

116TH CONGRESS
1ST SESSION

S. 3129

To provide for certain reforms with respect to the Medicare program under title XVIII of the Social Security Act, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 19, 2019

Mr. CRAPO (for himself, Mr. ENZI, Mr. BURR, Mr. BARRASSO, Mr. TILLIS, and Mr. RISCH) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To provide for certain reforms with respect to the Medicare program under title XVIII of the Social Security Act, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

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

6 **SEC. 2. TABLE OF CONTENTS.**

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

Sec. 1. Short title.

Sec. 2. Table of contents.

TITLE I—MEDICARE PARTS B AND D

Subtitle A—Medicare Part B Provisions

- Sec. 101. Improvements to Medicare site-of-service transparency.
- Sec. 102. Requiring manufacturers of certain single-dose container or single-use package drugs payable under part B of the Medicare program to provide refunds with respect to discarded amounts of such drugs.
- Sec. 103. Providing for variation in payment for certain drugs covered under part B of the Medicare program.
- Sec. 104. Establishment of maximum add-on payment for drugs and biologicals.
- Sec. 105. Treatment of drug administration services furnished by certain excepted off-campus outpatient departments of a provider.
- Sec. 106. Payment for biosimilar biological products during initial period.
- Sec. 107. Education on biological and biosimilar products.
- Sec. 108. GAO study and report on average sales price.

Subtitle B—Medicare Part D Provisions

- Sec. 111. Medicare part D benefit redesign.
- Sec. 112. Transitional coverage and retroactive Medicare part D coverage for certain low-income beneficiaries.
- Sec. 113. Allowing the offering of additional prescription drug plans under Medicare part D.
- Sec. 114. Allowing certain enrollees of prescription drug plans and MA–PD plans under the Medicare program to spread out cost-sharing under certain circumstances.
- Sec. 115. Establishing a monthly cap on beneficiary incurred costs for insulin products and supplies under a prescription drug plan or MA–PD plan.
- Sec. 116. Growth rate of Medicare part D out-of-pocket cost threshold.
- Sec. 117. Requiring prescription drug plan sponsors to include real-time benefit information as part of such sponsor’s electronic prescription program under the Medicare program.
- Sec. 118. Requiring prescription drug plans and MA–PD plans to report potential fraud, waste, and abuse to the Secretary of HHS.
- Sec. 119. Establishment of pharmacy quality measures under Medicare part D.

TITLE II—DRUG PRICE TRANSPARENCY

- Sec. 201. Reporting on explanation for drug price increases.
- Sec. 202. Public disclosure of drug discounts.
- Sec. 203. Requiring certain manufacturers to report drug pricing information with respect to drugs under the Medicare program.
- Sec. 204. Making prescription drug marketing sample information reported by manufacturers available to certain individuals and entities.
- Sec. 205. 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.
- Sec. 206. Sense of the Senate regarding the need to expand commercially available drug pricing comparison platforms.

TITLE III—REVENUE PROVISIONS

- Sec. 301. Permanent extension of reduction in medical expense deduction floor.

- Sec. 302. Safe harbor for high deductible health plans without deductible for insulin.
- Sec. 303. Inclusion of certain over-the-counter medical products as qualified medical expenses.

TITLE IV—MISCELLANEOUS

- Sec. 401. Improving coordination between the Food and Drug Administration and the Centers for Medicare & Medicaid Services.
- Sec. 402. Patient consultation in Medicare national and local coverage determinations in order to mitigate barriers to inclusion of such perspectives.
- Sec. 403. MedPAC report on shifting coverage of certain Medicare part B drugs to Medicare part D.
- Sec. 404. Requirement that direct-to-consumer advertisements for prescription drugs and biological products include truthful and non-misleading pricing information.
- Sec. 405. Chief Pharmaceutical Negotiator at the Office of the United States Trade Representative.

