;

10 (4) in section 529(a)(4)(A)(ii) (21 U.S.C.
11 360ff(a)(4)(A)(ii)), by striking “active ingredient
12 (including any ester or salt of the active ingredient)”
13 and inserting “active moiety (as defined by the Sec-
14 retary in section 314.3 of title 21, Code of Federal
15 Regulations (or any successor regulations))”; and

16 (5) in section 565A(a)(4)(D) (21 U.S.C.
17 360bbb-4a(a)(4)(D)), by striking “active ingredient
18 (including any ester or salt of the active ingredient)”
19 and inserting “active moiety (as defined by the Sec-
20 retary in section 314.3 of title 21, Code of Federal
21 Regulations (or any successor regulations))”.

1 **TITLE IV—REVENUE**
2 **PROVISIONS**

3 **SEC. 401. PERMANENT EXTENSION OF REDUCTION IN MED-**
4 **ICAL EXPENSE DEDUCTION FLOOR.**

5 (a) **IN GENERAL.**—Section 213(a) of the Internal
6 Revenue Code of 1986 is amended by striking “10 per-
7 cent” and inserting “7.5 percent”.

8 (b) **CONFORMING AMENDMENTS.**—

9 (1) Section 213 of such Code is amended by
10 striking subsection (f).

11 (2) Section 56(b)(1) of such Code is amended
12 by striking subparagraph (B) and by redesignating
13 subparagraphs (C), (D), (E), and (F), as subpara-
14 graphs (B), (C), (D), and (E), respectively.

15 (c) **EFFECTIVE DATE.**—The amendment made by
16 this section shall apply to taxable years ending after De-
17 cember 31, 2019.

18 **SEC. 402. SAFE HARBOR FOR HIGH DEDUCTIBLE HEALTH**
19 **PLANS WITHOUT DEDUCTIBLE FOR INSULIN.**

20 (a) **IN GENERAL.**—Section 223(c)(2)(C) of the Inter-
21 nal Revenue Code of 1986 is amended by inserting “or
22 for insulin or any device for the delivery of insulin” before
23 the period at the end.

1 (b) EFFECTIVE DATE.—The amendment made by
2 this section shall apply to months beginning after the date
3 of the enactment of this Act.

4 **SEC. 403. INCLUSION OF CERTAIN OVER-THE-COUNTER**
5 **MEDICAL PRODUCTS AS QUALIFIED MEDICAL**
6 **EXPENSES.**

7 (a) HSAs.—Section 223(d)(2) of the Internal Rev-
8 enue Code of 1986 is amended—

9 (1) by striking the last sentence of subpara-
10 graph (A) and inserting the following: “For pur-
11 poses of this subparagraph, amounts paid for men-
12 strual care products shall be treated as paid for
13 medical care.”; and

14 (2) by adding at the end the following new sub-
15 paragraph:

16 “(D) MENSTRUAL CARE PRODUCT.—For
17 purposes of this paragraph, the term ‘menstrual
18 care product’ means a tampon, pad, liner, cup,
19 sponge, or similar product used by individuals
20 with respect to menstruation or other genital-
21 tract secretions.”.

22 (b) ARCHER MSAs.—Section 220(d)(2)(A) of such
23 Code is amended by striking the last sentence and insert-
24 ing the following: “For purposes of this subparagraph,
25 amounts paid for menstrual care products (as defined in

1 section 223(d)(2)(D)) shall be treated as paid for medical
2 care.”.

3 (c) HEALTH FLEXIBLE SPENDING ARRANGEMENTS
4 AND HEALTH REIMBURSEMENT ARRANGEMENTS.—Sec-
5 tion 106 of such Code is amended by striking subsection
6 (f) and inserting the following new subsection:

7 “(f) REIMBURSEMENTS FOR MENSTRUAL CARE
8 PRODUCTS.—For purposes of this section and section
9 105, expenses incurred for menstrual care products (as
10 defined in section 223(d)(2)(D)) shall be treated as in-
11 curred for medical care.”.

12 (d) EFFECTIVE DATES.—

13 (1) DISTRIBUTIONS FROM SAVINGS AC-
14 COUNTS.—The amendment made by subsections (a)
15 and (b) shall apply to amounts paid after December
16 31, 2019.

17 (2) REIMBURSEMENTS.—The amendment made
18 by subsection (c) shall apply to expenses incurred
19 after December 31, 2019.

