

**Amendment to the Amendment in the Nature of a Substitute to H.R. 3
Offered by Rep. Brady of Texas**

The amendment would reduce out-of-pocket spending on drugs while preserving the hope of future cures.

AMENDMENT

OFFERED BY MR. BRADY OF TEXAS

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

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

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

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

9 (1) in paragraph (1)—

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

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

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

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

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

4 (C) in subparagraph (A)—

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

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

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

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

16 “(2) PHYSICIAN PAYMENT.—Beginning in
17 2021, the Secretary 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 1395-3a) is amended by adding at the end the following
9 new subsection:

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

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

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

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

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

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

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

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

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

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

12 “(3) REFUND AMOUNT.—

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

21 “(i) the product of—

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

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

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

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

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

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

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

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

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

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

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

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

25 “(6) ENFORCEMENT.—

1 “(A) AUDITS.—

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

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

17 “(B) CIVIL MONEY PENALTY.—

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

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

5 “(II) 25 percent of such amount.

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

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

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

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

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

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

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

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

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

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

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

6 (1) in paragraph (1)—

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

13 (B) in subparagraph (B) of paragraph (1),
14 by inserting after “106 percent” the following:
15 “(or, for a single source drug or biological fur-
16 nished on or after January 1, 2021, the appli-
17 cable percent specified in paragraph (9)(A) for
18 the drug or biological and quarter involved)”;
19 and

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

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

25 “(A) APPLICABLE PERCENT TO BE AP-
26 PLIED.—

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

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

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

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

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

1 “(ii) CASES WHERE DATA NOT SUFFI-
2 CIENTLY AVAILABLE TO COMPUTE PER
3 BENEFICIARY ALLOWED CHARGES.—In the
4 case of a drug or biological furnished for
5 which the amount of payment is deter-
6 mined under subparagraph (A) or (B) of
7 paragraph (1) and not under subsection
8 (c)(4), for calendar quarters during a pe-
9 riod in which data are not sufficiently
10 available to compute a per beneficiary al-
11 lowed charges for the drug or biological,
12 the applicable percent is 106 percent.

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

16 “(i) IN GENERAL.—With respect to a
17 calendar quarter beginning on or after
18 January 1, 2021, for drugs and biologicals
19 for which the amount of payment is deter-
20 mined under subparagraph (A) or (B) of
21 paragraph (1), except for drugs or
22 biologicals for which data are not suffi-
23 ciently available, the Secretary shall—

24 “(I) compute the per beneficiary
25 allowed charges (as defined in sub-

1 paragraph (C)) for each such drug or
2 biological;

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

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

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

20 “(iii) APPLICABLE DATA PERIOD.—
21 For purposes of this paragraph, the term
22 ‘applicable data period’ means the most re-
23 cent period for which the data necessary
24 for making the computations under clause

1 (i) are available, as determined by the Sec-
2 retary.

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

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

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

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

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

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

10 (b) APPLICATION OF JUDICIAL REVIEW PROVI-
11 SIONS.—Section 1847A(g) of the Social Security Act is
12 amended—

13 (1) by striking “and” at the end of paragraph
14 (4);

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

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

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

22 **SEC. 104. ESTABLISHMENT OF MAXIMUM ADD-ON PAYMENT**
23 **FOR DRUGS AND BIOLOGICALS.**

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

1 (1) in subsection (b)—

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

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

8 “(9) MAXIMUM ADD-ON PAYMENT AMOUNT.—

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

24 “(B) APPLICABLE ADD-ON PAYMENT DE-
25 FINED.—In this paragraph, the term ‘applicable

1 add-on payment' means the following amounts,
2 determined without regard to the application of
3 subparagraph (A):

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

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

10 “(II) the amount that would be
11 applied under such paragraph if ‘100
12 percent’ were substituted for ‘106 per-
13 cent’.

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 ‘106 per-
23 cent’.

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) for each of 2021 through 2028,
18 \$1,000; and

19 “(ii) for a subsequent year, the
20 amount specified in this subparagraph for
21 the preceding year increased by the per-
22 centage increase in the consumer price
23 index for all urban consumers (all items;
24 United States city average) for the 12-

1 month period ending with June of the pre-
2 vious year.

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

6 (2) in subsection (c)(4)(A)(ii), by striking “in
7 the case” and inserting “subject to subsection
8 (b)(9), in the case”.

9 (b) CONFORMING AMENDMENTS RELATING TO SEPA-
10 RATELY PAYABLE DRUGS.—

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

13 (A) in subparagraph (A)(iii)(II), by insert-
14 ing “, subject to subparagraph (I)” after “are
15 not available”; and

16 (B) by adding at the end the following new
17 subparagraph:

18 “(I) APPLICATION OF MAXIMUM ADD-ON
19 PAYMENT FOR SEPARATELY PAYABLE DRUGS
20 AND BIOLOGICALS.—In establishing the amount
21 of payment under subparagraph (A) for a speci-
22 fied covered outpatient drug that is furnished
23 as part of a covered OPD service (or group of
24 services) on or after January 1, 2021, if such
25 payment is determined based on the average

1 price for the year established under section
2 1847A pursuant to clause (iii)(II) of such sub-
3 paragraph, the provisions of subsection (b)(9)
4 of section 1847A shall apply to the amount of
5 payment so established in the same manner as
6 such provisions apply to the amount of payment
7 under section 1847A.”.

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

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

12 (B) by redesignating clause (vi) as clause
13 (vii); and

14 (C) by inserting after clause (v) the fol-
15 lowing new clause:

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

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

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

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

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

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

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

and

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

Subtitle B—Drug Price

Transparency

SEC. 111. REPORTING ON EXPLANATION FOR DRUG PRICE

INCREASES.

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

“PART W—DRUG PRICE REPORTING; DRUG

VALUE FUND

“SEC. 3990O. REPORTING ON EXPLANATION FOR DRUG

PRICE INCREASES.

“(a) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

19 “(iii) not a vaccine; and

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

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

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

7 “(b) REPORT.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 “(i) drug research and development;

2 or

3 “(ii) clinical trials, including on drugs
4 that failed to receive approval by the Food
5 and Drug Administration; and

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

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

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

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

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

3 “(g) PUBLIC POSTING.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 (1) addresses at minimum—

10 (A) whether pharmacy benefit managers—

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

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

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

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

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

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

20 (2) provides—

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

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

8 (C) policy or legislative recommendations
9 to—

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

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

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

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

25 (c) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

18 (1) in subsection (b)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 (1) in subsection (d)(4)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 “(b) DATA SHARING AGREEMENTS.—

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

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

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

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

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

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

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

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

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

22 “(e) PENALTIES.—

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

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

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

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

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

3 “(d) DRUG SAMPLE DISTRIBUTION INFORMATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 It is the sense of Congress that—

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

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

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

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

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

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

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

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

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

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

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

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

11 (1) in paragraph (2)—

12 (A) in subparagraph (A)—

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

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

24 (B) in subparagraph (C)—

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

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

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

6 (C) in subparagraph (D)—

7 (i) in clause (i)—

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

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

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

20 (2) in paragraph (3)(A)—

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

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

4 (3) in paragraph (4)—

5 (A) in subparagraph (A)—

6 (i) in clause (i)—

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

11 (II) in the matter preceding item
12 (aa), as redesignated by subclause (I),
13 by striking “is equal to the greater
14 of—” and inserting “is equal to—
15 “(I) for a year preceding 2022,
16 the greater of—”.

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

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

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

25 (ii) in clause (ii)—

- 1 (I) by striking “clause (i)(I)” and
2 inserting “clause (i)(I)(aa)”;
- 3 (II) by adding at the end the fol-
4 lowing new sentence: “The Secretary
5 shall continue to calculate the dollar
6 amounts specified in clause (i)(I)(aa),
7 including with the adjustment under
8 this clause, after 2021 for purposes of
9 section 1860D–14(a)(1)(D)(iii).”;
- 10 (B) in subparagraph (B)—
- 11 (i) in clause (i)—
- 12 (I) in subclause (V), by striking
13 “or” at the end;
- 14 (II) in subclause (VI)—
- 15 (aa) by striking “for a sub-
16 sequent year” and inserting “for
17 2021”; and
- 18 (bb) by striking the period
19 at the end and inserting a semi-
20 colon; and
- 21 (III) by adding at the end the
22 following new subclauses:
- 23 “(VII) for 2022, is equal to
24 \$3,100; or

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

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

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

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

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

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

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

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

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

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

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

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

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

3 (c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

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

19 “(b) TERMS OF AGREEMENT.—

20 “(1) IN GENERAL.—

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

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

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

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

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

24 “(4) LENGTH OF AGREEMENT.—

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

7 “(B) TERMINATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 “(2) MONITORING COMPLIANCE.—

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

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

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

7 “(d) ADMINISTRATION.—

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

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

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

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

1 individuals or entities the Secretary determines
2 appropriate;

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

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

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

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

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

4 “(e) ENFORCEMENT.—

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

8 “(2) CIVIL MONEY PENALTY.—

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

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

22 “(ii) 25 percent of such amount.

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

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

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

10 “(g) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

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

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

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

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

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

5 “(4) DISCOUNTED PRICE.—

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

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

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

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

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

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

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

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

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

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

6 “(h) SUNSET OF PROGRAM.—

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

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

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

22 (A) in subsection (b)(2)(C)(iii)—

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

1 “(I) the reinsurance”; and

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

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

9 (B) in subsection (c)(1)(C)—

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

13 “(i) the reinsurance”;

14 (ii) in clause (i), as added by clause

15 (i) of this subparagraph, by adding “and”
16 at the end; and

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

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

22 (d) DETERMINATION OF ALLOWABLE REINSURANCE

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

25 (1) in paragraph (2)—

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

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

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

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

17 (2) in paragraph (3)—

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

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

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

6 “(3) UPDATING RISK ADJUSTMENT METH-
7 ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA-
8 TION REDESIGN.—The Secretary shall update the
9 risk adjustment model used to adjust bid amounts
10 pursuant to this subsection as appropriate to take
11 into account changes in benefits under this part pur-
12 suant to the amendments made by section 301 of
13 the Lower Drug Costs Now Act of 2019.”.

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

17 (1) in subsection (a)—

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

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

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

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

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

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

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

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

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

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

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

3 (g) CONFORMING AMENDMENTS.—

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

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

10 (B) in subsection (c)(1)(C)—

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

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

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

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

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

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

5 (A) in paragraph (1)—

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

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

12 (iii) in subparagraph (E), by striking
13 “The elimination” and inserting “For a
14 year preceding 2022, the elimination”; and
15 (B) in paragraph (2)—

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

20 (ii) in subparagraph (E)—

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

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

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

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

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

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

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

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

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

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

1 (A) by inserting “for a year before 2022”
2 after “1860D–2(b)(3)”; and
3 (B) by inserting “for such year” before the
4 period.

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

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

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

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

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

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

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

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

1 “(2) LI NET ELIGIBLE INDIVIDUAL DEFINED.—

2 For purposes of this subsection, the term ‘LI NET
3 eligible individual’ means a part D eligible individual
4 who—

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

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

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

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

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

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

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

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

17 “(4) PROGRAM ADMINISTRATION.—

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

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

1 “(i) provides access to all covered part

2 D drugs under an open formulary;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 “(4) OFFERING OF ADDITIONAL PLANS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Subtitle E—MedPAC

SEC. 141. PROVIDING THE MEDICARE PAYMENT ADVISORY COMMISSION AND MEDICAID AND CHIP PAYMENT AND ACCESS COMMISSION WITH ACCESS TO CERTAIN DRUG PAYMENT INFORMATION, INCLUDING CERTAIN REBATE INFORMATION.

