

AMENDMENT

OFFERED BY M .

Strike titles I through V and insert the following
(and update the table of contents accordingly):

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 (a) IMPROVEMENTS.—Section 1834(t) of the Social
8 Security Act (42 U.S.C. 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

1 (iii) by inserting “(or 2021 with re-
2 spect to a physician for services furnished
3 in a physician’s office)” after “2018”; and
4 (C) in subparagraph (A)—

5 (i) by striking “and the” and insert-
6 ing “, the”; and

7 (ii) by inserting “, and the physician
8 fee schedule under section 1848 (with re-
9 spect to the practice expense component of
10 such payment amount)” after “such sec-
11 tion”;

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

14 (3) by inserting after paragraph (1) the fol-
15 lowing new paragraph:

16 “(2) PHYSICIAN PAYMENT.—Beginning in
17 2021, the Secretary may expand the information in-
18 cluded on the Internet website described in para-
19 graph (1) to include—

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

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

1 (b) APPLICATION OF MAXIMUM FAIR PRICES AND
2 CONFORMING AMENDMENTS.—

3 (1) UNDER GROUP HEALTH PLANS AND
4 HEALTH INSURANCE COVERAGE.—

5 (A) ERISA.—

6 (i) IN GENERAL.—Subpart B of part
7 7 of subtitle B of title I of the Employee
8 Retirement Income Security Act of 1974
9 (29 U.S.C. 1181 et. seq.) is amended by
10 adding at the end the following new sec-
11 tion:

12 **“SEC. 716. FAIR PRICE DRUG NEGOTIATION PROGRAM AND**
13 **APPLICATION OF MAXIMUM FAIR PRICES.**

14 “(a) IN GENERAL.—In the case of a group health
15 plan or health insurance issuer offering group health in-
16 surance coverage that is treated under section 1197 of the
17 Social Security Act as having in effect an agreement with
18 the Secretary under the Fair Price Drug Negotiation Pro-
19 gram under part E of title XI of such Act, with respect
20 to a price applicability period (as defined in section
21 1191(b) of such Act) and a selected drug (as defined in
22 section 1192(c) of such Act) with respect to such period
23 with respect to which coverage is provided under such plan
24 or coverage—

1 “(1) the provisions of such part shall apply to
2 the plans or coverage offered by such plan or issuer,
3 and to the individuals enrolled under such plans or
4 coverage, during such period, with respect to such
5 selected drug, in the same manner as such provi-
6 sions apply to prescription drug plans and MA–PD
7 plans, and to individuals enrolled under such pre-
8 scription drug plans and MA–PD plans;

9 “(2) the plan or issuer shall apply any cost-
10 sharing responsibilities under such plan or coverage,
11 with respect to such selected drug, by substituting
12 the maximum fair price negotiated under such part
13 for such drug in lieu of the contracted rate under
14 such plan or coverage for such selected drug; and

15 “(3) the Secretary shall apply the provisions of
16 such part to such plan, issuer, and coverage, and
17 such individuals so enrolled in such plans.

18 “(b) NOTIFICATION REGARDING NONPARTICIPATION
19 IN FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group
20 health plan or a health insurance issuer offering group
21 health insurance coverage shall publicly disclose in a man-
22 ner and in accordance with a process specified by the Sec-
23 retary any election made under section 1197 of the Social
24 Security Act by the plan or issuer to not participate in
25 the Fair Drug Price Negotiation Program under part E

1 of title XI of such Act with respect to a selected drug (as
2 defined in section 1192(c) of such Act) for which coverage
3 is provided under such plan or coverage before the begin-
4 ning of the plan year for which such election was made.”.

5 (ii) CLERICAL AMENDMENT.—The
6 table of sections for part 7 of subtitle B of
7 title I of the Employee Retirement Income
8 Security Act of 1974 is amended by adding
9 at the end the following:

“Sec. 716. Fair Price Drug Negotiation Program and application of maximum
fair prices.”.

10 (C) IRC.—

11 (i) IN GENERAL.—Subchapter B of
12 chapter 100 of the Internal Revenue Code
13 of 1986 is amended by adding at the end
14 the following new section:

15 **“SEC. 9816. FAIR PRICE DRUG NEGOTIATION PROGRAM**
16 **AND APPLICATION OF MAXIMUM FAIR**
17 **PRICES.**

18 “(a) IN GENERAL.—In the case of a group health
19 plan that is treated under section 1197 of the Social Secu-
20 rity Act as having in effect an agreement with the Sec-
21 retary under the Fair Price Drug Negotiation Program
22 under part E of title XI of such Act, with respect to a
23 price applicability period (as defined in section 1191(b)
24 of such Act) and a selected drug (as defined in section

1 1192(c) of such Act) with respect to such period with re-
2 spect to which coverage is provided under such plan—

3 “(1) the provisions of such part shall apply to
4 the plans offered by such plan, and to the individ-
5 uals enrolled under such plans, during such period,
6 with respect to such selected drug, in the same man-
7 ner as such provisions apply to prescription drug
8 plans and MA–PD plans, and to individuals enrolled
9 under such prescription drug plans and MA–PD
10 plans;

11 “(2) the plan shall apply any cost-sharing re-
12 sponsibilities under such plan, with respect to such
13 selected drug, by substituting the maximum fair
14 price negotiated under such part for such drug in
15 lieu of the contracted rate under such plan for such
16 selected drug; and

17 “(3) the Secretary shall apply the provisions of
18 such part to such plan and such individuals so en-
19 rolled in such plan.

20 “(b) NOTIFICATION REGARDING NONPARTICIPATION
21 IN FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group
22 health plan shall publicly disclose in a manner and in ac-
23 cordance with a process specified by the Secretary any
24 election made under section 1197 of the Social Security
25 Act by the plan to not participate in the Fair Drug Price

1 Negotiation Program under part E of title XI of such Act
2 with respect to a selected drug (as defined in section
3 1192(c) of such Act) for which coverage is provided under
4 such plan before the beginning of the plan year for which
5 such election was made.”.

6 (ii) CLERICAL AMENDMENT.—The
7 table of sections for subchapter B of chap-
8 ter 100 of such Code is amended by add-
9 ing at the end the following new item:

“Sec. 9816. Fair Price Drug Negotiation Program and application of maximum
fair prices.”.

10 **SEC. 102. SELECTED DRUG MANUFACTURER EXCISE TAX**
11 **IMPOSED DURING NONCOMPLIANCE PERI-**
12 **ODS.**

13 (a) IN GENERAL.—Subchapter E of chapter 32 of the
14 Internal Revenue Code of 1986 is amended by adding at
15 the end the following new section:

16 **“SEC. 4192. SELECTED DRUGS DURING NONCOMPLIANCE**
17 **PERIODS.**

18 “(a) IN GENERAL.—There is hereby imposed on the
19 sale by the manufacturer, producer, or importer of any
20 selected drug during a day described in subsection (b) a
21 tax in an amount such that the applicable percentage is
22 equal to the ratio of—

23 “(1) such tax, divided by

1 “(2) the sum of such tax and the price for
2 which so sold.

3 “(b) NONCOMPLIANCE PERIODS.—A day is described
4 in this subsection with respect to a selected drug if it is
5 a day during one of the following periods:

6 “(1) The period beginning on the June 16th
7 immediately following the selected drug publication
8 date and ending on the first date during which the
9 manufacturer of the drug has in place an agreement
10 described in subsection (a) of section 1193 of the
11 Social Security Act with respect to such drug.

12 “(2) The period beginning on the April 1st im-
13 mediately following the June 16th described in para-
14 graph (1) and ending on the first date during which
15 the manufacturer of the drug has agreed to a max-
16 imum fair price under such agreement.

17 “(3) In the case of a selected drug with respect
18 to which the Secretary of Health and Human Serv-
19 ices has specified a renegotiation period under such
20 agreement, the period beginning on the first date
21 after the last date of such renegotiation period and
22 ending on the first date during which the manufac-
23 turer of the drug has agreed to a renegotiated max-
24 imum fair price under such agreement.

1 “(4) With respect to information that is re-
2 quired to be submitted to the Secretary of Health
3 and Human Services under such agreement, the pe-
4 riod beginning on the date on which such Secretary
5 certifies that such information is overdue and ending
6 on the date that such information is so submitted.

7 “(5) In the case of a selected drug with respect
8 to which a payment is due under subsection (c) of
9 such section 1193, the period beginning on the date
10 on which the Secretary of Health and Human Serv-
11 ices certifies that such payment is overdue and end-
12 ing on the date that such payment is made in full.

13 “(c) APPLICABLE PERCENTAGE.—The term ‘applica-
14 ble percentage’ means—

15 “(1) in the case of sales of a selected drug dur-
16 ing the first 90 days described in subsection (b) with
17 respect to such drug, 65 percent,

18 “(2) in the case of sales of such drug during
19 the 91st day through the 180th day described in
20 subsection (b) with respect to such drug, 75 percent,

21 “(3) in the case of sales of such drug during
22 the 181st day through the 270th day described in
23 subsection (b) with respect to such drug, 85 percent,
24 and

1 “(4) in the case of sales of such drug during
2 any subsequent day, 95 percent.

3 “(d) DEFINITIONS.—The terms ‘selected drug publi-
4 cation date’ and ‘maximum fair price’ have the meaning
5 given such terms in section 1191 of the Social Security
6 Act and the term ‘selected drug’ has the meaning given
7 such term in section 1192 of such Act.

8 “(e) ANTI-ABUSE RULE.—In the case of a sale which
9 was timed for the purpose of avoiding the tax imposed by
10 this section, the Secretary may treat such sale as occur-
11 ring during a day described in subsection (b).”.

12 (b) NO DEDUCTION FOR EXCISE TAX PAYMENTS.—
13 Section 275 of the Internal Revenue Code of 1986 is
14 amended by adding “or by section 4192” before the period
15 at the end of subsection (a)(6).

16 (c) CONFORMING AMENDMENTS.—

17 (1) Section 4221(a) of the Internal Revenue
18 Code of 1986 is amended by inserting “or 4192”
19 after “section 4191”.

20 (2) Section 6416(b)(2) of such Code is amend-
21 ed by inserting “or 4192” after “section 4191”.

22 (d) CLERICAL AMENDMENTS.—

23 (1) The heading of subchapter E of chapter 32
24 of the Internal Revenue Code of 1986 is amended by

1 striking “**Medical Devices**” and inserting
2 “**Other Medical Products**”.

3 (2) The table of subchapters for chapter 32 of
4 such Code is amended by striking the item relating
5 to subchapter E and inserting the following new
6 item:

“SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

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

“Sec. 4192. Selected drugs during noncompliance periods.”.

10 (e) **EFFECTIVE DATE.**—The amendments made by
11 this section shall apply to sales after the date of the enact-
12 ment of this Act.

13 **SEC. 103. REQUIRING MANUFACTURERS OF CERTAIN SIN-**
14 **GLE-DOSE CONTAINER OR SINGLE-USE PACK-**
15 **AGE DRUGS PAYABLE UNDER PART B OF THE**
16 **MEDICARE PROGRAM TO PROVIDE REFUNDS**
17 **WITH RESPECT TO DISCARDED AMOUNTS OF**
18 **SUCH DRUGS.**

19 Section 1847A of the Social Security Act (42 U.S.C.
20 1395–3a) is amended by adding at the end the following
21 new subsection:

22 “(h) **REFUND FOR CERTAIN DISCARDED SINGLE-**
23 **DOSE CONTAINER OR SINGLE-USE PACKAGE DRUGS.**—

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

3 “(A) IN GENERAL.—For each calendar
4 quarter beginning on or after July 1, 2021, the
5 Secretary shall, with respect to a refundable
6 single-dose container or single-use package drug
7 (as defined in paragraph (8)), report to each
8 manufacturer (as defined in subsection
9 (c)(6)(A)) of such refundable single-dose con-
10 tainer or single-use package drug the following
11 for the calendar quarter:

12 “(i) Subject to subparagraph (C), in-
13 formation on the total number of units of
14 the billing and payment code of such drug,
15 if any, that were discarded during such
16 quarter, as determined using a mechanism
17 such as the JW modifier used as of the
18 date of enactment of this subsection (or
19 any such successor modifier that includes
20 such data as determined appropriate by
21 the Secretary).

22 “(ii) The refund amount that the
23 manufacturer is liable for pursuant to
24 paragraph (3).

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

9 “(C) EXCLUSION OF UNITS OF PACKAGED
10 DRUGS.—The total number of units of the bill-
11 ing and payment code of a refundable single-
12 dose container or single-use package drug of a
13 manufacturer furnished during a calendar quar-
14 ter for purposes of subparagraph (A)(i), and
15 the determination of the estimated total allowed
16 charges for the drug in the quarter for purposes
17 of paragraph (3)(A)(ii), shall not include such
18 units that are packaged into the payment
19 amount for an item or service and are not sepa-
20 rately payable.

21 “(2) MANUFACTURER REQUIREMENT.—For
22 each calendar quarter beginning on or after July 1,
23 2021, the manufacturer of a refundable single-dose
24 container or single-use package drug shall, for such
25 drug, provide to the Secretary a refund that is equal

1 to the amount specified in paragraph (3) for such
2 drug for such quarter.

3 “(3) REFUND AMOUNT.—

4 “(A) IN GENERAL.—The amount of the re-
5 fund specified in this paragraph is, with respect
6 to a refundable single-dose container or single-
7 use package drug of a manufacturer assigned to
8 a billing and payment code for a calendar quar-
9 ter beginning on or after July 1, 2021, an
10 amount equal to the estimated amount (if any)
11 by which—

12 “(i) the product of—

13 “(I) the total number of units of
14 the billing and payment code for such
15 drug that were discarded during such
16 quarter (as determined under para-
17 graph (1)); and

18 “(II)(aa) in the case of a refund-
19 able single-dose container or single-
20 use package drug that is a single
21 source drug or biological, the amount
22 determined for such drug under sub-
23 section (b)(4); or

24 “(bb) in the case of a refundable
25 single-dose container or single-use

1 package drug that is a biosimilar bio-
2 logical product, the average sales price
3 determined under subsection
4 (b)(8)(A); exceeds

5 “(ii) an amount equal to the applica-
6 ble percentage (as defined in subparagraph
7 (B)) of the estimated total allowed charges
8 for such drug during the quarter.

9 “(B) APPLICABLE PERCENTAGE DE-
10 FINED.—

11 “(i) IN GENERAL.—For purposes of
12 subparagraph (A)(ii), the term ‘applicable
13 percentage’ means—

14 “(I) subject to subclause (II), 10
15 percent; and

16 “(II) if applicable, in the case of
17 a refundable single-dose container or
18 single-use package drug described in
19 clause (ii), a percentage specified by
20 the Secretary pursuant to such clause.

21 “(ii) TREATMENT OF DRUGS THAT
22 HAVE UNIQUE CIRCUMSTANCES.—In the
23 case of a refundable single-dose container
24 or single-use package drug that has unique
25 circumstances involving similar loss of

1 product as that described in paragraph
2 (8)(B), the Secretary, through notice and
3 comment rulemaking, may increase the ap-
4 plicable percentage otherwise applicable
5 under clause (i)(I) as determined appro-
6 priate by the Secretary.

7 “(4) FREQUENCY.—Amounts required to be re-
8 funded pursuant to paragraph (2) shall be paid in
9 regular intervals (as determined appropriate by the
10 Secretary).

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

15 “(6) ENFORCEMENT.—

16 “(A) AUDITS.—

17 “(i) MANUFACTURER AUDITS.—Each
18 manufacturer of a refundable single-dose
19 container or single-use package drug that
20 is required to provide a refund under this
21 subsection shall be subject to periodic
22 audit with respect to such drug and such
23 refunds by the Secretary.

24 “(ii) PROVIDER AUDITS.—The Sec-
25 retary shall conduct periodic audits of

1 claims submitted under this part with re-
2 spect to refundable single-dose container or
3 single-use package drugs in accordance
4 with the authority under section 1833(e) to
5 ensure compliance with the requirements
6 applicable under this subsection.

7 “(B) CIVIL MONEY PENALTY.—

8 “(i) IN GENERAL.—The Secretary
9 shall impose a civil money penalty on a
10 manufacturer of a refundable single-dose
11 container or single-use package drug who
12 has failed to comply with the requirement
13 under paragraph (2) for such drug for a
14 calendar quarter in an amount equal to the
15 sum of—

16 “(I) the amount that the manu-
17 facturer would have paid under such
18 paragraph with respect to such drug
19 for such quarter; and

20 “(II) 25 percent of such amount.

21 “(ii) APPLICATION.—The provisions
22 of section 1128A (other than subsections
23 (a) and (b)) shall apply to a civil money
24 penalty under this subparagraph in the
25 same manner as such provisions apply to a

1 penalty or proceeding under section
2 1128A(a).

3 “(7) IMPLEMENTATION.—The Secretary shall
4 implement this subsection through notice and com-
5 ment rulemaking.

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

8 “(A) IN GENERAL.—Except as provided in
9 subparagraph (B), in this subsection, the term
10 ‘refundable single-dose container or single-use
11 package drug’ means a single source drug or bi-
12 ological (as defined in section 1847A(c)(6)(D))
13 or a biosimilar biological product (as defined in
14 section 1847A(c)(6)(H)) for which payment is
15 established under this part and that is fur-
16 nished from a single-dose container or single-
17 use package.

18 “(B) EXCLUSIONS.—The term ‘refundable
19 single-dose container or single-use package
20 drug’ does not include—

21 “(i) a drug or biological that is either
22 a radiopharmaceutical or an imaging
23 agent;

24 “(ii) a drug or biological for which
25 dosage and administration instructions ap-

1 proved by the Commissioner of Food and
2 Drugs require filtration during the drug
3 preparation process, prior to dilution and
4 administration, and require that any un-
5 used portion of such drug after the filtra-
6 tion process be discarded after the comple-
7 tion of such filtration process; or

8 “(iii) a drug or biological approved by
9 the Food and Drug Administration on or
10 after the date of enactment of this sub-
11 section and with respect to which payment
12 has been made under this part for less
13 than 18 months.”.

14 **SEC. 104. PROVIDING FOR VARIATION IN PAYMENT FOR**
15 **CERTAIN DRUGS COVERED UNDER PART B**
16 **OF THE MEDICARE PROGRAM.**

17 (a) COMPUTING PAYMENT RATES BY APPLYING
18 VARIABLE PERCENTAGES OF AVERAGE SALES PRICE
19 (ASP) BASED ON RELATIVE DRUG COST.—

20 (1) IN GENERAL.—Section 1847A(b) of the So-
21 cial Security Act (42 U.S.C. 1395w-3a(b)) is
22 amended—

23 (A) in paragraph (1)—

24 (i) in subparagraph (A), by inserting
25 after “or 106 percent” the following: “(or,

1 for a multiple source drug furnished on or
2 after January 1, 2021, the applicable per-
3 cent specified in paragraph (9)(A) for the
4 drug and quarter involved)”; and

5 (ii) in subparagraph (B), by inserting
6 after “106 percent” the following: “(or, for
7 a single source drug or biological furnished
8 on or after January 1, 2021, the applicable
9 percent specified in paragraph (9)(A) for
10 the drug or biological and quarter in-
11 volved)”; and

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

14 “(9) APPLICATION OF VARIABLE PERCENTAGES
15 BASED ON PERCENTILE RANKING OF PER BENE-
16 FICIARY ALLOWED CHARGES.—

17 “(A) APPLICABLE PERCENT TO BE AP-
18 PLIED.—

19 “(i) IN GENERAL.—Subject to clause
20 (ii), with respect to a drug or biological
21 furnished in a calendar quarter beginning
22 on or after January 1, 2021, if the Sec-
23 retary determines that the percentile rank
24 of a drug or biological under subparagraph
25 (B)(i)(III), with respect to per beneficiary

1 allowed charges for all such drugs or
2 biologicals, is—

3 “(I) at least equal to the 85th
4 percentile, the applicable percent for
5 the drug for such quarter under this
6 subparagraph is 102 percent;

7 “(II) at least equal to the 70th
8 percentile, but less than the 85th per-
9 centile, such applicable percent is 104
10 percent;

11 “(III) at least equal to the 50th
12 percentile, but less than the 70th per-
13 centile, such applicable percent is 106
14 percent; or

15 “(IV) less than the 50th per-
16 centile, such applicable percent is 108
17 percent.

