

1 (iii) by inserting “(or 2022 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 2022, the Secretary shall 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 **SEC. 102. REQUIRING MANUFACTURERS OF CERTAIN SIN-**
2 **GLE-DOSE CONTAINER OR SINGLE-USE PACK-**
3 **AGE DRUGS PAYABLE UNDER PART B OF THE**
4 **MEDICARE PROGRAM TO PROVIDE REFUNDS**
5 **WITH RESPECT TO DISCARDED AMOUNTS OF**
6 **SUCH DRUGS.**

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

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

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

14 “(A) IN GENERAL.—For each calendar
15 quarter beginning on or after January 1, 2022,
16 the Secretary shall, with respect to a refundable
17 single-dose container or single-use package drug
18 (as defined in paragraph (8)), report to each
19 manufacturer (as defined in subsection
20 (c)(6)(A)) of such refundable single-dose con-
21 tainer or single-use package drug the following
22 for the calendar quarter:

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

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

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

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

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

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

5 “(2) MANUFACTURER REQUIREMENT.—For
6 each calendar quarter beginning on or after January
7 1, 2022, the manufacturer of a refundable single-
8 dose container or single-use package drug shall, for
9 such drug, provide to the Secretary a refund that is
10 equal to the amount specified in paragraph (3) for
11 such drug for such quarter.

12 “(3) REFUND AMOUNT.—

13 “(A) IN GENERAL.—The amount of the re-
14 fund specified in this paragraph is, with respect
15 to a refundable single-dose container or single-
16 use package drug of a manufacturer assigned to
17 a billing and payment code for a calendar quar-
18 ter beginning on or after January 1, 2022, an
19 amount equal to the estimated amount (if any)
20 by which—

21 “(i) the product of—

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

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

3 “(II)(aa) in the case of a refund-
4 able single-dose container or single-
5 use package drug that is a single
6 source drug or biological, the amount
7 of payment determined for such drug
8 or biological under subsection
9 (b)(1)(B) for such quarter; or

10 “(bb) in the case of a refundable
11 single-dose container or single-use
12 package drug that is a biosimilar bio-
13 logical product, the amount of pay-
14 ment determined for such product
15 under subsection (b)(1)(C) for such
16 quarter; exceeds

17 “(ii) an amount equal to the applica-
18 ble percentage (as defined in subparagraph
19 (B)) of the estimated total allowed charges
20 for such drug under this part during the
21 quarter.

22 “(B) APPLICABLE PERCENTAGE DE-
23 FINED.—

1 “(i) IN GENERAL.—For purposes of
2 subparagraph (A)(ii), the term ‘applicable
3 percentage’ means—

4 “(I) subject to subclause (II), 10
5 percent; and

6 “(II) if applicable, in the case of
7 a refundable single-dose container or
8 single-use package drug described in
9 clause (ii), a percentage specified by
10 the Secretary pursuant to such clause.

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

22 “(4) FREQUENCY.—Amounts required to be re-
23 funded pursuant to paragraph (2) shall be paid in
24 regular intervals (as determined appropriate by the
25 Secretary).

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

5 “(6) ENFORCEMENT.—

6 “(A) AUDITS.—

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

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

22 “(B) CIVIL MONEY PENALTY.—

23 “(i) IN GENERAL.—The Secretary
24 shall impose a civil money penalty on a
25 manufacturer of a refundable single-dose

1 container or single-use package drug who
2 has failed to comply with the requirement
3 under paragraph (2) for such drug for a
4 calendar quarter in an amount equal to the
5 sum of—

6 “(I) the amount that the manu-
7 facturer would have paid under such
8 paragraph with respect to such drug
9 for such quarter; and

10 “(II) 25 percent of such amount.

11 “(ii) APPLICATION.—The provisions
12 of section 1128A (other than subsections
13 (a) and (b)) shall apply to a civil money
14 penalty under this subparagraph in the
15 same manner as such provisions apply to a
16 penalty or proceeding under section
17 1128A(a).

18 “(7) IMPLEMENTATION.—The Secretary shall
19 implement this subsection through notice and com-
20 ment rulemaking.

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

23 “(A) IN GENERAL.—Except as provided in
24 subparagraph (B), in this subsection, the term
25 ‘refundable single-dose container or single-use

1 package drug’ means a single source drug or bi-
2 ological (as defined in section 1847A(c)(6)(D))
3 or a biosimilar biological product (as defined in
4 section 1847A(c)(6)(H)) for which payment is
5 made under this part and that is furnished
6 from a single-dose container or single-use pack-
7 age.

8 “(B) EXCLUSIONS.—The term ‘refundable
9 single-dose container or single-use package
10 drug’ does not include—

11 “(i) a drug or biological that is either
12 a radiopharmaceutical or an imaging
13 agent;

14 “(ii) a drug or biological approved by
15 the Food and Drug Administration for
16 which dosage and administration instruc-
17 tions included in the labeling require filtra-
18 tion during the drug preparation process,
19 prior to dilution and administration, and
20 require that any unused portion of such
21 drug after the filtration process be dis-
22 carded after the completion of such filtra-
23 tion process; or

24 “(iii) a drug or biological approved by
25 the Food and Drug Administration on or

1 after the date of enactment of this sub-
2 section and with respect to which payment
3 has been made under this part for fewer
4 than 18 months.

5 “(9) REPORT TO CONGRESS.—Not later than 3
6 years after the date of enactment of this subsection,
7 the Office of the Inspector General, after consulta-
8 tion with the Centers for Medicare & Medicaid Serv-
9 ices and the Food and Drug Administration, shall
10 submit to the Committee on Energy and Commerce
11 and the Committee on Ways and Means of the
12 House of Representatives and the Committee on Fi-
13 nance in the Senate, a report on any impact this
14 section is reported to have on the licensure, market
15 entry, market retention, or marketing of biosimilar
16 biological products. Such report shall be updated pe-
17 riodically at the direction of the Committee on En-
18 ergy and Commerce and the Committee on Ways
19 and Means of the House of Representatives and the
20 Committee on Finance in the Senate.”.

21 **SEC. 103. PROVIDING FOR VARIATION IN PAYMENT FOR**
22 **CERTAIN DRUGS COVERED UNDER PART B**
23 **OF THE MEDICARE PROGRAM.**

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

1 (1) in paragraph (1)—

2 (A) in subparagraph (A), by inserting after
3 “or 106 percent” the following: “(or, for a mul-
4 tiple source drug (other than autologous cellular
5 immunotherapy) furnished on or after January
6 1, 2022, the applicable percent specified in
7 paragraph (9)(A) for the drug and quarter in-
8 volved)”; and

9 (B) in subparagraph (B) of paragraph (1),
10 by inserting after “106 percent” the following:
11 “(or, for a single source drug or biological
12 (other than autologous cellular immunotherapy)
13 furnished on or after January 1, 2022, the ap-
14 plicable percent specified in paragraph (9)(A)
15 for the drug or biological and quarter in-
16 volved)”; and

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

19 “(9) APPLICATION OF VARIABLE PERCENTAGES
20 BASED ON PERCENTILE RANKING OF PER BENE-
21 FICIARY ALLOWED CHARGES.—

22 “(A) APPLICABLE PERCENT TO BE AP-
23 PLIED.—

24 “(i) IN GENERAL.—Subject to clauses
25 (ii), with respect to a drug or biological

1 furnished in a calendar quarter beginning
2 on or after January 1, 2022, if the Sec-
3 retary determines that the percentile rank
4 of a drug or biological under subparagraph
5 (B)(i)(III), with respect to per beneficiary
6 allowed charges for all such drugs or
7 biologicals, is—

8 “(I) at least equal to the 85th
9 percentile, the applicable percent for
10 the drug for such quarter under this
11 subparagraph is 104 percent;

12 “(II) at least equal to the 70th
13 percentile, but less than the 85th per-
14 centile, such applicable percent is 106
15 percent;

16 “(III) at least equal to the 50th
17 percentile, but less than the 70th per-
18 centile, such applicable percent is 108
19 percent; or

20 “(IV) less than the 50th per-
21 centile, such applicable percent is 110
22 percent.

23 “(ii) CASES WHERE DATA NOT SUFFI-
24 CIENTLY AVAILABLE TO COMPUTE PER
25 BENEFICIARY ALLOWED CHARGES.—Sub-

1 ject to clause (iii), in the case of a drug or
2 biological furnished for which the amount
3 of payment is determined under subpara-
4 graph (A) or (B) of paragraph (1) and not
5 under subsection (c)(4), for calendar quar-
6 ters during a period in which data are not
7 sufficiently available to compute a per ben-
8 eficiary allowed charges for the drug or bi-
9 ological, the applicable percent is 106 per-
10 cent.

11 “(B) DETERMINATION OF PERCENTILE
12 RANK OF PER BENEFICIARY ALLOWED CHARGES
13 OF DRUGS.—

14 “(i) IN GENERAL.—With respect to a
15 calendar quarter beginning on or after
16 January 1, 2022, for drugs and biologicals
17 for which the amount of payment is deter-
18 mined under subparagraph (A) or (B) of
19 paragraph (1), except for drugs or
20 biologicals for which data are not suffi-
21 ciently available, the Secretary shall—

22 “(I) compute the per beneficiary
23 allowed charges (as defined in sub-
24 paragraph (C)) for each such drug or
25 biological;

1 “(II) adjust such per beneficiary
2 allowed charges for the quarter, to the
3 extent provided under subparagraph
4 (D); and

5 “(III) array such adjusted per
6 beneficiary allowed charges for all
7 such drugs or biologicals from high to
8 low and rank such drugs or biologicals
9 by percentile of such arrayed per ben-
10 eficiary allowed charges.

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

18 “(iii) APPLICABLE DATA PERIOD.—
19 For purposes of this paragraph, the term
20 ‘applicable data period’ means the most re-
21 cent period for which the data necessary
22 for making the computations under clause
23 (i) are available, as determined by the Sec-
24 retary.

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

7 “(i) the allowed charges for the drug
8 or biological for which payment is so made
9 for the applicable data period, as estimated
10 by the Secretary; divided by

11 “(ii) the number of individuals for
12 whom any payment for the drug or biologi-
13 cal was made under paragraph (1) for the
14 applicable data period, as estimated by the
15 Secretary.

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

24 “(i) the average sales price for the
25 drug or biological for the most recent cal-

1 (A) in paragraph (1), in the matter pre-
2 ceeding subparagraph (A), by striking “para-
3 graph (7)” and inserting “paragraphs (7) and
4 (10)”; and

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

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

8 “(A) IN GENERAL.—In determining the
9 payment amount under the provisions of sub-
10 paragraph (A), (B), or (C) of paragraph (1) of
11 this subsection, subsection (c)(4)(A)(ii), or sub-
12 section (d)(3)(C) for a drug or biological fur-
13 nished on or after January 1, 2022, if the ap-
14 plicable add-on payment (as defined in subpara-
15 graph (B)) for each drug or biological on a
16 claim for a date of service exceeds the max-
17 imum add-on payment amount specified under
18 subparagraph (C) for the drug or biological,
19 then the payment amount otherwise determined
20 for the drug or biological under those provi-
21 sions, as applicable, shall be reduced by the
22 amount of such excess.

23 “(B) APPLICABLE ADD-ON PAYMENT DE-
24 FINED.—In this paragraph, the term ‘applicable
25 add-on payment’ means the following amounts,

1 determined without regard to the application of
2 subparagraph (A):

3 “(i) In the case of a multiple source
4 drug, an amount equal to the difference
5 between—

6 “(I) the amount that would oth-
7 erwise be applied under paragraph
8 (1)(A); and

9 “(II) the amount that would be
10 applied under such paragraph if ‘100
11 percent’ were substituted for the ap-
12 plicable percent (as defined in para-
13 graph (9)) for such drug.

14 “(ii) In the case of a single source
15 drug or biological, an amount equal to the
16 difference between—

17 “(I) the amount that would oth-
18 erwise be applied under paragraph
19 (1)(B); and

20 “(II) the amount that would be
21 applied under such paragraph if ‘100
22 percent’ were substituted for the ap-
23 plicable percent (as defined in para-
24 graph (9)) for such drug or biological.

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

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

8 “(I) the amount that would oth-
9 erwise be applied under subsection
10 (c)(4)(A)(ii); and

11 “(II) the amount that would be
12 applied under such subsection if ‘100
13 percent’ were substituted, as applica-
14 ble, for—

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

17 “(bb) any percent in excess
18 of 100 percent applied under
19 subclause (II) of such subsection.

20 “(v) In the case of a drug or biologi-
21 cal to which subsection (d)(3)(C) applies,
22 an amount equal to the difference be-
23 tween—

1 “(I) the amount that would oth-
2 erwise be applied under such sub-
3 section; and

4 “(II) the amount that would be
5 applied under such subsection if ‘100
6 percent’ were substituted, as applica-
7 ble, for—

8 “(aa) any percent in excess
9 of 100 percent applied under
10 clause (i) of such subsection; or

11 “(bb) ‘103 percent’ in clause
12 (ii) of such subsection.

13 “(C) MAXIMUM ADD-ON PAYMENT AMOUNT
14 SPECIFIED.—For purposes of subparagraph
15 (A), the maximum add-on payment amount
16 specified in this subparagraph is—

17 “(i) with respect to a drug or biologi-
18 cal (other than autologous cellular
19 immunotherapy)—

20 “(I) for each of 2022 through
21 2029, \$1,000; and

22 “(II) for a subsequent year, the
23 amount specified in this subparagraph
24 for the preceding year increased by
25 the percentage increase in the con-

1 sumer price index for all urban con-
2 sumers (all items; United States city
3 average) for the 12-month period end-
4 ing with June of the previous year; or
5 “(ii) with respect to a drug or biologi-
6 cal consisting of autologous cellular
7 immunotherapy—

8 “(I) for each of 2022 through
9 2029, \$2,000; and

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

18 Any amount determined under this subpara-
19 graph that is not a multiple of \$10 shall be
20 rounded to the nearest multiple of \$10.”; and

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

24 (b) CONFORMING AMENDMENTS RELATING TO SEPA-
25 RATELY PAYABLE DRUGS.—

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

3 (A) in subparagraph (A)(iii)(II), by insert-
4 ing “, subject to subparagraph (I)” after “are
5 not available”; and

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

8 “(I) APPLICATION OF MAXIMUM ADD-ON
9 PAYMENT FOR SEPARATELY PAYABLE DRUGS
10 AND BIOLOGICALS.—In establishing the amount
11 of payment under subparagraph (A) for a speci-
12 fied covered outpatient drug that is furnished
13 as part of a covered OPD service (or group of
14 services) on or after January 1, 2022, if such
15 payment is determined based on the average
16 price for the year established under section
17 1847A pursuant to clause (iii)(II) of such sub-
18 paragraph, the provisions of subsection (b)(10)
19 of section 1847A shall apply to the amount of
20 payment so established in the same manner as
21 such provisions apply to the amount of payment
22 under section 1847A.”.

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

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

2 (B) by redesignating clause (vi) as clause

3 (vii); and

4 (C) by inserting after clause (v) the fol-

5 lowing new clause:

6 “(vi) If there is a separate payment

7 under the system described in clause (i) for

8 a drug or biological furnished on or after

9 January 1, 2022, the provisions of sub-

10 section (t)(14)(I) shall apply to the estab-

11 lishment of the amount of payment for the

12 drug or biological under such system in the

13 same manner in which such provisions

14 apply to the establishment of the amount

15 of payment under subsection (t)(14)(A).”.