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

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

(1) in paragraph (2)—

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

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

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

“(C) by the Executive Director of the Medicare Payment Advisory Commission for purposes of monitoring, making recommendations, and analysis of the program under this title and by the Executive Director of the Medicaid and CHIP Payment and Access Commission for purposes of monitoring, making recommendations, and analysis of the Medicaid

1 program established under title XIX and the
2 Children's Health Insurance Program under
3 title XXI."; and

4 (2) by adding at the end the following new
5 paragraph:

6 "(3) ADDITIONAL RESTRICTIONS ON DISCLO-
7 SURE OF INFORMATION.—The Executive Directors
8 described in paragraph (2)(C) shall not disclose any
9 of the following information disclosed to such Execu-
10 tive Directors or obtained by such Executive Direc-
11 tors pursuant to such paragraph, with respect to a
12 prescription drug plan offered by a PDP sponsor:

13 "(A) The specific amounts or the identity
14 of the source of any rebates, price concessions,
15 or other forms of direct or indirect remunera-
16 tion under such prescription drug plan.

17 "(B) Information submitted with the bid
18 submitted under section 1860D-11 by such
19 PDP sponsor.

20 "(C) In the case of such information from
21 prescription drug event records, in a form that
22 would not be permitted under section
23 423.505(m) of title 42, Code of Federal Regula-
24 tions, or any successor regulation, if made by
25 the Centers for Medicare & Medicaid Services."

1 (b) ACCESS TO CERTAIN REBATE AND PAYMENT
2 DATA UNDER MEDICARE AND MEDICAID.—Section
3 1927(b)(3)(D) of the Social Security Act (42 U.S.C.
4 1396r–8(b)(3)(D)) is amended—

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

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

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

11 (4) by inserting after clause (vi) the following
12 new clause:

13 “(vii) to permit the Executive Direc-
14 tor of the Medicare Payment Advisory
15 Commission and the Executive Director of
16 the Medicaid and CHIP Payment and Ac-
17 cess Commission to review the information
18 provided.”;

19 (5) in the matter at the end, by striking
20 “1860D–4(c)(2)(E)” and inserting “1860D–
21 4(c)(2)(G)”;

22 (6) by adding at the end the following new sen-
23 tence: “Any information disclosed to the Executive
24 Director of the Medicare Payment Advisory Commis-
25 sion or the Executive Director of the Medicaid and

1 CHIP Payment and Access Commission pursuant to
2 this subparagraph shall not be disclosed by either
3 such Executive Director in a form which discloses
4 the identity of a specific manufacturer or wholesaler
5 or prices charged for drugs by such manufacturer or
6 wholesaler.”.

7 **TITLE II—MEDICAID**

8 **SEC. 201. EXEMPTING EXCHANGE PLANS AND CHILD** 9 **HEALTH PLANS FROM DETERMINATION OF** 10 **BEST PRICE UNDER MEDICAID OUTPATIENT** 11 **DRUG PROGRAM.**

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

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

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

19 (3) by adding at the end of the following new
20 subclauses:

21 “(VII) any prices charged which
22 are negotiated by a qualified health
23 plan offered in the individual market
24 (as defined in section 2791 of the
25 Public Health Service Act), whether

1 or not through an exchange estab-
2 lished under title I of the Patient Pro-
3 tection and Affordable Care Act, with
4 respect to drugs on behalf of individ-
5 uals enrolled in such plan; and

6 “(VIII) any prices charged under
7 a State child health plan under title
8 XXI (or a waiver of such plan).”.

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

12 **SEC. 202. SENSE OF CONGRESS RELATING TO 340B DRUG**
13 **DISCOUNT PROGRAM.**

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

19 **SEC. 203. SUNSET OF LIMIT ON MAXIMUM REBATE AMOUNT**
20 **FOR SINGLE SOURCE DRUGS AND INNO-**
21 **VATOR MULTIPLE SOURCE DRUGS.**

22 Section 1927(c)(2)(D) of the Social Security Act (42
23 U.S.C. 1396r–8(c)(2)(D)) is amended by inserting after
24 “December 31, 2009,” the following: “and before January
25 1, 2023,”.

1 **SEC. 204. MEDICAID PHARMACY AND THERAPEUTICS COM-**

2 **MITTEE IMPROVEMENTS.**

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

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

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

15 “(I) is publicly accessible;

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

22 “(III) contains clear processes, such
23 as recusal from voting or discussion, for
24 those members who report a conflict of in-
25 terest, along with appropriate processes to

1 address any instance where a member fails
2 to report a conflict of interest.

3 “(iii) The membership of the pharmacy
4 and therapeutics committee—

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

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

13 “(bb) has expertise in the care of
14 1 or more Medicaid-specific popu-
15 lations such as elderly or disabled in-
16 dividuals, children with complex med-
17 ical needs, or low-income individuals
18 with chronic illnesses; and

19 “(II) is made publicly available.

20 “(iv) At the option of the State, the
21 State’s drug use review board established under
22 subsection (g)(3) may serve as the pharmacy
23 and therapeutics committee provided the State
24 ensures that such board meets the requirements
25 of clauses (ii) and (iii).

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

4 “(vi) If the Secretary determines it appro-
5 priate or necessary based on the findings and
6 recommendations of the Comptroller General of
7 the United States in the report submitted to
8 Congress under section 205 of the Lower Drug
9 Costs Now Act of 2019, the Secretary shall
10 issue guidance that States must follow for es-
11 tablishing conflict of interest policies for the
12 pharmacy and therapeutics committee in ac-
13 cordance with the requirements of clause (ii),
14 including appropriate standards and require-
15 ments for identifying, addressing, and reporting
16 on conflicts of interest.”.

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

21 (1) by striking “and (III)” and inserting
22 “(III)”;

23 (2) by striking the period at the end and insert-
24 ing “, and (IV) any formulary used by the entity for
25 covered outpatient drugs dispensed to individuals eli-

1 gible for medical assistance who are enrolled with
2 the entity is developed and reviewed by a pharmacy
3 and therapeutics committee that meets the require-
4 ments of clauses (ii) and (iii) of section
5 1927(d)(4)(A).”; and

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

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

10 **SEC. 205. GAO REPORT ON CONFLICTS OF INTEREST IN**
11 **STATE MEDICAID PROGRAM DRUG USE RE-**
12 **VIEW BOARDS AND PHARMACY AND THERA-**
13 **PEUTICS (P&T) COMMITTEES.**

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

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

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

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

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

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

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

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

23 (4) An analysis of whether and how States or
24 P&T Committees establish participation and inde-
25 pendence requirements for DUR Boards and P&T

1 Committees, including with respect to entities with
2 connections with drug manufacturers, State Med-
3 icaid programs, managed care organizations, and
4 other entities or individuals in the pharmaceutical
5 industry.

6 (5) A description outlining how States, DUR
7 Boards, or P&T Committees define conflicts of inter-
8 est.

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

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

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

20 (9) A review of strategies States may use to
21 guard against conflicts of interest on DUR Boards
22 and P&T Committees and to ensure compliance with
23 the requirements of titles XI and XIX of the Social
24 Security Act (42 U.S.C. 1301 et seq., 1396 et seq.)
25 and access to effective, clinically appropriate, and

1 medically necessary drug treatments for Medicaid
2 beneficiaries, including recommendations for such
3 legislative and administrative actions as the Comp-
4 troller General determines appropriate.

5 **SEC. 206. ENSURING THE ACCURACY OF MANUFACTURER**
6 **PRICE AND DRUG PRODUCT INFORMATION**
7 **UNDER THE MEDICAID DRUG REBATE PRO-**
8 **GRAM.**

9 (a) **AUDIT OF MANUFACTURER PRICE AND DRUG**
10 **PRODUCT INFORMATION.—**

11 (1) **IN GENERAL.**—Subparagraph (B) of section
12 1927(b)(3) of the Social Security Act (42 U.S.C.
13 1396r–8(b)(3)) is amended to read as follows:

14 “(B) **AUDITS AND SURVEYS OF MANUFAC-**
15 **TURER PRICE AND DRUG PRODUCT INFORMA-**
16 **TION.—**

17 “(i) **AUDITS.**—The Secretary shall
18 conduct ongoing audits of the price and
19 drug product information reported by man-
20 ufacturers under subparagraph (A) for the
21 most recently ended rebate period to en-
22 sure the accuracy and timeliness of such
23 information. In conducting such audits, the
24 Secretary may employ evaluations, surveys,

1 statistical sampling, predictive analytics
2 and other relevant tools and methods.

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

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

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

13 “(iv) REPORTS.—

14 “(I) REPORT TO CONGRESS.—

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

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

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

21 “(III) CONTENT.—Each report
22 submitted under subclause (II) shall,
23 with respect to the period that is the
24 subject of the report, include sum-
25 maries of—

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

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

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

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

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

23 “(ff) the findings of such
24 audits, including which manufac-

1 turers, if any, were penalized
2 under this subparagraph; and

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

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

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

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

23 (b) INCREASED PENALTIES FOR NONCOMPLIANCE
24 WITH REPORTING REQUIREMENTS.—

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

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

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

22 **SEC. 207. IMPROVING TRANSPARENCY AND PREVENTING**
23 **THE USE OF ABUSIVE SPREAD PRICING AND**
24 **RELATED PRACTICES IN MEDICAID.**

25 (a) PASS-THROUGH PRICING REQUIRED.—

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

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

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

19 “(i) is limited to—

20 “(I) ingredient cost; and

21 “(II) a professional dispensing
22 fee that is not less than the profes-
23 sional dispensing fee that the State
24 plan or waiver would pay if the plan

1 or waiver was making the payment di-
2 rectly;

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

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

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

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

1 voice fees. Discounts, or related adjustments
2 such as direct and indirect remuneration fees,
3 and any and all remuneration; and

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

15 (2) CONFORMING AMENDMENT.—Clause (xiii)
16 of section 1903(m)(2)(A) of such Act (42 U.S.C.
17 1396b(m)(2)(A)), as amended by section 204, is fur-
18 ther amended—

19 (A) by striking “and (IV)” and inserting
20 “(IV)”; and

21 (B) by inserting before the period at the
22 end the following: “, and (V) pharmacy benefit
23 management services provided by the entity, or
24 provided by a pharmacy benefit manager on be-
25 half of the entity under a contract or other ar-

1 rangement between the entity and the phar-
2 macy benefit manager, shall comply with the re-
3 quirements of section 1927(e)(6)”.

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

10 (b) SURVEY OF RETAIL PRICES.—

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

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

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

21 “(A) USE OF VENDOR.—The Secretary
22 may contract services for—

23 “(i) with respect to retail community
24 pharmacies, the determination on a month-
25 ly basis of retail survey prices of the na-

1 tional average drug acquisition cost for
2 covered outpatient drugs for such phar-
3 macies, net of all discounts and rebates (to
4 the extent any information with respect to
5 such discounts and rebates is available),
6 the average reimbursement received for
7 such drugs by such pharmacies from all
8 sources of payment, including third par-
9 ties, and, to the extent available, the usual
10 and customary charges to consumers for
11 such drugs; and”;

12 (B) by adding at the end of paragraph (1)
13 the following:

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

1 aged care entity, shall respond to surveys of re-
2 tail prices conducted under this subsection.

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

7 “(i) The monthly response rate of the
8 survey including a list of pharmacies not in
9 compliance with subparagraph (F).