18 “(ii) CASES WHERE DATA NOT SUFFI-
19 CIENTLY AVAILABLE TO COMPUTE PER
20 BENEFICIARY ALLOWED CHARGES.—In the
21 case of a drug or biological furnished for
22 which the amount of payment is deter-
23 mined under subparagraph (A) or (B) of
24 paragraph (1) and not under subsection
25 (c)(4), for calendar quarters during a pe-

1 riod in which data are not sufficiently
2 available to compute a per beneficiary al-
3 lowed charges for the drug or biological,
4 the applicable percent is 106 percent.

5 “(B) DETERMINATION OF PERCENTILE
6 RANK OF PER BENEFICIARY ALLOWED CHARGES
7 OF DRUGS.—

8 “(i) IN GENERAL.—With respect to a
9 calendar quarter beginning on or after
10 January 1, 2021, for drugs and biologicals
11 for which the amount of payment is deter-
12 mined under subparagraph (A) or (B) of
13 paragraph (1), except for drugs or
14 biologicals for which data are not suffi-
15 ciently available, the Secretary shall—

16 “(I) compute the per beneficiary
17 allowed charges (as defined in sub-
18 paragraph (C)) for each such drug or
19 biological;

20 “(II) adjust such per beneficiary
21 allowed charges for the quarter, to the
22 extent provided under subparagraph
23 (D); and

24 “(III) array such adjusted per
25 beneficiary allowed charges for all

1 such drugs or biologicals from high to
2 low and rank such drugs or biologicals
3 by percentile of such arrayed per ben-
4 eficiary allowed charges.

5 “(ii) FREQUENCY.—The Secretary
6 shall make the computations under clause
7 (i)(I) every 6 months (or, if necessary, as
8 determined by the Secretary, every 9 or 12
9 months) and such computations shall apply
10 to succeeding calendar quarters until a
11 new computation has been made.

12 “(iii) APPLICABLE DATA PERIOD.—
13 For purposes of this paragraph, the term
14 ‘applicable data period’ means the most re-
15 cent period for which the data necessary
16 for making the computations under clause
17 (i) are available, as determined by the Sec-
18 retary.

19 “(C) PER BENEFICIARY ALLOWED
20 CHARGES DEFINED.—In this paragraph, the
21 term ‘per beneficiary allowed charges’ means,
22 with respect to a drug or biological for which
23 the amount of payment is determined under
24 subparagraph (A) or (B) of paragraph (1)—

1 “(i) the allowed charges for the drug
2 or biological for which payment is so made
3 for the applicable data period, as estimated
4 by the Secretary; divided by

5 “(ii) the number of individuals for
6 whom any payment for the drug or biologi-
7 cal was made under paragraph (1) for the
8 applicable data period, as estimated by the
9 Secretary.

10 “(D) ADJUSTMENT TO REFLECT CHANGES
11 IN AVERAGE SALES PRICE.—In applying this
12 paragraph for a particular calendar quarter, the
13 Secretary shall adjust the per beneficiary al-
14 lowed charges for a drug or biological by multi-
15 plying such per beneficiary allowed charges
16 under subparagraph (C) for the applicable data
17 period by the ratio of—

18 “(i) the average sales price for the
19 drug or biological for the most recent cal-
20 endar quarter used under subsection
21 (c)(5)(B); to

22 “(ii) the average sales price for the
23 drug or biological for the calendar quarter
24 (or the weighted average for the quarters

1 involved) included in the applicable data
2 period.”.

3 (2) APPLICATION OF JUDICIAL REVIEW PROVI-
4 SIONS.—Section 1847A(g) of the Social Security Act
5 (42 U.S.C. 1395w–3a(g)) is amended—

6 (A) by striking “and” at the end of para-
7 graph (4);

8 (B) by striking the period at the end of
9 paragraph (5) and inserting “; and”; and

10 (C) by adding at the end the following new
11 paragraph:

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

15 (b) REQUIRING REGULATIONS ON ALLOCATION OF
16 BUNDLED DISCOUNTS AMONG DRUG PRODUCTS.—

17 (1) IN GENERAL.—The Secretary of Health and
18 Human Services shall promulgate final regulations,
19 to be effective no later than July 1, 2021, that re-
20 quire manufacturers, in implementing section 1847A
21 of the Social Security Act (42 U.S.C. 1395w–3a)
22 and in order that the average sales price for each
23 drug accurately reflects the average transaction
24 price for that drug, to allocate the total value of all
25 bundled discounts proportionately according to the

1 dollar value of the units of each drug sold under a
2 bundled arrangement.

3 (2) ALTERNATIVE APPROACHES.—After pro-
4 mulgating such regulations, the Secretary may revise
5 such regulations to incorporate alternative ap-
6 proaches, such as allocating discounts to reflect con-
7 tingencies in the contracts between manufacturers
8 and purchasers of drugs, in a way that more accu-
9 rately represents the average transaction prices for
10 drugs with bundled discounts.

11 **SEC. 105. TREATMENT OF DRUG ADMINISTRATION SERV-**
12 **ICES FURNISHED BY CERTAIN EXCEPTED**
13 **OFF-CAMPUS OUTPATIENT DEPARTMENTS OF**
14 **A PROVIDER.**

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

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

21 “(i) IN GENERAL.—In the case of a
22 covered OPD service that is a drug admin-
23 istration service (as defined by the Sec-
24 retary) furnished by a department of a
25 provider described in clause (ii) or (iv) of

1 paragraph (21)(B), the payment amount
2 for such service furnished on or after Jan-
3 uary 1, 2021, shall be the same payment
4 amount (as determined in paragraph
5 (21)(C)) that would apply if the drug ad-
6 ministration service was furnished by an
7 off-campus outpatient department of a pro-
8 vider (as defined in paragraph (21)(B)).

9 “(ii) APPLICATION WITHOUT REGARD
10 TO BUDGET NEUTRALITY.—The reductions
11 made under this subparagraph—

12 “(I) shall not be considered an
13 adjustment under paragraph (2)(E);
14 and

15 “(II) shall not be implemented in
16 a budget neutral manner.”.

17 **Subtitle B—METRIC Act**

18 **SEC. 111. REPORTING ON EXPLANATION FOR DRUG PRICE** 19 **INCREASES.**

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

1 **“PART W—DRUG PRICE REPORTING; DRUG**
2 **VALUE FUND**
3 **“SEC. 39900. REPORTING ON EXPLANATION FOR DRUG**
4 **PRICE INCREASES.**

5 “(a) DEFINITIONS.—In this section:

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

8 “(A) that holds the application for a drug
9 approved under section 505 of the Federal
10 Food, Drug, and Cosmetic Act or licensed
11 under section 351 of this Act; or

12 “(B) who is responsible for setting the
13 wholesale acquisition cost for the drug.

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

19 “(A) that has a wholesale acquisition cost
20 of \$100 or more, adjusted for inflation occur-
21 ring after the date of enactment of this section,
22 for a month’s supply or a typical course of
23 treatment that lasts less than a month, and
24 is—

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

4 “(ii) administered or otherwise dis-
5 pensed to treat a disease or condition af-
6 fecting more than 200,000 persons in the
7 United States; and

8 “(iii) not a vaccine; and

9 “(B) for which, during the previous cal-
10 endar year, at least 1 dollar of the total amount
11 of sales were for individuals enrolled under the
12 Medicare program under title XVIII of the So-
13 cial Security Act (42 U.S.C. 1395 et seq.) or
14 under a State Medicaid plan under title XIX of
15 such Act (42 U.S.C. 1396 et seq.) or under a
16 waiver of such plan.

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

21 “(b) REPORT.—

22 “(1) REPORT REQUIRED.—The manufacturer of
23 a qualifying drug shall submit a report to the Sec-
24 retary for each increase in the price of a qualifying

1 drug that results in an increase in the wholesale ac-
2 quisition cost of that drug that is equal to—

3 “(A) 10 percent or more within a single
4 calendar year beginning on or after January 1,
5 2019; or

6 “(B) 25 percent or more within three con-
7 secutive calendar years for which the first such
8 calendar year begins on or after January 1,
9 2019.

10 “(2) REPORT DEADLINE.—Each report de-
11 scribed in paragraph (1) shall be submitted to the
12 Secretary—

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

20 “(B) in the case of a report with respect
21 to an increase in the price of a qualifying drug
22 that occurs after the period described in sub-
23 paragraph (A), not later than 30 days prior to
24 the planned effective date of such price increase
25 for such qualifying drug.

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), and the effective
12 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 22102(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 generic drugs (as defined in section
2 1860D–14B(g)(5)).”.

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—

1 “(i) discounted prices for applicable
2 drugs of the manufacturer that are dis-
3 pensed on or after January 1, 2022; and

4 “(ii) discounted prices for generic
5 drugs of the manufacturer that are dis-
6 pensed on or after January 1, 2022.

7 “(B) PROVISION OF DISCOUNTED PRICES
8 AT THE POINT-OF-SALE.—The discounted prices
9 described in subparagraph (A) shall be provided
10 to the applicable beneficiary at the pharmacy or
11 by the mail order service at the point-of-sale of
12 an applicable drug or a generic drug, as the
13 case may be.

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

20 “(3) COMPLIANCE WITH REQUIREMENTS FOR
21 ADMINISTRATION OF PROGRAM.—Each manufac-
22 turer with an agreement in effect under this section
23 shall comply with requirements imposed by the Sec-
24 retary or a third party with a contract under sub-
25 section (d)(3), as applicable, for purposes of admin-

1 istering the program, including any determination
2 under subparagraph (A) of subsection (c)(1) or pro-
3 cedures established under such subsection (c)(1).

4 “(4) LENGTH OF AGREEMENT.—

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

11 “(B) TERMINATION.—

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

1 effective date to be repealed if the Sec-
2 retary determines appropriate.

3 “(ii) BY A MANUFACTURER.—A man-
4 ufacturer may terminate an agreement
5 under this section for any reason. Any
6 such termination shall be effective, with re-
7 spect to a plan year—

8 “(I) if the termination occurs be-
9 fore January 30 of a plan year, as of
10 the day after the end of the plan year;
11 and

12 “(II) if the termination occurs on
13 or after January 30 of a plan year, as
14 of the day after the end of the suc-
15 ceeding plan year.

16 “(iii) EFFECTIVENESS OF TERMI-
17 NATION.—Any termination under this sub-
18 paragraph shall not affect discounts for
19 applicable drugs of the manufacturer that
20 are due under the agreement before the ef-
21 fective date of its termination.

22 “(iv) NOTICE TO THIRD PARTY.—The
23 Secretary shall provide notice of such ter-
24 mination to a third party with a contract
25 under subsection (d)(3) within not less

1 than 30 days before the effective date of
2 such termination.

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

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

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

11 “(A) the determination of the amount of
12 the discounted price of an applicable drug of a
13 manufacturer and of the discounted price of a
14 generic drug of a manufacturer;

15 “(B) the establishment of procedures
16 under which discounted prices are provided to
17 applicable beneficiaries at pharmacies or by
18 mail order service at the point-of-sale of an ap-
19 plicable drug or a generic drug, as the case may
20 be;

21 “(C) the establishment of procedures to
22 ensure that, not later than the applicable num-
23 ber of calendar days after the dispensing of an
24 applicable drug or a generic drug, as the case
25 may be, by a pharmacy or mail order service,

1 the pharmacy or mail order service is reim-
2 bursed for an amount equal to the difference
3 between—

4 “(i) the negotiated price of the appli-
5 cable drug or generic drug, respectively;
6 and

7 “(ii) the discounted price of the appli-
8 cable drug or generic drug, respectively;

9 “(D) the establishment of procedures to
10 ensure that the discounted price for an applica-
11 ble drug or a generic drug under this section is
12 applied before any coverage or financial assist-
13 ance under other health benefit plans or pro-
14 grams that provide coverage or financial assist-
15 ance for the purchase or provision of prescrip-
16 tion drug coverage on behalf of applicable bene-
17 ficiaries as the Secretary may specify; and

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

23 “(2) MONITORING COMPLIANCE.—

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

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

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

17 “(d) ADMINISTRATION.—

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

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

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

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

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

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

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

1 drugs of the manufacturer and generic drugs of
2 the manufacturer under the program.

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

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

12 “(e) ENFORCEMENT.—

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

16 “(2) CIVIL MONEY PENALTY.—

17 “(A) IN GENERAL.—The Secretary shall
18 impose a civil money penalty on a manufacturer
19 that fails to provide applicable beneficiaries dis-
20 counts for applicable drugs of the manufacturer
21 or generic drugs of the manufacturer in accord-
22 ance with such agreement for each such failure
23 in an amount the Secretary determines is com-
24 mensurate with the sum of—

1 “(i) the amount that the manufac-
2 turer would have paid with respect to such
3 discounts under the agreement, which will
4 then be used to pay the discounts which
5 the manufacturer had failed to provide;
6 and

7 “(ii) 25 percent of such amount.

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

14 “(f) CLARIFICATION REGARDING AVAILABILITY OF
15 OTHER COVERED PART D DRUGS.—Nothing in this sec-
16 tion shall prevent an applicable beneficiary from pur-
17 chasing a covered part D drug that is not on the formulary
18 of the prescription drug plan or MA–PD plan that the
19 applicable beneficiary is enrolled in.

20 “(g) DEFINITIONS.—In this section:

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

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

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

3 “(C) has incurred costs for covered part D
4 drugs in the year that are equal to or exceed
5 the annual deductible specified in section
6 1860D–2(b)(1) for such year.

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

10 “(A) approved under a new drug applica-
11 tion under section 505(c) of the Federal Food,
12 Drug, and Cosmetic Act or, in the case of a bio-
13 logic product, licensed under section 351 of the
14 Public Health Service Act (including a product
15 licensed under subsection (k) of such section);
16 and

17 “(B)(i) if the PDP sponsor of the prescrip-
18 tion drug plan or the MA organization offering
19 the MA–PD plan uses a formulary, which is on
20 the formulary of the prescription drug plan or
21 MA–PD plan that the applicable beneficiary is
22 enrolled in;

23 “(ii) if the PDP sponsor of the prescrip-
24 tion drug plan or the MA organization offering
25 the MA–PD plan does not use a formulary, for

1 which benefits are available under the prescrip-
2 tion drug plan or MA–PD plan that the appli-
3 cable beneficiary is enrolled in; or

4 “(iii) is provided through an exception or
5 appeal.

6 “(3) APPLICABLE NUMBER OF CALENDAR
7 DAYS.—The term ‘applicable number of calendar
8 days’ means—

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

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

13 “(4) DISCOUNTED PRICE.—

14 “(A) IN GENERAL.—The term ‘discounted
15 price’ means—

16 “(i) with respect to an applicable drug
17 of a manufacturer furnished during a year
18 to an applicable beneficiary—

19 “(I) who has not incurred costs
20 for covered part D drugs in the year
21 that are equal to or exceed the annual
22 out-of-pocket threshold specified in
23 section 1860D–2(b)(4)(B)(i) for the
24 year, 90 percent of the negotiated
25 price of such drug; and

1 “(II) who has incurred such costs
2 in the year that are equal to or exceed
3 such threshold for the year, 90 per-
4 cent of the negotiated price of such
5 drug; and

6 “(ii) with respect to a generic drug of
7 a manufacturer furnished during a year to
8 an applicable beneficiary who has not in-
9 curred costs for covered part D drugs in
10 the year that are equal to or exceed the
11 annual out-of-pocket threshold specified in
12 section 1860D–2(b)(4)(B)(i) for the year,
13 90 percent of the negotiated price of such
14 drug.

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

20 “(C) SPECIAL CASE FOR CLAIMS SPANNING
21 DEDUCTIBLE.—In the case where the entire
22 amount of the negotiated price of an individual
23 claim for an applicable drug or a generic drug
24 with respect to an applicable beneficiary does
25 not fall at or above the annual deductible speci-

1 fied in section 1860D–2(b)(1) for the year, the
2 manufacturer of the applicable drug shall pro-
3 vide the discounted price under this section on
4 only the portion of the negotiated price of the
5 applicable drug or generic drug, respectively,
6 that falls at or above such annual deductible.

7 “(5) GENERIC DRUG.—The term ‘generic drug’
8 means, with respect to an applicable beneficiary, a
9 covered part D drug that is not an applicable drug.

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

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

1 “(8) QUALIFIED RETIREE PRESCRIPTION DRUG
2 PLAN.—The term ‘qualified retiree prescription drug
3 plan’ has the meaning given such term in section
4 11860D–22(a)(2).”.

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

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

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

14 “(h) SUNSET OF PROGRAM.—

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

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

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

5 (A) in subsection (b)(2)(C)(iii)—

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

9 “(I) the reinsurance”; and

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

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

17 (B) in subsection (c)(1)(C)—

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

21 “(i) the reinsurance”;

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

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

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

6 (d) DETERMINATION OF ALLOWABLE REINSURANCE
7 COSTS.—Section 1860D–15(b) of the Social Security Act
8 (42 U.S.C. 1395w–115(b)) is amended—

9 (1) in paragraph (2)—

10 (A) by striking “COSTS.—For purposes”
11 and inserting “COSTS.—

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

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

16 “(B) INCLUSION OF MANUFACTURER DIS-
17 COUNTS ON APPLICABLE DRUGS AND GENERIC
18 DRUGS.—For purposes of applying subpara-
19 graph (A), the term ‘allowable reinsurance
20 costs’ shall include the portion of the negotiated
21 price (as defined in section 1860D–14B(g)(7))
22 of an applicable drug (as defined in section
23 1860D–14(g)(2)) that was paid by a manufac-
24 turer under the manufacturer discount program
25 under section 1860D–14B and the portion of

1 the negotiated price (as so defined) of a generic
2 drug (as defined in section 1860D–14(g)(5))
3 that was paid by a manufacturer under such
4 program.”; and

5 (2) in paragraph (3)—

6 (A) in the first sentence, by striking “For
7 purposes” and inserting “Subject to paragraph
8 (2)(B), for purposes”; and

9 (B) in the second sentence, by inserting
10 “or, in the case of an applicable drug or a ge-
11 neric drug, by a manufacturer” after “by the
12 individual or under the plan”.

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

18 “(3) UPDATING RISK ADJUSTMENT METH-
19 ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA-
20 TION REDESIGN.—The Secretary shall update the
21 risk adjustment model used to adjust bid amounts
22 pursuant to this subsection as appropriate to take
23 into account changes in benefits under this part pur-
24 suant to the amendments made by section 121 of
25 the Lower Drug Costs Now Act of 2019.”.

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

4 (1) in subsection (a)—

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

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

9 (C) by adding at the end the following new
10 paragraphs:

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

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

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

21 (2) by striking subsection (b) and inserting the
22 following:

23 “(b) EFFECTIVE DATE.—Paragraphs (1) through (3)
24 of subsection (a) shall apply to covered part D drugs dis-
25 pensed under this part on or after January 1, 2011, and

1 before January 1, 2022, and paragraphs (4) through (6)
2 of such subsection shall apply to covered part D drugs
3 dispensed on or after January 1, 2022.”; and

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

6 “(2) the Secretary determines that in the period
7 beginning on January 1, 2011, and ending on De-
8 cember 31, 2011 (with respect to paragraphs (1)
9 through (3) of subsection (a)) or the period begin-
10 ning on January 1, 2022, and ending December 31,
11 2022 (with respect to paragraphs (4) through (6) of
12 such subsection), there were extenuating cir-
13 cumstances.”.