16 **SEC. 105. TREATMENT OF DRUG ADMINISTRATION SERV-**

17 **ICES FURNISHED BY CERTAIN EXCEPTED**

18 **OFF-CAMPUS OUTPATIENT DEPARTMENTS OF**

19 **A PROVIDER.**

20 Section 1833(t)(16) of the Social Security Act (42

21 U.S.C. 1395l(t)(16)) is amended by adding at the end the

22 following new subparagraph:

23 “(G) SPECIAL PAYMENT RULE FOR DRUG

24 ADMINISTRATION SERVICES FURNISHED BY AN

25 EXCEPTED DEPARTMENT OF A PROVIDER.—

1 “(i) IN GENERAL.—In the case of a
2 covered OPD service that is a drug admin-
3 istration service (as defined by the Sec-
4 retary) furnished by a department of a
5 provider described in clause (ii) or (iv) of
6 paragraph (21)(B), the payment amount
7 for such service furnished on or after Jan-
8 uary 1, 2022, shall be the same payment
9 amount (as determined in paragraph
10 (21)(C)) that would apply if the drug ad-
11 ministration service was furnished by an
12 off-campus outpatient department of a pro-
13 vider (as defined in paragraph (21)(B)).

14 “(ii) APPLICATION WITHOUT REGARD
15 TO BUDGET NEUTRALITY.—The reductions
16 made under this subparagraph—

17 “(I) shall not be considered an
18 adjustment under paragraph (2)(E);
19 and

20 “(II) shall not be implemented in
21 a budget neutral manner.”.

1 **Subchapter B—Drug Price Transparency**

2 **SEC. 111. REPORTING ON EXPLANATION FOR DRUG PRICE**
3 **INCREASES.**

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

7 **“PART W—DRUG PRICE REPORTING; DRUG**
8 **VALUE FUND**

9 **“SEC. 3990O. REPORTING ON EXPLANATION FOR DRUG**
10 **PRICE INCREASES.**

11 “(a) DEFINITIONS.—In this section:

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

14 “(A) that holds the application for a drug
15 approved under section 505 of the Federal
16 Food, Drug, and Cosmetic Act or licensed
17 under section 351 of this Act; or

18 “(B) who is responsible for setting the
19 wholesale acquisition cost for the drug.

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

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

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

10 “(ii) administered or otherwise dis-
11 pensed to treat a disease or condition af-
12 fecting more than 200,000 persons in the
13 United States; and

14 “(iii) not a vaccine; and

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

23 “(3) WHOLESALE ACQUISITION COST.—The
24 term ‘wholesale acquisition cost’ has the meaning

1 given that term in section 1847A(c)(6)(B) of the So-
2 cial Security Act (42 U.S.C. 1395w-3a(c)(6)(B)).

3 “(b) REPORT.—

4 “(1) REPORT REQUIRED.—The manufacturer of
5 a qualifying drug shall submit a report to the Sec-
6 retary for each increase in the price of a qualifying
7 drug that results in an increase in the wholesale ac-
8 quisition cost of that drug that is equal to—

9 “(A) 10 percent or more within a single
10 calendar year beginning on or after January 1,
11 2021; or

12 “(B) 25 percent or more within three con-
13 secutive calendar years for which the first such
14 calendar year begins on or after January 1,
15 2021.

16 “(2) REPORT DEADLINE.—Each report de-
17 scribed in paragraph (1) shall be submitted to the
18 Secretary—

19 “(A) in the case of a report with respect
20 to an increase in the price of a qualifying drug
21 that occurs during the period beginning on Jan-
22 uary 1, 2021, and ending on the day that is 60
23 days after the date of enactment of this section,
24 not later than 90 days after such date of enact-
25 ment; and

1 “(B) in the case of a report with respect
2 to an increase in the price of a qualifying drug
3 that occurs after the period described in sub-
4 paragraph (A), not later than 30 days prior to
5 the planned effective date of such price increase
6 for such qualifying drug.

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

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

13 “(A) the percentage by which the manufactur-
14 er will raise the wholesale acquisition cost of
15 the drug within the calendar year or three con-
16 secutive calendar years as described in sub-
17 section (b)(1)(A) or (b)(1)(B), if applicable, and
18 the effective date of such price increase;

19 “(B) an explanation for, and description
20 of, each price increase for such drug that will
21 occur during the calendar year period described
22 in subsection (b)(1)(A) or the three consecutive
23 calendar year period described in subsection
24 (b)(1)(B), as applicable;

1 “(C) if known and different from the man-
2 ufacturer of the qualifying drug, the identity
3 of—

4 “(i) the sponsor or sponsors of any in-
5 vestigational new drug applications under
6 section 505(i) of the Federal Food, Drug,
7 and Cosmetic Act for clinical investigations
8 with respect to such drug, for which the
9 full reports are submitted as part of the
10 application—

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

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

15 “(ii) the sponsor of an application for
16 the drug approved under such section 505
17 of the Federal Food, Drug, and Cosmetic
18 Act or licensed under section 351 of this
19 Act;

20 “(D) a description of the history of the
21 manufacturer’s price increases for the drug
22 since the approval of the application for the
23 drug under section 505 of the Federal Food,
24 Drug, and Cosmetic Act or the issuance of the
25 license for the drug under section 351 of this

1 Act, or since the manufacturer acquired such
2 approved application or license, if applicable;

3 “(E) the current wholesale acquisition cost
4 of the drug;

5 “(F) the total expenditures of the manu-
6 facturer on—

7 “(i) materials and manufacturing for
8 such drug; and

9 “(ii) acquiring patents and licensing
10 for such drug;

11 “(G) the percentage of total expenditures
12 of the manufacturer on research and develop-
13 ment for such drug that was derived from Fed-
14 eral funds;

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

22 “(I) the total expenditures of the manufac-
23 turer on pursuing new or expanded indications
24 or dosage changes for such drug under section

1 505 of the Federal Food, Drug, and Cosmetic
2 Act or section 351 of this Act;

3 “(J) the total expenditures of the manufac-
4 turer on carrying out postmarket requirements
5 related to such drug, including under section
6 505(o)(3) of the Federal Food, Drug, and Cos-
7 metic Act;

8 “(K) the total revenue and the net profit
9 generated from the qualifying drug for each cal-
10 endar year since the approval of the application
11 for the drug under section 505 of the Federal
12 Food, Drug, and Cosmetic Act or the issuance
13 of the license for the drug under section 351,
14 or since the manufacturer acquired such ap-
15 proved application or license; and

16 “(L) the total costs associated with mar-
17 keting and advertising for the qualifying drug;
18 “(2) with respect to the manufacturer—

19 “(A) the total revenue and the net profit
20 of the manufacturer for each of the 1-year pe-
21 riod described in subsection (b)(1)(A) or the 3-
22 year period described in subsection (b)(1)(B),
23 as applicable;

24 “(B) all stock-based performance metrics
25 used by the manufacturer to determine execu-

1 tive compensation for each of the 1-year period
2 described in subsection (b)(1)(A) or the 3-year
3 period described in subsection (b)(1)(B), as ap-
4 plicable; and

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

8 “(i) drug research and development;
9 or

10 “(ii) clinical trials, including on drugs
11 that failed to receive approval by the Food
12 and Drug Administration; and

13 “(3) such other related information as the Sec-
14 retary considers appropriate and as specified by the
15 Secretary through notice-and-comment rulemaking.

16 “(d) INFORMATION PROVIDED.—The manufacturer
17 of a qualifying drug that is required to submit a report
18 under subsection (b), shall ensure that such report and
19 any explanation for, and description of, each price increase
20 described in subsection (c)(1)(B) shall be truthful, not
21 misleading, and accurate.

22 “(e) CIVIL MONETARY PENALTY.—Any manufac-
23 turer of a qualifying drug that fails to submit a report
24 for the drug as required by this section, following notifica-
25 tion by the Secretary to the manufacturer that the manu-

1 factorer is not in compliance with this section, shall be
2 subject to a civil monetary penalty of \$75,000 for each
3 day on which the violation continues.

4 “(f) FALSE INFORMATION.—Any manufacturer that
5 submits a report for a drug as required by this section
6 that knowingly provides false information in such report
7 is subject to a civil monetary penalty in an amount not
8 to exceed \$75,000 for each item of false information.

9 “(g) PUBLIC POSTING.—

10 “(1) IN GENERAL.—Subject to paragraph (3),
11 the Secretary shall post each report submitted under
12 subsection (b) on the public website of the Depart-
13 ment of Health and Human Services the day the
14 price increase of a qualifying drug is scheduled to go
15 into effect.

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

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

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

3 “(3) PROTECTED INFORMATION.—Nothing in
4 this section shall be construed to authorize the pub-
5 lic disclosure of information submitted by a manu-
6 facturer that is prohibited from disclosure by appli-
7 cable laws concerning the protection of trade secrets,
8 commercial information, and other information cov-
9 ered under such laws.

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

11 “(a) IN GENERAL.—Subject to subsection (b), the
12 Secretary shall submit to Congress, and post on the public
13 website of the Department of Health and Human Services
14 in a way that is user-friendly to the public and written
15 in plain language that consumers can readily understand,
16 an annual report—

17 “(1) summarizing the information reported pur-
18 suant to section 39900;

19 “(2) including copies of the reports and sup-
20 porting detailed economic analyses submitted pursu-
21 ant to such section;

22 “(3) detailing the costs and expenditures in-
23 curred by the Department of Health and Human
24 Services in carrying out section 39900; and

1 “(4) explaining how the Department of Health
2 and Human Services is improving consumer and
3 provider information about drug value and drug
4 price transparency.

5 “(b) PROTECTED INFORMATION.—Nothing in this
6 section shall be construed to authorize the public disclo-
7 sure of information submitted by a manufacturer that is
8 prohibited from disclosure by applicable laws concerning
9 the protection of trade secrets, commercial information,
10 and other information covered under such laws.”.

11 (b) EFFECTIVE DATE.—The amendment made by
12 subsection (a) takes effect on the date of enactment of
13 this Act.

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

15 Section 1150A of the Social Security Act (42 U.S.C.
16 1320b–23) is amended—

17 (1) in subsection (e), in the matter preceding
18 paragraph (1), by inserting “(other than as per-
19 mitted under subsection (e))” after “disclosed by the
20 Secretary”; and

21 (2) by adding at the end the following new sub-
22 section:

23 “(e) PUBLIC AVAILABILITY OF CERTAIN INFORMA-
24 TION.—

1 “(1) IN GENERAL.—In order to allow the com-
2 parison of PBMs’ ability to negotiate rebates, dis-
3 counts, direct and indirect remuneration fees, ad-
4 ministrative fees, and price concessions and the
5 amount of such rebates, discounts, direct and indi-
6 rect remuneration fees, administrative fees, and
7 price concessions that are passed through to plan
8 sponsors, beginning January 1, 2022, the Secretary
9 shall make available on the Internet website of the
10 Department of Health and Human Services the in-
11 formation with respect to the second preceding cal-
12 endar year provided to the Secretary on generic dis-
13 pensing rates (as described in paragraph (1) of sub-
14 section (b)) and information provided to the Sec-
15 retary under paragraphs (2) and (3) of such sub-
16 section that, as determined by the Secretary, is with
17 respect to each PBM.

18 “(2) AVAILABILITY OF DATA.—In carrying out
19 paragraph (1), the Secretary shall ensure the fol-
20 lowing:

21 “(A) CONFIDENTIALITY.—The information
22 described in such paragraph is displayed in a
23 manner that prevents the disclosure of informa-
24 tion, with respect to an individual drug or an
25 individual plan, on rebates, discounts, direct

1 and indirect remuneration fees, administrative
2 fees, and price concessions.

3 “(B) CLASS OF DRUG.—The information
4 described in such paragraph is made available
5 by class of drug, using an existing classification
6 system, but only if the class contains such num-
7 ber of drugs, as specified by the Secretary (but
8 not fewer than three drugs), to ensure confiden-
9 tiality of proprietary information or other infor-
10 mation that is prevented to be disclosed under
11 subparagraph (A).”.

12 **SEC. 113. STUDY OF PHARMACEUTICAL SUPPLY CHAIN**
13 **INTERMEDIARIES AND MERGER ACTIVITY.**

14 (a) INITIAL REPORT.—Not later than 1 year after
15 the date of enactment of this Act, the Commission shall
16 submit to the appropriate committees of Congress a report
17 that—

18 (1) addresses at minimum—

19 (A) whether pharmacy benefit managers—

20 (i) charge payers a higher price than
21 the reimbursement rate at which the phar-
22 macy benefit managers reimburse com-
23 peting pharmacies;

24 (ii) steer patients for anticompetitive
25 purposes to any pharmacies, including re-

1 tail, mail-order, or any other type of phar-
2 macy, in which the pharmacy benefit man-
3 ager has an ownership interest;

4 (iii) audit or review proprietary data,
5 including acquisition costs, patient infor-
6 mation, or dispensing information, of com-
7 peting pharmacies that can be used for
8 anticompetitive purposes; or

9 (iv) use formulary designs to increase
10 the market share of higher cost prescrip-
11 tion drugs and depress the market share of
12 lower cost prescription drugs (each net of
13 rebates and discounts);

14 (B) how companies and payers assess the
15 benefits, costs, and risks of contracting with
16 intermediaries, including pharmacy services ad-
17 ministrative organizations, and whether more
18 information about the roles of intermediaries
19 should be available to consumers and payers;
20 and

21 (C) whether there are any specific legal or
22 regulatory obstacles the Commission currently
23 faces in ensuring a competitive and transparent
24 marketplace in the pharmaceutical supply
25 chain, including the pharmacy benefit manager

1 marketplace and pharmacy services administra-
2 tive organizations; and

3 (2) provides—

4 (A) observations or conclusions drawn
5 from the November 2017 roundtable entitled
6 “Understanding Competition in Prescription
7 Drug Markets: Entry and Supply Chain Dy-
8 namics”, and any similar efforts;

9 (B) specific actions the Commission in-
10 tends to take as a result of the November 2017
11 roundtable, and any similar efforts, including a
12 detailed description of relevant forthcoming ac-
13 tions, additional research or roundtable discus-
14 sions, consumer education efforts, or enforce-
15 ment actions; and

16 (C) policy or legislative recommendations
17 to—

18 (i) improve transparency and competi-
19 tion in the pharmaceutical supply chain;

20 (ii) prevent and deter anticompetitive
21 behavior in the pharmaceutical supply
22 chain; and

23 (iii) best ensure that consumers ben-
24 efit from any cost savings or efficiencies

1 that may result from mergers and consoli-
2 dations.

3 (b) INTERIM REPORT.—Not later than 180 days
4 after the date of enactment of this Act, the Commission
5 shall submit to the appropriate committees of Congress
6 an interim report on the progress of the report required
7 by subsection (a), along with preliminary findings and
8 conclusions based on information collected to that date.

9 (c) DEFINITIONS.—In this section:

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

13 (A) the Committee on Energy and Com-
14 merce of the House of Representatives;

15 (B) the Committee on the Judiciary of the
16 Senate; and

17 (C) the Committee on the Judiciary of the
18 House of Representatives.