10 “(ii) The sampling frame and number
11 of pharmacies sampled monthly.

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

16 “(iv) Reporting of a separate national
17 average drug acquisition cost for each drug
18 for independent retail pharmacies and
19 chain operated pharmacies.

20 “(v) Information on price concessions
21 including on and off invoice discounts, re-
22 bates, and other price concessions.

23 “(vi) Information on average profes-
24 sional dispensing fees paid.

25 “(H) PENALTIES.—

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

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

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

1 “(I) REPORT ON SPECIALTY PHAR-
2 MACIES.—

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

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

1 sold at specialty pharmacies and how such
2 specialty pharmacies should be defined.”;

3 (C) in paragraph (2)—

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

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

11 (D) in paragraph (4), by inserting “, and
12 \$5,000,000 for fiscal year 2020 and each fiscal
13 year thereafter,” after “2010”.

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

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

22 (1) in subparagraph (A)(i)—

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

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

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

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

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

17 (2) in subparagraph (D)—

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

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

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

1 (D) by inserting after clause (vii) the fol-
2 lowing:

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

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

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

22 (b) CONTENT OF REPORT.—

23 (1) REQUIRED CONTENT.—Each report re-
24 quired under subsection (a) for a calendar year shall
25 include the following information with respect to

1 each State (and, to the extent available, with respect
2 to Puerto Rico, the United States Virgin Islands,
3 Guam, the Northern Mariana Islands, and American
4 Samoa):

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

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

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

17 (iii) by episodes of care for—

18 (I) each chronic disease category,
19 as defined by the Secretary, that is
20 represented in the 10 conditions that
21 accounted for the greatest share of
22 total spending under the plan or waiv-
23 er during the year that is the subject
24 of the report;

25 (II) procedural groupings; and

1 (III) rare disease diagnosis codes;
2 (iv) by patient demographic character-
3 istics, including race (to the extent that
4 the Secretary determines that there is suf-
5 ficient data available with respect to such
6 characteristic in a majority of States), gen-
7 der, and age;

8 (v) by patient high-utilizer or risk sta-
9 tus; and

10 (vi) by high and low resource settings
11 by facility and place of service categories,
12 as determined by the Secretary.

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

22 (2) ADDITIONAL CONTENT.—A report required
23 under subsection (a) for a calendar year may include
24 State-specific information about prescription utiliza-

1 tion management tools under State Medicaid plans
2 or waivers of such plans, including—

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

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

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

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

22 (E) a comparison of the prescription utili-
23 zation management tools applicable under the
24 State Medicaid plan or waiver by patient high-
25 utilizer or risk status.

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

4 (A) analyses of national, State, and local
5 patterns of Medicaid population-based pre-
6 scribing behaviors; and

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

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

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

20 (2) as appropriate, include a description with
21 respect to each State of the quality and complete-
22 ness of the data, as well as any necessary caveats
23 describing the limitations of the data reported to the
24 Secretary by the State that are sufficient to commu-
25 nicate the appropriate uses for the information.

1 (d) PREPARATION OF REPORT.—Each report re-
2 quired under subsection (a) shall be prepared by the Ad-
3 ministrator for the Centers for Medicare & Medicaid Serv-
4 ices.

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

8 **SEC. 209. RISK-SHARING VALUE-BASED PAYMENT AGREE-**
9 **MENTS FOR COVERED OUTPATIENT DRUGS**
10 **UNDER MEDICAID.**

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

14 “(l) STATE OPTION TO PAY FOR COVERED OUT-
15 PATIENT DRUGS THROUGH RISK-SHARING VALUE-BASED
16 AGREEMENTS.—

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

1 “(2) SECRETARIAL APPROVAL.—

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

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

17 “(ii) NO INCREASE TO PROJECTED
18 NET FEDERAL SPENDING.—

19 “(I) IN GENERAL.—The Chief
20 Actuary certifies that the projected
21 payments for each covered outpatient
22 drug under such proposed agreement
23 would not result in greater estimated
24 Federal spending under this title than
25 the net Federal spending that would

1 result in the absence of the agree-
2 ment.

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

20 “(III) INFORMATION.—The Chief
21 Actuary shall make the certifications
22 required under this clause based on
23 the most recently available and reli-
24 able drug pricing and product infor-
25 mation. The State and manufacturer

1 shall provide the Secretary and the
2 Chief Actuary with all necessary infor-
3 mation required to make the estimates
4 needed for such certifications.

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

16 “(iv) CONFIDENTIALITY OF INFORMA-
17 TION; PENALTIES.—The provisions of sub-
18 paragraphs (C) and (D) of subsection
19 (b)(3) shall apply to a manufacturer that
20 fails to submit the information and docu-
21 mentation required under clauses (ii) and
22 (iii) on a timely basis, or that knowingly
23 provides false or misleading information, in
24 the same manner as such provisions apply

1 to a manufacturer with a rebate agreement
2 under this section.

3 “(B) CONSIDERATION OF STATE REQUEST
4 FOR APPROVAL.—

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

19 “(ii) TIMING.—The Secretary shall
20 consult with the Commissioner of Food
21 and Drugs as required under subpara-
22 graph (C) and make a determination on
23 whether to approve a request from a State
24 for approval of a proposed risk-sharing
25 value-based payment agreement (or request

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

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

22 “(3) INSTALLMENT-BASED PAYMENT STRUC-
23 TURE.—

24 “(A) IN GENERAL.—A risk-sharing value-
25 based payment agreement shall provide for a

1 payment structure under which, for every in-
2 stallment year of the agreement (subject to sub-
3 paragraph (B)), the State shall pay the total in-
4 stallment year amount in equal installments to
5 be paid at regular intervals over a period of
6 time that shall be specified in the agreement.

7 “(B) REQUIREMENTS FOR INSTALLMENT
8 PAYMENTS.—

9 “(i) TIMING OF FIRST PAYMENT.—

10 The State shall make the first of the in-
11 stallment payments described in subpara-
12 graph (A) for an installment year not later
13 than 30 days after the end of such year.

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

20 “(iii) NONPAYMENT OR REDUCED
21 PAYMENT OF INSTALLMENTS FOLLOWING
22 A FAILURE TO MEET CLINICAL PARAM-
23 ETER.—If, prior to the payment date (as
24 specified in the agreement) of any install-
25 ment payment described in subparagraph

1 (A) or any other alternative date or time
2 frame (as otherwise specified in the agree-
3 ment), the covered outpatient drug which
4 is subject to the agreement fails to meet a
5 relevant clinical parameter of the agree-
6 ment, the agreement shall provide that—

7 “(I) the installment payment
8 shall not be made; or

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

15 “(4) NOTICE OF INTENT.—

16 “(A) IN GENERAL.—Subject to subpara-
17 graph (B), a manufacturer of a covered out-
18 patient drug shall not be eligible to enter into
19 a risk-sharing value-based payment agreement
20 under this subsection with respect to such drug
21 unless the manufacturer notifies the Secretary
22 that the manufacturer is interested in entering
23 into such an agreement with respect to such
24 drug. The decision to submit and timing of a
25 request to enter into a proposed risk-sharing

1 value-based payment agreement shall remain
2 solely within the discretion of the State and
3 shall only be effective upon Secretarial approval
4 as required under this subsection.

5 “(B) TREATMENT OF SUBSEQUENTLY AP-
6 PROVED DRUGS.—

7 “(i) IN GENERAL.—In the case of a
8 manufacturer of a covered outpatient drug
9 approved under section 505 of the Federal
10 Food, Drug, and Cosmetic Act or licensed
11 under section 351 of the Public Health
12 Service Act after the date of enactment of
13 this subsection, not more than 90 days
14 after meeting with the Food and Drug Ad-
15 ministration following phase II clinical
16 trials for such drug (or, in the case of a
17 drug described in clause (ii), not later than
18 March 31, 2022), the manufacturer must
19 notify the Secretary of the manufacturer’s
20 intent to enter into a risk-sharing value-
21 based payment agreement under this sub-
22 section with respect to such drug. If no
23 such meeting has occurred, the Secretary
24 may use discretion as to whether a poten-
25 tially curative treatment intended for one-

1 time use may qualify for a risk-sharing
2 value-based payment agreement under this
3 section. A manufacturer notification of in-
4 terest shall not have any influence on a de-
5 cision for approval by the Food and Drug
6 Administration.

7 “(ii) APPLICATION TO CERTAIN SUB-
8 SEQUENTLY APPROVED DRUGS.—A drug
9 described in this clause is a covered out-
10 patient drug of a manufacturer—

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

17 “(II) with respect to which, as of
18 January 1, 2022, more than 90 days
19 have passed after the manufacturer’s
20 meeting with the Food and Drug Ad-
21 ministration following phase II clinical
22 trials for such drug.

23 “(iii) PARALLEL APPROVAL.—The
24 Secretary, in coordination with the Admin-
25 istrator of the Centers for Medicare &

1 Medicaid Services and the Commissioner of
2 Food and Drugs, shall, to the extent prac-
3 ticable, approve a State's request to enter
4 into a proposed risk-sharing value-based
5 payment agreement that otherwise meets
6 the requirements of this subsection at the
7 time that such a drug is approved by the
8 Food and Drug Administration to help
9 provide that no State that wishes to enter
10 into such an agreement is required to pay
11 for the drug in full at one time if the State
12 is seeking to pay over a period of time as
13 outlined in the proposed agreement.

14 “(iv) RULE OF CONSTRUCTION.—
15 Nothing in this paragraph shall be applied
16 or construed to modify or affect the time-
17 frames or factors involved in the Sec-
18 retary's determination of whether to ap-
19 prove or license a drug under section 505
20 of the Federal Food, Drug, and Cosmetic
21 Act or section 351 of the Public Health
22 Service Act.

23 “(5) SPECIAL PAYMENT RULES.—

24 “(A) IN GENERAL.—Except as otherwise
25 provided in this paragraph, with respect to an

1 individual who is administered a unit of a cov-
2 ered outpatient drug that is purchased under a
3 State plan by a State Medicaid agency under a
4 risk-sharing value-based payment agreement in
5 an installment year, the State shall remain lia-
6 ble to the manufacturer of such drug for pay-
7 ment for such unit without regard to whether
8 the individual remains enrolled in the State
9 plan under this title (or a waiver of such plan)
10 for each installment year for which the State is
11 to make installment payments for covered out-
12 patient drugs purchased under the agreement
13 in such year.

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

22 “(C) WITHDRAWAL OF APPROVAL.—In the
23 case of a covered outpatient drug that is the
24 subject of a risk-sharing value-based agreement
25 between a State and a manufacturer under this

1 subsection, including a drug approved in ac-
2 cordance with section 506(c) of the Federal
3 Food, Drug, and Cosmetic Act, and such drug
4 is the subject of an application that has been
5 withdrawn by the Secretary, the State plan
6 shall not be liable for any remaining payment
7 that is owed under the agreement.

8 “(D) ALTERNATIVE ARRANGEMENT UNDER
9 AGREEMENT.—Subject to approval by the Sec-
10 retary, the terms of a proposed risk-sharing
11 value-based payment agreement submitted for
12 approval by a State may provide that subpara-
13 graph (A) shall not apply.