14 (g) CONFORMING AMENDMENTS.—

15 (1) Section 1860D–2 of the Social Security Act
16 (42 U.S.C. 1395w–102) is amended—

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

21 (B) in subsection (c)(1)(C)—

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

1 (ii) by inserting “for a year preceding
2 2022 or the annual out-of-pocket threshold
3 specified in subsection (b)(4)(B) for the
4 year for 2022 and each subsequent year”
5 after “subsection (b)(3) for the year” each
6 place it appears; and

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

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

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

16 (A) in paragraph (1)—

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

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

23 (iii) in subparagraph (E), by striking
24 “The elimination” and inserting “For a
25 year preceding 2022, the elimination”; and

1 (B) in paragraph (2)—

2 (i) in subparagraph (C), by striking
3 “The continuation” and inserting “For a
4 year preceding 2022, the continuation”;
5 and

6 (ii) in subparagraph (E)—

7 (I) by inserting “for a year pre-
8 ceding 2022,” after “subsection (e)”;
9 and

10 (II) by striking “1860D-
11 2(b)(4)(A)(i)(I)” and inserting
12 “1860D-2(b)(4)(A)(i)(I)(aa)”.

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

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

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

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

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

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

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

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

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

13 (B) by inserting “for such year” before the
14 period.

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

18 **Subtitle D—Other Medicare Part D** 19 **Provisions**

20 **SEC. 131. TRANSITIONAL COVERAGE AND RETROACTIVE** 21 **MEDICARE PART D COVERAGE FOR CERTAIN** 22 **LOW-INCOME BENEFICIARIES.**

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

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

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

5 “(e) LIMITED INCOME NEWLY ELIGIBLE TRANSI-
6 TION PROGRAM.—

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

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

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

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

22 “(3) TRANSITIONAL COVERAGE.—For purposes
23 of this subsection, the term ‘transitional coverage’
24 means, with respect to an LI NET eligible indi-
25 vidual—

1 “(A) immediate access to covered part D
2 drugs at the point-of-sale during the period that
3 begins on the first day of the month such indi-
4 vidual is determined to meet the requirements
5 of clauses (ii) and (iii) of subsection (a)(3)(A)
6 and ends on the date that coverage under a pre-
7 scription drug plan or MA–PD plan takes effect
8 with respect to such individual; and

9 “(B) in the case of an LI NET eligible in-
10 dividual who is a full-benefit dual eligible indi-
11 vidual (as defined in section 1935(c)(6)) or a
12 recipient of supplemental security income bene-
13 fits under title XVI, retroactive coverage (in the
14 form of reimbursement of the amounts that
15 would have been paid under this part had such
16 individual been enrolled in a prescription drug
17 plan or MA–PD plan) of covered part D drugs
18 purchased by such individual during the period
19 that begins on the date that is the later of—

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

23 “(ii) the date that is 36 months prior
24 to the date such individual enrolls in a pre-
25 scription drug plan or MA–PD plan, and

1 ends on the date that coverage under such
2 plan takes effect.

3 “(4) PROGRAM ADMINISTRATION.—

4 “(A) SINGLE POINT OF CONTACT.—The
5 Secretary shall, to the extent feasible, admin-
6 ister the program under this subsection through
7 a contract with a single program administrator.

8 “(B) BENEFIT DESIGN.—The Secretary
9 shall ensure that the transitional coverage pro-
10 vided to LI NET eligible individuals under this
11 subsection—

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

14 “(ii) permits all pharmacies deter-
15 mined by the Secretary to be in good
16 standing to process claims under the pro-
17 gram;

18 “(iii) is consistent with such require-
19 ments as the Secretary considers necessary
20 to improve patient safety and ensure ap-
21 propriate dispensing of medication; and

22 “(iv) meets such other requirements
23 as the Secretary may establish.

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

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

4 “(i) Paragraphs (1) and (3)(B) of sec-
5 tion 1860D–4(a) (relating to dissemination
6 of general information; availability of infor-
7 mation on changes in formulary through
8 the internet).

9 “(ii) Subparagraphs (A) and (B) of
10 section 1860D–4(b)(3) (relating to require-
11 ments on development and application of
12 formularies; formulary development).

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

16 “(B) WAIVER AUTHORITY.—The Secretary
17 may waive such other requirements of title XI
18 and this title as may be necessary to carry out
19 the purposes of the program established under
20 this subsection.”.

21 **SEC. 132. DRUG DISCOUNTS REQUIRED TO BE PASSED**
22 **THROUGH TO THE PLAN SPONSOR.**

23 (a) IN GENERAL.—Section 1150A of the Social Secu-
24 rity Act (42 U.S.C. 1320b–23), as amended by section
25 112, is further amended—

1 (1) in the heading, by inserting “**;** **DRUG DIS-**
2 **COUNTS REQUIRED TO BE PASSED THROUGH**
3 **TO THE PLAN SPONSOR**” before the period at the
4 end; and

5 (2) by adding at the end the following new sub-
6 sections:

7 “(f) **DRUG DISCOUNTS REQUIRED TO BE PASSED**
8 **THROUGH TO THE PLAN SPONSOR.—**

9 “(1) **REQUIREMENT.—**Beginning January 1,
10 2022, a PBM that manages prescription drug cov-
11 erage under a contract with a PDP sponsor or MA
12 organization described in subsection (b)(1) or a
13 qualified health benefits plan described in subsection
14 (b)(2), shall, with respect to the plan sponsor of a
15 health benefits plan, pass through to the plan spon-
16 sor 100 percent of the aggregate amount of the re-
17 bates, discounts, or price concessions (other than
18 bona fide service fees (as defined in subsection (g)))
19 that the PBM negotiates that are attributable to pa-
20 tient utilization under the plan (including any re-
21 bates, discounts, or other price concessions (other
22 than bona fide service fees (as so defined)) that are
23 received by an agent or affiliate of the PBM acting
24 on the PBM’s behalf). Such a PBM may retain bona
25 fide service fees (as so defined), to the extent that

1 such fees are not based on a percentage of the sales
2 for a drug or otherwise linked in any way to the
3 price or formulary position or placement of a drug.

4 “(2) ENFORCEMENT.—A PDP sponsor of a
5 prescription drug plan or an MA organization offer-
6 ing an MA–PD plan under part D of title XVIII
7 may not contract with a PBM that is not in compli-
8 ance with the requirement under paragraph (1).

9 “(g) BONA FIDE SERVICE FEES DEFINED.—The
10 term ‘bona fide service fees’ means, with respect to a
11 PBM, fees paid to such PBM (or an agent or affiliate of
12 such PBM acting on the PBM’s behalf) by a manufac-
13 turer, customer, or client of the PBM that represent the
14 fair market value for a bona fide, itemized service actually
15 performed on behalf of the manufacturer, customer, or cli-
16 ent, that the manufacturer, customer, or client would oth-
17 erwise perform (or contract for) in the absence of the serv-
18 ice arrangement, and that the PBM does not pass on to
19 another party.”.

20 (b) EFFECTIVE DATE.—The amendments made by
21 subsection (a) shall take effect on January 1, 2022.

1 **SEC. 133. PART D NEGOTIATED PRICES REQUIRED TO TAKE**
2 **INTO ACCOUNT CERTAIN PRICE CONCES-**
3 **SIONS AT THE POINT-OF-SALE.**

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

7 (1) by striking “PRICES.—For purposes” and
8 inserting “PRICES.—

9 “(i) IN GENERAL.—For purposes”;

10 and

11 (2) by adding at the end the following new
12 clause:

13 “(ii) NEGOTIATED PRICES AT POINT-
14 OF-SALE.—

15 “(I) IN GENERAL.—Negotiated
16 prices for covered part D drugs de-
17 scribed in clause (i) shall be provided
18 at the point-of-sale of the covered part
19 D drug. If the negotiated price is not
20 possible to calculate at the point-of-
21 sale, an approximate negotiated price
22 (as established by the Secretary) shall
23 be used under the prescription drug
24 plan or MA–PD plan.

25 “(II) INCLUSION OF CERTAIN
26 PRICE CONCESSIONS.—Negotiated

1 prices described in subclause (I) shall
2 include the value of at least 80 per-
3 cent of all rebates, discounts, or other
4 price concessions received by a PDP
5 sponsor offering a prescription drug
6 plan or an MA organization offering
7 an MA–PD plan from a drug manu-
8 facturer, either directly or indirectly
9 from a PBM to such PDP sponsor or
10 MA organization.

11 “(III) APPROXIMATE NEGO-
12 TIATED PRICE.—In determining an
13 approximate negotiated price for a
14 covered part D drug under subclause
15 (I), the Secretary shall ensure that—

16 “(aa) such price reflects the
17 estimated negotiated price that is
18 based on the previous year’s ne-
19 gotiated price concessions nego-
20 tiated under the plan for all or
21 similar covered part D drugs or
22 is based on such other factors as
23 the Secretary may determine ap-
24 propriate; and

1 “(bb) the use of such price
2 does not prevent the use of value-
3 based contracts between drug
4 manufacturers, PDP sponsors,
5 MA organizations, and phar-
6 macies.”.

7 (b) **EFFECTIVE DATE.**—The amendments made by
8 subsection (a) shall apply to plan years beginning on or
9 after January 1, 2021.

10 **SEC. 134. ALLOWING CERTAIN ENROLLEES OF PRESCRIP-**
11 **TION DRUGS PLANS AND MA-PD PLANS**
12 **UNDER MEDICARE PROGRAM TO SPREAD**
13 **OUT COST-SHARING UNDER CERTAIN CIR-**
14 **CUMSTANCES.**

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

19 (1) in subparagraph (A), by striking “Subject
20 to subparagraphs (C) and (D)” and inserting “Sub-
21 ject to subparagraphs (C), (D), and (E)”; and

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

24 “(E) **ENROLLEE OPTION REGARDING**
25 **SPREADING COST-SHARING.**—

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

22 “(ii) SIGNIFICANT PERCENTAGE LIM-
23 TATIONS.—In specifying a significant per-
24 centage pursuant to the regulation estab-
25 lished by the Secretary under clause (i),

1 the Secretary may not specify a percentage
2 that is less than 30 percent or greater
3 than 100 percent.”.

4 (b) ALTERNATIVE PRESCRIPTION DRUG COV-
5 ERAGE.—Section 1860D–2(c) of the Social Security Act
6 (42 U.S.C. 1395w–102(c)) is amended by adding at the
7 end the following new paragraph:

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

14 **Subtitle E—MedPAC**

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

21 (a) ACCESS TO CERTAIN PART D PAYMENT DATA.—
22 Section 1860D–15(f) of the Social Security Act (42
23 U.S.C. 1395w–115(f)) is amended—
24 (1) in paragraph (2)—

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

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

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

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

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

20 “(3) ADDITIONAL RESTRICTIONS ON DISCLO-
21 SURE OF INFORMATION.—The Executive Directors
22 described in paragraph (2)(C) shall not disclose any
23 of the following information disclosed to such Execu-
24 tive Directors or obtained by such Executive Direc-

1 tors pursuant to such paragraph, with respect to a
2 prescription drug plan offered by a PDP sponsor:

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

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

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

16 (b) ACCESS TO CERTAIN REBATE AND PAYMENT
17 DATA UNDER MEDICARE AND MEDICAID.—Section
18 1927(b)(3)(D) of the Social Security Act (42 U.S.C.
19 1396r–8(b)(3)(D)) is amended—

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

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

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

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

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

9 (5) in the matter at the end, by striking
10 “1860D-4(c)(2)(E)” and inserting “1860D-
11 4(c)(2)(G)”; and

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

TITLE II—MEDICAID**SEC. 201. REQUIREMENT FOR CERTAIN COVERED ENTITIES
PASS THROUGH SAVINGS FROM 340B DRUG
DISCOUNT PROGRAM TO PATIENTS.**

(a) IN GENERAL.—Section 340B(a)(5) of the Public Health Service Act (42 U.S.C. 256b(a)(5)) is amended by adding at the end the following new subparagraph:

“(E) PASS-THROUGH OF SAVINGS.—

“(i) IN GENERAL.—A hospital that is a covered entity described in subparagraph (L), (M), (N), or (O) of paragraph (4) shall, with respect to a covered outpatient drug subject to an agreement under this section that is purchased on or after the date that is 180 days after the date of the enactment of this subparagraph, pass through the savings amount determined under clause (ii) with respect to such drug to the patient receiving such drug.

“(ii) SAVINGS AMOUNT.—The savings amount determined under this clause, with respect to a covered outpatient drug subject to an agreement under this section, is the amount equal to 75 percent of the re-

1 duction in the price of the drug provided
2 under such agreement.”.

3 (b) REQUIREMENT FOR COST-SHARING FOR 340B
4 DRUGS TO BE BASED ON 340B PRICE.—

5 (1) IN GENERAL.—Subpart II of part A of title
6 XXVII of the Public Health Service Act (42 U.S.C.
7 300gg–11 et seq.) is amended by adding at the end
8 the following new section:

9 **“SEC. 2729A. COST-SHARING FOR DRUGS PURCHASED**
10 **UNDER 340B DRUG DISCOUNT PROGRAM.**

11 “If a group health plan or a health insurance issuer
12 offering group or individual health insurance coverage pro-
13 vides or covers any benefits for a covered outpatient drug
14 (as defined in section 1927(k) of the Social Security Act)
15 subject to an agreement under section 340B and an en-
16 rollee of such plan or coverage is furnished such drug,
17 then such plan or issuer shall calculate the cost-sharing
18 requirement for an enrollee of such plan or coverage for
19 such drug as if the total amount charged for such drug
20 was the amount paid for such drug under an agreement
21 under the drug discount program under section 340B.”.

22 (2) EFFECTIVE DATE.—The amendment made
23 by paragraph (1) shall apply with respect to plan
24 years beginning on or after the date that is 180 days
25 after the date of the enactment of this Act.

1 **SEC. 202. SENSE OF CONGRESS RELATING TO 340B DRUG**
2 **DISCOUNT PROGRAM.**

3 It is the sense of Congress that the purpose of the
4 drug discount program under section 340B of the Public
5 Health Service Act (42 U.S.C. 256b) is to lower out-of-
6 pocket drugs costs for low-income and uninsured individ-
7 uals.

8 **SEC. 203. SUNSET OF LIMIT ON MAXIMUM REBATE AMOUNT**
9 **FOR SINGLE SOURCE DRUGS AND INNO-**
10 **VATOR MULTIPLE SOURCE DRUGS.**

11 Section 1927(c)(2)(D) of the Social Security Act (42
12 U.S.C. 1396r–8(c)(2)(D)) is amended by inserting after
13 “December 31, 2009,” the following: “and before January
14 1, 2023,”.

15 **SEC. 204. MEDICAID PHARMACY AND THERAPEUTICS COM-**
16 **MITTEE IMPROVEMENTS.**

17 (a) IN GENERAL.—Subparagraph (A) of section
18 1927(d)(4) of the Social Security Act (42 U.S.C. 1396r–
19 8(d)(4)) is amended to read as follows:

20 “(A)(i) The formulary is developed and re-
21 viewed by a pharmacy and therapeutics com-
22 mittee consisting of physicians, pharmacists,
23 and other appropriate individuals appointed by
24 the Governor of the State.

25 “(ii) Subject to clause (vi), the State estab-
26 lishes and implements a conflict of interest pol-

1 icy for the pharmacy and therapeutics com-
2 mittee that—

3 “(I) is publicly accessible;

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

10 “(III) contains clear processes, such
11 as recusal from voting or discussion, for
12 those members who report a conflict of in-
13 terest, along with appropriate processes to
14 address any instance where a member fails
15 to report a conflict of interest.

16 “(iii) The membership of the pharmacy
17 and therapeutics committee—

18 “(I) includes at least 1 actively prac-
19 ticing physician and at least 1 actively
20 practicing pharmacist, each of whom—

21 “(aa) is independent and free of
22 conflict with respect to manufacturers
23 and Medicaid participating plans or
24 subcontractors, including pharmacy
25 benefit managers; and

1 “(bb) has expertise in the care of
2 1 or more Medicaid-specific popu-
3 lations such as elderly or disabled in-
4 dividuals, children with complex med-
5 ical needs, or low-income individuals
6 with chronic illnesses; and

7 “(II) is made publicly available.

8 “(iv) At the option of the State, the
9 State’s drug use review board established under
10 subsection (g)(3) may serve as the pharmacy
11 and therapeutics committee provided the State
12 ensures that such board meets the requirements
13 of clauses (ii) and (iii).

14 “(v) The State reviews and has final ap-
15 proval of the formulary established by the phar-
16 macy and therapeutics committee.

17 “(vi) If the Secretary determines it appro-
18 priate or necessary based on the findings and
19 recommendations of the Comptroller General of
20 the United States in the report submitted to
21 Congress under section 205 of the Lower Drug
22 Costs Now Act of 2019, the Secretary shall
23 issue guidance that States must follow for es-
24 tablishing conflict of interest policies for the
25 pharmacy and therapeutics committee in ac-

1 cordance with the requirements of clause (ii),
2 including appropriate standards and require-
3 ments for identifying, addressing, and reporting
4 on conflicts of interest.”.

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

9 (1) by striking “and (III)” and inserting
10 “(III)”;

11 (2) by striking the period at the end and insert-
12 ing “, and (IV) any formulary used by the entity for
13 covered outpatient drugs dispensed to individuals eli-
14 gible for medical assistance who are enrolled with
15 the entity is developed and reviewed by a pharmacy
16 and therapeutics committee that meets the require-
17 ments of clauses (ii) and (iii) of section
18 1927(d)(4)(A).”; and

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

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

1 **SEC. 205. GAO REPORT ON CONFLICTS OF INTEREST IN**
2 **STATE MEDICAID PROGRAM DRUG USE RE-**
3 **VIEW BOARDS AND PHARMACY AND THERA-**
4 **PEUTICS (P&T) COMMITTEES.**

5 (a) INVESTIGATION.—The Comptroller General of the
6 United States shall conduct an investigation of potential
7 or existing conflicts of interest among members of State
8 Medicaid program State drug use review boards (in this
9 section referred to as “DUR Boards”) and pharmacy and
10 therapeutics committees (in this section referred to as
11 “P&T Committees”).

12 (b) REPORT.—Not later than 24 months after the
13 date of enactment of this Act, the Comptroller General
14 shall submit to Congress a report on the investigation con-
15 ducted under subsection (a) that includes the following:

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

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

21 (B) States that operate separate P&T
22 Committees for their fee-for-service Medicaid
23 program and their Medicaid managed care or-
24 ganizations or other Medicaid managed care ar-
25 rangements (collectively referred to in this sec-
26 tion as “Medicaid MCOs”); and

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

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

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

12 (4) An analysis of whether and how States or
13 P&T Committees establish participation and inde-
14 pendence requirements for DUR Boards and P&T
15 Committees, including with respect to entities with
16 connections with drug manufacturers, State Med-
17 icaid programs, managed care organizations, and
18 other entities or individuals in the pharmaceutical
19 industry.

20 (5) A description outlining how States, DUR
21 Boards, or P&T Committees define conflicts of inter-
22 est.

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

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

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

9 (9) A review of strategies States may use to
10 guard against conflicts of interest on DUR Boards
11 and P&T Committees and to ensure compliance with
12 the requirements of titles XI and XIX of the Social
13 Security Act (42 U.S.C. 1301 et seq., 1396 et seq.)
14 and access to effective, clinically appropriate, and
15 medically necessary drug treatments for Medicaid
16 beneficiaries, including recommendations for such
17 legislative and administrative actions as the Comp-
18 troller General determines appropriate.