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-

1 fice” after “surgical center under this
2 title”; and

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

7 (i) by striking “and the” and insert-
8 ing “, the”; and

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

14 (2) by redesignating paragraphs (2) through
15 (4) as paragraphs (3) through (5), respectively; and

16 (3) by inserting after paragraph (1) the fol-
17 lowing new paragraph:

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

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

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

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

9 Section 1847A of the Social Security Act (42 U.S.C.
10 1395–3a) is amended by adding at the end the following
11 new subsection:

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

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

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

1 “(i) Subject to subparagraph (C), in-
2 formation on the total number of units of
3 the billing and payment code of such drug,
4 if any, that were discarded during such
5 quarter, as determined using a mechanism
6 such as the JW modifier used as of the
7 date of enactment of this subsection (or
8 any such successor modifier that includes
9 such data as determined appropriate by
10 the Secretary).

11 “(ii) The refund amount that the
12 manufacturer is liable for pursuant to
13 paragraph (3).

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

22 “(C) EXCLUSION OF UNITS OF PACKAGED
23 DRUGS.—The total number of units of the bill-
24 ing and payment code of a refundable single-
25 dose container or single-use package drug of a

1 manufacturer furnished during a calendar quar-
2 ter for purposes of subparagraph (A)(i), and
3 the determination of the estimated total allowed
4 charges for the drug in the quarter for purposes
5 of paragraph (3)(A)(ii), shall not include such
6 units that are packaged into the payment
7 amount for an item or service and are not sepa-
8 rately payable.

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

16 “(3) REFUND AMOUNT.—

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

25 “(i) the product of—

1 “(I) the total number of units of
2 the billing and payment code for such
3 drug that were discarded during such
4 quarter (as determined under para-
5 graph (1)); and

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

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

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

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

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

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

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

“(ii) TREATMENT OF DRUGS THAT HAVE UNIQUE CIRCUMSTANCES.—In the case of a refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product as that described in paragraph (8)(B), the Secretary, through notice and comment rulemaking, may increase the applicable percentage otherwise applicable under clause (i)(I) as determined appropriate by the Secretary.

“(4) FREQUENCY.—Amounts required to be refunded pursuant to paragraph (2) shall be paid in regular intervals (as determined appropriate by the Secretary).

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

5 “(6) ENFORCEMENT.—

6 “(A) AUDITS.—

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

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

22 “(B) CIVIL MONEY PENALTY.—

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

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

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

10 “(II) 25 percent of such amount.

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

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

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

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

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

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

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

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

23 “(iii) a drug or biological approved by
24 the Food and Drug Administration on or
25 after the date of enactment of this sub-

1 section and with respect to which payment
 2 has been made under this part for less
 3 than 18 months.”.

4 **SEC. 103. PROVIDING FOR VARIATION IN PAYMENT FOR**
 5 **CERTAIN DRUGS COVERED UNDER PART B**
 6 **OF THE MEDICARE PROGRAM.**

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

9 (1) in paragraph (1)—

10 (A) in subparagraph (A), by inserting after
 11 “or 106 percent” the following: “(or, for a mul-
 12 tiple source drug (other than autologous cellular
 13 immunotherapy) furnished on or after January
 14 1, 2021, the applicable percent specified in
 15 paragraph (9)(A) for the drug and quarter in-
 16 volved)”; and

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

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

3 “(9) APPLICATION OF VARIABLE PERCENTAGES
4 BASED ON PERCENTILE RANKING OF PER BENE-
5 FICIARY ALLOWED CHARGES.—

6 “(A) APPLICABLE PERCENT TO BE AP-
7 PLIED.—

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

17 “(I) at least equal to the 85th
18 percentile, the applicable percent for
19 the drug for such quarter under this
20 subparagraph is 104 percent;

21 “(II) at least equal to the 70th
22 percentile, but less than the 85th per-
23 centile, such applicable percent is 106
24 percent;

1 “(III) at least equal to the 50th
 2 percentile, but less than the 70th per-
 3 centile, such applicable percent is 108
 4 percent; or

5 “(IV) less than the 50th per-
 6 centile, such applicable percent is 110
 7 percent.