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

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

17 “(7) ASSESSMENTS AND REPORT TO CON-
18 GRESS.—

19 “(A) ASSESSMENTS.—

20 “(i) IN GENERAL.—Not later than
21 180 days after the end of each assessment
22 period of any risk-sharing value-based pay-
23 ment agreement for a State approved
24 under this subsection, the Secretary shall
25 conduct an evaluation of such agreement

1 which shall include an evaluation by the
2 Chief Actuary to determine whether pro-
3 gram spending under the risk-sharing
4 value-based payment agreement aligned
5 with the projections for the agreement
6 made under paragraph (2)(A)(ii), including
7 an assessment of whether actual Federal
8 spending under this title under the agree-
9 ment was less or more than net Federal
10 spending would have been in the absence
11 of the agreement.

12 “(ii) ASSESSMENT PERIOD.—For pur-
13 poses of clause (i)—

14 “(I) the first assessment period
15 for a risk-sharing value-based pay-
16 ment agreement shall be the period of
17 time over which payments are sched-
18 uled to be made under the agreement
19 for the first 10 individuals who are
20 administered covered outpatient drugs
21 under the agreement except that such
22 period shall not exceed the 5-year pe-
23 riod after the date on which the Sec-
24 retary approves the agreement; and

1 “(II) each subsequent assessment
2 period for a risk-sharing value-based
3 payment agreement shall be the 5-
4 year period following the end of the
5 previous assessment period.

6 “(B) RESULTS OF ASSESSMENTS.—

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

23 “(ii) REPAYMENT REQUIRED.—

24 “(I) IN GENERAL.—If the Sec-
25 retary determines as a result of the

1 assessment by the Chief Actuary
2 under subparagraph (A) that the Fed-
3 eral spending under the risk-sharing
4 value-based agreement for a covered
5 outpatient drug that was subject to
6 such agreement was greater than the
7 net Federal spending that would have
8 resulted in the absence of the agree-
9 ment, the manufacturer shall repay
10 the difference to the State and Fed-
11 eral governments in a timely manner
12 as determined by the Secretary.

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

21 “(III) ADDITIONAL PEN-
22 ALTIES.—In the case of a manufac-
23 turer that fails to make repayments
24 required under subclause (I), the Sec-
25 retary may treat such manufacturer

1 in the same manner as a manufac-
2 turer that fails to pay required re-
3 bates under this section, and the Sec-
4 retary may—

5 “(aa) suspend or terminate
6 the manufacturer’s rebate agree-
7 ment under this section; and

8 “(bb) pursue any other rem-
9 edy that would be available if the
10 manufacturer had failed to pay
11 required rebates under this sec-
12 tion.

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

19 “(i) an assessment of the impact of
20 risk-sharing value-based payment agree-
21 ments on access for individuals who are eli-
22 gible for benefits under a State plan or
23 waiver under this title to medically nec-
24 essary covered outpatient drugs and re-
25 lated treatments;

1 “(ii) an analysis of the impact of such
2 agreements on overall State and Federal
3 spending under this title;

4 “(iii) an assessment of the impact of
5 such agreements on drug prices, including
6 launch price and price increases; and

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

9 “(8) GUIDANCE AND REGULATIONS.—

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

19 “(B) MODEL AGREEMENTS.—

20 “(i) IN GENERAL.—If a State ex-
21 presses an interest in pursuing a risk-shar-
22 ing value-based payment agreement under
23 this subsection with a manufacturer for
24 the purchase of a covered outpatient drug,
25 the Secretary may share with such State

1 any risk-sharing value-based agreement be-
2 tween a State and the manufacturer for
3 the purchase of such drug that has been
4 approved under this subsection. While such
5 shared agreement may serve as a template
6 for a State that wishes to propose, the use
7 of a previously approved agreement shall
8 not affect the submission and approval
9 process for approval of a proposed risk-
10 sharing value-based payment agreement
11 under this subsection, including the re-
12 quirements under paragraph (2)(A).

13 “(ii) CONFIDENTIALITY.—In the case
14 of a risk-sharing value-based payment
15 agreement that is disclosed to a State by
16 the Secretary under this subparagraph and
17 that is only in effect with respect to a sin-
18 gle State, the confidentiality of information
19 provisions described in subsection
20 (b)(3)(D) shall apply to such information.

21 “(C) OIG CONSULTATION.—

22 “(i) IN GENERAL.—The Secretary
23 shall consult with the Office of the Inspec-
24 tor General of the Department of Health
25 and Human Services to determine whether

1 there are potential program integrity con-
2 cerns with agreement approvals or tem-
3 plates and address accordingly.

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

15 “(9) **RULES OF CONSTRUCTION.**—

16 “(A) **MODIFICATIONS.**—Nothing in this
17 subsection or any regulations promulgated
18 under this subsection shall prohibit a State
19 from requesting a modification from the Sec-
20 retary to the terms of a risk-sharing value-
21 based payment agreement. A modification that
22 is expected to result in any increase to pro-
23 jected net State or Federal spending under the
24 agreement shall be subject to recertification by
25 the Chief Actuary as described in paragraph

1 (2)(A)(ii) before the modification may be ap-
2 proved.

3 “(B) REBATE AGREEMENTS.—Nothing in
4 this subsection shall be construed as requiring
5 a State to enter into a risk-sharing value-based
6 payment agreement or as limiting or super-
7 seding the ability of a State to enter into a sup-
8 plemental rebate agreement for a covered out-
9 patient drug.

10 “(C) FFP FOR PAYMENTS UNDER RISK-
11 SHARING VALUE-BASED PAYMENT AGREE-
12 MENTS.—Federal financial participation shall
13 be available under this title for any payment
14 made by a State to a manufacturer for a cov-
15 ered outpatient drug under a risk-sharing
16 value-based payment agreement in accordance
17 with this subsection, except that no Federal fi-
18 nancial participation shall be available for any
19 payment made by a State to a manufacturer
20 under such an agreement on and after the ef-
21 fective date of a disapproval of such agreement
22 by the Secretary.

23 “(D) CONTINUED APPLICATION OF OTHER
24 PROVISIONS.—Except as expressly provided in
25 this subsection, nothing in this subsection or in

1 any regulations promulgated under this sub-
2 section shall affect the application of any other
3 provision of this Act.

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

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

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

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

17 “(C) POTENTIALLY CURATIVE TREATMENT
18 INTENDED FOR ONE-TIME USE.—The term ‘po-
19 tentially curative treatment intended for one-
20 time use’ means a treatment that consists of
21 the administration of a covered outpatient drug
22 that—

23 “(i) is a form of gene therapy for a
24 rare disease, as defined by the Commis-
25 sioner of Food and Drugs, designated

1 under section 526 of the Federal Food,
2 Drug, and Cosmetics Act, and approved
3 under section 505 of such Act or licensed
4 under subsection (a) or (k) of section 351
5 of the Public Health Service Act to treat
6 a serious or life-threatening disease or con-
7 dition;

8 “(ii) if administered in accordance
9 with the labeling of such drug, is expected
10 to result in either—

11 “(I) the cure of such disease or
12 condition; or

13 “(II) a reduction in the symp-
14 toms of such disease or condition to
15 the extent that such disease or condi-
16 tion is not expected to lead to early
17 mortality; and

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

22 “(D) RELEVANT CLINICAL PARAMETER.—
23 The term ‘relevant clinical parameter’ means,
24 with respect to a covered outpatient drug that

1 is the subject of a risk-sharing value-based pay-
2 ment agreement—

3 “(i) a clinical endpoint specified in the
4 drug’s labeling or supported by one or
5 more of the compendia described in section
6 1861(t)(2)(B)(ii)(I) that—

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

12 “(II) is required to be achieved
13 (based on observed metrics in patient
14 populations) under the terms of the
15 agreement; or

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

21 “(I) is able to be measured or
22 evaluated on an annual basis for each
23 year of the agreement on an inde-
24 pendent basis by a provider or other
25 entity; and

1 “(II) has been qualified by the
2 Food and Drug Administration.

3 “(E) RISK-SHARING VALUE-BASED PAY-
4 MENT AGREEMENT.—The term ‘risk-sharing
5 value-based payment agreement’ means an
6 agreement between a State plan and a manu-
7 facturer—

8 “(i) for the purchase of a covered out-
9 patient drug of the manufacturer that is a
10 potentially curative treatment intended for
11 one-time use;

12 “(ii) under which payment for such
13 drug shall be made pursuant to an install-
14 ment-based payment structure that meets
15 the requirements of paragraph (3);

16 “(iii) which conditions payment on the
17 achievement of at least 2 relevant clinical
18 parameters (as defined in subparagraph
19 (C));

20 “(iv) which provides that—

21 “(I) the State plan will directly
22 reimburse the manufacturer for the
23 drug; or

1 “(II) a third party will reimburse
2 the manufacture in a manner ap-
3 proved by the Secretary; and

4 “(v) is approved by the Secretary in
5 accordance with paragraph (2).

6 “(F) TOTAL INSTALLMENT YEAR
7 AMOUNT.—The term ‘total installment year
8 amount’ means, with respect to a risk-sharing
9 value-based payment agreement for the pur-
10 chase of a covered outpatient drug and an in-
11 stallment year, an amount equal to the product
12 of—

13 “(i) the unit price of the drug charged
14 under the agreement; and

15 “(ii) the number of units of such drug
16 administered under the agreement during
17 such installment year.”.

18 (b) CONFORMING AMENDMENTS.—

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

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

3 (A) in paragraph (1)(A), by inserting “(ex-
4 cept for drugs for which payment is made by a
5 State under a risk-sharing value-based payment
6 agreement under subsection (l))” after “under
7 the State plan for such period”; and

8 (B) in paragraph (3)—

9 (i) in subparagraph (C)(i), by insert-
10 ing “or subsection (l)(2)(A)” after “sub-
11 paragraph (A)”; and

12 (ii) in subparagraph (D), in the mat-
13 ter preceding clause (i), by inserting “,
14 under subsection (l)(2)(A),” after “under
15 this paragraph”.

16 **SEC. 210. APPLYING MEDICAID DRUG REBATE REQUIRE-**
17 **MENT TO DRUGS PROVIDED AS PART OF OUT-**
18 **PATIENT HOSPITAL SERVICES.**

19 (a) IN GENERAL.—Section 1927(k)(3) of the Social
20 Security Act (42 U.S.C. 1396r-8(k)(3)) is amended to
21 read as follows:

22 “(3) LIMITING DEFINITION.—

23 “(A) IN GENERAL.—The term ‘covered
24 outpatient drug’ does not include any drug, bio-
25 logical product, or insulin provided as part of,

1 or as incident to and in the same setting as,
2 any of the following (and for which payment
3 may be made under this title as part of pay-
4 ment for the following and not as direct reim-
5 bursement for the drug):

6 “(i) Inpatient hospital services.

7 “(ii) Hospice services.

8 “(iii) Dental services, except that
9 drugs for which the State plan authorizes
10 direct reimbursement to the dispensing
11 dentist are covered outpatient drugs.

12 “(iv) Physicians’ services.

13 “(v) Outpatient hospital services.

14 “(vi) Nursing facility services and
15 services provided by an intermediate care
16 facility for the mentally retarded.

17 “(vii) Other laboratory and x-ray serv-
18 ices.

19 “(viii) Renal dialysis.

20 “(B) OTHER EXCLUSIONS.—Such term
21 also does not include any such drug or product
22 for which a National Drug Code number is not
23 required by the Food and Drug Administration
24 or a drug or biological used for a medical indi-

1 cation which is not a medically accepted indica-
2 tion.

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

13 “(D) NO EFFECT ON BEST PRICE.—Any
14 drug, biological product, or insulin excluded
15 from the definition of such term as a result of
16 this paragraph shall be treated as a covered
17 outpatient drug for purposes of determining the
18 best price (as defined in subsection (c)(1)(C))
19 for such drug, biological product, or insulin.”.