19 **SEC. 206. ENSURING THE ACCURACY OF MANUFACTURER**
20 **PRICE AND DRUG PRODUCT INFORMATION**
21 **UNDER THE MEDICAID DRUG REBATE PRO-**
22 **GRAM.**

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

1 (1) IN GENERAL.—Subparagraph (B) of section
2 1927(b)(3) of the Social Security Act (42 U.S.C.
3 1396r–8(b)(3)) is amended to read as follows:

4 “(B) AUDITS AND SURVEYS OF MANUFAC-
5 TURER PRICE AND DRUG PRODUCT INFORMA-
6 TION.—

7 “(i) AUDITS.—The Secretary shall
8 conduct ongoing audits of the price and
9 drug product information reported by man-
10 ufacturers under subparagraph (A) for the
11 most recently ended rebate period to en-
12 sure the accuracy and timeliness of such
13 information. In conducting such audits, the
14 Secretary may employ evaluations, surveys,
15 statistical sampling, predictive analytics
16 and other relevant tools and methods.

17 “(ii) VERIFICATIONS SURVEYS OF AV-
18 ERAGE MANUFACTURER PRICE AND MANU-
19 FACTURER’S AVERAGE SALES PRICE.—In
20 addition to the audits required under
21 clause (i), the Secretary may survey whole-
22 salers and manufacturers (including manu-
23 facturers that directly distribute their cov-
24 ered outpatient drugs (in this subpara-
25 graph referred to as ‘direct sellers’)), when

1 necessary, to verify manufacturer prices
2 and manufacturer's average sales prices
3 (including wholesale acquisition cost) to
4 make payment reported under subpara-
5 graph (A).

6 “(iii) PENALTIES.—In addition to
7 other penalties as may be prescribed by
8 law, including under subparagraph (C) of
9 this paragraph, the Secretary may impose
10 a civil monetary penalty in an amount not
11 to exceed \$185,000 on an annual basis on
12 a wholesaler, manufacturer, or direct sell-
13 er, if the wholesaler, manufacturer, or di-
14 rect seller of a covered outpatient drug re-
15 fuses a request for information about
16 charges or prices by the Secretary in con-
17 nection with an audit or survey under this
18 subparagraph or knowingly provides false
19 information. The provisions of section
20 1128A (other than subsections (a) (with
21 respect to amounts of penalties or addi-
22 tional assessments) and (b)) shall apply to
23 a civil money penalty under this clause in
24 the same manner as such provisions apply

1 to a penalty or proceeding under section
2 1128A(a).

3 “(iv) REPORTS.—

4 “(I) REPORT TO CONGRESS.—

5 The Secretary shall, not later than 18
6 months after date of enactment of
7 this subparagraph, submit a report to
8 the Committee on Energy and Com-
9 merce of the House of Representatives
10 and the Committee on Finance of the
11 Senate regarding additional regulatory
12 or statutory changes that may be re-
13 quired in order to ensure accurate and
14 timely reporting and oversight of
15 manufacturer price and drug product
16 information, including whether
17 changes should be made to reasonable
18 assumption requirements to ensure
19 such assumptions are reasonable and
20 accurate or whether another method-
21 ology for ensuring accurate and timely
22 reporting of price and drug product
23 information should be considered to
24 ensure the integrity of the drug rebate
25 program under this section.

1 “(II) ANNUAL REPORTS.—The
2 Secretary shall, on at least an annual
3 basis, submit a report to the Com-
4 mittee on Energy and Commerce of
5 the House of Representatives and the
6 Committee on Finance of the Senate
7 summarizing the results of the audits
8 and surveys conducted under this sub-
9 paragraph during the period that is
10 the subject of the report.

11 “(III) CONTENT.—Each report
12 submitted under subclause (II) shall,
13 with respect to the period that is the
14 subject of the report, include sum-
15 maries of—

16 “(aa) error rates in the
17 price, drug product, and other
18 relevant information supplied by
19 manufacturers under subpara-
20 graph (A);

21 “(bb) the timeliness with
22 which manufacturers, whole-
23 salers, and direct sellers provide
24 information required under sub-

1 paragraph (A) or under clause (i)
2 or (ii) of this subparagraph;

3 “(cc) the number of manu-
4 facturers, wholesalers, and direct
5 sellers and drug products audited
6 under this subparagraph;

7 “(dd) the types of price and
8 drug product information re-
9 viewed under the audits con-
10 ducted under this subparagraph;

11 “(ee) the tools and meth-
12 odologies employed in such au-
13 dits;

14 “(ff) the findings of such
15 audits, including which manufac-
16 turers, if any, were penalized
17 under this subparagraph; and

18 “(gg) such other relevant in-
19 formation as the Secretary shall
20 deem appropriate.

21 “(IV) PROTECTION OF INFORMA-
22 TION.—In preparing a report required
23 under subclause (II), the Secretary
24 shall redact such proprietary informa-
25 tion as the Secretary determines ap-

1 appropriate to prevent disclosure of, and
2 to safeguard, such information.

3 “(v) APPROPRIATIONS.—Out of any
4 funds in the Treasury not otherwise appro-
5 priated, there is appropriated to the Sec-
6 retary \$2,000,000 for fiscal year 2020 and
7 each fiscal year thereafter to carry out this
8 subparagraph.”.

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

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

15 (1) INCREASED PENALTY FOR LATE REPORTING
16 OF INFORMATION.—Section 1927(b)(3)(C)(i) of the
17 Social Security Act (42 U.S.C. 1396r–8(b)(3)(C)(i))
18 is amended by striking “increased by \$10,000 for
19 each day in which such information has not been
20 provided and such amount shall be paid to the
21 Treasury” and inserting “, for each covered out-
22 patient drug with respect to which such information
23 is not provided, \$50,000 for the first day that such
24 information is not provided on a timely basis and

1 \$19,000 for each subsequent day that such informa-
2 tion is not provided”.

3 (2) INCREASED PENALTY FOR KNOWINGLY RE-
4 PORTING FALSE INFORMATION.—Section
5 1927(b)(3)(C)(ii) of the Social Security Act (42
6 U.S.C. 1396r–8(b)(3)(C)(ii)) is amended by striking
7 “\$100,000” and inserting “\$500,000”.

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

12 **SEC. 207. IMPROVING TRANSPARENCY AND PREVENTING**
13 **THE USE OF ABUSIVE SPREAD PRICING AND**
14 **RELATED PRACTICES IN MEDICAID.**

15 (a) PASS-THROUGH PRICING REQUIRED.—

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

19 “(6) PASS-THROUGH PRICING REQUIRED.—A
20 contract between the State and a pharmacy benefit
21 manager (referred to in this paragraph as a ‘PBM’),
22 or a contract between the State and a managed care
23 entity or other specified entity (as such terms are
24 defined in section 1903(m)(9)(D)) that includes pro-
25 visions making the entity responsible for coverage of

1 covered outpatient drugs dispensed to individuals en-
2 rolled with the entity, shall require that payment for
3 such drugs and related administrative services (as
4 applicable), including payments made by a PBM on
5 behalf of the State or entity, is based on a pass-
6 through pricing model under which—

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

9 “(i) is limited to—

10 “(I) ingredient cost; and

11 “(II) a professional dispensing
12 fee that is not less than the profes-
13 sional dispensing fee that the State
14 plan or waiver would pay if the plan
15 or waiver was making the payment di-
16 rectly;

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

20 “(iii) is made in a manner that is con-
21 sistent with section 1902(a)(30)(A) and
22 sections 447.512, 447.514, and 447.518 of
23 title 42, Code of Federal Regulations (or
24 any successor regulation) as if such re-

1 requirements applied directly to the entity or
2 the PBM;

3 “(B) payment to the entity or the PBM
4 (as applicable) for administrative services per-
5 formed by the entity or PBM is limited to a
6 reasonable administrative fee that covers the
7 reasonable cost of providing such services;

8 “(C) the entity or the PBM (as applicable)
9 shall make available to the State, and the Sec-
10 retary upon request, all costs and payments re-
11 lated to covered outpatient drugs and accom-
12 panying administrative services incurred, re-
13 ceived, or made by the entity or the PBM, in-
14 cluding ingredient costs, professional dispensing
15 fees, administrative fees, post-sale and post-in-
16 voice fees. Discounts, or related adjustments
17 such as direct and indirect remuneration fees,
18 and any and all remuneration; and

19 “(D) any form of spread pricing whereby
20 any amount charged or claimed by the entity or
21 the PBM (as applicable) is in excess of the
22 amount paid to the pharmacies on behalf of the
23 entity, including any post-sale or post-invoice
24 fees, discounts, or related adjustments such as
25 direct and indirect remuneration fees or assess-

1 ments (after allowing for a reasonable adminis-
2 trative fee as described in subparagraph (B)) is
3 not allowable for purposes of claiming Federal
4 matching payments under this title.”.

5 (2) CONFORMING AMENDMENT.—Clause (xiii)
6 of section 1903(m)(2)(A) of such Act (42 U.S.C.
7 1396b(m)(2)(A)), as amended by section 204, is fur-
8 ther amended—

9 (A) by striking “and (IV)” and inserting
10 “(IV)”; and

11 (B) by inserting before the period at the
12 end the following: “, and (V) pharmacy benefit
13 management services provided by the entity, or
14 provided by a pharmacy benefit manager on be-
15 half of the entity under a contract or other ar-
16 rangement between the entity and the phar-
17 macy benefit manager, shall comply with the re-
18 quirements of section 1927(e)(6)”.

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

25 (b) SURVEY OF RETAIL PRICES.—

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

3 (A) by striking “and” after the semicolon
4 at the end of paragraph (1)(A)(i) and all that
5 precedes it through “(1)” and inserting the fol-
6 lowing:

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

11 “(A) USE OF VENDOR.—The Secretary
12 may contract services for—

13 “(i) with respect to retail community
14 pharmacies, the determination on a month-
15 ly basis of retail survey prices of the na-
16 tional average drug acquisition cost for
17 covered outpatient drugs for such phar-
18 macies, net of all discounts and rebates (to
19 the extent any information with respect to
20 such discounts and rebates is available),
21 the average reimbursement received for
22 such drugs by such pharmacies from all
23 sources of payment, including third par-
24 ties, and, to the extent available, the usual

1 and customary charges to consumers for
2 such drugs; and”;

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

5 “(F) SURVEY REPORTING.—In order to
6 meet the requirement of section 1902(a)(54), a
7 State shall require that any retail community
8 pharmacy in the State that receives any pay-
9 ment, administrative fee, discount, or rebate re-
10 lated to the dispensing of covered outpatient
11 drugs to individuals receiving benefits under
12 this title, regardless of whether such payment,
13 fee, discount, or rebate is received from the
14 State or a managed care entity directly or from
15 a pharmacy benefit manager or another entity
16 that has a contract with the State or a man-
17 aged care entity, shall respond to surveys of re-
18 tail prices conducted under this subsection.

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

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

1 “(ii) The sampling frame and number
2 of pharmacies sampled monthly.

3 “(iii) Characteristics of reporting
4 pharmacies, including type (such as inde-
5 pendent or chain), geographic or regional
6 location, and dispensing volume.

7 “(iv) Reporting of a separate national
8 average drug acquisition cost for each drug
9 for independent retail pharmacies and
10 chain operated pharmacies.

11 “(v) Information on price concessions
12 including on and off invoice discounts, re-
13 bates, and other price concessions.

14 “(vi) Information on average profes-
15 sional dispensing fees paid.

16 “(H) PENALTIES.—

17 “(i) FAILURE TO PROVIDE TIMELY IN-
18 FORMATION.—A retail community phar-
19 macy that fails to respond to a survey con-
20 ducted under this subsection on a timely
21 basis may be subject to a civil monetary
22 penalty in the amount of \$10,000 for each
23 day in which such information has not
24 been provided.

1 “(ii) FALSE INFORMATION.—A retail
2 community pharmacy that knowingly pro-
3 vides false information in response to a
4 survey conducted under this subsection
5 may be subject to a civil money penalty in
6 an amount not to exceed \$100,000 for
7 each item of false information.

8 “(iii) OTHER PENALTIES.—Any civil
9 money penalties imposed under this sub-
10 paragraph shall be in addition to other
11 penalties as may be prescribed by law. The
12 provisions of section 1128A (other than
13 subsections (a) and (b)) shall apply to a
14 civil money penalty under this subpara-
15 graph in the same manner as such provi-
16 sions apply to a penalty or proceedings
17 under section 1128A(a).

18 “(I) REPORT ON SPECIALTY PHAR-
19 MACIES.—

20 “(i) IN GENERAL.—Not later than 1
21 year after the effective date of this sub-
22 paragraph, the Secretary shall submit a re-
23 port to Congress examining specialty drug
24 coverage and reimbursement under this
25 title.

1 “(ii) CONTENT OF REPORT.—Such re-
2 port shall include a description of how
3 State Medicaid programs define specialty
4 drugs, how much State Medicaid programs
5 pay for specialty drugs, how States and
6 managed care plans determine payment for
7 specialty drugs, the settings in which spe-
8 cialty drugs are dispensed (such as retail
9 community pharmacies or specialty phar-
10 macies), whether acquisition costs for spe-
11 cialty drugs are captured in the national
12 average drug acquisition cost survey, and
13 recommendations as to whether specialty
14 pharmacies should be included in the sur-
15 vey of retail prices to ensure national aver-
16 age drug acquisition costs capture drugs
17 sold at specialty pharmacies and how such
18 specialty pharmacies should be defined.”;
19 (C) in paragraph (2)—
20 (i) in subparagraph (A), by inserting
21 “, including payments rates under Med-
22 icaid managed care plans,” after “under
23 this title”; and

1 (ii) in subparagraph (B), by inserting
2 “and the basis for such dispensing fees”
3 before the semicolon; and
4 (D) in paragraph (4), by inserting “, and
5 \$5,000,000 for fiscal year 2020 and each fiscal
6 year thereafter,” after “2010”.

7 (2) EFFECTIVE DATE.—The amendments made
8 by this subsection take effect on the 1st day of the
9 1st quarter that begins on or after the date that is
10 18 months after the date of enactment of this Act.

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

15 (1) in subparagraph (A)(i)—

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

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

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

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

23 “(III) in the case of rebate peri-
24 ods that begin on or after the date of
25 enactment of this subclause, on the

1 wholesale acquisition cost (as defined
2 in section 1847A(c)(6)(B)) for cov-
3 ered outpatient drugs for the rebate
4 period under the agreement (including
5 for all such drugs that are sold under
6 a new drug application approved
7 under section 505(c) of the Federal
8 Food, Drug, and Cosmetic Act);” and

9 (2) in subparagraph (D)—

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

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

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

17 (D) by inserting after clause (vii) the fol-
18 lowing:

19 “(viii) to the Secretary to disclose
20 (through a website accessible to the public)
21 the most recently reported wholesale acqui-
22 sition cost (as defined in section
23 1847A(c)(6)(B)) for each covered out-
24 patient drug (including for all such drugs
25 that are sold under a new drug application

1 approved under section 505(c) of the Fed-
2 eral Food, Drug, and Cosmetic Act), as re-
3 ported under subparagraph (A)(i)(III).”.

4 **SEC. 208. T-MSIS DRUG DATA ANALYTICS REPORTS.**

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

13 (b) CONTENT OF REPORT.—

14 (1) REQUIRED CONTENT.—Each report re-
15 quired under subsection (a) for a calendar year shall
16 include the following information with respect to
17 each State (and, to the extent available, with respect
18 to Puerto Rico, the United States Virgin Islands,
19 Guam, the Northern Mariana Islands, and American
20 Samoa):

21 (A) A comparison of covered outpatient
22 drug (as defined in section 1927(k)(2) of the
23 Social Security Act (42 U.S.C. 1396r–8(k)(2)))
24 prescribing patterns under the State Medicaid
25 plan or waiver of such plan (including drugs

1 prescribed on a fee-for-service basis and drugs
2 prescribed under managed care arrangements
3 under such plan or waiver)—

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

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

8 (iii) by episodes of care for—

9 (I) each chronic disease category,
10 as defined by the Secretary, that is
11 represented in the 10 conditions that
12 accounted for the greatest share of
13 total spending under the plan or waiv-
14 er during the year that is the subject
15 of the report;

16 (II) procedural groupings; and

17 (III) rare disease diagnosis codes;

18 (iv) by patient demographic character-
19 istics, including race (to the extent that
20 the Secretary determines that there is suf-
21 ficient data available with respect to such
22 characteristic in a majority of States), gen-
23 der, and age;

24 (v) by patient high-utilizer or risk sta-
25 tus; and

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

4 (B) In the case of medical assistance for
5 covered outpatient drugs (as so defined) pro-
6 vided under a State Medicaid plan or waiver of
7 such plan in a managed care setting, an anal-
8 ysis of the differences in managed care pre-
9 scribing patterns when a covered outpatient
10 drug is prescribed in a managed care setting as
11 compared to when the drug is prescribed in a
12 fee-for-service setting.

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

18 (A) a description of prescription utilization
19 management tools under State programs to pro-
20 vide long-term services and supports under a
21 State Medicaid plan or a waiver of such plan;

22 (B) a comparison of prescription utilization
23 management tools applicable to populations cov-
24 ered under a State Medicaid plan waiver under
25 section 1115 of the Social Security Act (42

1 U.S.C. 1315) and the models applicable to pop-
2 ulations that are not covered under the waiver;

3 (C) a comparison of the prescription utili-
4 zation management tools employed by different
5 Medicaid managed care organizations, phar-
6 macy benefit managers, and related entities
7 within the State;

8 (D) a comparison of the prescription utili-
9 zation management tools applicable to each en-
10 rollment category under a State Medicaid plan
11 or waiver; and

12 (E) a comparison of the prescription utili-
13 zation management tools applicable under the
14 State Medicaid plan or waiver by patient high-
15 utilizer or risk status.

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

19 (A) analyses of national, State, and local
20 patterns of Medicaid population-based pre-
21 scribing behaviors; and

22 (B) recommendations for administrative or
23 legislative action to improve the effectiveness of,
24 and reduce costs for, covered outpatient drugs
25 under Medicaid while ensuring timely bene-

1 ficiary access to medically necessary covered
2 outpatient drugs.

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

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

10 (2) as appropriate, include a description with
11 respect to each State of the quality and complete-
12 ness of the data, as well as any necessary caveats
13 describing the limitations of the data reported to the
14 Secretary by the State that are sufficient to commu-
15 nicate the appropriate uses for the information.

16 (d) PREPARATION OF REPORT.—Each report re-
17 quired under subsection (a) shall be prepared by the Ad-
18 ministrator for the Centers for Medicare & Medicaid Serv-
19 ices.

20 (e) APPROPRIATION.—For fiscal year 2020 and each
21 fiscal year thereafter, there is appropriated to the Sec-
22 retary \$2,000,000 to carry out this section.

1 **SEC. 209. RISK-SHARING VALUE-BASED PAYMENT AGREE-**
2 **MENTS FOR COVERED OUTPATIENT DRUGS**
3 **UNDER MEDICAID.**

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

7 “(1) STATE OPTION TO PAY FOR COVERED OUT-
8 PATIENT DRUGS THROUGH RISK-SHARING VALUE-BASED
9 AGREEMENTS.—

10 “(1) IN GENERAL.—Beginning January 1,
11 2022, a State shall have the option to pay (whether
12 on a fee-for-service or managed care basis) for cov-
13 ered outpatient drugs that are potentially curative
14 treatments intended for one-time use that are ad-
15 ministered to individuals under this title by entering
16 into a risk-sharing value-based payment agreement
17 with the manufacturer of the drug in accordance
18 with the requirements of this subsection.