20 **TITLE V—MISCELLANEOUS**

21 **SEC. 501. PAYMENT FOR BIOSIMILAR BIOLOGICAL PROD-** 22 **UCTS DURING INITIAL PERIOD.**

23 Section 1847A(c)(4) of the Social Security Act (42
24 U.S.C. 1395w–3a(c)(4)) is amended—

1 (1) in each of subparagraphs (A) and (B), by
2 redesignating clauses (i) and (ii) as subclauses (I)
3 and (II), respectively, and moving such subclauses
4 2 ems to the right;

5 (2) by redesignating subparagraphs (A) and
6 (B) as clauses (i) and (ii) and moving such clauses
7 2 ems to the right;

8 (3) by striking “UNAVAILABLE.—In the case”
9 and inserting “UNAVAILABLE.—

10 “(A) IN GENERAL.—Subject to subpara-
11 graph (B), in the case”; and

12 (4) by adding at the end the following new sub-
13 paragraph:

14 “(B) LIMITATION ON PAYMENT AMOUNT
15 FOR BIOSIMILAR BIOLOGICAL PRODUCTS DUR-
16 ING INITIAL PERIOD.—In the case of a bio-
17 similar biological product furnished on or after
18 July 1, 2020, in lieu of applying subparagraph
19 (A) during the initial period described in such
20 subparagraph with respect to the biosimilar bio-
21 logical product, the amount payable under this
22 section for the biosimilar biological product is
23 the lesser of the following:

1 “(i) The amount determined under
2 clause (ii) of such subparagraph for the
3 biosimilar biological product.

4 “(ii) The amount determined under
5 subsection (b)(1)(B) for the reference bio-
6 logical product.”.

7 **SEC. 502. GAO STUDY AND REPORT ON AVERAGE SALES**
8 **PRICE.**

9 (a) STUDY.—

10 (1) IN GENERAL.—The Comptroller General of
11 the United States (in this section referred to as the
12 “Comptroller General”) shall conduct a study on
13 spending for applicable drugs under part B of title
14 XVIII of the Social Security Act.

15 (2) APPLICABLE DRUGS DEFINED.—In this sec-
16 tion, the term “applicable drugs” means drugs and
17 biologicals—

18 (A) for which reimbursement under such
19 part B is based on the average sales price of
20 the drug or biological; and

21 (B) that account for the largest percentage
22 of total spending on drugs and biologicals under
23 such part B (as determined by the Comptroller
24 General, but in no case less than 25 drugs or
25 biologicals).

1 (3) REQUIREMENTS.—The study under para-
2 graph (1) shall include an analysis of the following:

3 (A) The extent to which each applicable
4 drug is paid for—

5 (i) under such part B for Medicare
6 beneficiaries; or

7 (ii) by private payers in the commer-
8 cial market.

9 (B) Any change in Medicare spending or
10 Medicare beneficiary cost-sharing that would
11 occur if the average sales price of an applicable
12 drug was based solely on payments by private
13 payers in the commercial market.

14 (C) The extent to which drug manufactur-
15 ers provide rebates, discounts, or other price
16 concessions to private payers in the commercial
17 market for applicable drugs, which the manu-
18 facturer includes in its average sales price cal-
19 culation, for—

20 (i) formulary placement;

21 (ii) utilization management consider-
22 ations; or

23 (iii) other purposes.

1 (D) Barriers to drug manufacturers pro-
2 viding such price concessions for applicable
3 drugs.

4 (E) Other areas determined appropriate by
5 the Comptroller General.

6 (b) REPORT.—Not later than 2 years after the date
7 of the enactment of this Act, the Comptroller General shall
8 submit to Congress a report on the study conducted under
9 subsection (a), together with recommendations for such
10 legislation and administrative action as the Secretary de-
11 termines appropriate.

12 **SEC. 503. REQUIRING PRESCRIPTION DRUG PLANS AND**
13 **MA-PD PLANS TO REPORT POTENTIAL**
14 **FRAUD, WASTE, AND ABUSE TO THE SEC-**
15 **RETARY OF HHS.**

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

19 “(p) REPORTING POTENTIAL FRAUD, WASTE, AND
20 ABUSE.—Beginning January 1, 2021, the PDP sponsor
21 of a prescription drug plan shall report to the Secretary,
22 as specified by the Secretary—

23 “(1) any substantiated or suspicious activities
24 (as defined by the Secretary) with respect to the

1 program under this part as it relates to fraud,
2 waste, and abuse; and

3 “(2) any steps made by the PDP sponsor after
4 identifying such activities to take corrective ac-
5 tions.”.