19 (2) COMMISSION.—The term “Commission”
20 means the Federal Trade Commission.

1 **SEC. 114. MAKING PRESCRIPTION DRUG MARKETING SAM-**
2 **PLE INFORMATION REPORTED BY MANUFAC-**
3 **TURERS AVAILABLE TO CERTAIN INDIVID-**
4 **UALS AND ENTITIES.**

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

7 (1) by redesignating subsection (b) as sub-
8 section (e); and

9 (2) by inserting after subsection (a) the fol-
10 lowing new subsections:

11 “(b) DATA SHARING AGREEMENTS.—

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

16 “(A) upon request of such an individual or
17 entity, as applicable, the Secretary makes avail-
18 able to such individual or entity the information
19 submitted under subsection (a) by manufactur-
20 ers and authorized distributors of record; and

21 “(B) such individual or entity agrees to
22 not disclose publicly or to another individual or
23 entity any information that identifies a par-
24 ticular practitioner or health care facility.

25 “(2) SPECIFIED DATA SHARING INDIVIDUALS
26 AND ENTITIES.—For purposes of paragraph (1), the

1 specified data sharing individuals and entities de-
2 scribed in this paragraph are the following:

3 “(A) OVERSIGHT AGENCIES.—Health over-
4 sight agencies (as defined in section 164.501 of
5 title 45, Code of Federal Regulations), includ-
6 ing the Centers for Medicare & Medicaid Serv-
7 ices, the Office of the Inspector General of the
8 Department of Health and Human Services, the
9 Government Accountability Office, the Congres-
10 sional Budget Office, the Medicare Payment
11 Advisory Commission, and the Medicaid and
12 CHIP Payment and Access Commission.

13 “(B) RESEARCHERS.—Individuals who
14 conduct scientific research (as defined in sec-
15 tion 164.501 of title 45, Code of Federal Regu-
16 lations) in relevant areas as determined by the
17 Secretary.

18 “(C) PAYERS.—Private and public health
19 care payers, including group health plans,
20 health insurance coverage offered by health in-
21 surance issuers, Federal health programs, and
22 State health programs.

23 “(3) EXEMPTION FROM FREEDOM OF INFORMA-
24 TION ACT.—Except as described in paragraph (1),
25 the Secretary may not be compelled to disclose the

1 information submitted under subsection (a) to any
2 individual or entity. For purposes of section 552 of
3 title 5, United States Code (commonly referred to as
4 the Freedom of Information Act), this paragraph
5 shall be considered a statute described in subsection
6 (b)(3)(B) of such section.

7 “(c) PENALTIES.—

8 “(1) DATA SHARING AGREEMENTS.—Subject to
9 paragraph (3), any specified data sharing individual
10 or entity described in subsection (b)(2) that violates
11 the terms of a data sharing agreement the individual
12 or entity has with the Secretary under subsection
13 (b)(1) shall be subject to a civil money penalty of
14 not less than \$1,000, but not more than \$10,000,
15 for each such violation. Such penalty shall be im-
16 posed and collected in the same manner as civil
17 money penalties under subsection (a) of section
18 1128A are imposed and collected under that section.

19 “(2) FAILURE TO REPORT.—Subject to para-
20 graph (3), any manufacturer or authorized dis-
21 tributor of record of an applicable drug under sub-
22 section (a) that fails to submit information required
23 under such subsection in a timely manner in accord-
24 ance with rules or regulations promulgated to carry
25 out such subsection shall be subject to a civil money

1 penalty of not less than \$1,000, but not more than
2 \$10,000, for each such failure. Such penalty shall be
3 imposed and collected in the same manner as civil
4 money penalties under subsection (a) of section
5 1128A are imposed and collected under that section.

6 “(3) LIMITATION.—The total amount of civil
7 money penalties imposed under paragraph (1) or (2)
8 with respect to a year and an individual or entity de-
9 scribed in paragraph (1) or a manufacturer or dis-
10 tributor described in paragraph (2), respectively,
11 shall not exceed \$150,000.

12 “(d) DRUG SAMPLE DISTRIBUTION INFORMATION.—

13 “(1) IN GENERAL.—Not later than January 1
14 of each year (beginning with 2022), the Secretary
15 shall maintain a list containing information related
16 to the distribution of samples of applicable drugs.
17 Such list shall provide the following information with
18 respect to the preceding year:

19 “(A) The name of the manufacturer or au-
20 thorized distributor of record of an applicable
21 drug for which samples were requested or dis-
22 tributed under this section.

23 “(B) The quantity and class of drug sam-
24 ples requested.

1 “(C) The quantity and class of drug sam-
2 ples distributed.

3 “(2) PUBLIC AVAILABILITY.—The Secretary
4 shall make the information in such list available to
5 the public on the Internet website of the Food and
6 Drug Administration.”.

7 (b) FDA MAINTENANCE OF INFORMATION.—The
8 Food and Drug Administration shall maintain information
9 available to affected reporting companies to ensure their
10 ability to fully comply with the requirements of section
11 1128H of the Social Security Act.

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

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

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

18 “(5) No person may distribute a drug sample of a
19 drug that is—

20 “(A) an applicable drug (as defined in section
21 1128H(e) of the Social Security Act);

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

1 “(C) approved under section 505 for use in the
2 management or treatment of pain (other than for
3 the management or treatment of a substance use
4 disorder).”.

5 (d) MEDPAC REPORT.—Not later than 3 years after
6 the date of the enactment of this Act, the Medicare Pay-
7 ment Advisory Commission shall conduct a study on the
8 impact of drug samples on provider prescribing practices
9 and health care costs and may, as the Commission deems
10 appropriate, make recommendations on such study.

11 **SEC. 115. SENSE OF CONGRESS REGARDING THE NEED TO**
12 **EXPAND COMMERCIALLY AVAILABLE DRUG**
13 **PRICING COMPARISON PLATFORMS.**

14 It is the sense of Congress that—

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

19 (2) such platforms should be integrated, to the
20 maximum extent possible, in the health care delivery
21 ecosystem; and

22 (3) pharmacy benefit managers should work to
23 disclose generic and brand name drug prices to such
24 platforms to ensure that—

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

3 (B) overall drug prices can be reduced as
4 more educated purchasing decisions are made
5 based on price transparency.

6 **Subchapter C—Medicare Part D Benefit**
7 **Redesign**

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

9 (a) BENEFIT STRUCTURE REDESIGN.—Section
10 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
11 102(b)) is amended—

12 (1) in paragraph (2)—

13 (A) in subparagraph (A)—

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

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

1 (iii) in clause (ii), by inserting “(or,
2 for 2022 and each subsequent year, 15
3 percent)” after “25 percent”;

4 (B) in subparagraph (C)—

5 (i) in clause (i), in the matter pre-
6 ceding subclause (I), by inserting “for a
7 year preceding 2022,” after “paragraph
8 (4),”; and

9 (ii) in clause (ii)(III), by striking
10 “and each subsequent year” and inserting
11 “and 2021”; and

12 (C) in subparagraph (D)—

13 (i) in clause (i)—

14 (I) in the matter preceding sub-
15 clause (I), by inserting “for a year
16 preceding 2022,” after “paragraph
17 (4),”; and

18 (II) in subclause (I)(bb), by
19 striking “a year after 2018” and in-
20 serting “each of years 2018 through
21 2021”; and

22 (ii) in clause (ii)(V), by striking
23 “2019 and each subsequent year” and in-
24 serting “each of years 2019 through
25 2021”;

1 (2) in paragraph (3)(A)—

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

5 (B) in clause (ii), by striking “for a subse-
6 quent year” and inserting “for each of years
7 2007 through 2021”;

8 (3) in paragraph (4)—

9 (A) in subparagraph (A)—

10 (i) in clause (i)—

11 (I) by redesignating subclauses
12 (I) and (II) as items (aa) and (bb),
13 respectively, and indenting appro-
14 priately;

15 (II) in the matter preceding item
16 (aa), as redesignated by subclause (I),
17 by striking “is equal to the greater
18 of—” and inserting “is equal to—

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

21 (III) by striking the period at the
22 end of item (bb), as redesignated by
23 subclause (I), and inserting “; and”;
24 and

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

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

5 (ii) in clause (ii)—

6 (I) by striking “clause (i)(I)” and
7 inserting “clause (i)(I)(aa)”;

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

15 (B) in subparagraph (B)—

16 (i) in clause (i)—

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

19 (II) in subclause (VI)—

20 (aa) by striking “for a sub-
21 sequent year” and inserting “for
22 2021”; and

23 (bb) by striking the period
24 at the end and inserting a semi-
25 colon; and

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

3 “(VII) for 2022, is equal to
4 \$3,100; or

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

11 (ii) in clause (ii), by striking “clause
12 (i)(II)” and inserting “clause (i)”;

13 (C) in subparagraph (C)(i), by striking
14 “and for amounts” and inserting “and for a
15 year preceding 2022 for amounts”; and

16 (D) in subparagraph (E), by striking “In
17 applying” and inserting “For each of 2011
18 through 2021, in applying”.

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

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

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

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

4 (3) by adding at the end the following new sub-
5 paragraph:

6 “(B) for 2022 and each subsequent year,
7 the sum of—

8 “(i) an amount equal to 20 percent of
9 the allowable reinsurance costs (as speci-
10 fied in paragraph (2)) attributable to that
11 portion of gross covered prescription drug
12 costs as specified in paragraph (3) in-
13 curred in the coverage year after such indi-
14 vidual has incurred costs that exceed the
15 annual out-of-pocket threshold specified in
16 section 1860D–2(b)(4)(B) with respect to
17 applicable drugs (as defined in section
18 1860D–14B(g)(2)); and

19 “(ii) an amount equal to 30 percent of
20 the allowable reinsurance costs (as speci-
21 fied in paragraph (2)) attributable to that
22 portion of gross covered prescription drug
23 costs as specified in paragraph (3) in-
24 curred in the coverage year after such indi-
25 vidual has incurred costs that exceed the

1 annual out-of-pocket threshold specified in
2 section 1860D–2(b)(4)(B) with respect to
3 covered part D drugs that are not applica-
4 ble drugs (as so defined).”.

5 (c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

11 “(a) ESTABLISHMENT.—The Secretary shall estab-
12 lish a manufacturer discount program (in this section re-
13 ferred to as the ‘program’). Under the program, the Sec-
14 retary shall enter into agreements described in subsection
15 (b) with manufacturers and provide for the performance
16 of the duties described in subsection (c). The Secretary
17 shall establish a model agreement for use under the pro-
18 gram by not later than January 1, 2023, in consultation
19 with manufacturers, and allow for comment on such model
20 agreement.

21 “(b) TERMS OF AGREEMENT.—

22 “(1) IN GENERAL.—

23 “(A) AGREEMENT.—An agreement under
24 this section shall require the manufacturer to
25 provide applicable beneficiaries access to dis-

1 counted prices for applicable drugs of the man-
2 ufacturer that are dispensed on or after Janu-
3 ary 1, 2024.

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

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

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

25 “(4) LENGTH OF AGREEMENT.—

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

7 “(B) TERMINATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 “(2) MONITORING COMPLIANCE.—

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

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

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

7 “(d) ADMINISTRATION.—

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

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

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

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

1 individuals or entities the Secretary determines
2 appropriate;

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

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

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

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

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

4 “(e) ENFORCEMENT.—

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

8 “(2) CIVIL MONEY PENALTY.—

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

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

22 “(ii) 25 percent of such amount.

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

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

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

10 “(g) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

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

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

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

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

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

5 “(4) DISCOUNTED PRICE.—

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

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

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

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

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

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

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

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

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

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

6 “(h) SUNSET OF PROGRAM.—

7 “(1) IN GENERAL.—The program shall not
8 apply to applicable drugs dispensed on or after Jan-
9 uary 1, 2024, and, subject to paragraph (2), agree-
10 ments under this section shall be terminated as of
11 such date.

12 “(2) CONTINUED APPLICATION FOR APPLICA-
13 BLE DRUGS DISPENSED PRIOR TO SUNSET.—The
14 provisions of this section (including all responsibil-
15 ities and duties) shall continue to apply after Janu-
16 ary 1, 2024, with respect to applicable drugs dis-
17 pensed prior to such date.”.

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

22 (A) in subsection (b)(2)(C)(iii)—

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

1 “(I) the reinsurance”; and
2 (ii) by adding at the end the fol-
3 lowing:

4 “(II) for 2024 and each subse-
5 quent year, the manufacturer dis-
6 counts provided under section 1860D-
7 14B subtracted from the actuarial
8 value to produce such bid; and”; and
9 (B) in subsection (c)(1)(C)—

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

13 “(i) the reinsurance”;

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

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

19 “(ii) for 2024 and each subsequent
20 year, the manufacturer discounts provided
21 under section 1860D-14B;”.

22 (4) CLARIFICATION REGARDING EXCLUSION OF
23 MANUFACTURER DISCOUNTS FROM TROOP.—Section
24 1860D-2(b)(4) of the Social Security Act (42
25 U.S.C. 1395w-102(b)(4)) is amended—

1 (A) in subparagraph (C), by inserting “and
2 subject to subparagraph (F)” after “subpara-
3 graph (E)”; and

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

6 “(F) CLARIFICATION REGARDING EXCLU-
7 SION OF MANUFACTURER DISCOUNTS.—In ap-
8 plying subparagraph (A), incurred costs shall
9 not include any manufacturer discounts pro-
10 vided under section 1860D–14B.”.

11 (d) DETERMINATION OF ALLOWABLE REINSURANCE
12 COSTS.—Section 1860D–15(b) of the Social Security Act
13 (42 U.S.C. 1395w–115(b)) is amended—

14 (1) in paragraph (2)—

15 (A) by striking “COSTS.—For purposes”
16 and inserting “COSTS.—

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

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

21 “(B) INCLUSION OF MANUFACTURER DIS-
22 COUNTS ON APPLICABLE DRUGS.—For purposes
23 of applying subparagraph (A), the term ‘allow-
24 able reinsurance costs’ shall include the portion
25 of the negotiated price (as defined in section

1 1860D–14B(g)(6)) of an applicable drug (as
2 defined in section 1860D–14(g)(2)) that was
3 paid by a manufacturer under the manufacturer
4 discount program under section 1860D–14B.”;
5 and

6 (2) in paragraph (3)—

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

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

14 (e) UPDATING RISK ADJUSTMENT METHODOLOGIES
15 TO ACCOUNT FOR PART D MODERNIZATION REDESIGN.—

16 Section 1860D–15(c) of the Social Security Act (42
17 U.S.C. 1395w–115(e)) is amended by adding at the end
18 the following new paragraph:

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

1 subtitle B of title I of the Act titled ‘An Act to pro-
2 vide for reconciliation pursuant to title II of S. Con.
3 Res. 14’.’.