19 “(2) SECRETARIAL APPROVAL.—

20 “(A) IN GENERAL.—A State shall submit a
21 request to the Secretary to enter into a risk-
22 sharing value based payment agreement, and
23 the Secretary shall not approve a proposed risk-
24 sharing value-based payment agreement be-
25 tween a State and a manufacturer for payment

1 for a covered outpatient drug of the manufac-
2 turer unless the following requirements are met:

3 “(i) MANUFACTURER IS PARTY TO RE-
4 BATE AGREEMENT AND IN COMPLIANCE
5 WITH REQUIREMENTS.—The manufacturer
6 has a rebate agreement in effect as re-
7 quired under subsection (a) and (b) of this
8 section and is in compliance with all appli-
9 cable requirements under this title.

10 “(ii) NO INCREASE TO PROJECTED
11 NET FEDERAL SPENDING.—

12 “(I) IN GENERAL.—The Chief
13 Actuary certifies that the projected
14 payments for each covered outpatient
15 drug under such proposed agreement
16 would not result in greater estimated
17 Federal spending under this title than
18 the net Federal spending that would
19 result in the absence of the agree-
20 ment.

21 “(II) NET FEDERAL SPENDING
22 DEFINED.—For purposes of this sub-
23 section, the term ‘net Federal spend-
24 ing’ means the amount of Federal
25 payments the Chief Actuary estimates

1 would be made under this title for ad-
2 ministering a covered outpatient drug
3 to an individual eligible for medical
4 assistance under a State plan or a
5 waiver of such plan, reduced by the
6 amount of all rebates the Chief Actu-
7 ary estimates would be paid with re-
8 spect to the administering of such
9 drug, including all rebates under this
10 title and any supplemental or other
11 additional rebates, in the absence of
12 such an agreement.

13 “(III) INFORMATION.—The Chief
14 Actuary shall make the certifications
15 required under this clause based on
16 the most recently available and reli-
17 able drug pricing and product infor-
18 mation. The State and manufacturer
19 shall provide the Secretary and the
20 Chief Actuary with all necessary infor-
21 mation required to make the estimates
22 needed for such certifications.

23 “(iii) LAUNCH AND LIST PRICE JUS-
24 TIFICATIONS.—The manufacturer submits
25 all relevant information and supporting

1 documentation necessary for pricing deci-
2 sions as deemed appropriate by the Sec-
3 retary, which shall be truthful and non-
4 misleading, including manufacturer infor-
5 mation and supporting documentation for
6 launch price or list price increases, and
7 any applicable justification required under
8 section 1128L.

9 “(iv) CONFIDENTIALITY OF INFORMA-
10 TION; PENALTIES.—The provisions of sub-
11 paragraphs (C) and (D) of subsection
12 (b)(3) shall apply to a manufacturer that
13 fails to submit the information and docu-
14 mentation required under clauses (ii) and
15 (iii) on a timely basis, or that knowingly
16 provides false or misleading information, in
17 the same manner as such provisions apply
18 to a manufacturer with a rebate agreement
19 under this section.

20 “(B) CONSIDERATION OF STATE REQUEST
21 FOR APPROVAL.—

22 “(i) IN GENERAL.—The Secretary
23 shall treat a State request for approval of
24 a risk-sharing value-based payment agree-
25 ment in the same manner that the Sec-

1 retary treats a State plan amendment, and
2 subpart B of part 430 of title 42, Code of
3 Federal Regulations, including, subject to
4 clause (ii), the timing requirements of sec-
5 tion 430.16 of such title (as in effect on
6 the date of enactment of this subsection),
7 shall apply to a request for approval of a
8 risk-sharing value-based payment agree-
9 ment in the same manner as such subpart
10 applies to a State plan amendment.

11 “(ii) TIMING.—The Secretary shall
12 consult with the Commissioner of Food
13 and Drugs as required under subpara-
14 graph (C) and make a determination on
15 whether to approve a request from a State
16 for approval of a proposed risk-sharing
17 value-based payment agreement (or request
18 additional information necessary to allow
19 the Secretary to make a determination
20 with respect to such request for approval)
21 within the time period, to the extent prac-
22 ticable, specified in section 430.16 of title
23 42, Code of Federal Regulations (as in ef-
24 fect on the date of enactment of this sub-
25 section), but in no case shall the Secretary

1 take more than 180 days after the receipt
2 of such request for approval or response to
3 such request for additional information to
4 make such a determination (or request ad-
5 ditional information).

6 “(C) CONSULTATION WITH THE COMMIS-
7 SIONER OF FOOD AND DRUGS.—In considering
8 whether to approve a risk-sharing value-based
9 payment agreement, the Secretary, to the ex-
10 tent necessary, shall consult with the Commis-
11 sioner of Food and Drugs to determine whether
12 the relevant clinical parameters specified in
13 such agreement are appropriate.

14 “(3) INSTALLMENT-BASED PAYMENT STRUC-
15 TURE.—

16 “(A) IN GENERAL.—A risk-sharing value-
17 based payment agreement shall provide for a
18 payment structure under which, for every in-
19 stallment year of the agreement (subject to sub-
20 paragraph (B)), the State shall pay the total in-
21 stallment year amount in equal installments to
22 be paid at regular intervals over a period of
23 time that shall be specified in the agreement.

24 “(B) REQUIREMENTS FOR INSTALLMENT
25 PAYMENTS.—

1 “(i) TIMING OF FIRST PAYMENT.—

2 The State shall make the first of the in-
3 stallment payments described in subpara-
4 graph (A) for an installment year not later
5 than 30 days after the end of such year.

6 “(ii) LENGTH OF INSTALLMENT PE-
7 RIOD.—The period of time over which the
8 State shall make the installment payments
9 described in subparagraph (A) for an in-
10 stallment year shall not be longer than 5
11 years.

12 “(iii) NONPAYMENT OR REDUCED
13 PAYMENT OF INSTALLMENTS FOLLOWING
14 A FAILURE TO MEET CLINICAL PARAM-
15 ETER.—If, prior to the payment date (as
16 specified in the agreement) of any install-
17 ment payment described in subparagraph
18 (A) or any other alternative date or time
19 frame (as otherwise specified in the agree-
20 ment), the covered outpatient drug which
21 is subject to the agreement fails to meet a
22 relevant clinical parameter of the agree-
23 ment, the agreement shall provide that—

24 “(I) the installment payment
25 shall not be made; or

1 “(II) the installment payment
2 shall be reduced by a percentage spec-
3 ified in the agreement that is based
4 on the outcome achieved by the drug
5 relative to the relevant clinical param-
6 eter.

7 “(4) NOTICE OF INTENT.—

8 “(A) IN GENERAL.—Subject to subpara-
9 graph (B), a manufacturer of a covered out-
10 patient drug shall not be eligible to enter into
11 a risk-sharing value-based payment agreement
12 under this subsection with respect to such drug
13 unless the manufacturer notifies the Secretary
14 that the manufacturer is interested in entering
15 into such an agreement with respect to such
16 drug. The decision to submit and timing of a
17 request to enter into a proposed risk-sharing
18 value-based payment agreement shall remain
19 solely within the discretion of the State and
20 shall only be effective upon Secretarial approval
21 as required under this subsection.

22 “(B) TREATMENT OF SUBSEQUENTLY AP-
23 PROVED DRUGS.—

24 “(i) IN GENERAL.—In the case of a
25 manufacturer of a covered outpatient drug

1 approved under section 505 of the Federal
2 Food, Drug, and Cosmetic Act or licensed
3 under section 351 of the Public Health
4 Service Act after the date of enactment of
5 this subsection, not more than 90 days
6 after meeting with the Food and Drug Ad-
7 ministration following phase II clinical
8 trials for such drug (or, in the case of a
9 drug described in clause (ii), not later than
10 March 31, 2022), the manufacturer must
11 notify the Secretary of the manufacturer’s
12 intent to enter into a risk-sharing value-
13 based payment agreement under this sub-
14 section with respect to such drug. If no
15 such meeting has occurred, the Secretary
16 may use discretion as to whether a poten-
17 tially curative treatment intended for one-
18 time use may qualify for a risk-sharing
19 value-based payment agreement under this
20 section. A manufacturer notification of in-
21 terest shall not have any influence on a de-
22 cision for approval by the Food and Drug
23 Administration.

24 “(ii) APPLICATION TO CERTAIN SUB-
25 SEQUENTLY APPROVED DRUGS.—A drug

1 described in this clause is a covered out-
2 patient drug of a manufacturer—

3 “(I) that is approved under sec-
4 tion 505 of the Federal Food, Drug,
5 and Cosmetic Act or licensed under
6 section 351 of the Public Health Serv-
7 ice Act after the date of enactment of
8 this subsection; and

9 “(II) with respect to which, as of
10 January 1, 2022, more than 90 days
11 have passed after the manufacturer’s
12 meeting with the Food and Drug Ad-
13 ministration following phase II clinical
14 trials for such drug.

15 “(iii) PARALLEL APPROVAL.—The
16 Secretary, in coordination with the Admin-
17 istrator of the Centers for Medicare &
18 Medicaid Services and the Commissioner of
19 Food and Drugs, shall, to the extent prac-
20 ticable, approve a State’s request to enter
21 into a proposed risk-sharing value-based
22 payment agreement that otherwise meets
23 the requirements of this subsection at the
24 time that such a drug is approved by the
25 Food and Drug Administration to help

1 provide that no State that wishes to enter
2 into such an agreement is required to pay
3 for the drug in full at one time if the State
4 is seeking to pay over a period of time as
5 outlined in the proposed agreement.

6 “(iv) RULE OF CONSTRUCTION.—
7 Nothing in this paragraph shall be applied
8 or construed to modify or affect the time-
9 frames or factors involved in the Sec-
10 retary’s determination of whether to ap-
11 prove or license a drug under section 505
12 of the Federal Food, Drug, and Cosmetic
13 Act or section 351 of the Public Health
14 Service Act.

15 “(5) SPECIAL PAYMENT RULES.—

16 “(A) IN GENERAL.—Except as otherwise
17 provided in this paragraph, with respect to an
18 individual who is administered a unit of a cov-
19 ered outpatient drug that is purchased under a
20 State plan by a State Medicaid agency under a
21 risk-sharing value-based payment agreement in
22 an installment year, the State shall remain lia-
23 ble to the manufacturer of such drug for pay-
24 ment for such unit without regard to whether
25 the individual remains enrolled in the State

1 plan under this title (or a waiver of such plan)
2 for each installment year for which the State is
3 to make installment payments for covered out-
4 patient drugs purchased under the agreement
5 in such year.

6 “(B) DEATH.—In the case of an individual
7 described in subparagraph (A) who dies during
8 the period described in such subparagraph, the
9 State plan shall not be liable for any remaining
10 payment for the unit of the covered outpatient
11 drug administered to the individual which is
12 owed under the agreement described in such
13 subparagraph.

14 “(C) WITHDRAWAL OF APPROVAL.—In the
15 case of a covered outpatient drug that is the
16 subject of a risk-sharing value-based agreement
17 between a State and a manufacturer under this
18 subsection, including a drug approved in ac-
19 cordance with section 506(c) of the Federal
20 Food, Drug, and Cosmetic Act, and such drug
21 is the subject of an application that has been
22 withdrawn by the Secretary, the State plan
23 shall not be liable for any remaining payment
24 that is owed under the agreement.

1 “(D) ALTERNATIVE ARRANGEMENT UNDER
2 AGREEMENT.—Subject to approval by the Sec-
3 retary, the terms of a proposed risk-sharing
4 value-based payment agreement submitted for
5 approval by a State may provide that subpara-
6 graph (A) shall not apply.

7 “(E) GUIDANCE.—Not later than January
8 1, 2022, the Secretary shall issue guidance to
9 States establishing a process for States to no-
10 tify the Secretary when an individual who is ad-
11 ministered a unit of a covered outpatient drug
12 that is purchased by a State plan under a risk-
13 sharing value-based payment agreement ceases
14 to be enrolled under the State plan under this
15 title (or a waiver of such plan) or dies before
16 the end of the installment period applicable to
17 such unit under the agreement.

18 “(6) TREATMENT OF PAYMENTS UNDER RISK-
19 SHARING VALUE-BASED AGREEMENTS FOR PUR-
20 POSES OF AVERAGE MANUFACTURER PRICE; BEST
21 PRICE.—The Secretary shall treat any payments
22 made to the manufacturer of a covered outpatient
23 drug under a risk-sharing value-based payment
24 agreement under this subsection during a rebate pe-
25 riod in the same manner that the Secretary treats

1 payments made under a State supplemental rebate
2 agreement under sections 447.504(c)(19) and
3 447.505(c)(7) of title 42, Code of Federal Regula-
4 tions (or any successor regulations) for purposes of
5 determining average manufacturer price and best
6 price under this section with respect to the covered
7 outpatient drug and a rebate period and for pur-
8 poses of offsets required under subsection (b)(1)(B).

9 “(7) ASSESSMENTS AND REPORT TO CON-
10 GRESS.—

11 “(A) ASSESSMENTS.—

12 “(i) IN GENERAL.—Not later than
13 180 days after the end of each assessment
14 period of any risk-sharing value-based pay-
15 ment agreement for a State approved
16 under this subsection, the Secretary shall
17 conduct an evaluation of such agreement
18 which shall include an evaluation by the
19 Chief Actuary to determine whether pro-
20 gram spending under the risk-sharing
21 value-based payment agreement aligned
22 with the projections for the agreement
23 made under paragraph (2)(A)(ii), including
24 an assessment of whether actual Federal
25 spending under this title under the agree-

1 ment was less or more than net Federal
2 spending would have been in the absence
3 of the agreement.

4 “(ii) ASSESSMENT PERIOD.—For pur-
5 poses of clause (i)—

6 “(I) the first assessment period
7 for a risk-sharing value-based pay-
8 ment agreement shall be the period of
9 time over which payments are sched-
10 uled to be made under the agreement
11 for the first 10 individuals who are
12 administered covered outpatient drugs
13 under the agreement except that such
14 period shall not exceed the 5-year pe-
15 riod after the date on which the Sec-
16 retary approves the agreement; and

17 “(II) each subsequent assessment
18 period for a risk-sharing value-based
19 payment agreement shall be the 5-
20 year period following the end of the
21 previous assessment period.

22 “(B) RESULTS OF ASSESSMENTS.—

23 “(i) TERMINATION OPTION.—If the
24 Secretary determines as a result of the as-
25 sessment by the Chief Actuary under sub-

1 paragraph (A) that the actual Federal
2 spending under this title for any covered
3 outpatient drug that was the subject of the
4 State’s risk-sharing value-based payment
5 agreement was greater than the net Fed-
6 eral spending that would have resulted in
7 the absence of the agreement, the Sec-
8 retary may terminate approval of such
9 agreement and shall immediately conduct
10 an assessment under this paragraph of any
11 other ongoing risk-sharing value-based
12 payment agreement to which the same
13 manufacturer is a party.

14 “(ii) REPAYMENT REQUIRED.—

15 “(I) IN GENERAL.—If the Sec-
16 retary determines as a result of the
17 assessment by the Chief Actuary
18 under subparagraph (A) that the Fed-
19 eral spending under the risk-sharing
20 value-based agreement for a covered
21 outpatient drug that was subject to
22 such agreement was greater than the
23 net Federal spending that would have
24 resulted in the absence of the agree-
25 ment, the manufacturer shall repay

1 the difference to the State and Fed-
2 eral governments in a timely manner
3 as determined by the Secretary.

4 “(II) TERMINATION FOR FAIL-
5 URE TO PAY.—The failure of a manu-
6 facturer to make repayments required
7 under subclause (I) in a timely man-
8 ner shall result in immediate termi-
9 nation of all risk-sharing value-based
10 agreements to which the manufacturer
11 is a party.

12 “(III) ADDITIONAL PEN-
13 ALTIES.—In the case of a manufac-
14 turer that fails to make repayments
15 required under subclause (I), the Sec-
16 retary may treat such manufacturer
17 in the same manner as a manufac-
18 turer that fails to pay required re-
19 bates under this section, and the Sec-
20 retary may—

21 “(aa) suspend or terminate
22 the manufacturer’s rebate agree-
23 ment under this section; and

24 “(bb) pursue any other rem-
25 edy that would be available if the

1 manufacturer had failed to pay
2 required rebates under this sec-
3 tion.

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

10 “(i) an assessment of the impact of
11 risk-sharing value-based payment agree-
12 ments on access for individuals who are eli-
13 gible for benefits under a State plan or
14 waiver under this title to medically nec-
15 essary covered outpatient drugs and re-
16 lated treatments;

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

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

23 “(iv) such recommendations to Con-
24 gress as the Secretary deems appropriate.

25 “(8) GUIDANCE AND REGULATIONS.—

1 “(A) IN GENERAL.—Not later than Janu-
2 ary 1, 2022, the Secretary shall issue guidance
3 to States seeking to enter into risk-sharing
4 value-based payment agreements under this
5 subsection that includes a model template for
6 such agreements. The Secretary may issue any
7 additional guidance or promulgate regulations
8 as necessary to implement and enforce the pro-
9 visions of this subsection.

10 “(B) MODEL AGREEMENTS.—

11 “(i) IN GENERAL.—If a State ex-
12 presses an interest in pursuing a risk-shar-
13 ing value-based payment agreement under
14 this subsection with a manufacturer for
15 the purchase of a covered outpatient drug,
16 the Secretary may share with such State
17 any risk-sharing value-based agreement be-
18 tween a State and the manufacturer for
19 the purchase of such drug that has been
20 approved under this subsection. While such
21 shared agreement may serve as a template
22 for a State that wishes to propose, the use
23 of a previously approved agreement shall
24 not affect the submission and approval
25 process for approval of a proposed risk-

1 sharing value-based payment agreement
2 under this subsection, including the re-
3 quirements under paragraph (2)(A).

4 “(ii) CONFIDENTIALITY.—In the case
5 of a risk-sharing value-based payment
6 agreement that is disclosed to a State by
7 the Secretary under this subparagraph and
8 that is only in effect with respect to a sin-
9 gle State, the confidentiality of information
10 provisions described in subsection
11 (b)(3)(D) shall apply to such information.

12 “(C) OIG CONSULTATION.—

13 “(i) IN GENERAL.—The Secretary
14 shall consult with the Office of the Inspec-
15 tor General of the Department of Health
16 and Human Services to determine whether
17 there are potential program integrity con-
18 cerns with agreement approvals or tem-
19 plates and address accordingly.

20 “(ii) OIG POLICY UPDATES AS NEC-
21 ESSARY.—The Inspector General of the
22 Department of Health and Human Serv-
23 ices shall review and update, as necessary,
24 any policies or guidelines of the Office of
25 the Inspector General of the Department

1 of Human Services (including policies re-
2 lated to the enforcement of section 1128B)
3 to accommodate the use of risk-sharing
4 value-based payment agreements in accord-
5 ance with this section.

6 “(9) RULES OF CONSTRUCTION.—

7 “(A) MODIFICATIONS.—Nothing in this
8 subsection or any regulations promulgated
9 under this subsection shall prohibit a State
10 from requesting a modification from the Sec-
11 retary to the terms of a risk-sharing value-
12 based payment agreement. A modification that
13 is expected to result in any increase to pro-
14 jected net State or Federal spending under the
15 agreement shall be subject to recertification by
16 the Chief Actuary as described in paragraph
17 (2)(A)(ii) before the modification may be ap-
18 proved.

19 “(B) REBATE AGREEMENTS.—Nothing in
20 this subsection shall be construed as requiring
21 a State to enter into a risk-sharing value-based
22 payment agreement or as limiting or super-
23 seding the ability of a State to enter into a sup-
24 plemental rebate agreement for a covered out-
25 patient drug.