20 (b) EFFECTIVE DATE; IMPLEMENTATION GUID-
21 ANCE.—

22 (1) IN GENERAL.—The amendment made by
23 subsection (a) shall take effect on the date that is
24 1 year after the date of enactment of this Act.

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

11 **SEC. 211. PROHIBITION ON ADDITIONAL REBATE UNDER**
12 **MEDICAID FOR CERTAIN NONINNOVATOR**
13 **MULTIPLE SOURCE DRUGS.**

14 Section 1927(c)(3)(C) of the Social Security Act (42
15 U.S.C. 1396r–8(c)(3)(C)) is amended—

16 (1) in clause (i), by striking “The amount” and
17 inserting “Subject to clause (v), the amount”; and
18 (2) by adding at the end the following new
19 clause:

20 “(v) PROHIBITION ON ADDITIONAL
21 REBATE FOR CERTAIN NONINNOVATOR
22 MULTIPLE SOURCE DRUGS.—With respect
23 to a rebate period beginning on or after
24 January 1, 2020, and a dosage form and
25 strength of a covered outpatient drug de-

1 scribed in clause (i), the amount of the re-
2 bate specified in subparagraph (A) for
3 such dosage form and strength for such re-
4 bate period may not be increased if the av-
5 erage manufacturer price for a unit of
6 such dosage form and strength for such re-
7 bate period is less than \$1.”.

8 **TITLE III—FOOD AND DRUG**
9 **ADMINISTRATION**

10 **Subtitle A—CREATES Act**

11 **SEC. 301. ACTIONS FOR DELAYS OF GENERIC DRUGS AND**
12 **BIOSIMILAR BIOLOGICAL PRODUCTS.**

13 (a) DEFINITIONS.—In this section—

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

16 (A) a nondiscriminatory price for the sale
17 of the covered product at or below, but not
18 greater than, the most recent wholesale acquisi-
19 tion cost for the drug, as defined in section
20 1847A(c)(6)(B) of the Social Security Act (42
21 U.S.C. 1395w-3a(c)(6)(B));

22 (B) a schedule for delivery that results in
23 the transfer of the covered product to the eligi-
24 ble product developer consistent with the timing
25 under subsection (b)(2)(A)(iv); and

1 (C) no additional conditions are imposed
2 on the sale of the covered product;

3 (2) the term “covered product”—

4 (A) means—

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

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

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

1 (B) does not include any drug or biological
2 product that appears on the drug shortage list
3 in effect under section 506E of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C.
5 356e), unless—

6 (i) the drug or biological product has
7 been on the drug shortage list in effect
8 under such section 506E continuously for
9 more than 6 months; or

10 (ii) the Secretary determines that in-
11 clusion of the drug or biological product as
12 a covered product is likely to contribute to
13 alleviating or preventing a shortage;

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

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

1 (5) the term “license holder” means the holder
2 of an application approved under subsection (c) or
3 (j) of section 505 of the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 355) or the holder of a li-
5 cense under subsection (a) or (k) of section 351 of
6 the Public Health Service Act (42 U.S.C. 262) for
7 a covered product;

8 (6) the term “REMS” means a risk evaluation
9 and mitigation strategy under section 505–1 of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 355–1);

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

16 (8) the term “Secretary” means the Secretary
17 of Health and Human Services;

18 (9) the term “single, shared system of elements
19 to assure safe use” means a single, shared system
20 of elements to assure safe use under section 505–
21 1(f) of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 355–1(f)); and

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

1 (A) conduct testing to support an applica-
2 tion under—

3 (i) subsection (b)(2) or (j) of section
4 505 of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 355); or

6 (ii) section 351(k) of the Public
7 Health Service Act (42 U.S.C. 262(k));
8 and

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

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

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

21 (2) ELEMENTS.—

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

1 (i) that—

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

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

6 (aa) the eligible product de-
7 veloper has obtained a covered
8 product authorization from the
9 Secretary in accordance with sub-
10 paragraph (B); and

11 (bb) the eligible product de-
12 veloper has provided a copy of
13 the covered product authorization
14 to the license holder;

15 (ii) that, as of the date on which the
16 civil action is filed, the product developer
17 has not obtained sufficient quantities of
18 the covered product on commercially rea-
19 sonable, market-based terms;

20 (iii) that the eligible product developer
21 has submitted a written request to pur-
22 chase sufficient quantities of the covered
23 product to the license holder and such re-
24 quest—

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

3 (II) was made by certified or reg-
4 istered mail with return receipt re-
5 quested;

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

14 (IV) specified an address to
15 which the covered product was to be
16 shipped upon reaching an agreement
17 to transfer the covered product; and

18 (iv) that the license holder has not de-
19 livered to the eligible product developer
20 sufficient quantities of the covered product
21 on commercially reasonable, market-based
22 terms—

23 (I) for a covered product that is
24 not subject to a REMS with ETASU,
25 by the date that is 31 days after the

1 date on which the license holder re-
2 ceived the request for the covered
3 product; and

4 (II) for a covered product that is
5 subject to a REMS with ETASU, by
6 31 days after the later of—

7 (aa) the date on which the
8 license holder received the re-
9 quest for the covered product; or

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

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

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

23 (ii) AUTHORIZATION.—Not later than
24 120 days after the date on which a request
25 under clause (i) is received, the Secretary

1 shall, by written notice, authorize the eligi-
2 ble product developer to obtain sufficient
3 quantities of an individual covered product
4 subject to a REMS with ETASU for pur-
5 poses of—

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

11 (II) development and testing that
12 involves human clinical trials, if the
13 eligible product developer has—

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

22 (BB) otherwise satisfied the
23 Secretary that such protections
24 will be provided; and

1 (bb) met any other require-
2 ments the Secretary may estab-
3 lish.

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

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

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

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

24 (ii) neither the license holder nor any
25 of its agents, wholesalers, or distributors

1 otherwise had access to inventory of the
2 covered product to supply to the eligible
3 product developer on commercially reason-
4 able, market-based terms;

5 (B) that—

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

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

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

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

1 product developer at commercially reasonable
2 market-based terms—

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

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

22 (4) REMEDIES.—

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

1 (i) order the license holder to provide
2 to the eligible product developer without
3 delay sufficient quantities of the covered
4 product on commercially reasonable, mar-
5 ket-based terms;

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

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

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

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

1 (B) MAXIMUM MONETARY AMOUNT.—A

2 monetary amount awarded under subparagraph

3 (A)(iii) shall not be greater than the revenue

4 that the license holder earned on the covered

5 product during the period—

6 (i) beginning on—

7 (I) for a covered product that is

8 not subject to a REMS with ETASU,

9 the date that is 31 days after the date

10 on which the license holder received

11 the request; or

12 (II) for a covered product that is

13 subject to a REMS with ETASU, the

14 date that is 31 days after the later

15 of—

16 (aa) the date on which the

17 license holder received the re-

18 quest; or

19 (bb) the date on which the

20 license holder received a copy of

21 the covered product authorization

22 issued by the Secretary in ac-

23 cordance with paragraph (2)(B);

24 and

1 (ii) ending on the date on which the
2 eligible product developer received suffi-
3 cient quantities of the covered product.

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

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

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

23 “(I) PROVISION OF SAMPLES NOT A VIOLATION OF
24 STRATEGY.—The provision of samples of a covered prod-
25 uct to an eligible product developer (as those terms are

1 defined in section 301(a) of the Lower Drug Costs Now
2 Act of 2019) shall not be considered a violation of the
3 requirements of any risk evaluation and mitigation strat-
4 egy that may be in place under this section for such
5 drug.”

6 (e) RULE OF CONSTRUCTION.—

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

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

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

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

19 **SEC. 302. REMS APPROVAL PROCESS FOR SUBSEQUENT**
20 **FILERS.**

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

24 (1) in subsection (g)(4)(B)—

1 (A) in clause (i) by striking “or” after the
2 semicolon;

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

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

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

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

13 “(C)(i) Elements to assure safe use, if re-
14 quired under subsection (f) for the listed drug,
15 which, subject to clause (ii), for a drug that is
16 the subject of an application under section
17 505(j) may use—

18 “(I) a single, shared system with
19 the listed drug under subsection (f);
20 or

21 “(II) a different, comparable as-
22 pect of the elements to assure safe use
23 under subsection (f).

24 “(ii) The Secretary may require a
25 drug that is the subject of an application

1 under section 505(j) and the listed drug to
2 use a single, shared system under sub-
3 section (f), if the Secretary determines
4 that no different, comparable aspect of the
5 elements to assure safe use could satisfy
6 the requirements of subsection (f).”;

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

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

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

21 “(m) SEPARATE REMS.—When used in this section,
22 the terms ‘different, comparable aspect of the elements to
23 assure safe use’ or ‘different, comparable approved risk
24 evaluation and mitigation strategies’ means a risk evalua-
25 tion and mitigation strategy for a drug that is the subject

1 of an application under section 505(j) that uses different
2 methods or operational means than the strategy required
3 under subsection (a) for the applicable listed drug, or
4 other application under section 505(j) with the same such
5 listed drug, but achieves the same level of safety as such
6 strategy.”.

7 **SEC. 303. RULE OF CONSTRUCTION.**

8 (a) IN GENERAL.—Nothing in this subtitle, the
9 amendments made by this subtitle, or in section 505–1
10 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 355–1), shall be construed as—

12 (1) prohibiting a license holder from providing
13 an eligible product developer access to a covered
14 product in the absence of an authorization under
15 this subtitle; or

16 (2) in any way negating the applicability of a
17 REMS with ETASU, as otherwise required under
18 such section 505–1, with respect to such covered
19 product.

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

1 **Subtitle B—Pay-for-Delay**

2 **SEC. 311. UNLAWFUL AGREEMENTS.**

3 (a) **AGREEMENTS PROHIBITED.**—Subject to sub-
4 sections (b) and (c), it shall be unlawful for an NDA or
5 BLA holder and a subsequent filer (or for two subsequent
6 filers) to enter into, or carry out, an agreement resolving
7 or settling a covered patent infringement claim on a final
8 or interim basis if under such agreement—

9 (1) a subsequent filer directly or indirectly re-
10 ceives from such holder (or in the case of such an
11 agreement between two subsequent filers, the other
12 subsequent filer) anything of value, including a li-
13 cense; and

14 (2) the subsequent filer agrees to limit or fore-
15 go research on, or development, manufacturing,
16 marketing, or sales, for any period of time, of the
17 covered product that is the subject of the application
18 described in subparagraph (A) or (B) of subsection
19 (g)(8).

20 (b) **EXCLUSION.**—It shall not be unlawful under sub-
21 section (a) if a party to an agreement described in such
22 subsection demonstrates by clear and convincing evidence
23 that the value described in subsection (a)(1) is compensa-
24 tion solely for other goods or services that the subsequent
25 filer has promised to provide.

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

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

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

13 (B) any patent right or other statutory ex-
14 clusivity that would prevent the marketing of
15 such covered product.

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

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

20 (d) ENFORCEMENT BY FEDERAL TRADE COMMIS-
21 SION.—

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

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

5 (B) a person, partnership, or corporation
6 over which the Commission would have author-
7 ity pursuant to such section but for the fact
8 that such person, partnership, or corporation is
9 not organized to carry on business for its own
10 profit or that of its members.

11 (2) UNFAIR OR DECEPTIVE ACTS OR PRACTICES
12 ENFORCEMENT AUTHORITY.—

13 (A) IN GENERAL.—A violation of this sec-
14 tion shall be treated as an unfair or deceptive
15 act or practice in violation of section 5(a)(1) of
16 the Federal Trade Commission Act (15 U.S.C.
17 45(a)(1)).