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

7 (1) in subsection (a)—

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

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

12 (C) by adding at the end the following new
13 paragraphs:

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

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

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

24 (2) by striking subsection (b) and inserting the
25 following:

1 “(b) EFFECTIVE DATE.—Paragraphs (1) through (3)
2 of subsection (a) shall apply to covered part D drugs dis-
3 pensed under this part on or after January 1, 2011, and
4 before January 1, 2024, and paragraphs (4) through (6)
5 of such subsection shall apply to covered part D drugs
6 dispensed on or after January 1, 2024.”; and

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

9 “(2) the Secretary determines that in the period
10 beginning on January 1, 2011, and ending on De-
11 cember 31, 2011 (with respect to paragraphs (1)
12 through (3) of subsection (a)) or the period begin-
13 ning on January 1, 2024, and ending December 31,
14 2024 (with respect to paragraphs (4) through (6) of
15 such subsection), there were extenuating cir-
16 cumstances.”.

17 (g) CONFORMING AMENDMENTS.—

18 (1) Section 1860D–2 of the Social Security Act
19 (42 U.S.C. 1395w–102) is amended—

20 (A) in subsection (a)(2)(A)(i)(I), by strik-
21 ing “, or an increase in the initial” and insert-
22 ing “or for a year preceding 2024 an increase
23 in the initial”;

24 (B) in subsection (c)(1)(C)—

1 (i) in the subparagraph heading, by
2 striking “AT INITIAL COVERAGE LIMIT”;
3 and

4 (ii) by inserting “for a year preceding
5 2024 or the annual out-of-pocket threshold
6 specified in subsection (b)(4)(B) for the
7 year for 2024 and each subsequent year”
8 after “subsection (b)(3) for the year” each
9 place it appears; and

10 (C) in subsection (d)(1)(A), by striking “or
11 an initial” and inserting “or for a year pre-
12 ceding 2024, an initial”.

13 (2) Section 1860D–4(a)(4)(B)(i) of the Social
14 Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is
15 amended by striking “the initial” and inserting “for
16 a year preceding 2024, the initial”.

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

19 (A) in paragraph (1)—

20 (i) in subparagraph (C), by striking
21 “The continuation” and inserting “For a
22 year preceding 2024, the continuation”;

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

1 (iii) in subparagraph (E), by striking
2 “The elimination” and inserting “For a
3 year preceding 2024, the elimination”; and
4 (B) in paragraph (2)—

5 (i) in subparagraph (C), by striking
6 “The continuation” and inserting “For a
7 year preceding 2024, the continuation”;
8 and

9 (ii) in subparagraph (E)—
10 (I) by inserting “for a year pre-
11 ceding 2024,” after “subsection (e)”;
12 and

13 (II) by striking “1860D-
14 2(b)(4)(A)(i)(I)” and inserting
15 “1860D-2(b)(4)(A)(i)(I)(aa)”.

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

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

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

1 “(i) for years prior to 2024, any dis-
2 count”;

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

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

8 “(ii) for 2024 and each subsequent
9 year, any discount provided pursuant to
10 section 1860D–14B.”.

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

13 (A) by inserting “for a year before 2024”
14 after “1860D–2(b)(3)”; and

15 (B) by inserting “for such year” before the
16 period.

17 (h) EFFECTIVE DATE.—The amendments made by
18 this section shall apply to plan year 2024 and subsequent
19 plan years.

1 **Subchapter D—Other Medicare Part D**
2 **Provisions**

3 **SEC. 131. ALLOWING THE OFFERING OF ADDITIONAL PRE-**
4 **SCRIPTION DRUG PLANS UNDER MEDICARE**
5 **PART D.**

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

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

17 (2) issue new guidance specifying that a PDP
18 sponsor may offer up to 4 (or a greater number if
19 determined appropriate by the Secretary) prescrip-
20 tion drug plans in each PDP region, except in cases
21 where the PDP sponsor may offer up to 2 additional
22 plans in a PDP region pursuant to section 1860D–
23 11(d)(4) of the Social Security Act (42 U.S.C.
24 1395w–111(d)(4)), as added by subsection (b).

1 (b) OFFERING OF ADDITIONAL PLANS.—Section
2 1860D–11(d) of the Social Security Act (42 U.S.C.
3 1395w–111(d)) is amended by adding at the end the fol-
4 lowing new paragraph:

5 “(4) OFFERING OF ADDITIONAL PLANS.—

6 “(A) IN GENERAL.—For plan year 2022
7 and each subsequent plan year, a PDP sponsor
8 may offer up to 2 additional prescription drug
9 plans in a PDP region (in addition to any limit
10 established by the Secretary under this part)
11 provided that the PDP sponsor complies with
12 subparagraph (B) with respect to at least one
13 such prescription drug plan.

14 “(B) REQUIREMENTS.—In order to be eli-
15 gible to offer up to 2 additional plans in a PDP
16 region pursuant to subparagraph (A), a PDP
17 sponsor must ensure that, with respect to at
18 least one such prescription drug plan, the spon-
19 sor or any entity that provides pharmacy bene-
20 fits management services under a contract with
21 any such sponsor or plan does not receive direct
22 or indirect remuneration, as defined in section
23 423.308 of title 42, Code of Federal Regula-
24 tions (or any successor regulation), unless at
25 least 25 percent of the aggregate reductions in

1 price or other remuneration received by the
2 PDP sponsor or entity from drug manufactur-
3 ers with respect to the plan and plan year—

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

6 “(ii) are used to reduce total bene-
7 ficiary cost-sharing estimated by the PDP
8 sponsor for prescription drug coverage
9 under the plan in the annual bid submitted
10 by the PDP sponsor under section 1860D-
11 11(b).

12 “(C) DEFINITION OF REDUCTIONS IN
13 PRICE.—For purposes of subparagraph (B), the
14 term ‘reductions in price’ refers only to collect-
15 ible amounts, as determined by the Secretary,
16 which excludes amounts which after adjudica-
17 tion and reconciliation with pharmacies and
18 manufacturers are duplicate in nature, contrary
19 to other contractual clauses, or otherwise ineli-
20 gible (such as due to beneficiary disenrollment
21 or coordination of benefits).”.

22 (c) RULE OF CONSTRUCTION.—Nothing in the provi-
23 sions of, or amendments made by, this section shall be
24 construed as limiting the ability of the Secretary to in-
25 crease any limit otherwise applicable on the number of

1 prescription drug plans that a PDP sponsor may offer,
2 at the discretion of the PDP sponsor, in a PDP region
3 under part D of title XVIII of the Social Security Act (42
4 U.S.C. 1395w–101 et seq.).

5 **SEC. 132. ALLOWING CERTAIN ENROLLEES OF PRESCRIP-**
6 **TION DRUG PLANS AND MA-PD PLANS UNDER**
7 **MEDICARE PROGRAM TO SPREAD OUT COST-**
8 **SHARING UNDER CERTAIN CIRCUMSTANCES.**

9 (a) STANDARD PRESCRIPTION DRUG COVERAGE.—
10 Section 1860D–2(b)(2) of the Social Security Act (42
11 U.S.C. 1395w–102(b)(2)), as amended by section 121, is
12 further amended—

13 (1) in subparagraph (A), by striking “Subject
14 to subparagraphs (C) and (D)” and inserting “Sub-
15 ject to subparagraphs (C), (D), and (E)”; and

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

18 “(E) ENROLLEE OPTION REGARDING
19 SPREADING COST-SHARING.—

20 “(i) IN GENERAL.—The Secretary
21 shall establish by regulation a process
22 under which, with respect to plan year
23 2022 and subsequent plan years, a pre-
24 scription drug plan or an MA–PD plan
25 shall, in the case of a part D eligible indi-

1 vidual enrolled with such plan for such
2 plan year with respect to whom the plan
3 projects that the dispensing of a covered
4 part D drug to such individual will result
5 in the individual incurring costs within a
6 30-day period that are equal to a signifi-
7 cant percentage (as specified by the Sec-
8 retary pursuant to such regulation) of the
9 annual out-of-pocket threshold specified in
10 paragraph (4)(B) for such plan year, pro-
11 vide such individual with the option to
12 make the coinsurance payment required
13 under subparagraph (A) for such costs in
14 the form of equal monthly installments
15 over the remainder of such plan year.

16 “(ii) SIGNIFICANT PERCENTAGE LIM-
17 TATIONS.—In specifying a significant per-
18 centage pursuant to the regulation estab-
19 lished by the Secretary under clause (i),
20 the Secretary may not specify a percentage
21 that is less than 30 percent or greater
22 than 100 percent.”.

23 (b) ALTERNATIVE PRESCRIPTION DRUG COV-
24 ERAGE.—Section 1860D–2(c) of the Social Security Act

1 (42 U.S.C. 1395w–102(c)) is amended by adding at the
2 end the following new paragraph:

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

9 **SEC. 133. ESTABLISHING A MONTHLY CAP ON BENEFICIARY**
10 **INCURRED COSTS FOR INSULIN PRODUCTS**
11 **AND SUPPLIES UNDER A PRESCRIPTION**
12 **DRUG PLAN OR MA–PD PLAN.**

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

16 (1) in subsection (b)(2)—

17 (A) in subparagraph (A), by striking “and
18 (E)” and inserting “(E), and (F)”;

19 (B) in subparagraph (B), by striking “and
20 (D)” and inserting “(D), and (F)”;

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

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

1 “(i) IN GENERAL.—The coverage pro-
2 vides benefits, for costs above the annual
3 deductible specified in paragraph (1) and
4 up to the annual out-of-pocket threshold
5 described in paragraph (4)(B) and with re-
6 spect to a month (beginning with January
7 of 2022), with cost sharing that is equal to
8 \$0 for a specified covered part D drug (as
9 defined in clause (iii)) furnished to an indi-
10 vidual who has incurred costs during such
11 month with respect to specified covered
12 part D drugs equal to—

13 “(I) for months occurring in
14 2022, \$50; or

15 “(II) for months occurring in a
16 subsequent year, the amount applica-
17 ble under this clause for months oc-
18 curring in the year preceding such
19 subsequent year, increased by the an-
20 nual percentage increase specified in
21 paragraph (6) for such subsequent
22 year and rounded to the nearest dol-
23 lar.

24 “(ii) APPLICATION.—The provisions
25 of clauses (i) through (iii) of paragraph

1 (4)(C) shall apply with respect to the de-
2 termination of the incurred costs for speci-
3 fied covered part D drugs for purposes of
4 clause (i) in the same manner as such pro-
5 visions apply with respect to the deter-
6 mination of incurred costs for covered part
7 D drugs for purposes of paragraph (4)(A).

8 “(iii) SPECIFIED COVERED PART D
9 DRUG.—For purposes of this subpara-
10 graph, the term ‘specified covered part D
11 drug’ means a covered part D drug that
12 is—

13 “(I) insulin; or

14 “(II) a medical supply associated
15 with the injection of insulin (as de-
16 fined in regulations of the Secretary
17 promulgated pursuant to subsection
18 (e)(1)(B)).”; and

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

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

25 (b) CONFORMING AMENDMENTS.—

1 (1) IN GENERAL.—Section 1860D–14(a)(1)(D)
2 of the Social Security Act (42 U.S.C. 1395w–
3 114(a)(1)(D)), as amended by section 121, is fur-
4 ther amended—

5 (A) in clause (ii), by striking “section
6 1860D–2(b)(2)” and inserting “section 1860D–
7 2(b)(2)(A)”; and

8 (B) in clause (iii), by striking “section
9 1860D–2(b)(2)” and inserting “section 1860D–
10 2(b)(2)(A)”.

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

14 **SEC. 134. GROWTH RATE OF MEDICARE PART D OUT-OF-**
15 **POCKET COST THRESHOLD.**

16 (a) PROVIDING MEDICARE PART D BENEFICIARIES
17 WITH CERTAIN 2020 OFFSET PAYMENTS.—Section
18 1860D–2(b)(4) of the Social Security Act (42 U.S.C.
19 1395w–102(b)(4)) is amended by adding at the end the
20 following new subparagraph:

21 “(F) 2020 OFFSET PAYMENTS.—

22 “(i) IN GENERAL.—Subject to clause
23 (iv), the Secretary shall provide for pay-
24 ment from the Medicare Prescription Drug
25 Account as follows:

1 “(I) In the case of a specified in-
2 dividual (as defined in clause (ii)(I))
3 who as of the last day of a calendar
4 quarter in 2020 has incurred costs for
5 covered part D drugs so that the indi-
6 vidual has exceeded the annual out-of-
7 pocket threshold applied under sub-
8 paragraph (B)(i)(V) for 2020, pay-
9 ment to the individual by not later
10 than 15th day of the third month fol-
11 lowing the end of such quarter of the
12 amount by which such threshold so
13 applied exceeded the target threshold
14 for 2020.

15 “(II) In the case of a specified
16 individual who is not described in sub-
17 clause (I) and who as of the last day
18 of 2020 has incurred costs for covered
19 part D drugs so that the individual
20 has exceeded the target threshold for
21 2020, payment to the individual by
22 not later than December 31, 2021, of
23 the amount by which such incurred
24 costs exceeded the target threshold for
25 2020.

1 “(ii) DEFINITIONS.—For purposes of
2 this subparagraph:

3 “(I) SPECIFIED INDIVIDUAL.—
4 The term ‘specified individual’ means
5 an individual who—

6 “(aa) is enrolled in a pre-
7 scription drug plan or an MA-
8 PD plan;

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

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

15 “(II) TARGET THRESHOLD FOR
16 2020.—The term ‘target threshold for
17 2020’ means the annual out-of-pocket
18 threshold that would have been ap-
19 plied under subparagraph (B)(i) for
20 2020 if such threshold had been de-
21 termined in accordance with subclause
22 (IV) of such subparagraph instead of
23 subclause (V) of such subparagraph.

24 “(iii) NOTIFICATION.—In the case of
25 any specified individual who during 2020

1 has incurred costs for covered part D
2 drugs so that the individual has exceeded
3 the target threshold for 2020, the Sec-
4 retary shall, not later than September 30,
5 2021, provide to such individual a notifica-
6 tion informing such individual of such indi-
7 vidual’s right to a payment described in
8 clause (i) and the estimated timing of such
9 payment.

10 “(iv) CLARIFICATION.—The Secretary
11 shall provide only 1 payment under this
12 subparagraph with respect to any indi-
13 vidual.

14 “(v) IMPLEMENTATION.—The Sec-
15 retary may implement this subparagraph
16 by program instruction or otherwise.”.

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

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

23 (2) by redesignating subclause (VI) as sub-
24 clause (VIII); and

1 (3) by inserting after subclause (V) the fol-
2 lowing new subclauses:

3 “(VI) for 2021, is equal to the
4 amount that would have been applied
5 under this subparagraph for 2020 if
6 such amount had been determined in
7 accordance with subclause (IV) in-
8 stead of subclause (V), increased by
9 the lesser of—

10 “(aa) the annual percentage
11 increase described in paragraph
12 (7) for 2021, plus 2 percentage
13 points; or

14 “(bb) the annual percentage
15 increase described in paragraph
16 (6) for 2021;

17 “(VII) for 2022, is equal to the
18 amount that would have been applied
19 under this subparagraph for 2022 if
20 the amendments made by section
21 1101(d)(1) of the Health Care and
22 Education Reconciliation Act of 2010
23 and by section 134 of subtitle B of
24 title I of the Act titled ‘An Act to pro-
25 vide for reconciliation pursuant to

1 title II of S. Con. Res. 14' had not
2 been enacted; or”.