1 “(C) FFP FOR PAYMENTS UNDER RISK-
2 SHARING VALUE-BASED PAYMENT AGREE-
3 MENTS.—Federal financial participation shall
4 be available under this title for any payment
5 made by a State to a manufacturer for a cov-
6 ered outpatient drug under a risk-sharing
7 value-based payment agreement in accordance
8 with this subsection, except that no Federal fi-
9 nancial participation shall be available for any
10 payment made by a State to a manufacturer
11 under such an agreement on and after the ef-
12 fective date of a disapproval of such agreement
13 by the Secretary.

14 “(D) CONTINUED APPLICATION OF OTHER
15 PROVISIONS.—Except as expressly provided in
16 this subsection, nothing in this subsection or in
17 any regulations promulgated under this sub-
18 section shall affect the application of any other
19 provision of this Act.

20 “(10) APPROPRIATIONS.—For fiscal year 2020
21 and each fiscal year thereafter, there are appro-
22 priated to the Secretary \$5,000,000 for the purpose
23 of carrying out this subsection.

24 “(11) DEFINITIONS.—In this subsection:

1 “(A) CHIEF ACTUARY.—The term ‘Chief
2 Actuary’ means the Chief Actuary of the Cen-
3 ters for Medicare & Medicaid Services.

4 “(B) INSTALLMENT YEAR.—The term ‘in-
5 stallment year’ means, with respect to a risk-
6 sharing value-based payment agreement, a 12-
7 month period during which a covered outpatient
8 drug is administered under the agreement.

9 “(C) POTENTIALLY CURATIVE TREATMENT
10 INTENDED FOR ONE-TIME USE.—The term ‘po-
11 tentially curative treatment intended for one-
12 time use’ means a treatment that consists of
13 the administration of a covered outpatient drug
14 that—

15 “(i) is a form of gene therapy for a
16 rare disease, as defined by the Commis-
17 sioner of Food and Drugs, designated
18 under section 526 of the Federal Food,
19 Drug, and Cosmetics Act, and approved
20 under section 505 of such Act or licensed
21 under subsection (a) or (k) of section 351
22 of the Public Health Service Act to treat
23 a serious or life-threatening disease or con-
24 dition;

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

4 “(I) the cure of such disease or
5 condition; or

6 “(II) a reduction in the symp-
7 toms of such disease or condition to
8 the extent that such disease or condi-
9 tion is not expected to lead to early
10 mortality; and

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

15 “(D) RELEVANT CLINICAL PARAMETER.—
16 The term ‘relevant clinical parameter’ means,
17 with respect to a covered outpatient drug that
18 is the subject of a risk-sharing value-based pay-
19 ment agreement—

20 “(i) a clinical endpoint specified in the
21 drug’s labeling or supported by one or
22 more of the compendia described in section
23 1861(t)(2)(B)(ii)(I) that—

24 “(I) is able to be measured or
25 evaluated on an annual basis for each

1 year of the agreement on an inde-
2 pendent basis by a provider or other
3 entity; and

4 “(II) is required to be achieved
5 (based on observed metrics in patient
6 populations) under the terms of the
7 agreement; or

8 “(ii) a surrogate endpoint (as defined
9 in section 507(e)(9) of the Federal Food,
10 Drug, and Cosmetic Act), including those
11 developed by patient-focused drug develop-
12 ment tools, that—

13 “(I) is able to be measured or
14 evaluated on an annual basis for each
15 year of the agreement on an inde-
16 pendent basis by a provider or other
17 entity; and

18 “(II) has been qualified by the
19 Food and Drug Administration.

20 “(E) RISK-SHARING VALUE-BASED PAY-
21 MENT AGREEMENT.—The term ‘risk-sharing
22 value-based payment agreement’ means an
23 agreement between a State plan and a manu-
24 facturer—

1 “(i) for the purchase of a covered out-
2 patient drug of the manufacturer that is a
3 potentially curative treatment intended for
4 one-time use;

5 “(ii) under which payment for such
6 drug shall be made pursuant to an install-
7 ment-based payment structure that meets
8 the requirements of paragraph (3);

9 “(iii) which conditions payment on the
10 achievement of at least 2 relevant clinical
11 parameters (as defined in subparagraph
12 (C));

13 “(iv) which provides that—

14 “(I) the State plan will directly
15 reimburse the manufacturer for the
16 drug; or

17 “(II) a third party will reimburse
18 the manufacture in a manner ap-
19 proved by the Secretary; and

20 “(v) is approved by the Secretary in
21 accordance with paragraph (2).

22 “(F) TOTAL INSTALLMENT YEAR
23 AMOUNT.—The term ‘total installment year
24 amount’ means, with respect to a risk-sharing
25 value-based payment agreement for the pur-

1 chase of a covered outpatient drug and an in-
2 stallment year, an amount equal to the product
3 of—

4 “(i) the unit price of the drug charged
5 under the agreement; and

6 “(ii) the number of units of such drug
7 administered under the agreement during
8 such installment year.”.

9 (b) CONFORMING AMENDMENTS.—

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

17 (2) Section 1927(b) of the Social Security Act
18 (42 U.S.C. 1396r–8(b)) is amended—

19 (A) in paragraph (1)(A), by inserting “(ex-
20 cept for drugs for which payment is made by a
21 State under a risk-sharing value-based payment
22 agreement under subsection (l))” after “under
23 the State plan for such period”; and

24 (B) in paragraph (3)—

1 (i) in subparagraph (C)(i), by insert-
2 ing “or subsection (l)(2)(A)” after “sub-
3 paragraph (A)”;

4 (ii) in subparagraph (D), in the mat-
5 ter preceding clause (i), by inserting “,
6 under subsection (l)(2)(A),” after “under
7 this paragraph”.

8 **SEC. 210. APPLYING MEDICAID DRUG REBATE REQUIRE-**
9 **MENT TO DRUGS PROVIDED AS PART OF OUT-**
10 **PATIENT HOSPITAL SERVICES.**

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

14 “(3) LIMITING DEFINITION.—

15 “(A) IN GENERAL.—The term ‘covered
16 outpatient drug’ does not include any drug, bio-
17 logical product, or insulin provided as part of,
18 or as incident to and in the same setting as,
19 any of the following (and for which payment
20 may be made under this title as part of pay-
21 ment for the following and not as direct reim-
22 bursement for the drug):

23 “(i) Inpatient hospital services.

24 “(ii) Hospice services.

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

5 “(iv) Physicians’ services.

6 “(v) Outpatient hospital services.

7 “(vi) Nursing facility services and
8 services provided by an intermediate care
9 facility for the mentally retarded.

10 “(vii) Other laboratory and x-ray serv-
11 ices.

12 “(viii) Renal dialysis.

13 “(B) OTHER EXCLUSIONS.—Such term
14 also does not include any such drug or product
15 for which a National Drug Code number is not
16 required by the Food and Drug Administration
17 or a drug or biological used for a medical indi-
18 cation which is not a medically accepted indica-
19 tion.

20 “(C) STATE OPTION.—At the option of a
21 State, such term may include any drug, biologi-
22 cal product, or insulin for which the State is
23 the primary payer under this title or a dem-
24 onstration project concerning this title, and that
25 is provided on an outpatient basis as part of, or

1 as incident to and in the same setting as, de-
2 scribed in clause (iv) or (v) of subparagraph (A)
3 and for which payment is made as part of pay-
4 ment for such services.

5 “(D) NO EFFECT ON BEST PRICE.—Any
6 drug, biological product, or insulin excluded
7 from the definition of such term as a result of
8 this paragraph shall be treated as a covered
9 outpatient drug for purposes of determining the
10 best price (as defined in subsection (c)(1)(C))
11 for such drug, biological product, or insulin.”.

12 (b) EFFECTIVE DATE; IMPLEMENTATION GUID-
13 ANCE.—

14 (1) IN GENERAL.—The amendment made by
15 subsection (a) shall take effect on the date that is
16 1 year after the date of enactment of this Act.

17 (2) IMPLEMENTATION AND GUIDANCE.—Not
18 later than 1 year after the date of enactment of this
19 Act, the Secretary of Health and Human Services
20 shall issue guidance and relevant informational bul-
21 letins for States, manufacturers (as defined in sec-
22 tion 1927(k)(5) of the Social Security Act (42
23 U.S.C. 1396r–8(k)(5)), and other relevant stake-
24 holders, including health care providers, regarding

1 implementation of the amendment made by sub-
2 section (a).

3 **SEC. 211. PROHIBITION ON ADDITIONAL REBATE UNDER**
4 **MEDICAID FOR CERTAIN NONINNOVATOR**
5 **MULTIPLE SOURCE DRUGS.**

6 Section 1927(c)(3)(C) of the Social Security Act (42
7 U.S.C. 1396r-8(c)(3)(C)) is amended—

- 8 (1) in clause (i), by striking “The amount” and
9 inserting “Subject to clause (v), the amount”; and
10 (2) by adding at the end the following new
11 clause:

12 “(v) PROHIBITION ON ADDITIONAL
13 REBATE FOR CERTAIN NONINNOVATOR
14 MULTIPLE SOURCE DRUGS.—With respect
15 to a rebate period beginning on or after
16 January 1, 2020, and a dosage form and
17 strength of a covered outpatient drug de-
18 scribed in clause (i), the amount of the re-
19 bate specified in subparagraph (A) for
20 such dosage form and strength for such re-
21 bate period may not be increased if the av-
22 erage manufacturer price for a unit of
23 such dosage form and strength for such re-
24 bate period is less than \$1.”.

1 **SEC. 212. EXEMPTING EXCHANGE PLANS AND CHILD**
2 **HEALTH PLANS FROM DETERMINATION OF**
3 **BEST PRICE UNDER MEDICAID OUTPATIENT**
4 **DRUG PROGRAM.**

5 (a) IN GENERAL.—Section 1927(c)(1)(C)(i) of the
6 Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(i)) is
7 amended—

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

10 (2) in subclause (VI), by striking the period at
11 the end and inserting a semicolon; and

12 (3) by adding at the end of the following new
13 subclauses:

14 “(VII) any prices charged which
15 are negotiated by a qualified health
16 plan offered in the individual market
17 (as defined in section 2791 of the
18 Public Health Service Act), whether
19 or not through an exchange estab-
20 lished under title I of the Patient Pro-
21 tection and Affordable Care Act, with
22 respect to drugs on behalf of individ-
23 uals enrolled in such plan; and

24 “(VIII) any prices charged under
25 a State child health plan under title
26 XXI (or a waiver of such plan).”.

1 (b) EFFECTIVE DATE.—The amendments made by
2 subsection (a) shall apply with respect to rebate periods
3 beginning on or after January 1, 2021.

4 **TITLE III—FOOD AND DRUG**
5 **ADMINISTRATION**
6 **Subtitle A—CREATES Act**

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

9 (a) DEFINITIONS.—In this section—

10 (1) the term “commercially reasonable, market-
11 based terms” means—

12 (A) a nondiscriminatory price for the sale
13 of the covered product at or below, but not
14 greater than, the most recent wholesale acquisi-
15 tion cost for the drug, as defined in section
16 1847A(c)(6)(B) of the Social Security Act (42
17 U.S.C. 1395w–3a(c)(6)(B));

18 (B) a schedule for delivery that results in
19 the transfer of the covered product to the eligi-
20 ble product developer consistent with the timing
21 under subsection (b)(2)(A)(iv); and

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

24 (2) the term “covered product”—

25 (A) means—

1 (i) any drug approved under sub-
2 section (e) or (j) of section 505 of the Fed-
3 eral Food, Drug, and Cosmetic Act (21
4 U.S.C. 355) or biological product licensed
5 under subsection (a) or (k) of section 351
6 of the Public Health Service Act (42
7 U.S.C. 262);

8 (ii) any combination of a drug or bio-
9 logical product described in clause (i); or

10 (iii) when reasonably necessary to
11 support approval of an application under
12 section 505 of the Federal Food, Drug,
13 and Cosmetic Act (21 U.S.C. 355), or sec-
14 tion 351 of the Public Health Service Act
15 (42 U.S.C. 262), as applicable, or other-
16 wise meet the requirements for approval
17 under either such section, any product, in-
18 cluding any device, that is marketed or in-
19 tended for use with such a drug or biologi-
20 cal product; and

21 (B) does not include any drug or biological
22 product that appears on the drug shortage list
23 in effect under section 506E of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C.
25 356e), unless—

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

5 (ii) the Secretary determines that in-
6 clusion of the drug or biological product as
7 a covered product is likely to contribute to
8 alleviating or preventing a shortage;

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

12 (4) the term “eligible product developer” means
13 a person that seeks to develop a product for ap-
14 proval pursuant to an application for approval under
15 subsection (b)(2) or (j) of section 505 of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or
17 for licensing pursuant to an application under sec-
18 tion 351(k) of the Public Health Service Act (42
19 U.S.C. 262(k));

20 (5) the term “license holder” means the holder
21 of an application approved under subsection (c) or
22 (j) of section 505 of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 355) or the holder of a li-
24 cense under subsection (a) or (k) of section 351 of

1 the Public Health Service Act (42 U.S.C. 262) for
2 a covered product;

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

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

11 (8) the term “Secretary” means the Secretary
12 of Health and Human Services;

13 (9) the term “single, shared system of elements
14 to assure safe use” means a single, shared system
15 of elements to assure safe use under section 505–
16 1(f) of the Federal Food, Drug, and Cosmetic Act
17 (21 U.S.C. 355–1(f)); and

18 (10) the term “sufficient quantities” means an
19 amount of a covered product that the eligible prod-
20 uct developer determines allows it to—

21 (A) conduct testing to support an applica-
22 tion under—

23 (i) subsection (b)(2) or (j) of section
24 505 of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 355); or

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

4 (B) fulfill any regulatory requirements re-
5 lating to approval of such an application.

6 (b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFI-
7 CIENT QUANTITIES OF A COVERED PRODUCT.—

8 (1) IN GENERAL.—An eligible product developer
9 may bring a civil action against the license holder
10 for a covered product seeking relief under this sub-
11 section in an appropriate district court of the United
12 States alleging that the license holder has declined
13 to provide sufficient quantities of the covered prod-
14 uct to the eligible product developer on commercially
15 reasonable, market-based terms.

16 (2) ELEMENTS.—

17 (A) IN GENERAL.—To prevail in a civil ac-
18 tion brought under paragraph (1), an eligible
19 product developer shall prove, by a preponder-
20 ance of the evidence—

21 (i) that—

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

24 (II) if the covered product is sub-
25 ject to a REMS with ETASU—

1 (aa) the eligible product de-
2 veloper has obtained a covered
3 product authorization from the
4 Secretary in accordance with sub-
5 paragraph (B); and

6 (bb) the eligible product de-
7 veloper has provided a copy of
8 the covered product authorization
9 to the license holder;

10 (ii) that, as of the date on which the
11 civil action is filed, the product developer
12 has not obtained sufficient quantities of
13 the covered product on commercially rea-
14 sonable, market-based terms;

15 (iii) that the eligible product developer
16 has submitted a written request to pur-
17 chase sufficient quantities of the covered
18 product to the license holder and such re-
19 quest—

20 (I) was sent to a named cor-
21 porate officer of the license holder;

22 (II) was made by certified or reg-
23 istered mail with return receipt re-
24 quested;

1 (III) specified an individual as
2 the point of contact for the license
3 holder to direct communications re-
4 lated to the sale of the covered prod-
5 uct to the eligible product developer
6 and a means for electronic and writ-
7 ten communications with that indi-
8 vidual; and

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

13 (iv) that the license holder has not de-
14 livered to the eligible product developer
15 sufficient quantities of the covered product
16 on commercially reasonable, market-based
17 terms—

18 (I) for a covered product that is
19 not subject to a REMS with ETASU,
20 by the date that is 31 days after the
21 date on which the license holder re-
22 ceived the request for the covered
23 product; and

1 (II) for a covered product that is
2 subject to a REMS with ETASU, by
3 31 days after the later of—

4 (aa) the date on which the
5 license holder received the re-
6 quest for the covered product; or

7 (bb) the date on which the
8 license holder received a copy of
9 the covered product authorization
10 issued by the Secretary in ac-
11 cordance with subparagraph (B).

12 (B) AUTHORIZATION FOR COVERED PROD-
13 UCT SUBJECT TO A REMS WITH ETASU.—

14 (i) REQUEST.—An eligible product de-
15 veloper may submit to the Secretary a
16 written request for the eligible product de-
17 veloper to be authorized to obtain suffi-
18 cient quantities of an individual covered
19 product subject to a REMS with ETASU.

20 (ii) AUTHORIZATION.—Not later than
21 120 days after the date on which a request
22 under clause (i) is received, the Secretary
23 shall, by written notice, authorize the eligi-
24 ble product developer to obtain sufficient
25 quantities of an individual covered product

1 subject to a REMS with ETASU for pur-
2 poses of—

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

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

11 (aa)(AA) submitted proto-
12 cols, informed consent docu-
13 ments, and informational mate-
14 rials for testing that include pro-
15 tections that provide safety pro-
16 tections comparable to those pro-
17 vided by the REMS for the cov-
18 ered product; or

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

22 (bb) met any other require-
23 ments the Secretary may estab-
24 lish.

1 (iii) NOTICE.—A covered product au-
2 thORIZATION issued under this subparagraph
3 shall state that the provision of the covered
4 product by the license holder under the
5 terms of the authorization will not be a
6 violation of the REMS for the covered
7 product.

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

12 (A) that, on the date on which the eligible
13 product developer requested to purchase suffi-
14 cient quantities of the covered product from the
15 license holder—

16 (i) neither the license holder nor any
17 of its agents, wholesalers, or distributors
18 was engaged in the manufacturing or com-
19 mercial marketing of the covered product;
20 and

21 (ii) neither the license holder nor any
22 of its agents, wholesalers, or distributors
23 otherwise had access to inventory of the
24 covered product to supply to the eligible

1 product developer on commercially reason-
2 able, market-based terms;

3 (B) that—

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

7 (ii) the license holder has placed no
8 restrictions, explicit or implicit, on its
9 agents, distributors, or wholesalers to sell
10 covered products to eligible product devel-
11 opers; and

12 (iii) the covered product can be pur-
13 chased by the eligible product developer in
14 sufficient quantities on commercially rea-
15 sonable, market-based terms from the
16 agents, distributors, or wholesalers of the
17 license holder; or

18 (C) that the license holder made an offer
19 to the individual specified pursuant to para-
20 graph (2)(A)(iii)(III), by a means of commu-
21 nication (electronic, written, or both) specified
22 pursuant to such paragraph, to sell sufficient
23 quantities of the covered product to the eligible
24 product developer at commercially reasonable
25 market-based terms—

1 (i) for a covered product that is not
2 subject to a REMS with ETASU, by the
3 date that is 14 days after the date on
4 which the license holder received the re-
5 quest for the covered product, and the eli-
6 gible product developer did not accept such
7 offer by the date that is 7 days after the
8 date on which the eligible product devel-
9 oper received such offer from the license
10 holder; or

11 (ii) for a covered product that is sub-
12 ject to a REMS with ETASU, by the date
13 that is 20 days after the date on which the
14 license holder received the request for the
15 covered product, and the eligible product
16 developer did not accept such offer by the
17 date that is 10 days after the date on
18 which the eligible product developer re-
19 ceived such offer from the license holder.

20 (4) REMEDIES.—

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

24 (i) order the license holder to provide
25 to the eligible product developer without

1 delay sufficient quantities of the covered
2 product on commercially reasonable, mar-
3 ket-based terms;

4 (ii) award to the eligible product de-
5 veloper reasonable attorney's fees and costs
6 of the civil action; and

7 (iii) award to the eligible product de-
8 veloper a monetary amount sufficient to
9 deter the license holder from failing to pro-
10 vide eligible product developers with suffi-
11 cient quantities of a covered product on
12 commercially reasonable, market-based
13 terms, if the court finds, by a preponder-
14 ance of the evidence—

15 (I) that the license holder delayed
16 providing sufficient quantities of the
17 covered product to the eligible product
18 developer without a legitimate busi-
19 ness justification; or

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

23 (B) MAXIMUM MONETARY AMOUNT.—A
24 monetary amount awarded under subparagraph
25 (A)(iii) shall not be greater than the revenue

1 that the license holder earned on the covered
2 product during the period—

3 (i) beginning on—

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

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

13 (aa) the date on which the
14 license holder received the re-
15 quest; or

16 (bb) the date on which the
17 license holder received a copy of
18 the covered product authorization
19 issued by the Secretary in ac-
20 cordance with paragraph (2)(B);
21 and

22 (ii) ending on the date on which the
23 eligible product developer received suffi-
24 cient quantities of the covered product.