6 **SEC. 504. ESTABLISHMENT OF PHARMACY QUALITY MEAS-**
7 **URES UNDER MEDICARE PART D.**

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

11 “(8) APPLICATION OF PHARMACY QUALITY
12 MEASURES.—

13 “(A) IN GENERAL.—A PDP sponsor that
14 implements incentive payments to a pharmacy
15 or price concessions paid by a pharmacy based
16 on quality measures shall use measures estab-
17 lished or approved by the Secretary under sub-
18 paragraph (B) with respect to payment for cov-
19 ered part D drugs dispensed by such pharmacy.

20 “(B) STANDARD PHARMACY QUALITY
21 MEASURES.—The Secretary shall establish or
22 approve standard quality measures from a con-
23 sensus and evidence-based organization for pay-
24 ments described in subparagraph (A). Such
25 measures shall focus on patient health outcomes

1 and be based on proven criteria measuring
2 pharmacy performance.

3 “(C) EFFECTIVE DATE.—The requirement
4 under subparagraph (A) shall take effect for
5 plan years beginning on or after January 1,
6 2023, or such earlier date specified by the Sec-
7 retary if the Secretary determines there are suf-
8 ficient measures established or approved under
9 subparagraph (B) to meet the requirement
10 under subparagraph (A).”.

11 **SEC. 505. IMPROVING COORDINATION BETWEEN THE FOOD**
12 **AND DRUG ADMINISTRATION AND THE CEN-**
13 **TERS FOR MEDICARE & MEDICAID SERVICES.**

14 (a) IN GENERAL.—

15 (1) PUBLIC MEETING.—

16 (A) IN GENERAL.—Not later than 12
17 months after the date of the enactment of this
18 Act, the Secretary of Health and Human Serv-
19 ices (referred to in this section as the “Sec-
20 retary”) shall convene a public meeting for the
21 purposes of discussing and providing input on
22 improvements to coordination between the Food
23 and Drug Administration and the Centers for
24 Medicare & Medicaid Services in preparing for
25 the availability of novel medical products de-

1 scribed in subsection (c) on the market in the
2 United States.

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

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

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

16 (iii) representatives of commercial
17 health insurance payers;

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

21 (v) stakeholders representing patients
22 and with expertise in the utilization of pa-
23 tient experience data in medical product
24 development.

1 (C) TOPICS.—The public meeting shall in-
2 clude a discussion of—

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

6 (ii) the anticipated expertise necessary
7 to review the safety and effectiveness of
8 such products at the Food and Drug Ad-
9 ministration and current gaps in such ex-
10 pertise, if any;

11 (iii) the expertise necessary to make
12 coding, coverage, and payment decisions
13 with respect to such products within the
14 Centers for Medicare & Medicaid Services,
15 and current gaps in such expertise, if any;

16 (iv) trends in the differences in the
17 data necessary to determine the safety and
18 effectiveness of a novel medical product
19 and the data necessary to determine
20 whether a novel medical product meets the
21 reasonable and necessary requirements for
22 coverage and payment under title XVIII of
23 the Social Security Act pursuant to section
24 1862(a)(1)(A) of such Act (42 U.S.C.
25 1395y(a)(1)(A));

1 (v) the availability of information for
2 sponsors of such novel medical products to
3 meet each of those requirements; and

4 (vi) the coordination of information
5 related to significant clinical improvement
6 over existing therapies for patients between
7 the Food and Drug Administration and the
8 Centers for Medicare & Medicaid Services
9 with respect to novel medical products.

10 (D) TRADE SECRETS AND CONFIDENTIAL
11 INFORMATION.—No information discussed as a
12 part of the public meeting under this paragraph
13 shall be construed as authorizing the Secretary
14 to disclose any information that is a trade se-
15 cret or confidential information subject to sec-
16 tion 552(b)(4) of title 5, United States Code.