3 **CHAPTER 2—MEDICAID**

4 **SEC. 201. MEDICAID PHARMACY AND THERAPEUTICS COM-**
5 **MITTEE IMPROVEMENTS.**

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

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

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

18 “(I) is publicly accessible;

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

1 “(III) contains clear processes, such
2 as recusal from voting or discussion, for
3 those members who report a conflict of in-
4 terest, along with appropriate processes to
5 address any instance where a member fails
6 to report a conflict of interest.

7 “(iii) The membership of the pharmacy
8 and therapeutics committee—

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

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

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

23 “(II) is made publicly available.

24 “(iv) At the option of the State, the
25 State’s drug use review board established under

1 subsection (g)(3) may serve as the pharmacy
2 and therapeutics committee provided the State
3 ensures that such board meets the requirements
4 of clauses (ii) and (iii).

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

8 “(vi) If the Secretary determines it appro-
9 priate or necessary based on the findings and
10 recommendations of the Comptroller General of
11 the United States in the report submitted to
12 Congress under section 203 of subtitle B of
13 title I of the Act titled ‘An Act to provide for
14 reconciliation pursuant to title II of S. Con.
15 Res. 14’, the Secretary shall issue guidance
16 that States must follow for establishing conflict
17 of interest policies for the pharmacy and thera-
18 peutics committee in accordance with the re-
19 quirements of clause (ii), including appropriate
20 standards and requirements for identifying, ad-
21 dressing, and reporting on conflicts of inter-
22 est.’”.

23 (b) APPLICATION TO MEDICAID MANAGED CARE OR-
24 GANIZATIONS.—Clause (xiii) of section 1903(m)(2)(A) of

1 the Social Security Act (42 U.S.C. 1396b(m)(2)(A)) is
2 amended—

3 (1) by striking “and (III)” and inserting
4 “(III)”;

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

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

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

17 **SEC. 202. GAO REPORT ON CONFLICTS OF INTEREST IN**
18 **STATE MEDICAID PROGRAM DRUG USE RE-**
19 **VIEW BOARDS AND PHARMACY AND THERA-**
20 **PEUTICS (P&T) COMMITTEES.**

21 (a) INVESTIGATION.—The Comptroller General of the
22 United States shall conduct an investigation of potential
23 or existing conflicts of interest among members of State
24 Medicaid program State drug use review boards (in this
25 section referred to as “DUR Boards”) and pharmacy and

1 therapeutics committees (in this section referred to as
2 “P&T Committees”).

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

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

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

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

18 (C) States that allow Medicaid MCOs to
19 have their own P&T Committees and the extent
20 to which pharmacy benefit managers administer
21 or participate in such P&T Committees.

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

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

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

12 (5) A description outlining how States, DUR
13 Boards, or P&T Committees define conflicts of inter-
14 est.

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

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

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

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

11 **SEC. 203. ENSURING THE ACCURACY OF MANUFACTURER**
12 **PRICE AND DRUG PRODUCT INFORMATION**
13 **UNDER THE MEDICAID DRUG REBATE PRO-**
14 **GRAM.**

15 (a) AUDIT OF MANUFACTURER PRICE AND DRUG
16 PRODUCT INFORMATION.—

17 (1) IN GENERAL.—Subparagraph (B) of section
18 1927(b)(3) of the Social Security Act (42 U.S.C.
19 1396r-8(b)(3)) is amended to read as follows:

20 “(B) AUDITS AND SURVEYS OF MANUFAC-
21 TURER PRICE AND DRUG PRODUCT INFORMA-
22 TION.—

23 “(i) AUDITS.—The Secretary shall
24 conduct ongoing audits of the price and
25 drug product information reported by man-

1 ufacturers under subparagraph (A) for the
2 most recently ended rebate period to en-
3 sure the accuracy and timeliness of such
4 information. In conducting such audits, the
5 Secretary may employ evaluations, surveys,
6 statistical sampling, predictive analytics
7 and other relevant tools and methods.

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

22 “(iii) PENALTIES.—In addition to
23 other penalties as may be prescribed by
24 law, including under subparagraph (C) of
25 this paragraph, the Secretary may impose

1 a civil monetary penalty in an amount not
2 to exceed \$185,000 on an annual basis on
3 a wholesaler, manufacturer, or direct sell-
4 er, if the wholesaler, manufacturer, or di-
5 rect seller of a covered outpatient drug re-
6 fuses a request for information about
7 charges or prices by the Secretary in con-
8 nection with an audit or survey under this
9 subparagraph or knowingly provides false
10 information. The provisions of section
11 1128A (other than subsections (a) (with
12 respect to amounts of penalties or addi-
13 tional assessments) and (b)) shall apply to
14 a civil money penalty under this clause in
15 the same manner as such provisions apply
16 to a penalty or proceeding under section
17 1128A(a).

18 “(iv) REPORTS.—

19 “(I) REPORT TO CONGRESS.—

20 The Secretary shall, not later than 18
21 months after date of enactment of
22 this subparagraph, submit a report to
23 the Committee on Energy and Com-
24 merce of the House of Representatives
25 and the Committee on Finance of the

1 Senate regarding additional regulatory
2 or statutory changes that may be re-
3 quired in order to ensure accurate and
4 timely reporting and oversight of
5 manufacturer price and drug product
6 information, including whether
7 changes should be made to reasonable
8 assumption requirements to ensure
9 such assumptions are reasonable and
10 accurate or whether another method-
11 ology for ensuring accurate and timely
12 reporting of price and drug product
13 information should be considered to
14 ensure the integrity of the drug rebate
15 program under this section.

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

1 “(III) CONTENT.—Each report
2 submitted under subclause (II) shall,
3 with respect to the period that is the
4 subject of the report, include sum-
5 maries of—

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

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

17 “(cc) the number of manu-
18 facturers, wholesalers, and direct
19 sellers and drug products audited
20 under this subparagraph;

21 “(dd) the types of price and
22 drug product information re-
23 viewed under the audits con-
24 ducted under this subparagraph;

1 “(ee) the tools and meth-
2 odologies employed in such au-
3 dits;

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

8 “(gg) such other relevant in-
9 formation as the Secretary shall
10 deem appropriate.

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

18 “(v) APPROPRIATIONS.—Out of any
19 funds in the Treasury not otherwise appro-
20 priated, there is appropriated to the Sec-
21 retary \$2,000,000 for fiscal year 2022 and
22 each fiscal year thereafter to carry out this
23 subparagraph.”.

24 (2) EFFECTIVE DATE.—The amendments made
25 by this subsection shall take effect on the first day

1 of the first fiscal quarter that begins after the date
2 of enactment of this Act.

3 (b) INCREASED PENALTIES FOR NONCOMPLIANCE
4 WITH REPORTING REQUIREMENTS.—

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

17 (2) INCREASED PENALTY FOR KNOWINGLY RE-
18 PORTING FALSE INFORMATION.—Section
19 1927(b)(3)(C)(ii) of the Social Security Act (42
20 U.S.C. 1396r–8(b)(3)(C)(ii)) is amended by striking
21 “\$100,000” and inserting “\$500,000”.

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

1 **SEC. 204. IMPROVING TRANSPARENCY AND PREVENTING**
2 **THE USE OF ABUSIVE SPREAD PRICING AND**
3 **RELATED PRACTICES IN MEDICAID.**

4 (a) PASS-THROUGH PRICING REQUIRED.—

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

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

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

23 “(i) is limited to—

24 “(I) ingredient cost; and

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

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

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

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

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

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

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

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

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

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

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

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

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

12 (b) SURVEY OF RETAIL PRICES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 “(H) PENALTIES.—

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

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

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

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

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

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

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

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

5 (C) in paragraph (2)—

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

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

13 (D) in paragraph (4), by inserting “, and
14 \$5,000,000 for fiscal year 2022 and each fiscal
15 year thereafter,” after “2010”.

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

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

24 (1) in subparagraph (A)(i)—

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

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

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

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

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

19 (2) in subparagraph (D)—

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

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

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

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

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

15 **SEC. 205. T-MSIS DRUG DATA ANALYTICS REPORTS.**

16 (a) IN GENERAL.—Not later than May 1 of each cal-
17 endar year beginning with calendar year 2023, the Sec-
18 retary of Health and Human Services (in this section re-
19 ferred to as the “Secretary”) shall publish on a website
20 of the Centers for Medicare & Medicaid Services that is
21 accessible to the public a report of the most recently avail-
22 able data on provider prescribing patterns under the Med-
23 icaid program.

24 (b) CONTENT OF REPORT.—

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

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

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

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

20 (iii) by episodes of care for—

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

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

3 (II) procedural groupings; and

4 (III) rare disease diagnosis codes;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 “(2) SECRETARIAL APPROVAL.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 whether to approve a request from a State
2 for approval of a proposed risk-sharing
3 value-based payment agreement (or request
4 additional information necessary to allow
5 the Secretary to make a determination
6 with respect to such request for approval)
7 within the time period, to the extent prac-
8 ticable, specified in section 430.16 of title
9 42, Code of Federal Regulations (as in ef-
10 fect on the date of enactment of this sub-
11 section), but in no case shall the Secretary
12 take more than 180 days after the receipt
13 of such request for approval or response to
14 such request for additional information to
15 make such a determination (or request ad-
16 ditional information).

17 “(C) CONSULTATION WITH THE COMMIS-
18 SIONER OF FOOD AND DRUGS.—In considering
19 whether to approve a risk-sharing value-based
20 payment agreement, the Secretary, to the ex-
21 tent necessary, shall consult with the Commis-
22 sioner of Food and Drugs to determine whether
23 the relevant clinical parameters specified in
24 such agreement are appropriate.

1 “(3) INSTALLMENT-BASED PAYMENT STRUC-
2 TURE.—

3 “(A) IN GENERAL.—A risk-sharing value-
4 based payment agreement shall provide for a
5 payment structure under which, for every in-
6 stallment year of the agreement (subject to sub-
7 paragraph (B)), the State shall pay the total in-
8 stallment year amount in equal installments to
9 be paid at regular intervals over a period of
10 time that shall be specified in the agreement.

11 “(B) REQUIREMENTS FOR INSTALLMENT
12 PAYMENTS.—

13 “(i) TIMING OF FIRST PAYMENT.—
14 The State shall make the first of the in-
15 stallment payments described in subpara-
16 graph (A) for an installment year not later
17 than 30 days after the end of such year.

18 “(ii) LENGTH OF INSTALLMENT PE-
19 RIOD.—The period of time over which the
20 State shall make the installment payments
21 described in subparagraph (A) for an in-
22 stallment year shall not be longer than 5
23 years.

24 “(iii) NONPAYMENT OR REDUCED
25 PAYMENT OF INSTALLMENTS FOLLOWING

1 A FAILURE TO MEET CLINICAL PARAM-
2 ETER.—If, prior to the payment date (as
3 specified in the agreement) of any install-
4 ment payment described in subparagraph
5 (A) or any other alternative date or time
6 frame (as otherwise specified in the agree-
7 ment), the covered outpatient drug which
8 is subject to the agreement fails to meet a
9 relevant clinical parameter of the agree-
10 ment, the agreement shall provide that—

11 “(I) the installment payment
12 shall not be made; or

13 “(II) the installment payment
14 shall be reduced by a percentage spec-
15 ified in the agreement that is based
16 on the outcome achieved by the drug
17 relative to the relevant clinical param-
18 eter.

19 “(4) NOTICE OF INTENT.—

20 “(A) IN GENERAL.—Subject to subpara-
21 graph (B), a manufacturer of a covered out-
22 patient drug shall not be eligible to enter into
23 a risk-sharing value-based payment agreement
24 under this subsection with respect to such drug
25 unless the manufacturer notifies the Secretary

1 that the manufacturer is interested in entering
2 into such an agreement with respect to such
3 drug. The decision to submit and timing of a
4 request to enter into a proposed risk-sharing
5 value-based payment agreement shall remain
6 solely within the discretion of the State and
7 shall only be effective upon Secretarial approval
8 as required under this subsection.

9 “(B) TREATMENT OF SUBSEQUENTLY AP-
10 PROVED DRUGS.—

11 “(i) IN GENERAL.—In the case of a
12 manufacturer of a covered outpatient drug
13 approved under section 505 of the Federal
14 Food, Drug, and Cosmetic Act or licensed
15 under section 351 of the Public Health
16 Service Act after the date of enactment of
17 this subsection, not more than 90 days
18 after meeting with the Food and Drug Ad-
19 ministration following phase II clinical
20 trials for such drug (or, in the case of a
21 drug described in clause (ii), not later than
22 March 31, 2022), the manufacturer must
23 notify the Secretary of the manufacturer’s
24 intent to enter into a risk-sharing value-
25 based payment agreement under this sub-

1 section with respect to such drug. If no
2 such meeting has occurred, the Secretary
3 may use discretion as to whether a poten-
4 tially curative treatment intended for one-
5 time use may qualify for a risk-sharing
6 value-based payment agreement under this
7 section. A manufacturer notification of in-
8 terest shall not have any influence on a de-
9 cision for approval by the Food and Drug
10 Administration.

11 “(ii) APPLICATION TO CERTAIN SUB-
12 SEQUENTLY APPROVED DRUGS.—A drug
13 described in this clause is a covered out-
14 patient drug of a manufacturer—

15 “(I) that is approved under sec-
16 tion 505 of the Federal Food, Drug,
17 and Cosmetic Act or licensed under
18 section 351 of the Public Health Serv-
19 ice Act after the date of enactment of
20 this subsection; and

21 “(II) with respect to which, as of
22 January 1, 2022, more than 90 days
23 have passed after the manufacturer’s
24 meeting with the Food and Drug Ad-

1 ministration following phase II clinical
2 trials for such drug.

3 “(iii) PARALLEL APPROVAL.—The
4 Secretary, in coordination with the Admin-
5 istrator of the Centers for Medicare &
6 Medicaid Services and the Commissioner of
7 Food and Drugs, shall, to the extent prac-
8 ticable, approve a State’s request to enter
9 into a proposed risk-sharing value-based
10 payment agreement that otherwise meets
11 the requirements of this subsection at the
12 time that such a drug is approved by the
13 Food and Drug Administration to help
14 provide that no State that wishes to enter
15 into such an agreement is required to pay
16 for the drug in full at one time if the State
17 is seeking to pay over a period of time as
18 outlined in the proposed agreement.

19 “(iv) RULE OF CONSTRUCTION.—
20 Nothing in this paragraph shall be applied
21 or construed to modify or affect the time-
22 frames or factors involved in the Sec-
23 retary’s determination of whether to ap-
24 prove or license a drug under section 505
25 of the Federal Food, Drug, and Cosmetic

1 Act or section 351 of the Public Health
2 Service Act.

3 “(5) SPECIAL PAYMENT RULES.—

4 “(A) IN GENERAL.—Except as otherwise
5 provided in this paragraph, with respect to an
6 individual who is administered a unit of a cov-
7 ered outpatient drug that is purchased under a
8 State plan by a State Medicaid agency under a
9 risk-sharing value-based payment agreement in
10 an installment year, the State shall remain lia-
11 ble to the manufacturer of such drug for pay-
12 ment for such unit without regard to whether
13 the individual remains enrolled in the State
14 plan under this title (or a waiver of such plan)
15 for each installment year for which the State is
16 to make installment payments for covered out-
17 patient drugs purchased under the agreement
18 in such year.