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

8 (e) LIMITATION OF LIABILITY.—A license holder for
9 a covered product shall not be liable for any claim under
10 Federal, State, or local law arising out of the failure of
11 an eligible product developer to follow adequate safeguards
12 to assure safe use of the covered product during develop-
13 ment or testing activities described in this section, includ-
14 ing transportation, handling, use, or disposal of the cov-
15 ered product by the eligible product developer.

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

20 “(1) PROVISION OF SAMPLES NOT A VIOLATION OF
21 STRATEGY.—The provision of samples of a covered prod-
22 uct to an eligible product developer (as those terms are
23 defined in section 301(a) of the Lower Drug Costs Now
24 Act of 2019) shall not be considered a violation of the
25 requirements of any risk evaluation and mitigation strat-

1 egy that may be in place under this section for such
2 drug.”.

3 (e) RULE OF CONSTRUCTION.—

4 (1) DEFINITION.—In this subsection, the term
5 “antitrust laws”—

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

9 (B) includes section 5 of the Federal
10 Trade Commission Act (15 U.S.C. 45) to the
11 extent that such section applies to unfair meth-
12 ods of competition.

13 (2) ANTITRUST LAWS.—Nothing in this section
14 shall be construed to limit the operation of any pro-
15 vision of the antitrust laws.

16 **SEC. 302. REMS APPROVAL PROCESS FOR SUBSEQUENT**
17 **FILERS.**

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

21 (1) in subsection (g)(4)(B)—

22 (A) in clause (i) by striking “or” after the
23 semicolon;

24 (B) in clause (ii) by striking the period at
25 the end and inserting “; or”; and

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

2 “(iii) accommodate different, com-
3 parable aspects of the elements to assure
4 safe use for a drug that is the subject of
5 an application under section 505(j), and
6 the applicable listed drug.”;

7 (2) in subsection (i)(1), by striking subpara-
8 graph (C) and inserting the following:

9 “(C)(i) Elements to assure safe use, if re-
10 quired under subsection (f) for the listed drug,
11 which, subject to clause (ii), for a drug that is
12 the subject of an application under section
13 505(j) may use—

14 “(I) a single, shared system with
15 the listed drug under subsection (f);
16 or

17 “(II) a different, comparable as-
18 pect of the elements to assure safe use
19 under subsection (f).

20 “(ii) The Secretary may require a
21 drug that is the subject of an application
22 under section 505(j) and the listed drug to
23 use a single, shared system under sub-
24 section (f), if the Secretary determines
25 that no different, comparable aspect of the

1 elements to assure safe use could satisfy
2 the requirements of subsection (f).”;

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

5 “(3) SHARED REMS.—If the Secretary ap-
6 proves, in accordance with paragraph (1)(C)(i)(II), a
7 different, comparable aspect of the elements to as-
8 sure safe use under subsection (f) for a drug that
9 is the subject of an abbreviated new drug application
10 under section 505(j), the Secretary may require that
11 such different comparable aspect of the elements to
12 assure safe use can be used with respect to any
13 other drug that is the subject of an application
14 under section 505(j) or 505(b) that references the
15 same listed drug.”; and

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

17 “(m) SEPARATE REMS.—When used in this section,
18 the terms ‘different, comparable aspect of the elements to
19 assure safe use’ or ‘different, comparable approved risk
20 evaluation and mitigation strategies’ means a risk evalua-
21 tion and mitigation strategy for a drug that is the subject
22 of an application under section 505(j) that uses different
23 methods or operational means than the strategy required
24 under subsection (a) for the applicable listed drug, or
25 other application under section 505(j) with the same such

1 listed drug, but achieves the same level of safety as such
2 strategy.”.

3 **SEC. 303. RULE OF CONSTRUCTION.**

4 (a) IN GENERAL.—Nothing in this subtitle, the
5 amendments made by this subtitle, or in section 505–1
6 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 355–1), shall be construed as—

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

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

16 (b) DEFINITIONS.—In this section, the terms “cov-
17 ered product”, “eligible product developer”, “license hold-
18 er”, and “REMS with ETASU” have the meanings given
19 such terms in section 301(a).

20 **Subtitle B—Pay-for-Delay**

21 **SEC. 311. UNLAWFUL AGREEMENTS.**

22 (a) AGREEMENTS PROHIBITED.—Subject to sub-
23 sections (b) and (c), it shall be unlawful for an NDA or
24 BLA holder and a subsequent filer (or for two subsequent
25 filers) to enter into, or carry out, an agreement resolving

1 or settling a covered patent infringement claim on a final
2 or interim basis if under such agreement—

3 (1) a subsequent filer directly or indirectly re-
4 ceives from such holder (or in the case of such an
5 agreement between two subsequent filers, the other
6 subsequent filer) anything of value, including a li-
7 cense; and

8 (2) the subsequent filer agrees to limit or fore-
9 go research on, or development, manufacturing,
10 marketing, or sales, for any period of time, of the
11 covered product that is the subject of the application
12 described in subparagraph (A) or (B) of subsection
13 (g)(8).

14 (b) EXCLUSION.—It shall not be unlawful under sub-
15 section (a) if a party to an agreement described in such
16 subsection demonstrates by clear and convincing evidence
17 that the value described in subsection (a)(1) is compensa-
18 tion solely for other goods or services that the subsequent
19 filer has promised to provide.

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

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

5 (A) any patent that is the basis of the cov-
6 ered patent infringement claim; or

7 (B) any patent right or other statutory ex-
8 clusivity that would prevent the marketing of
9 such covered product.

10 (2) A payment for reasonable litigation ex-
11 penses not to exceed \$7,500,000 in the aggregate.

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

14 (d) ENFORCEMENT BY FEDERAL TRADE COMMIS-
15 SION.—

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

19 (A) a person, partnership, or corporation
20 over which the Commission has authority pur-
21 suant to section 5(a)(2) of the Federal Trade
22 Commission Act (15 U.S.C. 45(a)(2)); or

23 (B) a person, partnership, or corporation
24 over which the Commission would have author-
25 ity pursuant to such section but for the fact

1 that such person, partnership, or corporation is
2 not organized to carry on business for its own
3 profit or that of its members.

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

6 (A) IN GENERAL.—A violation of this sec-
7 tion shall be treated as an unfair or deceptive
8 act or practice in violation of section 5(a)(1) of
9 the Federal Trade Commission Act (15 U.S.C.
10 45(a)(1)).

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

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

22 (ii) any NDA or BLA holder or subse-
23 quent filer that violates this section shall
24 be subject to the penalties and entitled to

1 the privileges and immunities provided in
2 the Federal Trade Commission Act.

3 (C) JUDICIAL REVIEW.—In the case of a
4 cease and desist order issued by the Commis-
5 sion under section 5 of the Federal Trade Com-
6 mission Act (15 U.S.C. 45) for violation of this
7 section, a party to such order may obtain judi-
8 cial review of such order as provided in such
9 section 5, except that—

10 (i) such review may only be obtained
11 in—

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

15 (II) the United States Court of
16 Appeals for the circuit in which the
17 ultimate parent entity, as defined in
18 section 801.1(a)(3) of title 16, Code
19 of Federal Regulations, or any suc-
20 cessor thereto, of the NDA or BLA
21 holder (if any such holder is a party
22 to such order) is incorporated as of
23 the date that the application described
24 in subparagraph (A) or (B) of sub-
25 section (g)(8) or an approved applica-

1 tion that is deemed to be a license for
2 a biological product under section
3 351(k) of the Public Health Service
4 Act (42 U.S.C. 262(k)) pursuant to
5 section 7002(e)(4) of the Biologics
6 Price Competition and Innovation Act
7 of 2009 (Public Law 111–148; 124
8 Stat. 817) is submitted to the Com-
9 missioner of Food and Drugs; or

10 (III) the United States Court of
11 Appeals for the circuit in which the
12 ultimate parent entity, as so defined,
13 of any subsequent filer that is a party
14 to such order is incorporated as of the
15 date that the application described in
16 subparagraph (A) or (B) of subsection
17 (g)(8) is submitted to the Commis-
18 sioner of Food and Drugs; and

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

23 (3) ADDITIONAL ENFORCEMENT AUTHORITY.—

24 (A) CIVIL PENALTY.—The Commission
25 may commence a civil action to recover a civil

1 penalty in a district court of the United States
2 against any NDA or BLA holder or subsequent
3 filer that violates this section.

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

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

12 (I) the Commission may com-
13 mence a civil action under subpara-
14 graph (A) to recover a civil penalty
15 against any party to such order at
16 any time before the expiration of the
17 1-year period beginning on the date
18 on which such order becomes final
19 under section 5(g) of such Act (15
20 U.S.C. 45(g)); and

21 (II) in such civil action, the find-
22 ings of the Commission as to the ma-
23 terial facts in such proceeding shall be
24 conclusive, unless—

1 (aa) the terms of such order
2 expressly provide that the Com-
3 mission's findings shall not be
4 conclusive; or

5 (bb) such order became final
6 by reason of section 5(g)(1) of
7 such Act (15 U.S.C. 45(g)(1)), in
8 which case such findings shall be
9 conclusive if supported by evi-
10 dence.

11 (ii) RELATIONSHIP TO PENALTY FOR
12 VIOLATION OF AN ORDER.—The penalty
13 provided in clause (i) for violation of this
14 section is separate from and in addition to
15 any penalty that may be incurred for viola-
16 tion of an order of the Commission under
17 section 5(l) of the Federal Trade Commis-
18 sion Act (15 U.S.C. 45(l)).

19 (C) AMOUNT OF PENALTY.—

20 (i) IN GENERAL.—The amount of a
21 civil penalty imposed in a civil action under
22 subparagraph (A) on a party to an agree-
23 ment described in subsection (a) shall be
24 sufficient to deter violations of this section,
25 but in no event greater than—

1 (I) if such party is the NDA or
2 BLA holder (or, in the case of an
3 agreement between two subsequent fil-
4 ers, the subsequent filer who gave the
5 value described in subsection (a)(1)),
6 the greater of—

7 (aa) 3 times the value re-
8 ceived by such NDA or BLA
9 holder (or by such subsequent
10 filer) that is reasonably attrib-
11 utable to the violation of this sec-
12 tion; or

13 (bb) 3 times the value given
14 to the subsequent filer (or to the
15 other subsequent filer) reason-
16 ably attributable to the violation
17 of this section; and

18 (II) if such party is the subse-
19 quent filer (or, in the case of an
20 agreement between two subsequent fil-
21 ers, the subsequent filer who received
22 the value described in subsection
23 (a)(1)), 3 times the value received by
24 such subsequent filer that is reason-

1 ably attributable to the violation of
2 this section.

3 (ii) FACTORS FOR CONSIDERATION.—

4 In determining such amount, the court
5 shall take into account—

6 (I) the nature, circumstances, ex-
7 tent, and gravity of the violation;

8 (II) with respect to the violator,
9 the degree of culpability, any history
10 of violations, the ability to pay, any
11 effect on the ability to continue doing
12 business, profits earned by the NDA
13 or BLA holder (or, in the case of an
14 agreement between two subsequent fil-
15 ers, the subsequent filer who gave the
16 value described in subsection (a)(1)),
17 compensation received by the subse-
18 quent filer (or, in the case of an
19 agreement between two subsequent fil-
20 ers, the subsequent filer who received
21 the value described in subsection
22 (a)(1)), and the amount of commerce
23 affected; and

24 (III) other matters that justice
25 requires.

1 (D) INJUNCTIONS AND OTHER EQUITABLE
2 RELIEF.—In a civil action under subparagraph
3 (A), the United States district courts are em-
4 powered to grant mandatory injunctions and
5 such other and further equitable relief as they
6 deem appropriate.

7 (4) REMEDIES IN ADDITION.—Remedies pro-
8 vided in this subsection are in addition to, and not
9 in lieu of, any other remedy provided by Federal
10 law.

11 (5) PRESERVATION OF AUTHORITY OF COMMIS-
12 SION.—Nothing in this section shall be construed to
13 affect any authority of the Commission under any
14 other provision of law.

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

22 (f) ANTITRUST LAWS.—Nothing in this section shall
23 modify, impair, limit, or supersede the applicability of the
24 antitrust laws as defined in subsection (a) of the first sec-
25 tion of the Clayton Act (15 U.S.C. 12(a)), and of section

1 5 of the Federal Trade Commission Act (15 U.S.C. 45)
2 to the extent that such section 5 applies to unfair methods
3 of competition. Nothing in this section shall modify, im-
4 pair, limit, or supersede the right of a subsequent filer
5 to assert claims or counterclaims against any person,
6 under the antitrust laws or other laws relating to unfair
7 competition.

8 (g) DEFINITIONS.—In this section:

9 (1) AGREEMENT RESOLVING OR SETTLING A
10 COVERED PATENT INFRINGEMENT CLAIM.—The
11 term “agreement resolving or settling a covered pat-
12 ent infringement claim” means any agreement
13 that—

14 (A) resolves or settles a covered patent in-
15 fringement claim; or

16 (B) is contingent upon, provides for a con-
17 tingent condition for, or is otherwise related to
18 the resolution or settlement of a covered patent
19 infringement claim.

20 (2) COMMISSION.—The term “Commission”
21 means the Federal Trade Commission.

22 (3) COVERED PATENT INFRINGEMENT CLAIM.—
23 The term “covered patent infringement claim”
24 means an allegation made by the NDA or BLA hold-
25 er to a subsequent filer (or, in the case of an agree-

1 ment between two subsequent filers, by one subse-
2 quent filer to another), whether or not included in
3 a complaint filed with a court of law, that—

4 (A) the submission of the application de-
5 scribed in subparagraph (A) or (B) of para-
6 graph (9), or the manufacture, use, offering for
7 sale, sale, or importation into the United States
8 of a covered product that is the subject of such
9 an application—

10 (i) in the case of an agreement be-
11 tween an NDA or BLA holder and a sub-
12 sequent filer, infringes any patent owned
13 by, or exclusively licensed to, the NDA or
14 BLA holder of the covered product; or

15 (ii) in the case of an agreement be-
16 tween two subsequent filers, infringes any
17 patent owned by the subsequent filer; or

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

23 (4) COVERED PRODUCT.—The term “covered
24 product” means a drug (as defined in section 201(g)
25 of the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 321(g))), including a biological product (as
2 defined in section 351(i) of the Public Health Serv-
3 ice Act (42 U.S.C. 262(i)).

4 (5) NDA OR BLA HOLDER.—The term “NDA
5 or BLA holder” means—

6 (A) the holder of—

7 (i) an approved new drug application
8 filed under section 505(b)(1) of the Fed-
9 eral Food, Drug, and Cosmetic Act (21
10 U.S.C. 355(b)(1)) for a covered product;

11 or

12 (ii) a biologics license application filed
13 under section 351(a) of the Public Health
14 Service Act (42 U.S.C. 262(a)) with re-
15 spect to a biological product;

16 (B) a person owning or controlling enforce-
17 ment of the patent on—

18 (i) the list published under section
19 505(j)(7) of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 355(j)(7)) in con-
21 nection with the application described in
22 subparagraph (A)(i); or

23 (ii) any list published under section
24 351 of the Public Health Service Act (42
25 U.S.C. 262) comprised of patents associ-

1 ated with biologics license applications filed
2 under section 351(a) of such Act (42
3 U.S.C. 262(a)); or

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

12 (6) PATENT.—The term “patent” means a pat-
13 ent issued by the United States Patent and Trade-
14 mark Office.

15 (7) STATUTORY EXCLUSIVITY.—The term
16 “statutory exclusivity” means those prohibitions on
17 the submission or approval of drug applications
18 under clauses (ii) through (iv) of section
19 505(c)(3)(E) (5- and 3-year exclusivity), clauses (ii)
20 through (iv) of section 505(j)(5)(F) (5-year and 3-
21 year exclusivity), section 505(j)(5)(B)(iv) (180-day
22 exclusivity), section 527 (orphan drug exclusivity),
23 section 505A (pediatric exclusivity), or section 505E
24 (qualified infectious disease product exclusivity) of
25 the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 355(j)(5)(F),
2 360cc, 355a, 355f), or prohibitions on the submis-
3 sion or licensing of biologics license applications
4 under section 351(k)(6) (interchangeable biological
5 product exclusivity) or section 351(k)(7) (biological
6 product reference product exclusivity) of the Public
7 Health Service Act (42 U.S.C. 262(k)(6), (7)).

8 (8) SUBSEQUENT FILER.—The term “subse-
9 quent filer” means—

10 (A) in the case of a drug, a party that
11 owns or controls an abbreviated new drug appli-
12 cation submitted pursuant to section 505(j) of
13 the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 355(j)) or a new drug application sub-
15 mitted pursuant to section 505(b)(2) of the
16 Federal Food, Drug, and Cosmetic Act
17 (21U.S.C. 355(b)(2)) and filed under section
18 505(b)(1) of such Act (21 U.S.C. 355(b)(1)) or
19 has the exclusive rights to distribute the cov-
20 ered product that is the subject of such applica-
21 tion; or

22 (B) in the case of a biological product, a
23 party that owns or controls an application filed
24 with the Food and Drug Administration under
25 section 351(k) of the Public Health Service Act

1 (42 U.S.C. 262(k)) or has the exclusive rights
2 to distribute the biological product that is the
3 subject of such application.

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

7 **SEC. 312. NOTICE AND CERTIFICATION OF AGREEMENTS.**

8 (a) NOTICE OF ALL AGREEMENTS.—Section 1111(7)
9 of the Medicare Prescription Drug, Improvement, and
10 Modernization Act of 2003 (21 U.S.C. 355 note) is
11 amended by inserting “or the owner of a patent for which
12 a claim of infringement could reasonably be asserted
13 against any person for making, using, offering to sell, sell-
14 ing, or importing into the United States a biological prod-
15 uct that is the subject of a biosimilar biological product
16 application” before the period at the end.

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

20 “(d) CERTIFICATION.—The Chief Executive Officer
21 or the company official responsible for negotiating any
22 agreement under subsection (a) or (b) that is required to
23 be filed under subsection (c) shall, within 30 days of such
24 filing, execute and file with the Assistant Attorney General
25 and the Commission a certification as follows: ‘I declare

1 that the following is true, correct, and complete to the best
2 of my knowledge: The materials filed with the Federal
3 Trade Commission and the Department of Justice under
4 section 1112 of the Medicare Prescription Drug, Improve-
5 ment, and Modernization Act of 2003, with respect to the
6 agreement referenced in this certification—

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

9 “(2) include any ancillary agreements that are
10 contingent upon, provide a contingent condition for,
11 were entered into within 30 days of, or are otherwise
12 related to, the referenced agreement; and

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

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

19 Section 505(j)(5)(D)(i)(V) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))
21 is amended by inserting “section 311 of the Lower Drug
22 Costs Now Act of 2019 or” after “that the agreement has
23 violated”.

1 **SEC. 314. COMMISSION LITIGATION AUTHORITY.**

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

4 (1) in subparagraph (D), by striking “or” after
5 the semicolon;

6 (2) in subparagraph (E), by inserting “or”
7 after the semicolon; and

8 (3) by inserting after subparagraph (E) the fol-
9 lowing:

10 “(F) under section 311(d)(3)(A) of the
11 Lower Drug Costs Now Act of 2019;”.