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

21 “(B) DETERMINATION OF PERCENTILE
 22 RANK OF PER BENEFICIARY ALLOWED CHARGES
 23 OF DRUGS.—

24 “(i) IN GENERAL.—With respect to a
 25 calendar quarter beginning on or after

1 January 1, 2021, for drugs and biologicals
2 for which the amount of payment is deter-
3 mined under subparagraph (A) or (B) of
4 paragraph (1), except for drugs or
5 biologicals for which data are not suffi-
6 ciently available, the Secretary shall—

7 “(I) compute the per beneficiary
8 allowed charges (as defined in sub-
9 paragraph (C)) for each such drug or
10 biological;

11 “(II) adjust such per beneficiary
12 allowed charges for the quarter, to the
13 extent provided under subparagraph
14 (D); and

15 “(III) arrange such adjusted per
16 beneficiary allowed charges for all
17 such drugs or biologicals from high to
18 low and rank such drugs or biologicals
19 by percentile of such per beneficiary
20 allowed charges.

21 “(ii) FREQUENCY.—The Secretary
22 shall make the computations under clause
23 (i)(I) every 6 months (or, if necessary, as
24 determined by the Secretary, every 9 or 12
25 months) and such computations shall apply

1 to succeeding calendar quarters until a
2 new computation has been made.

3 “(iii) APPLICABLE DATA PERIOD.—
4 For purposes of this paragraph, the term
5 ‘applicable data period’ means the most re-
6 cent period for which the data necessary
7 for making the computations under clause
8 (i) are available, as determined by the Sec-
9 retary.

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

16 “(i) the allowed charges for the drug
17 or biological for which payment is so made
18 for the applicable data period, as estimated
19 by the Secretary; divided by

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

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

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

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

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

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

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

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

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

6 **SEC. 104. ESTABLISHMENT OF MAXIMUM ADD-ON PAYMENT**
7 **FOR DRUGS AND BIOLOGICALS.**

8 (a) IN GENERAL.—Section 1847A of the Social Secu-
9 rity Act (42 U.S.C. 1395w–3a), as amended by section
10 103, is amended—

11 (1) in subsection (b)—

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

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

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

19 “(A) IN GENERAL.—In determining the
20 payment amount under the provisions of sub-
21 paragraph (A), (B), or (C) of paragraph (1) of
22 this subsection, subsection (c)(4)(A)(ii), or sub-
23 section (d)(3)(C) for a drug or biological fur-
24 nished on or after January 1, 2021, if the ap-
25 plicable add-on payment (as defined in subpara-

graph (B)) for each drug or biological on a claim for a date of service exceeds the maximum add-on payment amount specified under subparagraph (C) for the drug or biological, then the payment amount otherwise determined for the drug or biological under those provisions, as applicable, shall be reduced by the amount of such excess.

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

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

“(I) the amount that would otherwise be applied under paragraph (1)(A); and

“(II) the amount that would be applied under such paragraph if ‘100 percent’ were substituted for the applicable percent (as defined in paragraph (9)) for such drug.

1 “(ii) In the case of a single source
2 drug or biological, an amount equal to the
3 difference between—

4 “(I) the amount that would oth-
5 erwise be applied under paragraph
6 (1)(B); and

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

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

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

19 “(I) the amount that would oth-
20 erwise be applied under subsection
21 (c)(4)(A)(ii); and

22 “(II) the amount that would be
23 applied under such subsection if ‘100
24 percent’ were substituted, as applica-
25 ble, for—

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

3 “(bb) any percent in excess
4 of 100 percent applied under
5 subclause (II) of such subsection.

6 “(v) In the case of a drug or biologi-
7 cal to which subsection (d)(3)(C) applies,
8 an amount equal to the difference be-
9 tween—

10 “(I) the amount that would oth-
11 erwise be applied under such sub-
12 section; and

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

17 “(aa) any percent in excess
18 of 100 percent applied under
19 clause (i) of such subsection; or

20 “(bb) ‘103 percent’ in clause
21 (ii) of such subsection.