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

19 (A) DRAFT GUIDANCE.—Not later than 18
20 months after the public meeting under para-
21 graph (1), the Secretary shall update the final
22 guidance titled “National Coverage Determina-
23 tions with Data Collection as a Condition of
24 Coverage: Coverage with Evidence Develop-
25 ment” to address any opportunities to improve

1 the availability and coordination of information
2 as described in clauses (iv) through (vi) of para-
3 graph (1)(C).

4 (B) FINAL GUIDANCE.—Not later than 12
5 months after issuing draft guidance under sub-
6 paragraph (A), the Secretary shall finalize the
7 updated guidance to address any such opportu-
8 nities.

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

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

23 (2) Recommendations to—

24 (A) incorporate patient experience data
25 (such as the impact of a disease or condition on

1 the lives of patients and patient treatment pref-
2 erences) into the coverage and payment proc-
3 esses within the Centers for Medicare & Med-
4 icaid Services;

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

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

15 (D) identify potential mechanisms to incor-
16 porate novel payment designs similar to those
17 in development in commercial insurance plans
18 and State plans under title XIX of such Act
19 (42 U.S.C. 1396 et seq.) into the Medicare pro-
20 gram.

21 (c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For
22 purposes of this section, a novel medical product described
23 in this subsection is a medical product, including a drug,
24 biological (including gene and cell therapy), or medical de-
25 vice, that has been designated as a breakthrough therapy

1 under section 506(a) of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 356(a)), a breakthrough device
3 under section 515B of such Act (21 U.S.C. 360e-3), or
4 a regenerative advanced therapy under section 506(g) of
5 such Act (21 U.S.C. 356(g)).

6 **SEC. 506. PATIENT CONSULTATION IN MEDICARE NA-**
7 **TIONAL AND LOCAL COVERAGE DETERMINA-**
8 **TIONS IN ORDER TO MITIGATE BARRIERS TO**
9 **INCLUSION OF SUCH PERSPECTIVES.**

10 Section 1862(l) of the Social Security Act (42 U.S.C.
11 1395y(l)) is amended by adding at the end the following
12 new paragraph:

13 “(7) PATIENT CONSULTATION IN NATIONAL
14 AND LOCAL COVERAGE DETERMINATIONS.—The Sec-
15 retary may consult with patients and organizations
16 representing patients in making national and local
17 coverage determinations.”.

18 **SEC. 507. MEDPAC REPORT ON SHIFTING COVERAGE OF**
19 **CERTAIN MEDICARE PART B DRUGS TO MEDI-**
20 **CARE PART D.**

21 (a) STUDY.—The Medicare Payment Advisory Com-
22 mission (in this section referred to as the “Commission”)
23 shall conduct a study on shifting coverage of certain drugs
24 and biologicals for which payment is currently made under
25 part B of title XVIII of the Social Security Act (42 U.S.C.

1 1395j et seq.) to part D of such title (42 U.S.C. 1395w–
2 21 et seq.). Such study shall include an analysis of—

3 (1) differences in program structures and pay-
4 ment methods for drugs and biologicals covered
5 under such parts B and D, including effects of such
6 a shift on program spending, beneficiary cost-shar-
7 ing liability, and utilization management techniques
8 for such drugs and biologicals; and

9 (2) the feasibility and policy implications of
10 shifting coverage of drugs and biologicals for which
11 payment is currently made under such part B to
12 such part D.

13 (b) REPORT.—

14 (1) IN GENERAL.—Not later than June 30,
15 2021, the Commission shall submit to Congress a re-
16 port containing the results of the study conducted
17 under subsection (a).

18 (2) CONTENTS.—The report under paragraph
19 (1) shall include information, and recommendations
20 as the Commission deems appropriate, regarding—

21 (A) formulary design under such part D;

22 (B) the ability of the benefit structure
23 under such part D to control total spending on
24 drugs and biologicals for which payment is cur-
25 rently made under such part B;

1 (C) changes to the bid process under such
2 part D, if any, that may be necessary to inte-
3 grate coverage of such drugs and biologicals
4 into such part D; and

5 (D) any other changes to the program that
6 Congress should consider in determining wheth-
7 er to shift coverage of such drugs and
8 biologicals from such part B to such part D.