19 “(B) DEATH.—In the case of an individual
20 described in subparagraph (A) who dies during
21 the period described in such subparagraph, the
22 State plan shall not be liable for any remaining
23 payment for the unit of the covered outpatient
24 drug administered to the individual which is

1 owed under the agreement described in such
2 subparagraph.

3 “(C) WITHDRAWAL OF APPROVAL.—In the
4 case of a covered outpatient drug that is the
5 subject of a risk-sharing value-based agreement
6 between a State and a manufacturer under this
7 subsection, including a drug approved in ac-
8 cordance with section 506(c) of the Federal
9 Food, Drug, and Cosmetic Act, and such drug
10 is the subject of an application that has been
11 withdrawn by the Secretary, the State plan
12 shall not be liable for any remaining payment
13 that is owed under the agreement.

14 “(D) ALTERNATIVE ARRANGEMENT UNDER
15 AGREEMENT.—Subject to approval by the Sec-
16 retary, the terms of a proposed risk-sharing
17 value-based payment agreement submitted for
18 approval by a State may provide that subpara-
19 graph (A) shall not apply.

20 “(E) GUIDANCE.—Not later than January
21 1, 2022, the Secretary shall issue guidance to
22 States establishing a process for States to no-
23 tify the Secretary when an individual who is ad-
24 ministered a unit of a covered outpatient drug
25 that is purchased by a State plan under a risk-

1 sharing value-based payment agreement ceases
2 to be enrolled under the State plan under this
3 title (or a waiver of such plan) or dies before
4 the end of the installment period applicable to
5 such unit under the agreement.

6 “(6) TREATMENT OF PAYMENTS UNDER RISK-
7 SHARING VALUE-BASED AGREEMENTS FOR PUR-
8 POSES OF AVERAGE MANUFACTURER PRICE; BEST
9 PRICE.—The Secretary shall treat any payments
10 made to the manufacturer of a covered outpatient
11 drug under a risk-sharing value-based payment
12 agreement under this subsection during a rebate pe-
13 riod in the same manner that the Secretary treats
14 payments made under a State supplemental rebate
15 agreement under sections 447.504(c)(19) and
16 447.505(c)(7) of title 42, Code of Federal Regula-
17 tions (or any successor regulations), for purposes of
18 determining average manufacturer price and best
19 price under this section with respect to the covered
20 outpatient drug and a rebate period and for pur-
21 poses of offsets required under subsection (b)(1)(B).

22 “(7) ASSESSMENTS AND REPORT TO CON-
23 GRESS.—

24 “(A) ASSESSMENTS.—

1 “(i) IN GENERAL.—Not later than
2 180 days after the end of each assessment
3 period of any risk-sharing value-based pay-
4 ment agreement for a State approved
5 under this subsection, the Secretary shall
6 conduct an evaluation of such agreement
7 which shall include an evaluation by the
8 Chief Actuary to determine whether pro-
9 gram spending under the risk-sharing
10 value-based payment agreement aligned
11 with the projections for the agreement
12 made under paragraph (2)(A)(ii), including
13 an assessment of whether actual Federal
14 spending under this title under the agree-
15 ment was less or more than net Federal
16 spending would have been in the absence
17 of the agreement.

18 “(ii) ASSESSMENT PERIOD.—For pur-
19 poses of clause (i)—

20 “(I) the first assessment period
21 for a risk-sharing value-based pay-
22 ment agreement shall be the period of
23 time over which payments are sched-
24 uled to be made under the agreement
25 for the first 10 individuals who are

1 administered covered outpatient drugs
2 under the agreement except that such
3 period shall not exceed the 5-year pe-
4 riod after the date on which the Sec-
5 retary approves the agreement; and

6 “(II) each subsequent assessment
7 period for a risk-sharing value-based
8 payment agreement shall be the 5-
9 year period following the end of the
10 previous assessment period.

11 “(B) RESULTS OF ASSESSMENTS.—

12 “(i) TERMINATION OPTION.—If the
13 Secretary determines as a result of the as-
14 sessment by the Chief Actuary under sub-
15 paragraph (A) that the actual Federal
16 spending under this title for any covered
17 outpatient drug that was the subject of the
18 State’s risk-sharing value-based payment
19 agreement was greater than the net Fed-
20 eral spending that would have resulted in
21 the absence of the agreement, the Sec-
22 retary may terminate approval of such
23 agreement and shall immediately conduct
24 an assessment under this paragraph of any
25 other ongoing risk-sharing value-based

1 payment agreement to which the same
2 manufacturer is a party.

3 “(ii) REPAYMENT REQUIRED.—

4 “(I) IN GENERAL.—If the Sec-
5 retary determines as a result of the
6 assessment by the Chief Actuary
7 under subparagraph (A) that the Fed-
8 eral spending under the risk-sharing
9 value-based agreement for a covered
10 outpatient drug that was subject to
11 such agreement was greater than the
12 net Federal spending that would have
13 resulted in the absence of the agree-
14 ment, the manufacturer shall repay
15 the difference to the State and Fed-
16 eral governments in a timely manner
17 as determined by the Secretary.

18 “(II) TERMINATION FOR FAIL-
19 URE TO PAY.—The failure of a manu-
20 facturer to make repayments required
21 under subclause (I) in a timely man-
22 ner shall result in immediate termi-
23 nation of all risk-sharing value-based
24 agreements to which the manufacturer
25 is a party.

1 “(III) ADDITIONAL PEN-
2 ALTIES.—In the case of a manufac-
3 turer that fails to make repayments
4 required under subclause (I), the Sec-
5 retary may treat such manufacturer
6 in the same manner as a manufac-
7 turer that fails to pay required re-
8 bates under this section, and the Sec-
9 retary may—

10 “(aa) suspend or terminate
11 the manufacturer’s rebate agree-
12 ment under this section; and

13 “(bb) pursue any other rem-
14 edy that would be available if the
15 manufacturer had failed to pay
16 required rebates under this sec-
17 tion.

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

24 “(i) an assessment of the impact of
25 risk-sharing value-based payment agree-

1 ments on access for individuals who are eli-
2 gible for benefits under a State plan or
3 waiver under this title to medically nec-
4 essary covered outpatient drugs and re-
5 lated treatments;

6 “(ii) an analysis of the impact of such
7 agreements on overall State and Federal
8 spending under this title;

9 “(iii) an assessment of the impact of
10 such agreements on drug prices, including
11 launch price and price increases; and

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

14 “(8) GUIDANCE AND REGULATIONS.—

15 “(A) IN GENERAL.—Not later than Janu-
16 ary 1, 2022, the Secretary shall issue guidance
17 to States seeking to enter into risk-sharing
18 value-based payment agreements under this
19 subsection that includes a model template for
20 such agreements. The Secretary may issue any
21 additional guidance or promulgate regulations
22 as necessary to implement and enforce the pro-
23 visions of this subsection.

24 “(B) MODEL AGREEMENTS.—

1 “(i) IN GENERAL.—If a State ex-
2 presses an interest in pursuing a risk-shar-
3 ing value-based payment agreement under
4 this subsection with a manufacturer for
5 the purchase of a covered outpatient drug,
6 the Secretary may share with such State
7 any risk-sharing value-based agreement be-
8 tween a State and the manufacturer for
9 the purchase of such drug that has been
10 approved under this subsection. While such
11 shared agreement may serve as a template
12 for a State that wishes to propose, the use
13 of a previously approved agreement shall
14 not affect the submission and approval
15 process for approval of a proposed risk-
16 sharing value-based payment agreement
17 under this subsection, including the re-
18 quirements under paragraph (2)(A).

19 “(ii) CONFIDENTIALITY.—In the case
20 of a risk-sharing value-based payment
21 agreement that is disclosed to a State by
22 the Secretary under this subparagraph and
23 that is only in effect with respect to a sin-
24 gle State, the confidentiality of information

1 provisions described in subsection
2 (b)(3)(D) shall apply to such information.

3 “(C) **OIG CONSULTATION.**—

4 “(i) **IN GENERAL.**—The Secretary
5 shall consult with the Office of the Inspec-
6 tor General of the Department of Health
7 and Human Services to determine whether
8 there are potential program integrity con-
9 cerns with agreement approvals or tem-
10 plates and address accordingly.

11 “(ii) **OIG POLICY UPDATES AS NEC-**
12 **CESSARY.**—The Inspector General of the
13 Department of Health and Human Serv-
14 ices shall review and update, as necessary,
15 any policies or guidelines of the Office of
16 the Inspector General of the Department
17 of Human Services (including policies re-
18 lated to the enforcement of section 1128B)
19 to accommodate the use of risk-sharing
20 value-based payment agreements in accord-
21 ance with this section.

22 “(9) **RULES OF CONSTRUCTION.**—

23 “(A) **MODIFICATIONS.**—Nothing in this
24 subsection or any regulations promulgated
25 under this subsection shall prohibit a State

1 from requesting a modification from the Sec-
2 retary to the terms of a risk-sharing value-
3 based payment agreement. A modification that
4 is expected to result in any increase to pro-
5 jected net State or Federal spending under the
6 agreement shall be subject to recertification by
7 the Chief Actuary as described in paragraph
8 (2)(A)(ii) before the modification may be ap-
9 proved.

10 “(B) REBATE AGREEMENTS.—Nothing in
11 this subsection shall be construed as requiring
12 a State to enter into a risk-sharing value-based
13 payment agreement or as limiting or super-
14 seding the ability of a State to enter into a sup-
15 plemental rebate agreement for a covered out-
16 patient drug.

17 “(C) FFP FOR PAYMENTS UNDER RISK-
18 SHARING VALUE-BASED PAYMENT AGREE-
19 MENTS.—Federal financial participation shall
20 be available under this title for any payment
21 made by a State to a manufacturer for a cov-
22 ered outpatient drug under a risk-sharing
23 value-based payment agreement in accordance
24 with this subsection, except that no Federal fi-
25 nancial participation shall be available for any

1 payment made by a State to a manufacturer
2 under such an agreement on and after the ef-
3 fective date of a disapproval of such agreement
4 by the Secretary.

5 “(D) CONTINUED APPLICATION OF OTHER
6 PROVISIONS.—Except as expressly provided in
7 this subsection, nothing in this subsection or in
8 any regulations promulgated under this sub-
9 section shall affect the application of any other
10 provision of this Act.

11 “(10) APPROPRIATIONS.—For fiscal year 2022
12 and each fiscal year thereafter, there are appro-
13 priated to the Secretary \$5,000,000 for the purpose
14 of carrying out this subsection.

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

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

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

24 “(C) POTENTIALLY CURATIVE TREATMENT
25 INTENDED FOR ONE-TIME USE.—The term ‘po-

1 tentially curative treatment intended for one-
2 time use’ means a treatment that consists of
3 the administration of a covered outpatient drug
4 that—

5 “(i) is a form of gene therapy for a
6 rare disease, as defined by the Commis-
7 sioner of Food and Drugs, designated
8 under section 526 of the Federal Food,
9 Drug, and Cosmetics Act, and approved
10 under section 505 of such Act or licensed
11 under subsection (a) or (k) of section 351
12 of the Public Health Service Act to treat
13 a serious or life-threatening disease or con-
14 dition;

15 “(ii) if administered in accordance
16 with the labeling of such drug, is expected
17 to result in either—

18 “(I) the cure of such disease or
19 condition; or

20 “(II) a reduction in the symp-
21 toms of such disease or condition to
22 the extent that such disease or condi-
23 tion is not expected to lead to early
24 mortality; and

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

5 “(D) RELEVANT CLINICAL PARAMETER.—
6 The term ‘relevant clinical parameter’ means,
7 with respect to a covered outpatient drug that
8 is the subject of a risk-sharing value-based pay-
9 ment agreement—

10 “(i) a clinical endpoint specified in the
11 drug’s labeling or supported by one or
12 more of the compendia described in section
13 1861(t)(2)(B)(ii)(I) that—

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

19 “(II) is required to be achieved
20 (based on observed metrics in patient
21 populations) under the terms of the
22 agreement; or

23 “(ii) a surrogate endpoint (as defined
24 in section 507(e)(9) of the Federal Food,
25 Drug, and Cosmetic Act), including those

1 developed by patient-focused drug develop-
2 ment tools, that—

3 “(I) is able to be measured or
4 evaluated on an annual basis for each
5 year of the agreement on an inde-
6 pendent basis by a provider or other
7 entity; and

8 “(II) has been qualified by the
9 Food and Drug Administration.

10 “(E) RISK-SHARING VALUE-BASED PAY-
11 MENT AGREEMENT.—The term ‘risk-sharing
12 value-based payment agreement’ means an
13 agreement between a State plan and a manu-
14 facturer—

15 “(i) for the purchase of a covered out-
16 patient drug of the manufacturer that is a
17 potentially curative treatment intended for
18 one-time use;

19 “(ii) under which payment for such
20 drug shall be made pursuant to an install-
21 ment-based payment structure that meets
22 the requirements of paragraph (3);

23 “(iii) which conditions payment on the
24 achievement of at least 2 relevant clinical

1 parameters (as defined in subparagraph
2 (C));

3 “(iv) which provides that—

4 “(I) the State plan will directly
5 reimburse the manufacturer for the
6 drug; or

7 “(II) a third party will reimburse
8 the manufacture in a manner ap-
9 proved by the Secretary; and

10 “(v) is approved by the Secretary in
11 accordance with paragraph (2).

12 “(F) TOTAL INSTALLMENT YEAR
13 AMOUNT.—The term ‘total installment year
14 amount’ means, with respect to a risk-sharing
15 value-based payment agreement for the pur-
16 chase of a covered outpatient drug and an in-
17 stallment year, an amount equal to the product
18 of—

19 “(i) the unit price of the drug charged
20 under the agreement; and

21 “(ii) the number of units of such drug
22 administered under the agreement during
23 such installment year.”.

24 (b) CONFORMING AMENDMENTS.—

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

8 (2) Section 1927(b) of the Social Security Act
9 (42 U.S.C. 1396r-8(b)) is amended—

10 (A) in paragraph (1)(A), by inserting “(ex-
11 cept for drugs for which payment is made by a
12 State under a risk-sharing value-based payment
13 agreement under subsection (l))” after “under
14 the State plan for such period”; and

15 (B) in paragraph (3)—

16 (i) in subparagraph (C)(i), by insert-
17 ing “or subsection (l)(2)(A)” after “sub-
18 paragraph (A)”; and

19 (ii) in subparagraph (D), in the mat-
20 ter preceding clause (i), by inserting “,
21 under subsection (l)(2)(A),” after “under
22 this paragraph”.

1 **SEC. 207. APPLYING MEDICAID DRUG REBATE REQUIRE-**
2 **MENT TO DRUGS PROVIDED AS PART OF OUT-**
3 **PATIENT HOSPITAL SERVICES.**

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

7 “(3) LIMITING DEFINITION.—

8 “(A) IN GENERAL.—The term ‘covered
9 outpatient drug’ does not include any drug, bio-
10 logical product, or insulin provided as part of,
11 or as incident to and in the same setting as,
12 any of the following (and for which payment
13 may be made under this title as part of pay-
14 ment for the following and not as direct reim-
15 bursement for the drug):

16 “(i) Inpatient hospital services.