18 (B) POWERS OF COMMISSION.—Except as
19 provided in subparagraph (C) and paragraphs
20 (1)(B) and (3)—

21 (i) the Commission shall enforce this
22 section in the same manner, by the same
23 means, and with the same jurisdiction,
24 powers, and duties as though all applicable
25 terms and provisions of the Federal Trade

1 Commission Act (15 U.S.C. 41 et seq.)
2 were incorporated into and made a part of
3 this section; and

4 (ii) any NDA or BLA holder or subse-
5 quent filer that violates this section shall
6 be subject to the penalties and entitled to
7 the privileges and immunities provided in
8 the Federal Trade Commission Act.

9 (C) JUDICIAL REVIEW.—In the case of a
10 cease and desist order issued by the Commis-
11 sion under section 5 of the Federal Trade Com-
12 mission Act (15 U.S.C. 45) for violation of this
13 section, a party to such order may obtain judi-
14 cial review of such order as provided in such
15 section 5, except that—

16 (i) such review may only be obtained
17 in—

18 (I) the United States Court of
19 Appeals for the District of Columbia
20 Circuit;

21 (II) the United States Court of
22 Appeals for the circuit in which the
23 ultimate parent entity, as defined in
24 section 801.1(a)(3) of title 16, Code
25 of Federal Regulations, or any suc-

1 cessor thereto, of the NDA or BLA
2 holder (if any such holder is a party
3 to such order) is incorporated as of
4 the date that the application described
5 in subparagraph (A) or (B) of sub-
6 section (g)(8) or an approved applica-
7 tion that is deemed to be a license for
8 a biological product under section
9 351(k) of the Public Health Service
10 Act (42 U.S.C. 262(k)) pursuant to
11 section 7002(e)(4) of the Biologics
12 Price Competition and Innovation Act
13 of 2009 (Public Law 111-148; 124
14 Stat. 817) is submitted to the Com-
15 missioner of Food and Drugs; or

16 (III) the United States Court of
17 Appeals for the circuit in which the
18 ultimate parent entity, as so defined,
19 of any subsequent filer that is a party
20 to such order is incorporated as of the
21 date that the application described in
22 subparagraph (A) or (B) of subsection
23 (g)(8) is submitted to the Commis-
24 sioner of Food and Drugs; and

1 (ii) the petition for review shall be
2 filed in the court not later than 30 days
3 after such order is served on the party
4 seeking review.

5 (3) ADDITIONAL ENFORCEMENT AUTHORITY.—

6 (A) CIVIL PENALTY.—The Commission
7 may commence a civil action to recover a civil
8 penalty in a district court of the United States
9 against any NDA or BLA holder or subsequent
10 filer that violates this section.

11 (B) SPECIAL RULE FOR RECOVERY OF
12 PENALTY IF CEASE AND DESIST ORDER
13 ISSUED.—

14 (i) IN GENERAL.—If the Commission
15 has issued a cease and desist order in a
16 proceeding under section 5 of the Federal
17 Trade Commission Act (15 U.S.C. 45) for
18 violation of this section—

19 (I) the Commission may com-
20 mence a civil action under subpara-
21 graph (A) to recover a civil penalty
22 against any party to such order at
23 any time before the expiration of the
24 1-year period beginning on the date
25 on which such order becomes final

1 under section 5(g) of such Act (15
2 U.S.C. 45(g)); and

3 (II) in such civil action, the find-
4 ings of the Commission as to the ma-
5 terial facts in such proceeding shall be
6 conclusive, unless—

7 (aa) the terms of such order
8 expressly provide that the Com-
9 mission's findings shall not be
10 conclusive; or

11 (bb) such order became final
12 by reason of section 5(g)(1) of
13 such Act (15 U.S.C. 45(g)(1)), in
14 which case such findings shall be
15 conclusive if supported by evi-
16 dence.

17 (ii) RELATIONSHIP TO PENALTY FOR
18 VIOLATION OF AN ORDER.—The penalty
19 provided in clause (i) for violation of this
20 section is separate from and in addition to
21 any penalty that may be incurred for viola-
22 tion of an order of the Commission under
23 section 5(l) of the Federal Trade Commis-
24 sion Act (15 U.S.C. 45(l)).

25 (C) AMOUNT OF PENALTY.—

1 (i) IN GENERAL.—The amount of a
2 civil penalty imposed in a civil action under
3 subparagraph (A) on a party to an agree-
4 ment described in subsection (a) shall be
5 sufficient to deter violations of this section,
6 but in no event greater than—

7 (I) if such party is the NDA or
8 BLA holder (or, in the case of an
9 agreement between two subsequent fil-
10 ers, the subsequent filer who gave the
11 value described in subsection (a)(1)),
12 the greater of—

13 (aa) 3 times the value re-
14 ceived by such NDA or BLA
15 holder (or by such subsequent
16 filer) that is reasonably attrib-
17 utable to the violation of this sec-
18 tion; or

19 (bb) 3 times the value given
20 to the subsequent filer (or to the
21 other subsequent filer) reason-
22 ably attributable to the violation
23 of this section; and

24 (II) if such party is the subse-
25 quent filer (or, in the case of an

1 agreement between two subsequent fil-
2 ers, the subsequent filer who received
3 the value described in subsection
4 (a)(1)), 3 times the value received by
5 such subsequent filer that is reason-
6 ably attributable to the violation of
7 this section.

8 (ii) FACTORS FOR CONSIDERATION.—

9 In determining such amount, the court
10 shall take into account—

11 (I) the nature, circumstances, ex-
12 tent, and gravity of the violation;

13 (II) with respect to the violator,
14 the degree of culpability, any history
15 of violations, the ability to pay, any
16 effect on the ability to continue doing
17 business, profits earned by the NDA
18 or BLA holder (or, in the case of an
19 agreement between two subsequent fil-
20 ers, the subsequent filer who gave the
21 value described in subsection (a)(1)),
22 compensation received by the subse-
23 quent filer (or, in the case of an
24 agreement between two subsequent fil-
25 ers, the subsequent filer who received

1 the value described in subsection
2 (a)(1)), and the amount of commerce
3 affected; and

4 (III) other matters that justice
5 requires.

6 (D) INJUNCTIONS AND OTHER EQUITABLE
7 RELIEF.—In a civil action under subparagraph
8 (A), the United States district courts are em-
9 powered to grant mandatory injunctions and
10 such other and further equitable relief as they
11 deem appropriate.

12 (4) REMEDIES IN ADDITION.—Remedies pro-
13 vided in this subsection are in addition to, and not
14 in lieu of, any other remedy provided by Federal
15 law.

16 (5) PRESERVATION OF AUTHORITY OF COMMIS-
17 SION.—Nothing in this section shall be construed to
18 affect any authority of the Commission under any
19 other provision of law.

20 (e) FEDERAL TRADE COMMISSION RULEMAKING.—
21 The Commission may, in its discretion, by rule promul-
22 gated under section 553 of title 5, United States Code,
23 exempt from this section certain agreements described in
24 subsection (a) if the Commission finds such agreements

1 to be in furtherance of market competition and for the
2 benefit of consumers.

3 (f) ANTITRUST LAWS.—Nothing in this section shall
4 modify, impair, limit, or supersede the applicability of the
5 antitrust laws as defined in subsection (a) of the first sec-
6 tion of the Clayton Act (15 U.S.C. 12(a)), and of section
7 5 of the Federal Trade Commission Act (15 U.S.C. 45)
8 to the extent that such section 5 applies to unfair methods
9 of competition. Nothing in this section shall modify, im-
10 pair, limit, or supersede the right of a subsequent filer
11 to assert claims or counterclaims against any person,
12 under the antitrust laws or other laws relating to unfair
13 competition.

14 (g) DEFINITIONS.—In this section:

15 (1) AGREEMENT RESOLVING OR SETTLING A
16 COVERED PATENT INFRINGEMENT CLAIM.—The
17 term “agreement resolving or settling a covered pat-
18 ent infringement claim” means any agreement
19 that—

20 (A) resolves or settles a covered patent in-
21 fringement claim; or

22 (B) is contingent upon, provides for a con-
23 tingent condition for, or is otherwise related to
24 the resolution or settlement of a covered patent
25 infringement claim.

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

3 (3) COVERED PATENT INFRINGEMENT CLAIM.—
4 The term “covered patent infringement claim”
5 means an allegation made by the NDA or BLA hold-
6 er to a subsequent filer (or, in the case of an agree-
7 ment between two subsequent filers, by one subse-
8 quent filer to another), whether or not included in
9 a complaint filed with a court of law, that—

10 (A) the submission of the application de-
11 scribed in subparagraph (A) or (B) of para-
12 graph (9), or the manufacture, use, offering for
13 sale, sale, or importation into the United States
14 of a covered product that is the subject of such
15 an application—

16 (i) in the case of an agreement be-
17 tween an NDA or BLA holder and a sub-
18 sequent filer, infringes any patent owned
19 by, or exclusively licensed to, the NDA or
20 BLA holder of the covered product; or

21 (ii) in the case of an agreement be-
22 tween two subsequent filers, infringes any
23 patent owned by the subsequent filer; or

24 (B) in the case of an agreement between
25 an NDA or BLA holder and a subsequent filer,

1 the covered product to be manufactured under
2 such application uses a covered product as
3 claimed in a published patent application.

4 (4) COVERED PRODUCT.—The term “covered
5 product” means a drug (as defined in section 201(g)
6 of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 321(g))), including a biological product (as
8 defined in section 351(i) of the Public Health Serv-
9 ice Act (42 U.S.C. 262(i)).

10 (5) NDA OR BLA HOLDER.—The term “NDA
11 or BLA holder” means—

12 (A) the holder of—

13 (i) an approved new drug application
14 filed under section 505(b)(1) of the Fed-
15 eral Food, Drug, and Cosmetic Act (21
16 U.S.C. 355(b)(1)) for a covered product;

17 or

18 (ii) a biologics license application filed
19 under section 351(a) of the Public Health
20 Service Act (42 U.S.C. 262(a)) with re-
21 spect to a biological product;

22 (B) a person owning or controlling enforce-
23 ment of the patent on—

24 (i) the list published under section
25 505(j)(7) of the Federal Food, Drug, and

1 Cosmetic Act (21 U.S.C. 355(j)(7)) in con-
2 nection with the application described in
3 subparagraph (A)(i); or

4 (ii) any list published under section
5 351 of the Public Health Service Act (42
6 U.S.C. 262) comprised of patents associ-
7 ated with biologics license applications filed
8 under section 351(a) of such Act (42
9 U.S.C. 262(a)); or

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

18 (6) PATENT.—The term “patent” means a pat-
19 ent issued by the United States Patent and Trade-
20 mark Office.

21 (7) STATUTORY EXCLUSIVITY.—The term
22 “statutory exclusivity” means those prohibitions on
23 the submission or approval of drug applications
24 under clauses (ii) through (iv) of section
25 505(c)(3)(E) (5- and 3-year exclusivity), clauses (ii)

1 through (iv) of section 505(j)(5)(F) (5-year and 3-
2 year exclusivity), section 505(j)(5)(B)(iv) (180-day
3 exclusivity), section 527 (orphan drug exclusivity),
4 section 505A (pediatric exclusivity), or section 505E
5 (qualified infectious disease product exclusivity) of
6 the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 355(j)(5)(F),
8 360cc, 355a, 355f), or prohibitions on the submis-
9 sion or licensing of biologics license applications
10 under section 351(k)(6) (interchangeable biological
11 product exclusivity) or section 351(k)(7) (biological
12 product reference product exclusivity) of the Public
13 Health Service Act (42 U.S.C. 262(k)(6), (7)).