12 **SEC. 315. STATUTE OF LIMITATIONS.**

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

21 (b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND
22 DESIST ORDER.—If the Commission has issued a cease
23 and desist order under section 5 of the Federal Trade
24 Commission Act (15 U.S.C. 45) for violation of section
25 311 of this Act and the proceeding for the issuance of
26 such order was commenced within the period required by

1 subsection (a) of this section, such subsection does not
2 prohibit the commencement, after such period, of a civil
3 action under section 311(d)(3)(A) against a party to such
4 order or a civil action under subsection (l) of such section
5 5 for violation of such order.

6 **Subtitle C—BLOCKING Act**

7 **SEC. 321. CHANGE CONDITIONS OF FIRST GENERIC EXCLU-** 8 **SIVITY TO SPUR ACCESS AND COMPETITION.**

9 Section 505(j)(5)(B)(iv) of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amend-
11 ed—

12 (1) in subclause (I), by striking “180 days
13 after” and all that follows through the period at the
14 end and inserting the following: “180 days after the
15 earlier of—

16 “(aa) the date of the first com-
17 mercial marketing of the drug (includ-
18 ing the commercial marketing of the
19 listed drug) by any first applicant; or

20 “(bb) the applicable date speci-
21 fied in subclause (III).”; and

22 (2) by adding at the end the following new sub-
23 clause:

24 “(III) APPLICABLE DATE.—The appli-
25 cable date specified in this subclause, with

1 respect to an application for a drug de-
2 scribed in subclause (I), is the date on
3 which each of the following conditions is
4 first met:

5 “(aa) The approval of such an
6 application could be made effective,
7 but for the eligibility of a first appli-
8 cant for 180-day exclusivity under
9 this clause.

10 “(bb) At least 30 months have
11 passed since the date of submission of
12 an application for the drug by at least
13 one first applicant.

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

18 “(dd) No application for the drug
19 submitted by any first applicant is ap-
20 proved at the time the conditions
21 under items (aa), (bb), and (cc) are
22 all met, regardless of whether such an
23 application is subsequently ap-
24 proved.”.

1 **Subtitle D—Purple Book**

2 **SEC. 331. PUBLIC LISTING.**

3 Section 351(k) of the Public Health Service Act (42
4 U.S.C. 262(k)) is amended by adding at the end the fol-
5 lowing:

6 “(9) PUBLIC LISTING.—

7 “(A) IN GENERAL.—

8 “(i) INITIAL PUBLICATION.—Not later
9 than 180 days after the date of enactment
10 of the Lower Drug Costs Now Act of
11 2019, the Secretary shall publish and
12 make available to the public in a search-
13 able, electronic format—

14 “(I) a list in alphabetical order of
15 the nonproprietary or proper name of
16 each biological product for which a
17 biologics license under subsection (a)
18 or this subsection is in effect, or that
19 has been deemed to be licensed under
20 this section pursuant to section
21 7002(e)(4) of the Biologics Price
22 Competition and Innovation Act of
23 2009, as of such date of enactment;

1 “(II) the date of approval of the
2 marketing application and the applica-
3 tion number; and

4 “(III) the marketing or licensure
5 status of the biological product for
6 which a biologics license under sub-
7 section (a) or this subsection is in ef-
8 fect or that has been deemed to be li-
9 censed under this section pursuant to
10 section 7002(e)(4) of the Biologics
11 Price Competition and Innovation Act
12 of 2009.

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

19 “(iii) PATENT INFORMATION.—Not
20 later than 30 days after a list of patents
21 under subsection (l)(3)(A), or a supple-
22 ment to such list under subsection (l)(7),
23 has been provided by the reference product
24 sponsor to the subsection (k) applicant re-
25 specting a biological product included on

1 the list published under this subparagraph,
2 the reference product sponsor shall provide
3 such list of patents (or supplement there-
4 to) and their corresponding expiry dates to
5 the Secretary, and the Secretary shall, in
6 revisions made under clause (ii), include
7 such information for such biological prod-
8 uct. Within 30 days of providing any sub-
9 sequent or supplemental list of patents to
10 any subsequent subsection (k) applicant
11 under subsection (l)(3)(A) or (l)(7), the
12 reference product sponsor shall update the
13 information provided to the Secretary
14 under this clause with any additional pat-
15 ents from such subsequent or supplemental
16 list and their corresponding expiry dates.

17 “(iv) LISTING OF EXCLUSIVITIES.—
18 For each biological product included on the
19 list published under this subparagraph, the
20 Secretary shall specify each exclusivity pe-
21 riod that is applicable and has not con-
22 cluded under paragraph (6) or paragraph
23 (7).

24 “(B) WITHDRAWAL OR SUSPENSION OF LI-
25 CENSURE.—If the licensing of a biological prod-

1 uct was withdrawn or suspended for safety, pu-
2 rity, or potency reasons, it may not be pub-
3 lished in the list under subparagraph (A). If the
4 withdrawal or suspension occurred after its
5 publication in such list, the reference product
6 sponsor shall notify the Secretary that—

7 “(i) the biological product shall be im-
8 mediately removed from such list—

9 “(I) for the same period as the
10 withdrawal or suspension; or

11 “(II) if the biological product has
12 been withdrawn from sale, for the pe-
13 riod of withdrawal from sale or, if ear-
14 lier, the period ending on the date the
15 Secretary determines that the with-
16 drawal from sale is not for safety, pu-
17 rity, or potency reasons; and

18 “(ii) a notice of the removal shall be
19 published in the Federal Register.”.

20 **SEC. 332. REVIEW AND REPORT ON TYPES OF INFORMA-**
21 **TION TO BE LISTED.**

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

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

6 (2) transmit to Congress an evaluation of such
7 comments, including any recommendations about the
8 types of information that should be added to or re-
9 moved from the list.

10 **Subtitle E—Orange Book**

11 **SEC. 341. ORANGE BOOK.**

12 (a) SUBMISSION OF PATENT INFORMATION FOR
13 BRAND NAME DRUGS.—Paragraph (1) of section 505(b)
14 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 355(b)) is amended to read as follows:

16 “(b)(1) Any person may file with the Secretary an
17 application with respect to any drug subject to the provi-
18 sions of subsection (a). Such persons shall submit to the
19 Secretary as part of the application—

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

23 “(B) a full list of the articles used as compo-
24 nents of such drug;

1 “(C) a full statement of the composition of such
2 drug;

3 “(D) a full description of the methods used in,
4 and the facilities and controls used for, the manufac-
5 ture, processing, and packing of such drug;

6 “(E) such samples of such drug and of the arti-
7 cles used as components thereof as the Secretary
8 may require;

9 “(F) specimens of the labeling proposed to be
10 used for such drug;

11 “(G) any assessments required under section
12 505B; and

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

19 “(i) The applicant shall file with the appli-
20 cation the patent number and the expiration
21 date of—

22 “(I) any patent which claims the drug
23 for which the applicant submitted the ap-
24 plication and is a drug substance (includ-
25 ing active ingredient) patent or a drug

1 product (including formulation and com-
2 position) patent; and

3 “(II) any patent which claims the
4 method of using such drug.

5 “(ii) If an application is filed under this
6 subsection for a drug and a patent of the type
7 described in clause (i) which claims such drug
8 or a method of using such drug is issued after
9 the filing date but before approval of the appli-
10 cation, the applicant shall amend the applica-
11 tion to include such patent information.

12 Upon approval of the application, the Secretary shall pub-
13 lish the information submitted under subparagraph (H).
14 The Secretary shall, in consultation with the Director of
15 the National Institutes of Health and with representatives
16 of the drug manufacturing industry, review and develop
17 guidance, as appropriate, on the inclusion of women and
18 minorities in clinical trials required by subparagraph
19 (A).”.

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

1 (1) by inserting after “the patent number and
2 the expiration date of any patent which” the fol-
3 lowing: “fulfills the criteria in subsection (b) and”;

4 (2) by inserting after the first sentence the fol-
5 lowing: “Patent information that is not the type of
6 patent information required by subsection (b) shall
7 not be submitted.”; and

8 (3) by inserting after “could not file patent in-
9 formation under subsection (b) because no patent”
10 the following: “of the type required to be submitted
11 in subsection (b)”.

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

16 “(iv) For each drug included on the list, the Sec-
17 retary shall specify each exclusivity period that is applica-
18 ble and has not concluded under—

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

21 “(II) clause (iv) or (v) of paragraph (5)(B) of
22 this subsection;

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

25 “(IV) section 505A;

1 “(V) section 505E; or

2 “(VI) section 527(a).”.

3 (d) REMOVAL OF INVALID PATENTS.—

4 (1) IN GENERAL.—Section 505(j)(7) of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 355(j)(7)) is amended by adding at the end the fol-
7 lowing:

8 “(D)(i) The holder of an application approved under
9 subsection (c) for a drug on the list shall notify within
10 14 days the Secretary in writing if either of the following
11 occurs:

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

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

18 “(ii) The holder of an approved application shall in-
19 clude in any notification under clause (i) a copy of the
20 decision described in subclause (I) or (II) of clause (i).

21 “(iii) The Secretary shall remove from the list any
22 patent that is determined to be invalid in a decision de-
23 scribed in subclause (I) or (II) of clause (i)—

24 “(I) promptly; but

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

5 (2) APPLICABILITY.—Subparagraph (D) of sec-
6 tion 505(j)(7) of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 355(j)(7)), as added by para-
8 graph (1), applies only with respect to a decision de-
9 scribed in such subparagraph that is issued on or
10 after the date of enactment of this Act.

11 (e) REVIEW AND REPORT.—Not later than one year
12 after the date of enactment of this Act, the Secretary of
13 Health and Human Services, acting through the Commis-
14 sioner of Food and Drugs, shall—

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

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

23 **SEC. 342. GAO REPORT TO CONGRESS.**

24 (a) IN GENERAL.—Not later than one year after the
25 date of enactment of this Act, the Comptroller General

1 of the United States (referred to in this section as the
2 “Comptroller General”) shall submit to the Committee on
3 Energy and Commerce of the House of Representatives
4 a report on the patents included in the list published under
5 section 505(j)(7) of the Federal Food, Drug and Cosmetic
6 Act (21 U.S.C. 355(j)(7)), including an analysis and eval-
7 uation of the types of patents included in such list and
8 the claims such patents make about the products they
9 claim.

10 (b) CONTENTS.—The Comptroller General shall in-
11 clude in the report under subsection (a)—

12 (1) data on the number of—

13 (A) patents included in the list published
14 under paragraph (7) of section 505(j) of the
15 Federal Food, Drug and Cosmetic Act (21
16 U.S.C. 355(j)), that claim the active ingredient
17 or formulation of a drug in combination with a
18 device that is used for delivery of the drug, to-
19 gether comprising the finished dosage form of
20 the drug; and

21 (B) claims in each patent that claim a de-
22 vice that is used for the delivery of the drug,
23 but do not claim such device in combination
24 with an active ingredient or formulation of a
25 drug;

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

6 (3) an analysis regarding the impact of includ-
7 ing on the list under paragraph (7) of such section
8 505(j) certain types of patent information for drug
9 product applicants and approved application holders,
10 including an analysis of whether—

11 (A) the listing of the patents described in
12 paragraph (1)(A) delayed the market entry of
13 one or more drugs approved under such section
14 505(j); and

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

18 (4) recommendations about which kinds of pat-
19 ents relating to devices described in paragraph
20 (1)(A) should be submitted to the Secretary of
21 Health and Human Services for inclusion on the list
22 under paragraph (7) of such section 505(j) and
23 which patents should not be required to be so sub-
24 mitted.

1 **Subtitle F—Advancing Education**
2 **on Biosimilars**

3 **SEC. 351. EDUCATION ON BIOLOGICAL PRODUCTS.**

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

8 **“SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.**

9 “(a) INTERNET WEBSITE.—

10 “(1) IN GENERAL.—The Secretary shall main-
11 tain and operate an internet website to provide edu-
12 cational materials for health care providers, patients,
13 and caregivers, regarding the meaning of the terms,
14 and the standards for review and licensing of, bio-
15 logical products, including biosimilar biological prod-
16 ucts and interchangeable biosimilar biological prod-
17 ucts.

18 “(2) CONTENT.—Educational materials pro-
19 vided under paragraph (1) may include—

20 “(A) explanations of key statutory and
21 regulatory terms, including ‘biosimilar’ and
22 ‘interchangeable’, and clarification regarding
23 the use of interchangeable biosimilar biological
24 products;

1 “(B) information related to development
2 programs for biological products, including bio-
3 similar biological products and interchangeable
4 biosimilar biological products and relevant clin-
5 ical considerations for prescribers, which may
6 include, as appropriate and applicable, informa-
7 tion related to the comparability of such biologi-
8 cal products;

9 “(C) an explanation of the process for re-
10 porting adverse events for biological products,
11 including biosimilar biological products and
12 interchangeable biosimilar biological products;
13 and

14 “(D) an explanation of the relationship be-
15 tween biosimilar biological products and inter-
16 changeable biosimilar biological products li-
17 censed under section 351(k) and reference
18 products (as defined in section 351(i)), includ-
19 ing the standards for review and licensing of
20 each such type of biological product.

21 “(3) FORMAT.—The educational materials pro-
22 vided under paragraph (1) may be—

23 “(A) in formats such as webinars, con-
24 tinuing medical education modules, videos, fact
25 sheets, infographics, stakeholder toolkits, or

1 other formats as appropriate and applicable;
2 and

3 “(B) tailored for the unique needs of
4 health care providers, patients, caregivers, and
5 other audiences, as the Secretary determines
6 appropriate.

7 “(4) OTHER INFORMATION.—In addition to the
8 information described in paragraph (2), the Sec-
9 retary shall continue to publish the following infor-
10 mation:

11 “(A) The action package of each biological
12 product licensed under subsection (a) or (k).

13 “(B) The summary review of each biologi-
14 cal product licensed under subsection (a) or (k).

15 “(5) CONFIDENTIAL AND TRADE SECRET IN-
16 FORMATION.—This subsection does not authorize
17 the disclosure of any trade secret, confidential com-
18 mercial or financial information, or other matter de-
19 scribed in section 552(b) of title 5.

20 “(b) CONTINUING EDUCATION.—The Secretary shall
21 advance education and awareness among health care pro-
22 viders regarding biological products, including biosimilar
23 biological products and interchangeable biosimilar biologi-
24 cal products, as appropriate, including by developing or
25 improving continuing education programs that advance

1 the education of such providers on the prescribing of, and
2 relevant clinical considerations with respect to, biological
3 products, including biosimilar biological products and
4 interchangeable biosimilar biological products.”.

5 (b) APPLICATION UNDER THE MEDICARE MERIT-
6 BASED INCENTIVE PAYMENT SYSTEM.—Section
7 1848(q)(5)(C) of the Social Security Act (42 U.S.C.
8 1395w–4(q)(5)(C)) is amended by adding at the end the
9 following new clause:

10 “(iv) CLINICAL MEDICAL EDUCATION
11 PROGRAM ON BIOSIMILAR BIOLOGICAL
12 PRODUCTS.—Completion of a clinical med-
13 ical education program developed or im-
14 proved under section 352A(b) of the Public
15 Health Service Act by a MIPS eligible pro-
16 fessional during a performance period shall
17 earn such eligible professional one-half of
18 the highest potential score for the perform-
19 ance category described in paragraph
20 (2)(A)(iii) for such performance period. A
21 MIPS eligible professional may only count
22 the completion of such a program for pur-
23 poses of such category one time during the
24 eligible professional’s lifetime.”.

1 **TITLE V—MISCELLANEOUS**

2 **SEC. 501. PAYMENT FOR BIOSIMILAR BIOLOGICAL PROD-**
3 **UCTS DURING INITIAL PERIOD.**

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

6 (1) in each of subparagraphs (A) and (B), by
7 redesignating clauses (i) and (ii) as subclauses (I)
8 and (II), respectively, and moving such subclauses 2
9 ems to the right;

10 (2) by redesignating subparagraphs (A) and
11 (B) as clauses (i) and (ii) and moving such clauses
12 2 ems to the right;

13 (3) by striking “UNAVAILABLE.—In the case”
14 and inserting “UNAVAILABLE.—

15 “(A) IN GENERAL.—Subject to subpara-
16 graph (B), in the case”; and

17 (4) by adding at the end the following new sub-
18 paragraph:

19 “(B) LIMITATION ON PAYMENT AMOUNT
20 FOR BIOSIMILAR BIOLOGICAL PRODUCTS DUR-
21 ING INITIAL PERIOD.—In the case of a bio-
22 similar biological product furnished on or after
23 July 1, 2020, in lieu of applying subparagraph
24 (A) during the initial period described in such
25 subparagraph with respect to the biosimilar bio-

1 logical product, the amount payable under this
2 section for the biosimilar biological product is
3 the lesser of the following:

4 “(i) The amount determined under
5 clause (ii) of such subparagraph for the
6 biosimilar biological product.

7 “(ii) The amount determined under
8 subsection (b)(1)(B) for the reference bio-
9 logical product.”.

10 **SEC. 502. GAO STUDY AND REPORT ON AVERAGE SALES**
11 **PRICE.**

12 (a) STUDY.—

13 (1) IN GENERAL.—The Comptroller General of
14 the United States (in this section referred to as the
15 “Comptroller General”) shall conduct a study on
16 spending for applicable drugs under part B of title
17 XVIII of the Social Security Act.

18 (2) APPLICABLE DRUGS DEFINED.—In this sec-
19 tion, the term “applicable drugs” means drugs and
20 biologicals—

21 (A) for which reimbursement under such
22 part B is based on the average sales price of
23 the drug or biological; and

24 (B) that account for the largest percentage
25 of total spending on drugs and biologicals under

1 such part B (as determined by the Comptroller
2 General, but in no case less than 25 drugs or
3 biologicals).

4 (3) REQUIREMENTS.—The study under para-
5 graph (1) shall include an analysis of the following:

6 (A) The extent to which each applicable
7 drug is paid for—

8 (i) under such part B for Medicare
9 beneficiaries; or

10 (ii) by private payers in the commer-
11 cial market.

12 (B) Any change in Medicare spending or
13 Medicare beneficiary cost-sharing that would
14 occur if the average sales price of an applicable
15 drug was based solely on payments by private
16 payers in the commercial market.

17 (C) The extent to which drug manufactur-
18 ers provide rebates, discounts, or other price
19 concessions to private payers in the commercial
20 market for applicable drugs, which the manu-
21 facturer includes in its average sales price cal-
22 culation, for—

23 (i) formulary placement;

24 (ii) utilization management consider-
25 ations; or

1 (iii) other purposes.

2 (D) Barriers to drug manufacturers pro-
3 viding such price concessions for applicable
4 drugs.

5 (E) Other areas determined appropriate by
6 the Comptroller General.

7 (b) REPORT.—Not later than 2 years after the date
8 of the enactment of this Act, the Comptroller General shall
9 submit to Congress a report on the study conducted under
10 subsection (a), together with recommendations for such
11 legislation and administrative action as the Secretary de-
12 termines appropriate.

13 **SEC. 503. REQUIRING PRESCRIPTION DRUG PLANS AND**
14 **MA-PD PLANS TO REPORT POTENTIAL**
15 **FRAUD, WASTE, AND ABUSE TO THE SEC-**
16 **RETARY OF HHS.**

17 Section 1860D–4 of the Social Security Act (42
18 U.S.C. 1395w–104) is amended by adding at the end the
19 following new subsection:

20 “(p) REPORTING POTENTIAL FRAUD, WASTE, AND
21 ABUSE.—Beginning January 1, 2021, the PDP sponsor
22 of a prescription drug plan shall report to the Secretary,
23 as specified by the Secretary—

24 “(1) any substantiated or suspicious activities
25 (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.