17 “(ii) Hospice services.

18 “(iii) Dental services, except that
19 drugs for which the State plan authorizes
20 direct reimbursement to the dispensing
21 dentist are covered outpatient drugs.

22 “(iv) Physicians’ services.

23 “(v) Outpatient hospital services.

24 “(vi) Nursing facility services and
25 services provided by an intermediate care
26 facility for the mentally retarded.

1 “(vii) Other laboratory and x-ray serv-
2 ices.

3 “(viii) Renal dialysis.

4 “(B) OTHER EXCLUSIONS.—Such term
5 also does not include any such drug or product
6 for which a National Drug Code number is not
7 required by the Food and Drug Administration
8 or a drug or biological used for a medical indi-
9 cation which is not a medically accepted indica-
10 tion.

11 “(C) STATE OPTION.—At the option of a
12 State, such term may include any drug, biologi-
13 cal product, or insulin for which the State is
14 the primary payer under this title or a dem-
15 onstration project concerning this title, and that
16 is provided on an outpatient basis as part of, or
17 as incident to and in the same setting as, de-
18 scribed in clause (iv) or (v) of subparagraph (A)
19 and for which payment is made as part of pay-
20 ment for such services.

21 “(D) NO EFFECT ON BEST PRICE.—Any
22 drug, biological product, or insulin excluded
23 from the definition of such term as a result of
24 this paragraph shall be treated as a covered
25 outpatient drug for purposes of determining the

1 best price (as defined in subsection (e)(1)(C))
2 for such drug, biological product, or insulin.”.

3 (b) EFFECTIVE DATE; IMPLEMENTATION GUID-
4 ANCE.—

5 (1) IN GENERAL.—The amendment made by
6 subsection (a) shall take effect on the date that is
7 1 year after the date of enactment of this Act.

8 (2) IMPLEMENTATION AND GUIDANCE.—Not
9 later than 1 year after the date of enactment of this
10 Act, the Secretary of Health and Human Services
11 shall issue guidance and relevant informational bul-
12 letins for States, manufacturers (as defined in sec-
13 tion 1927(k)(5) of the Social Security Act (42
14 U.S.C. 1396r–8(k)(5))), and other relevant stake-
15 holders, including health care providers, regarding
16 implementation of the amendment made by sub-
17 section (a).

18 **CHAPTER 3—FOOD AND DRUG**

19 **ADMINISTRATION**

20 **Subchapter A—Pay-for-Delay**

21 **SEC. 301. 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 (21
17 U.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. 302. 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. 303. 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 301 of subtitle B of title
22 I of the Act titled ‘An Act to provide for reconciliation
23 pursuant to title II of S. Con. Res. 14’ or” after “that
24 the agreement has violated”.

1 **SEC. 304. 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 moving the margin
7 2 ems to the left and inserting “or” after the semi-
8 colon; and

9 (3) by inserting after subparagraph (E) the fol-
10 lowing:

11 “(F) under section 301(d)(3)(A) of subtitle B
12 of title I of the Act titled ‘An Act to provide for rec-
13 onciliation pursuant to title II of S. Con. Res. 14’;”.

14 **SEC. 305. STATUTE OF LIMITATIONS.**

15 (a) IN GENERAL.—Except as provided in subsection
16 (b), the Commission shall commence any administrative
17 proceeding or civil action to enforce section 301 of this
18 subtitle not later than 6 years after the date on which
19 the parties to the agreement file the Notice of Agreement
20 as provided by section 1112(c)(2) and (d) of the Medicare
21 Prescription Drug, Improvement, and Modernization Act
22 of 2003 (21 U.S.C. 355 note).

23 (b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND
24 DESIST ORDER.—If the Commission has issued a cease
25 and desist order under section 5 of the Federal Trade
26 Commission Act (15 U.S.C. 45) for violation of section

1 “(2) CONTENT.—Educational materials pro-
2 vided under paragraph (1) may include—

3 “(A) explanations of key statutory and
4 regulatory terms, including ‘biosimilar’ and
5 ‘interchangeable’, and clarification regarding
6 the use of interchangeable biosimilar biological
7 products;

8 “(B) information related to development
9 programs for biological products, including bio-
10 similar biological products and interchangeable
11 biosimilar biological products and relevant clin-
12 ical considerations for prescribers, which may
13 include, as appropriate and applicable, informa-
14 tion related to the comparability of such biologi-
15 cal products;

16 “(C) an explanation of the process for re-
17 porting adverse events for biological products,
18 including biosimilar biological products and
19 interchangeable biosimilar biological products;
20 and

21 “(D) an explanation of the relationship be-
22 tween biosimilar biological products and inter-
23 changeable biosimilar biological products li-
24 censed under section 351(k) and reference
25 products (as defined in section 351(i)), includ-

1 ing the standards for review and licensing of
2 each such type of biological product.

3 “(3) FORMAT.—The educational materials pro-
4 vided under paragraph (1) may be—

5 “(A) in formats such as webinars, con-
6 tinuing medical education modules, videos, fact
7 sheets, infographics, stakeholder toolkits, or
8 other formats as appropriate and applicable;
9 and

10 “(B) tailored for the unique needs of
11 health care providers, patients, caregivers, and
12 other audiences, as the Secretary determines
13 appropriate.

14 “(4) OTHER INFORMATION.—In addition to the
15 information described in paragraph (2), the Sec-
16 retary shall continue to publish the following infor-
17 mation:

18 “(A) The action package of each biological
19 product licensed under subsection (a) or (k).

20 “(B) The summary review of each biologi-
21 cal product licensed under subsection (a) or (k).

22 “(5) CONFIDENTIAL AND TRADE SECRET IN-
23 FORMATION.—This subsection does not authorize
24 the disclosure of any trade secret, confidential com-

1 the highest potential score for the perform-
2 ance category described in paragraph
3 (2)(A)(iii) for such performance period. A
4 MIPS eligible professional may only count
5 the completion of such a program for pur-
6 poses of such category one time during the
7 eligible professional’s lifetime.”.

8 **Subchapter C—Other Provisions**

9 **SEC. 331. CLARIFYING THE MEANING OF NEW CHEMICAL** 10 **ENTITY.**

11 Chapter V of the Federal Food, Drug, and Cosmetic
12 Act is amended—

13 (1) in section 505 (21 U.S.C. 355)—

14 (A) in subsection (c)(3)(E)—

15 (i) in clause (ii), by striking “active
16 ingredient (including any ester or salt of
17 the active ingredient)” and inserting “ac-
18 tive moiety (as defined by the Secretary in
19 section 314.3 of title 21, Code of Federal
20 Regulations (or any successor regula-
21 tions))”; and

22 (ii) in clause (iii), by striking “active
23 ingredient (including any ester or salt of
24 the active ingredient)” and inserting “ac-
25 tive moiety (as defined by the Secretary in

1 section 314.3 of title 21, Code of Federal
2 Regulations (or any successor regula-
3 tions))”;

4 (B) in subsection (j)(5)(F)—

5 (i) in clause (ii), by striking “active
6 ingredient (including any ester or salt of
7 the active ingredient)” and inserting “ac-
8 tive moiety (as defined by the Secretary in
9 section 314.3 of title 21, Code of Federal
10 Regulations (or any successor regula-
11 tions))”; and

12 (ii) in clause (iii), by striking “active
13 ingredient (including any ester or salt of
14 the active ingredient)” and inserting “ac-
15 tive moiety (as defined by the Secretary in
16 section 314.3 of title 21, Code of Federal
17 Regulations (or any successor regula-
18 tions))”;

19 (C) in subsection (l)(2)(A)(i), by striking
20 “active ingredient (including any ester or salt of
21 the active ingredient)” and inserting “active
22 moiety (as defined by the Secretary in section
23 314.3 of title 21, Code of Federal Regulations
24 (or any successor regulations))”;

1 (D) in subsection (s), in the matter pre-
2 ceding paragraph (1), by striking “active ingre-
3 dient (including any ester or salt of the active
4 ingredient)” and inserting “active moiety (as
5 defined by the Secretary in section 314.3 of
6 title 21, Code of Federal Regulations (or any
7 successor regulations))”; and

8 (E) in subsection (u)(1), in the matter pre-
9 ceding subparagraph (A)—

10 (i) by striking “active ingredient (in-
11 cluding any ester or salt of the active in-
12 gredient)” and inserting “active moiety (as
13 defined by the Secretary in section 314.3
14 of title 21, Code of Federal Regulations (or
15 any successor regulations))”; and

16 (ii) by striking “same active ingre-
17 dient” and inserting “same active moiety”;

18 (2) in section 512(c)(2)(F) (21 U.S.C.
19 360b(c)(2)(F))—

20 (A) in clause (i), by striking “active ingre-
21 dient (including any ester or salt of the active
22 ingredient)” and inserting “active moiety (as
23 defined by the Secretary in section 314.3 of
24 title 21, Code of Federal Regulations (or any
25 successor regulations))”;

1 (B) in clause (ii), by striking “active ingre-
2 dient (including any ester or salt of the active
3 ingredient)” and inserting “active moiety (as
4 defined by the Secretary in section 314.3 of
5 title 21, Code of Federal Regulations (or any
6 successor regulations))”; and

7 (C) in clause (v), by striking “active ingre-
8 dient (including any ester or salt of the active
9 ingredient)” and inserting “active moiety (as
10 defined by the Secretary in section 314.3 of
11 title 21, Code of Federal Regulations (or any
12 successor regulations))”;

13 (3) in section 524(a)(4)(C) (21 U.S.C.
14 360n(a)(4)(C)), by striking “active ingredient (in-
15 cluding any ester or salt of the active ingredient)”
16 and inserting “active moiety (as defined by the Sec-
17 retary in section 314.3 of title 21, Code of Federal
18 Regulations (or any successor regulations))”;

19 (4) in section 529(a)(4)(A)(ii) (21 U.S.C.
20 360ff(a)(4)(A)(ii)), by striking “active ingredient
21 (including any ester or salt of the active ingredient)”
22 and inserting “active moiety (as defined by the Sec-
23 retary in section 314.3 of title 21, Code of Federal
24 Regulations (or any successor regulations))”; and

1 (5) in section 565A(a)(4)(D) (21 U.S.C.
2 360bbb-4a(a)(4)(D)), by striking “active ingredient
3 (including any ester or salt of the active ingredient)”
4 and inserting “active moiety (as defined by the Sec-
5 retary in section 314.3 of title 21, Code of Federal
6 Regulations (or any successor regulations))”.

7 **CHAPTER 4—REVENUE PROVISION**

8 **SEC. 401. SAFE HARBOR FOR HIGH DEDUCTIBLE HEALTH**
9 **PLANS WITHOUT DEDUCTIBLE FOR INSULIN.**

10 (a) IN GENERAL.—Section 223(c)(2)(C) of the Inter-
11 nal Revenue Code of 1986 is amended by inserting “or
12 for insulin or any device for the delivery of insulin” before
13 the period at the end.

14 (b) EFFECTIVE DATE.—The amendment made by
15 this section shall apply to months beginning after the date
16 of the enactment of this Act.

17 **CHAPTER 5—MISCELLANEOUS**

18 **SEC. 501. PAYMENT FOR BIOSIMILAR BIOLOGICAL PROD-**
19 **UCTS DURING INITIAL PERIOD.**

20 Section 1847A(c)(4) of the Social Security Act (42
21 U.S.C. 1395w-3a(c)(4)) is amended—

22 (1) in each of subparagraphs (A) and (B), by
23 redesignating clauses (i) and (ii) as subclauses (I)
24 and (II), respectively, and moving such subclauses 2
25 ems to the right;

1 (2) by redesignating subparagraphs (A) and
2 (B) as clauses (i) and (ii) and moving such clauses
3 2 ems to the right;

4 (3) by striking “UNAVAILABLE.—In the case”
5 and inserting “UNAVAILABLE.—

6 “(A) IN GENERAL.—Subject to subpara-
7 graph (B), in the case”; and

8 (4) by adding at the end the following new sub-
9 paragraph:

10 “(B) LIMITATION ON PAYMENT AMOUNT
11 FOR BIOSIMILAR BIOLOGICAL PRODUCTS DUR-
12 ING INITIAL PERIOD.—In the case of a bio-
13 similar biological product furnished on or after
14 July 1, 2023, in lieu of applying subparagraph
15 (A) during the initial period described in such
16 subparagraph with respect to the biosimilar bio-
17 logical product, the amount payable under this
18 section for the biosimilar biological product is
19 the lesser of the following:

20 “(i) The amount determined under
21 clause (ii) of such subparagraph for the
22 biosimilar biological product.

23 “(ii) The amount determined under
24 subsection (b)(1)(B) for the reference bio-
25 logical product.”.

1 **SEC. 502. GAO STUDY AND REPORT ON AVERAGE SALES**

2 **PRICE.**

3 (a) STUDY.—

4 (1) IN GENERAL.—The Comptroller General of
5 the United States (in this section referred to as the
6 “Comptroller General”) shall conduct a study on
7 spending for applicable drugs under part B of title
8 XVIII of the Social Security Act.

9 (2) APPLICABLE DRUGS DEFINED.—In this sec-
10 tion, the term “applicable drugs” means drugs and
11 biologicals—

12 (A) for which reimbursement under such
13 part B is based on the average sales price of
14 the drug or biological; and

15 (B) that account for the largest percentage
16 of total spending on drugs and biologicals under
17 such part B (as determined by the Comptroller
18 General, but in no case less than 25 drugs or
19 biologicals).

20 (3) REQUIREMENTS.—The study under para-
21 graph (1) shall include an analysis of the following:

22 (A) The extent to which each applicable
23 drug is paid for—

24 (i) under such part B for Medicare
25 beneficiaries; or

1 (ii) by private payers in the commer-
2 cial market.

3 (B) Any change in Medicare spending or
4 Medicare beneficiary cost-sharing that would
5 occur if the average sales price of an applicable
6 drug was based solely on payments by private
7 payers in the commercial market.

8 (C) The extent to which drug manufactur-
9 ers provide rebates, discounts, or other price
10 concessions to private payers in the commercial
11 market for applicable drugs, which the manu-
12 facturer includes in its average sales price cal-
13 culation, for—

14 (i) formulary placement;

15 (ii) utilization management consider-
16 ations; or

17 (iii) other purposes.

18 (D) Barriers to drug manufacturers pro-
19 viding such price concessions for applicable
20 drugs.

21 (E) Other areas determined appropriate by
22 the Comptroller General.

23 (b) REPORT.—Not later than 2 years after the date
24 of the enactment of this Act, the Comptroller General shall
25 submit to Congress a report on the study conducted under

1 subsection (a), together with recommendations for such
2 legislation and administrative action as the Secretary de-
3 termines appropriate.

4 **SEC. 503. REQUIRING PRESCRIPTION DRUG PLANS AND**
5 **MA-PD PLANS TO REPORT POTENTIAL**
6 **FRAUD, WASTE, AND ABUSE TO THE SEC-**
7 **RETARY OF HHS.**

8 Section 1860D–4 of the Social Security Act (42
9 U.S.C. 1395w–104) is amended by adding at the end the
10 following new subsection:

11 “(p) REPORTING POTENTIAL FRAUD, WASTE, AND
12 ABUSE.—Beginning January 1, 2022, the PDP sponsor
13 of a prescription drug plan shall report to the Secretary,
14 as specified by the Secretary—

15 “(1) any substantiated or suspicious activities
16 (as defined by the Secretary) with respect to the
17 program under this part as it relates to fraud,
18 waste, and abuse; and

19 “(2) any steps made by the PDP sponsor after
20 identifying such activities to take corrective ac-
21 tions.”.