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

13 (i) prescription drug plans negotiate
14 reimbursement rates and other arrange-
15 ments with drug manufacturers on behalf
16 of a wholesaler;

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

21 (iii) physicians and hospitals purchase
22 the drug from the wholesaler via the dis-
23 tributor;

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

4 (v) to be reimbursed for the purchase
5 of the drug from the distributor, the physi-
6 cian furnishes the claim for the drug itself
7 to the wholesaler and the wholesaler would
8 refund the cost of the drug to the physi-
9 cian; and

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

12 **SEC. 508. REQUIREMENT THAT DIRECT-TO-CONSUMER AD-**
13 **VERTISEMENTS FOR PRESCRIPTION DRUGS**
14 **AND BIOLOGICAL PRODUCTS INCLUDE**
15 **TRUTHFUL AND NON-MISLEADING PRICING**
16 **INFORMATION.**

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

19 **“SEC. 1150C. REQUIREMENT THAT DIRECT-TO-CONSUMER**
20 **ADVERTISEMENTS FOR PRESCRIPTION**
21 **DRUGS AND BIOLOGICAL PRODUCTS IN-**
22 **CLUDE TRUTHFUL AND NON-MISLEADING**
23 **PRICING INFORMATION.**

24 “(a) IN GENERAL.—The Secretary shall require that
25 each direct-to-consumer advertisement for a prescription

1 drug or biological product for which payment is available
2 under title XVIII or XIX includes an appropriate disclo-
3 sure of truthful and non-misleading pricing information
4 with respect to the drug or product.

5 “(b) DETERMINATION BY CMS.—The Secretary, act-
6 ing through the Administrator of the Centers for Medicare
7 & Medicaid Services, shall determine the components of
8 the requirement under subsection (a), such as the forms
9 of advertising, the manner of disclosure, the price point
10 listing, and the price information for disclosure.”.

11 **SEC. 509. CHIEF PHARMACEUTICAL NEGOTIATOR AT THE**
12 **OFFICE OF THE UNITED STATES TRADE REP-**
13 **RESENTATIVE.**

14 (a) IN GENERAL.—Section 141 of the Trade Act of
15 1974 (19 U.S.C. 2171) is amended—

16 (1) in subsection (b)(2)—

17 (A) by striking “and one Chief Innovation
18 and Intellectual Property Negotiator” and in-
19 serting “one Chief Innovation and Intellectual
20 Property Negotiator, and one Chief Pharma-
21 ceutical Negotiator”;

22 (B) by striking “or the Chief Innovation
23 and Intellectual Property Negotiator” and in-
24 serting “the Chief Innovation and Intellectual

1 Property Negotiator, or the Chief Pharma-
2 ceutical Negotiator”; and

3 (C) by striking “and the Chief Innovation
4 and Intellectual Property Negotiator” and in-
5 serting “the Chief Innovation and Intellectual
6 Property Negotiator, and the Chief Pharma-
7 ceutical Negotiator”; and

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

10 “(7) The principal function of the Chief Phar-
11 maceutical Negotiator shall be to conduct trade ne-
12 gotiations and to enforce trade agreements relating
13 to United States pharmaceutical products and serv-
14 ices. The Chief Pharmaceutical Negotiator shall be
15 a vigorous advocate on behalf of United States phar-
16 maceutical interests. The Chief Pharmaceutical Ne-
17 gotiator shall perform such other functions as the
18 United States Trade Representative may direct.”.

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

23 “Chief Innovation and Intellectual Property Ne-
24 gotiator, Office of the United States Trade Rep-
25 resentative.

1 “Chief Pharmaceutical Negotiator, Office of the
2 United States Trade Representative.”.

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

12 (1) enforcement actions taken by the United
13 States Trade Representative during the one-year pe-
14 riod preceding the submission of the report to en-
15 sure the protection of United States pharmaceutical
16 products and services; and

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

20 **SEC. 510. WAIVING MEDICARE COINSURANCE FOR**
21 **COLORECTAL CANCER SCREENING TESTS.**

22 Section 1833(a) of the Social Security Act (42 U.S.C.
23 1395l(a)) is amended—

24 (1) by moving the flush text following para-
25 graph (9) 2 ems to the left; and

1 (2) by adding at the end of such flush text the
2 following new sentence: “For items and services fur-
3 nished on or after January 1, 2021, paragraph
4 (1)(Y) shall apply with respect to a colorectal cancer
5 screening test regardless of the code that is billed
6 for the establishment of a diagnosis as a result of
7 the test, or for the removal of tissue or other matter
8 or other procedure that is furnished in connection
9 with, as a result of, and in the same clinical encoun-
10 ter as the screening test.”.