14 (8) SUBSEQUENT FILER.—The term “subse-
15 quent filer” means—

16 (A) in the case of a drug, a party that
17 owns or controls an abbreviated new drug appli-
18 cation submitted pursuant to section 505(j) of
19 the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 355(j)) or a new drug application sub-
21 mitted pursuant to section 505(b)(2) of the
22 Federal Food, Drug, and Cosmetic Act
23 (21U.S.C. 355(b)(2)) and filed under section
24 505(b)(1) of such Act (21 U.S.C. 355(b)(1)) or
25 has the exclusive rights to distribute the cov-

1 ered product that is the subject of such applica-
2 tion; or

3 (B) in the case of a biological product, a
4 party that owns or controls an application filed
5 with the Food and Drug Administration under
6 section 351(k) of the Public Health Service Act
7 (42 U.S.C. 262(k)) or has the exclusive rights
8 to distribute the biological product that is the
9 subject of such application.

10 (h) EFFECTIVE DATE.—This section applies with re-
11 spect to agreements described in subsection (a) entered
12 into on or after the date of the enactment of this Act.

13 **SEC. 312. NOTICE AND CERTIFICATION OF AGREEMENTS.**

14 (a) NOTICE OF ALL AGREEMENTS.—Section 1111(7)
15 of the Medicare Prescription Drug, Improvement, and
16 Modernization Act of 2003 (21 U.S.C. 355 note) is
17 amended by inserting “or the owner of a patent for which
18 a claim of infringement could reasonably be asserted
19 against any person for making, using, offering to sell, sell-
20 ing, or importing into the United States a biological prod-
21 uct that is the subject of a biosimilar biological product
22 application” before the period at the end.

23 (b) CERTIFICATION OF AGREEMENTS.—Section 1112
24 of such Act (21 U.S.C. 355 note) is amended by adding
25 at the end the following:

1 “(d) CERTIFICATION.—The Chief Executive Officer
2 or the company official responsible for negotiating any
3 agreement under subsection (a) or (b) that is required to
4 be filed under subsection (c) shall, within 30 days of such
5 filing, execute and file with the Assistant Attorney General
6 and the Commission a certification as follows: ‘I declare
7 that the following is true, correct, and complete to the best
8 of my knowledge: The materials filed with the Federal
9 Trade Commission and the Department of Justice under
10 section 1112 of the Medicare Prescription Drug, Improve-
11 ment, and Modernization Act of 2003, with respect to the
12 agreement referenced in this certification—

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

15 “(2) include any ancillary agreements that are
16 contingent upon, provide a contingent condition for,
17 were entered into within 30 days of, or are otherwise
18 related to, the referenced agreement; and

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

1 **SEC. 313. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

2 Section 505(j)(5)(D)(i)(V) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))
4 is amended by inserting “section 311 of the Lower Drug
5 Costs Now Act of 2019 or” after “that the agreement has
6 violated”.

7 **SEC. 314. COMMISSION LITIGATION AUTHORITY.**

8 Section 16(a)(2) of the Federal Trade Commission
9 Act (15 U.S.C. 56(a)(2)) is amended—

10 (1) in subparagraph (D), by striking “or” after
11 the semicolon;

12 (2) in subparagraph (E), by inserting “or”
13 after the semicolon; and

14 (3) by inserting after subparagraph (E) the fol-
15 lowing:

16 “(F) under section 311(d)(3)(A) of the
17 Lower Drug Costs Now Act of 2019;”.

18 **SEC. 315. STATUTE OF LIMITATIONS.**

19 (a) IN GENERAL.—Except as provided in subsection
20 (b), the Commission shall commence any administrative
21 proceeding or civil action to enforce section 311 of this
22 Act not later than 6 years after the date on which the
23 parties to the agreement file the Notice of Agreement as
24 provided by section 1112(c)(2) and (d) of the Medicare
25 Prescription Drug, Improvement, and Modernization Act
26 of 2003 (21 U.S.C. 355 note).

(b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND DESIST ORDER.—If the Commission has issued a cease and desist order under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) for violation of section 311 of this Act and the proceeding for the issuance of such order was commenced within the period required by subsection (a) of this section, such subsection does not prohibit the commencement, after such period, of a civil action under section 311(d)(3)(A) against a party to such order or a civil action under subsection (l) of such section 5 for violation of such order.

Subtitle C—BLOCKING Act

SEC. 321. CHANGE CONDITIONS OF FIRST GENERIC EXCLUSIVITY TO SPUR ACCESS AND COMPETITION.

Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amended—

(1) in subclause (I), by striking “180 days after” and all that follows through the period at the end and inserting the following: “180 days after the earlier of—

“(aa) the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant; or

1 “(bb) the applicable date speci-
2 fied in subclause (III).”; and

3 (2) by adding at the end the following new sub-
4 clause:

5 “(III) APPLICABLE DATE.—The appli-
6 cable date specified in this subclause, with
7 respect to an application for a drug de-
8 scribed in subclause (I), is the date on
9 which each of the following conditions is
10 first met:

11 “(aa) The approval of such an
12 application could be made effective,
13 but for the eligibility of a first appli-
14 cant for 180-day exclusivity under
15 this clause.

16 “(bb) At least 30 months have
17 passed since the date of submission of
18 an application for the drug by at least
19 one first applicant.

20 “(cc) Approval of an application
21 for the drug submitted by at least one
22 first applicant is not precluded under
23 clause (iii).

24 “(dd) No application for the drug
25 submitted by any first applicant is ap-

1 proved at the time the conditions
2 under items (aa), (bb), and (cc) are
3 all met, regardless of whether such an
4 application is subsequently ap-
5 proved.”.

6 **Subtitle D—Purple Book**

7 **SEC. 331. PUBLIC LISTING.**

8 Section 351(k) of the Public Health Service Act (42
9 U.S.C. 262(k)) is amended by adding at the end the fol-
10 lowing:

11 “(9) PUBLIC LISTING.—

12 “(A) IN GENERAL.—

13 “(i) INITIAL PUBLICATION.—Not later
14 than 180 days after the date of enactment
15 of the Lower Drug Costs Now Act 2019,
16 the Secretary shall publish and make avail-
17 able to the public in a searchable, elec-
18 tronic format—

19 “(I) a list in alphabetical order of
20 the nonproprietary or proper name of
21 each biological product for which a
22 biologics license under subsection (a)
23 or this subsection is in effect, or that
24 has been deemed to be licensed under
25 this section pursuant to section

1 7002(e)(4) of the Biologics Price
2 Competition and Innovation Act of
3 2009, as of such date of enactment;

4 “(II) the date of approval of the
5 marketing application and the applica-
6 tion number; and

7 “(III) the marketing or licensure
8 status of the biological product for
9 which a biologics license under sub-
10 section (a) or this subsection is in ef-
11 fect or that has been deemed to be li-
12 censed under this section pursuant to
13 section 7002(e)(4) of the Biologics
14 Price Competition and Innovation Act
15 of 2009.

16 “(ii) REVISIONS.—Every 30 days
17 after the publication of the first list under
18 clause (i), the Secretary shall revise the list
19 to include each biological product which
20 has been licensed under subsection (a) or
21 this subsection during the 30-day period.

22 “(iii) PATENT INFORMATION.—Not
23 later than 30 days after a list of patents
24 under subsection (l)(3)(A), or a supple-
25 ment to such list under subsection (l)(7),

1 has been provided by the reference product
2 sponsor to the subsection (k) applicant re-
3 specting a biological product included on
4 the list published under this subparagraph,
5 the reference product sponsor shall provide
6 such list of patents (or supplement there-
7 to) and their corresponding expiry dates to
8 the Secretary, and the Secretary shall, in
9 revisions made under clause (ii), include
10 such information for such biological prod-
11 uct. Within 30 days of providing any sub-
12 sequent or supplemental list of patents to
13 any subsequent subsection (k) applicant
14 under subsection (l)(3)(A) or (l)(7), the
15 reference product sponsor shall update the
16 information provided to the Secretary
17 under this clause with any additional pat-
18 ents from such subsequent or supplemental
19 list and their corresponding expiry dates.

20 “(iv) LISTING OF EXCLUSIVITIES.—

21 For each biological product included on the
22 list published under this subparagraph, the
23 Secretary shall specify each exclusivity pe-
24 riod that is applicable and has not con-

1 cluded under paragraph (6) or paragraph
2 (7).

3 “(B) WITHDRAWAL OR SUSPENSION OF LI-
4 CENSURE.—If the licensing of a biological prod-
5 uct was withdrawn or suspended for safety, pu-
6 rity, or potency reasons, it may not be pub-
7 lished in the list under subparagraph (A). If the
8 withdrawal or suspension occurred after its
9 publication in such list, the reference product
10 sponsor shall notify the Secretary that—

11 “(i) the biological product shall be im-
12 mediately removed from such list—

13 “(I) for the same period as the
14 withdrawal or suspension; or

15 “(II) if the biological product has
16 been withdrawn from sale, for the pe-
17 riod of withdrawal from sale or, if ear-
18 lier, the period ending on the date the
19 Secretary determines that the with-
20 drawal from sale is not for safety, pu-
21 rity, or potency reasons; and

22 “(ii) a notice of the removal shall be
23 published in the Federal Register.”.

1 **SEC. 332. REVIEW AND REPORT ON TYPES OF INFORMA-**
2 **TION TO BE LISTED.**

3 Not later than 3 years after the date of enactment
4 of this Act, the Secretary of Health and Human Services
5 shall—

6 (1) solicit public comment regarding the type of
7 information, if any, that should be added to or re-
8 moved from the list required by paragraph (9) of
9 section 351(k) of the Public Health Service Act (42
10 U.S.C. 262(k)), as added by section 331; and

11 (2) transmit to Congress an evaluation of such
12 comments, including any recommendations about the
13 types of information that should be added to or re-
14 moved from the list.

15 **Subtitle E—Orange Book**

16 **SEC. 341. ORANGE BOOK.**

17 (a) SUBMISSION OF PATENT INFORMATION FOR
18 BRAND NAME DRUGS.—Paragraph (1) of section 505(b)
19 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 355(b)) is amended to read as follows:

21 “(b)(1) Any person may file with the Secretary an
22 application with respect to any drug subject to the provi-
23 sions of subsection (a). Such persons shall submit to the
24 Secretary as part of the application—

1 “(A) full reports of investigations which have
2 been made to show whether or not such drug is safe
3 for use and whether such drug is effective in use;

4 “(B) a full list of the articles used as compo-
5 nents of such drug;

6 “(C) a full statement of the composition of such
7 drug;

8 “(D) a full description of the methods used in,
9 and the facilities and controls used for, the manufac-
10 ture, processing, and packing of such drug;

11 “(E) such samples of such drug and of the arti-
12 cles used as components thereof as the Secretary
13 may require;

14 “(F) specimens of the labeling proposed to be
15 used for such drug;

16 “(G) any assessments required under section
17 505B; and

18 “(H) patent information, with respect to each
19 patent for which a claim of patent infringement
20 could reasonably be asserted if a person not licensed
21 by the owner engaged in the manufacture, use, or
22 sale of the drug, and consistent with the following
23 requirements:

1 “(i) The applicant shall file with the appli-
2 cation the patent number and the expiration
3 date of—

4 “(I) any patent which claims the drug
5 for which the applicant submitted the ap-
6 plication and is a drug substance (includ-
7 ing active ingredient) patent or a drug
8 product (including formulation and com-
9 position) patent; and

10 “(II) any patent which claims the
11 method of using such drug.