1 **SEC. 504. ESTABLISHMENT OF PHARMACY QUALITY MEAS-**
2 **URES UNDER MEDICARE PART D.**

3 Section 1860D–4(c) of the Social Security Act (42
4 U.S.C. 1395w–104(e)) is amended by adding at the end
5 the following new paragraph:

6 “(8) APPLICATION OF PHARMACY QUALITY
7 MEASURES.—

8 “(A) IN GENERAL.—A PDP sponsor that
9 implements incentive payments to a pharmacy
10 or price concessions paid by a pharmacy based
11 on quality measures shall use measures estab-
12 lished or approved by the Secretary under sub-
13 paragraph (B) with respect to payment for cov-
14 ered part D drugs dispensed by such pharmacy.

15 “(B) STANDARD PHARMACY QUALITY
16 MEASURES.—The Secretary shall establish or
17 approve standard quality measures from a con-
18 sensus and evidence-based organization for pay-
19 ments described in subparagraph (A). Such
20 measures shall focus on patient health outcomes
21 and be based on proven criteria measuring
22 pharmacy performance.

23 “(C) EFFECTIVE DATE.—The requirement
24 under subparagraph (A) shall take effect for
25 plan years beginning on or after January 1,
26 2023, or such earlier date specified by the Sec-

1 retary if the Secretary determines there are suf-
2 ficient measures established or approved under
3 subparagraph (B) to meet the requirement
4 under subparagraph (A).”.

5 **SEC. 505. IMPROVING COORDINATION BETWEEN THE FOOD**
6 **AND DRUG ADMINISTRATION AND THE CEN-**
7 **TERS FOR MEDICARE & MEDICAID SERVICES.**

8 (a) IN GENERAL.—

9 (1) PUBLIC MEETING.—

10 (A) IN GENERAL.—Not later than 12
11 months after the date of the enactment of this
12 Act, the Secretary of Health and Human Serv-
13 ices (referred to in this section as the “Sec-
14 retary”) shall convene a public meeting for the
15 purposes of discussing and providing input on
16 improvements to coordination between the Food
17 and Drug Administration and the Centers for
18 Medicare & Medicaid Services in preparing for
19 the availability of novel medical products de-
20 scribed in subsection (c) on the market in the
21 United States.

22 (B) ATTENDEES.—The public meeting
23 shall include—

24 (i) representatives of relevant Federal
25 agencies, including representatives from

1 each of the medical product centers within
2 the Food and Drug Administration and
3 representatives from the coding, coverage,
4 and payment offices within the Centers for
5 Medicare & Medicaid Services;

6 (ii) stakeholders with expertise in the
7 research and development of novel medical
8 products, including manufacturers of such
9 products;

10 (iii) representatives of commercial
11 health insurance payers;

12 (iv) stakeholders with expertise in the
13 administration and use of novel medical
14 products, including physicians; and

15 (v) stakeholders representing patients
16 and with expertise in the utilization of pa-
17 tient experience data in medical product
18 development.

19 (C) TOPICS.—The public meeting shall in-
20 clude a discussion of—

21 (i) the status of the drug and medical
22 device development pipeline related to the
23 availability of novel medical products;

24 (ii) the anticipated expertise necessary
25 to review the safety and effectiveness of

1 such products at the Food and Drug Ad-
2 ministration and current gaps in such ex-
3 pertise, if any;

4 (iii) the expertise necessary to make
5 coding, coverage, and payment decisions
6 with respect to such products within the
7 Centers for Medicare & Medicaid Services,
8 and current gaps in such expertise, if any;

9 (iv) trends in the differences in the
10 data necessary to determine the safety and
11 effectiveness of a novel medical product
12 and the data necessary to determine
13 whether a novel medical product meets the
14 reasonable and necessary requirements for
15 coverage and payment under title XVIII of
16 the Social Security Act pursuant to section
17 1862(a)(1)(A) of such Act (42 U.S.C.
18 1395y(a)(1)(A));

19 (v) the availability of information for
20 sponsors of such novel medical products to
21 meet each of those requirements; and

22 (vi) the coordination of information
23 related to significant clinical improvement
24 over existing therapies for patients between
25 the Food and Drug Administration and the

1 Centers for Medicare & Medicaid Services
2 with respect to novel medical products.

3 (D) TRADE SECRETS AND CONFIDENTIAL
4 INFORMATION.—No information discussed as a
5 part of the public meeting under this paragraph
6 shall be construed as authorizing the Secretary
7 to disclose any information that is a trade se-
8 cret or confidential information subject to sec-
9 tion 552(b)(4) of title 5, United States Code.

10 (2) IMPROVING TRANSPARENCY OF CRITERIA
11 FOR MEDICARE COVERAGE.—

12 (A) DRAFT GUIDANCE.—Not later than 18
13 months after the public meeting under para-
14 graph (1), the Secretary shall update the final
15 guidance titled “National Coverage Determina-
16 tions with Data Collection as a Condition of
17 Coverage: Coverage with Evidence Develop-
18 ment” to address any opportunities to improve
19 the availability and coordination of information
20 as described in clauses (iv) through (vi) of para-
21 graph (1)(C).

22 (B) FINAL GUIDANCE.—Not later than 12
23 months after issuing draft guidance under sub-
24 paragraph (A), the Secretary shall finalize the

1 updated guidance to address any such opportu-
2 nities.

3 (b) REPORT ON CODING, COVERAGE, AND PAYMENT
4 PROCESSES UNDER MEDICARE FOR NOVEL MEDICAL
5 PRODUCTS.—Not later than 12 months after the date of
6 the enactment of this Act, the Secretary shall publish a
7 report on the internet website of the Department of
8 Health and Human Services regarding processes under
9 the Medicare program under title XVIII of the Social Se-
10 curity Act (42 U.S.C. 1395 et seq.) with respect to the
11 coding, coverage, and payment of novel medical products
12 described in subsection (c). Such report shall include the
13 following:

14 (1) A description of challenges in the coding,
15 coverage, and payment processes under the Medicare
16 program for novel medical products.

17 (2) Recommendations to—

18 (A) incorporate patient experience data
19 (such as the impact of a disease or condition on
20 the lives of patients and patient treatment pref-
21 erences) into the coverage and payment proc-
22 esses within the Centers for Medicare & Med-
23 icaid Services;

24 (B) decrease the length of time to make
25 national and local coverage determinations

1 under the Medicare program (as those terms
2 are defined in subparagraph (A) and (B), re-
3 spectively, of section 1862(l)(6) of the Social
4 Security Act (42 U.S.C. 1395y(l)(6)));

5 (C) streamline the coverage process under
6 the Medicare program and incorporate input
7 from relevant stakeholders into such coverage
8 determinations; and

9 (D) identify potential mechanisms to incor-
10 porate novel payment designs similar to those
11 in development in commercial insurance plans
12 and State plans under title XIX of such Act
13 (42 U.S.C. 1396 et seq.) into the Medicare pro-
14 gram.

15 (c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For
16 purposes of this section, a novel medical product described
17 in this subsection is a medical product, including a drug,
18 biological (including gene and cell therapy), or medical de-
19 vice, that has been designated as a breakthrough therapy
20 under section 506(a) of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 356(a)), a breakthrough device
22 under section 515B of such Act (21 U.S.C. 360e–3), or
23 a regenerative advanced therapy under section 506(g) of
24 such Act (21 U.S.C. 356(g)).

1 **SEC. 506. PATIENT CONSULTATION IN MEDICARE NA-**
2 **TIONAL AND LOCAL COVERAGE DETERMINA-**
3 **TIONS IN ORDER TO MITIGATE BARRIERS TO**
4 **INCLUSION OF SUCH PERSPECTIVES.**

5 Section 1862(l) of the Social Security Act (42 U.S.C.
6 1395y(l)) is amended by adding at the end the following
7 new paragraph:

8 “(7) PATIENT CONSULTATION IN NATIONAL
9 AND LOCAL COVERAGE DETERMINATIONS.—The Sec-
10 retary may consult with patients and organizations
11 representing patients in making national and local
12 coverage determinations.”.

13 **SEC. 507. MEDPAC REPORT ON SHIFTING COVERAGE OF**
14 **CERTAIN MEDICARE PART B DRUGS TO MEDI-**
15 **CARE PART D.**

16 (a) STUDY.—The Medicare Payment Advisory Com-
17 mission (in this section referred to as the “Commission”)
18 shall conduct a study on shifting coverage of certain drugs
19 and biologicals for which payment is currently made under
20 part B of title XVIII of the Social Security Act (42 U.S.C.
21 1395j et seq.) to part D of such title (42 U.S.C. 1395w-
22 21 et seq.). Such study shall include an analysis of—

23 (1) differences in program structures and pay-
24 ment methods for drugs and biologicals covered
25 under such parts B and D, including effects of such
26 a shift on program spending, beneficiary cost-shar-

1 ing liability, and utilization management techniques
2 for such drugs and biologicals; and

3 (2) the feasibility and policy implications of
4 shifting coverage of drugs and biologicals for which
5 payment is currently made under such part B to
6 such part D.

7 (b) REPORT.—

8 (1) IN GENERAL.—Not later than June 30,
9 2023, the Commission shall submit to Congress a re-
10 port containing the results of the study conducted
11 under subsection (a).

12 (2) CONTENTS.—The report under paragraph
13 (1) shall include information, and recommendations
14 as the Commission deems appropriate, regarding—

15 (A) formulary design under such part D;

16 (B) the ability of the benefit structure
17 under such part D to control total spending on
18 drugs and biologicals for which payment is cur-
19 rently made under such part B;

20 (C) changes to the bid process under such
21 part D, if any, that may be necessary to inte-
22 grate coverage of such drugs and biologicals
23 into such part D;

24 (D) any other changes to the program that
25 Congress should consider in determining wheth-

1 er to shift coverage of such drugs and
2 biologicals from such part B to such part D;
3 and

4 (E) the feasibility and policy implications
5 of creating a methodology to preserve the
6 healthcare provider's ability to take title of the
7 drug, including a methodology under which—

8 (i) prescription drug plans negotiate
9 reimbursement rates and other arrange-
10 ments with drug manufacturers on behalf
11 of a wholesaler;

12 (ii) wholesalers purchase the drugs
13 from the manufacturers at the negotiated
14 rate and ship them through distributors to
15 physicians to administer to patients;

16 (iii) physicians and hospitals purchase
17 the drug from the wholesaler via the dis-
18 tributor;

19 (iv) after administering the drug, the
20 physician submits a claim to the MAC for
21 their drug administration fee;

22 (v) to be reimbursed for the purchase
23 of the drug from the distributor, the physi-
24 cian furnishes the claim for the drug itself
25 to the wholesaler and the wholesaler would

1 refund the cost of the drug to the physi-
2 cian; and

3 (vi) the wholesaler passes this claim to
4 the PDP to receive reimbursement.

5 **SEC. 508. REQUIREMENT THAT DIRECT-TO-CONSUMER AD-**
6 **VERTISEMENTS FOR PRESCRIPTION DRUGS**
7 **AND BIOLOGICAL PRODUCTS INCLUDE**
8 **TRUTHFUL AND NON-MISLEADING PRICING**
9 **INFORMATION.**

10 Part A of title XI of the Social Security Act is
11 amended by adding at the end the following new section:

12 **“SEC. 1150C. REQUIREMENT THAT DIRECT-TO-CONSUMER**
13 **ADVERTISEMENTS FOR PRESCRIPTION**
14 **DRUGS AND BIOLOGICAL PRODUCTS IN-**
15 **CLUDE TRUTHFUL AND NON-MISLEADING**
16 **PRICING INFORMATION.**

17 “(a) IN GENERAL.—The Secretary shall require that
18 each direct-to-consumer advertisement for a prescription
19 drug or biological product for which payment is available
20 under title XVIII or XIX includes an appropriate disclo-
21 sure of truthful and non-misleading pricing information
22 with respect to the drug or product.

23 “(b) DETERMINATION BY CMS.—The Secretary, act-
24 ing through the Administrator of the Centers for Medicare
25 & Medicaid Services, shall determine the components of

1 the requirement under subsection (a), such as the forms
2 of advertising, the manner of disclosure, the price point
3 listing, and the price information for disclosure.”.

4 **SEC. 509. CHIEF PHARMACEUTICAL NEGOTIATOR AT THE**
5 **OFFICE OF THE UNITED STATES TRADE REP-**
6 **RESENTATIVE.**

7 (a) IN GENERAL.—Section 141 of the Trade Act of
8 1974 (19 U.S.C. 2171) is amended—

9 (1) in subsection (b)(2)—

10 (A) by striking “and one Chief Innovation
11 and Intellectual Property Negotiator” and in-
12 serting “one Chief Innovation and Intellectual
13 Property Negotiator, and one Chief Pharma-
14 ceutical Negotiator”;

15 (B) by striking “or the Chief Innovation
16 and Intellectual Property Negotiator” and in-
17 serting “the Chief Innovation and Intellectual
18 Property Negotiator, or the Chief Pharma-
19 ceutical Negotiator”; and

20 (C) by striking “and the Chief Innovation
21 and Intellectual Property Negotiator” and in-
22 serting “the Chief Innovation and Intellectual
23 Property Negotiator, and the Chief Pharma-
24 ceutical Negotiator”; and

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

3 “(7) The principal function of the Chief Phar-
4 maceutical Negotiator shall be to conduct trade ne-
5 gotiations and to enforce trade agreements relating
6 to United States pharmaceutical products and serv-
7 ices. The Chief Pharmaceutical Negotiator shall be
8 a vigorous advocate on behalf of United States phar-
9 maceutical interests. The Chief Pharmaceutical Ne-
10 gotiator shall perform such other functions as the
11 United States Trade Representative may direct.”.

12 (b) COMPENSATION.—Section 5314 of title 5, United
13 States Code, is amended by striking “Chief Innovation
14 and Intellectual Property Negotiator, Office of the United
15 States Trade Representative.” and inserting the following:

16 “Chief Innovation and Intellectual Property Ne-
17 gotiator, Office of the United States Trade Rep-
18 resentative.

19 “Chief Pharmaceutical Negotiator, Office of the
20 United States Trade Representative.”.

21 (c) REPORT REQUIRED.—Not later than the date
22 that is one year after the appointment of the first Chief
23 Pharmaceutical Negotiator pursuant to paragraph (2) of
24 section 141(b) of the Trade Act of 1974, as amended by
25 subsection (a), and annually thereafter, the United States

1 Trade Representative shall submit to the Committee on
2 Finance of the Senate and the Committee on Ways and
3 Means of the House of Representatives a report describing
4 in detail—

5 (1) enforcement actions taken by the United
6 States Trade Representative during the one-year pe-
7 riod preceding the submission of the report to en-
8 sure the protection of United States pharmaceutical
9 products and services; and

10 (2) other actions taken by the United States
11 Trade Representative to advance United States
12 pharmaceutical products and services.