12 “(ii) If an application is filed under this
13 subsection for a drug and a patent of the type
14 described in clause (i) which claims such drug
15 or a method of using such drug is issued after
16 the filing date but before approval of the appli-
17 cation, the applicant shall amend the applica-
18 tion to include such patent information.

19 Upon approval of the application, the Secretary shall pub-
20 lish the information submitted under subparagraph (H).
21 The Secretary shall, in consultation with the Director of
22 the National Institutes of Health and with representatives
23 of the drug manufacturing industry, review and develop
24 guidance, as appropriate, on the inclusion of women and

1 minorities in clinical trials required by subparagraph
2 (A).”.

3 (b) CONFORMING CHANGES TO REQUIREMENTS FOR
4 SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—

5 Section 505(c)(2) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 355(j)(7)) is amended—

7 (1) by inserting after “the patent number and
8 the expiration date of any patent which” the fol-
9 lowing: “fulfills the criteria in subsection (b) and”;

10 (2) by inserting after the first sentence the fol-
11 lowing: “Patent information that is not the type of
12 patent information required by subsection (b) shall
13 not be submitted.”; and

14 (3) by inserting after “could not file patent in-
15 formation under subsection (b) because no patent”
16 the following: “of the type required to be submitted
17 in subsection (b)”.

18 (c) LISTING OF EXCLUSIVITIES.—Subparagraph (A)
19 of section 505(j)(7) of the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 355(j)(7)) is amended by adding at
21 the end the following:

22 “(iv) For each drug included on the list, the Sec-
23 retary shall specify each exclusivity period that is applica-
24 ble and has not concluded under—

1 “(I) clause (ii), (iii), or (iv) of subsection
2 (c)(3)(E) of this section;

3 “(II) clause (iv) or (v) of paragraph (5)(B) of
4 this subsection;

5 “(III) clause (ii), (iii), or (iv) of paragraph
6 (5)(F) of this subsection;

7 “(IV) section 505A;

8 “(V) section 505E; or

9 “(VI) section 527(a).”.

10 (d) REMOVAL OF INVALID PATENTS.—

11 (1) IN GENERAL.—Section 505(j)(7) of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 355(j)(7)) is amended by adding at the end the fol-
14 lowing:

15 “(D)(i) The holder of an application approved under
16 subsection (c) for a drug on the list shall notify within
17 14 days the Secretary in writing if either of the following
18 occurs:

19 “(I) The Patent Trial and Appeals Board issues
20 a decision from which no appeal has been or can be
21 taken that a patent for such drug is invalid.

22 “(II) A court issues a decision from which no
23 appeal has been or can be taken that a patent for
24 such drug is invalid.

1 “(ii) The holder of an approved application shall in-
2 clude in any notification under clause (i) a copy of the
3 decision described in subclause (I) or (II) of clause (i).

4 “(iii) The Secretary shall remove from the list any
5 patent that is determined to be invalid in a decision de-
6 scribed in subclause (I) or (II) of clause (i)—

7 “(I) promptly; but

8 “(II) not before the expiration of any 180-day
9 exclusivity period under paragraph (5)(B)(iv) that
10 relies on a certification described in paragraph
11 (2)(A)(vii)(IV) that such patent was invalid.”.

12 (2) APPLICABILITY.—Subparagraph (D) of sec-
13 tion 505(j)(7) of the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 355(j)(7)), as added by para-
15 graph (1), applies only with respect to a decision de-
16 scribed in such subparagraph that is issued on or
17 after the date of enactment of this Act.

18 (e) REVIEW AND REPORT.—Not later than one year
19 after the date of enactment of this Act, the Secretary of
20 Health and Human Services, acting through the Commis-
21 sioner of Food and Drugs, shall—

22 (1) solicit public comment regarding the types
23 of patent information that should be included on the
24 list under section 507(j)(7) of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)); and

1 (2) transmit to the Congress an evaluation of
2 such comments, including any recommendations
3 about the types of patent information that should be
4 included on or removed from such list.

5 **SEC. 342. GAO REPORT TO CONGRESS.**

6 (a) IN GENERAL.—Not later than one year after the
7 date of enactment of this Act, the Comptroller General
8 of the United States (referred to in this section as the
9 “Comptroller General”) shall submit to the Committee on
10 Energy and Commerce of the House of Representatives
11 a report on the patents included in the list published under
12 section 505(j)(7) of the Federal Food, Drug and Cosmetic
13 Act (21 U.S.C. 355(j)(7)), including an analysis and eval-
14 uation of the types of patents included in such list and
15 the claims such patents make about the products they
16 claim.

17 (b) CONTENTS.—The Comptroller General shall in-
18 clude in the report under subsection (a)—

19 (1) data on the number of—

20 (A) patents included in the list published
21 under paragraph (7) of section 505(j) of the
22 Federal Food, Drug and Cosmetic Act (21
23 U.S.C. 355(j)), that claim the active ingredient
24 or formulation of a drug in combination with a
25 device that is used for delivery of the drug, to-

1 gether comprising the finished dosage form of
2 the drug; and

3 (B) claims in each patent that claim a de-
4 vice that is used for the delivery of the drug,
5 but do not claim such device in combination
6 with an active ingredient or formulation of a
7 drug;

8 (2) data on the date of inclusion in the list
9 under paragraph (7) of such section 505(j) for all
10 patents under such list, as compared to patents that
11 claim a method of using the drug in combination
12 with a device;

13 (3) an analysis regarding the impact of includ-
14 ing on the list under paragraph (7) of such section
15 505(j) certain types of patent information for drug
16 product applicants and approved application holders,
17 including an analysis of whether—

18 (A) the listing of the patents described in
19 paragraph (1)(A) delayed the market entry of
20 one or more drugs approved under such section
21 505(j); and

22 (B) not listing the patents described in
23 paragraph (1)(A) would delay the market entry
24 of one or more such drugs; and

1 (4) recommendations about which kinds of pat-
2 ents relating to devices described in paragraph
3 (1)(A) should be submitted to the Secretary of
4 Health and Human Services for inclusion on the list
5 under paragraph (7) of such section 505(j) and
6 which patents should not be required to be so sub-
7 mitted.

8 **Subtitle F—Advancing Education** 9 **on Biosimilars**

10 **SEC. 351. EDUCATION ON BIOLOGICAL PRODUCTS.**

11 (a) WEBSITE; CONTINUING EDUCATION.—Subpart 1
12 of part F of title III of the Public Health Service Act (42
13 U.S.C. 262 et seq.) is amended by adding at the end the
14 following:

15 **“SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.**

16 **“(a) INTERNET WEBSITE.—**

17 **“(1) IN GENERAL.—**The Secretary shall main-
18 tain and operate an internet website to provide edu-
19 cational materials for health care providers, patients,
20 and caregivers, regarding the meaning of the terms,
21 and the standards for review and licensing of, bio-
22 logical products, including biosimilar biological prod-
23 ucts and interchangeable biosimilar biological prod-
24 ucts.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 mercial or financial information, or other matter de-
2 scribed in section 552(b) of title 5.

3 “(b) CONTINUING EDUCATION.—The Secretary shall
4 advance education and awareness among health care pro-
5 viders regarding biological products, including biosimilar
6 biological products and interchangeable biosimilar biologi-
7 cal products, as appropriate, including by developing or
8 improving continuing education programs that advance
9 the education of such providers on the prescribing of, and
10 relevant clinical considerations with respect to, biological
11 products, including biosimilar biological products and
12 interchangeable biosimilar biological products.”.

13 (b) APPLICATION UNDER THE MEDICARE MERIT-
14 BASED INCENTIVE PAYMENT SYSTEM.—Section
15 1848(q)(5)(C) of the Social Security Act (42 U.S.C.
16 1395w-4(q)(5)(C)) is amended by adding at the end the
17 following new clause:

18 “(iv) CLINICAL MEDICAL EDUCATION
19 PROGRAM ON BIOSIMILAR BIOLOGICAL
20 PRODUCTS.—Completion of a clinical med-
21 ical education program developed or im-
22 proved under section 352A(b) of the Public
23 Health Service Act by a MIPS eligible pro-
24 fessional during a performance period shall
25 earn such eligible professional one-half of

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 **TITLE IV—REVENUE** 9 **PROVISIONS**

10 **SEC. 401. REPEAL OF MEDICAL DEVICE EXCISE TAX.**

11 (a) IN GENERAL.—Chapter 32 of the Internal Rev-
12 enue Code of 1986 is amended by striking subchapter E.

13 (b) CONFORMING AMENDMENTS.—

14 (1) Subsection (a) of section 4221 of such Code
15 is amended by striking the last sentence.

16 (2) Paragraph (2) of section 6416(b) of such
17 Code is amended by striking the last sentence.

18 (c) CLERICAL AMENDMENT.—The table of sub-
19 chapters for chapter 32 of such Code is amended by strik-
20 ing the item relating to subchapter E.

21 (d) EFFECTIVE DATE.—The amendments made by
22 this section shall apply to sales after December 31, 2019.

1 **SEC. 402. PERMANENT EXTENSION OF REDUCTION IN MED-**
2 **ICAL EXPENSE DEDUCTION FLOOR.**

3 (a) IN GENERAL.—Section 213(a) of the Internal
4 Revenue Code of 1986 is amended by striking “10 per-
5 cent” and inserting “7.5 percent”.

6 (b) CONFORMING AMENDMENTS.—

7 (1) Section 213 of such Code is amended by
8 striking subsection (f).

9 (2) Section 56(b)(1) of such Code is amended
10 by striking subparagraph (B) and by redesignating
11 subparagraphs (C), (D), (E), and (F), as subpara-
12 graphs (B), (C), (D), and (E), respectively.

13 (c) EFFECTIVE DATE.—The amendment made by
14 this section shall apply to taxable years ending after De-
15 cember 31, 2018.

16 **TITLE V—MISCELLANEOUS**

17 **SEC. 501. PAYMENT FOR BIOSIMILAR BIOLOGICAL PROD-**
18 **UCTS DURING INITIAL PERIOD.**

19 Section 1847A(c)(4) of the Social Security Act (42
20 U.S.C. 1395w-3a(c)(4)) is amended—

21 (1) in each of subparagraphs (A) and (B), by
22 redesignating clauses (i) and (ii) as subclauses (I)
23 and (II), respectively, and moving such subclauses 2
24 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, 2020, 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, 2021, 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(e) 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 2021, 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; and

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 (E) the feasibility and policy implications
4 of creating a methodology to preserve the
5 healthcare provider's ability to take title of the
6 drug, including a methodology under which—

7 (i) prescription drug plans negotiate
8 reimbursement rates and other arrange-
9 ments with drug manufacturers on behalf
10 of a wholesaler;

11 (ii) wholesalers purchase the drugs
12 from the manufacturers at the negotiated
13 rate and ship them through distributors to
14 physicians to administer to patients;

15 (iii) physicians and hospitals purchase
16 the drug from the wholesaler via the dis-
17 tributor;

18 (iv) after administering the drug, the
19 physician submits a claim to the MAC for
20 their drug administration fee;

21 (v) to be reimbursed for the purchase
22 of the drug from the distributor, the physi-
23 cian furnishes the claim for the drug itself
24 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.”.