22 “(C) MAXIMUM ADD-ON PAYMENT AMOUNT
23 SPECIFIED.—For purposes of subparagraph
24 (A), the maximum add-on payment amount
25 specified in this subparagraph is—

1 “(i) with respect to a drug or biologi-
2 cal (other than autologous or allogeneric
3 cellular immunotherapy)—

4 “(I) for each of 2021 through
5 2028, \$1,000; and

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

14 “(ii) with respect to a drug or biologi-
15 cal consisting of autologous or allogeneric
16 cellular immunotherapy—

17 “(I) for each of 2021 through
18 2028, \$2,000; and

19 “(II) for a subsequent year, the
20 amount specified in this subparagraph
21 for the preceding year increased by
22 the percentage increase in the con-
23 sumer price index for all urban con-
24 sumers (all items; United States city

1 average) for the 12-month period end-
 2 ing with June of the previous 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.”; and

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

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

11 (1) OPPS.—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)(10)
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 U.S.C. 1395l(t)(16)) is amended by adding at the end the
 7 following new subparagraph:

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

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

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

1 “(I) shall not be considered an
 2 adjustment under paragraph (2)(E);
 3 and
 4 “(II) shall not be implemented in
 5 a budget neutral manner.”.

6 **SEC. 106. PAYMENT FOR BIOSIMILAR BIOLOGICAL PROD-**
 7 **UCTS DURING INITIAL PERIOD.**

8 Section 1847A(c)(4) of the Social Security Act (42
 9 U.S.C. 1395w-3a(c)(4)) is amended—

10 (1) in each of subparagraphs (A) and (B), by
 11 redesignating clauses (i) and (ii) as subclauses (I)
 12 and (II), respectively, and moving such subclauses 2
 13 ems to the right;

14 (2) by redesignating subparagraphs (A) and
 15 (B) as clauses (i) and (ii) and moving such clauses
 16 2 ems to the right;

17 (3) by striking “UNAVAILABLE.—In the case”
 18 and inserting “UNAVAILABLE.—

19 “(A) IN GENERAL.—Subject to subpara-
 20 graph (B), in the case”; and

21 (4) by adding at the end the following new sub-
 22 paragraph:

23 “(B) LIMITATION ON PAYMENT AMOUNT
 24 FOR BIOSIMILAR BIOLOGICAL PRODUCTS DUR-
 25 ING INITIAL PERIOD.—In the case of a bio-

similar biological product furnished on or after July 1, 2020, in lieu of applying subparagraph (A) during the initial period described in such subparagraph with respect to the biosimilar biological product, the amount payable under this section for the biosimilar biological product is the lesser of the following:

“(i) The amount determined under clause (ii) of such subparagraph for the biosimilar biological product.

“(ii) The amount determined under subsection (b)(1)(B) for the reference biological product.”.

SEC. 107. EDUCATION ON BIOLOGICAL AND BIOSIMILAR PRODUCTS.

(a) IN GENERAL.—The Secretary of Health and Human Services shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological

1 products and interchangeable biosimilar biological prod-
2 ucts.

3 (b) APPLICATION UNDER THE MEDICARE MERIT-
4 BASED INCENTIVE PAYMENT SYSTEM.—Section
5 1848(q)(5)(C) of the Social Security Act (42 U.S.C.
6 1395w-4(q)(5)(C)) is amended by adding at the end the
7 following new clause:

8 “(iv) CLINICAL MEDICAL EDUCATION
9 PROGRAM ON BIOSIMILAR BIOLOGICAL
10 PRODUCTS.—Completion of a clinical med-
11 ical education program developed or im-
12 proved under section 107(a) of the Lower
13 Costs, More Cures Act of 2019 by a MIPS
14 eligible professional during a performance
15 period shall earn such eligible professional
16 one-half of the highest potential score for
17 the performance category described in
18 paragraph (2)(A)(iii) for such performance
19 period. A MIPS eligible professional may
20 only count the completion of such a pro-
21 gram for purposes of such category one
22 time during the eligible professional’s life-
23 time.”.

1 **SEC. 108. 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 **Subtitle B—Medicare Part D** 5 **Provisions**

6 **SEC. 111. MEDICARE PART D BENEFIT REDESIGN.**

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

10 (1) in paragraph (2)—

11 (A) in subparagraph (A)—

12 (i) in the matter preceding clause (i),
 13 by inserting “for a year preceding 2022
 14 and for costs above the annual deductible
 15 specified in paragraph (1) and up to the
 16 annual out-of-pocket threshold specified in
 17 paragraph (4)(B) for 2022 and each subse-
 18 quent year” after “paragraph (3)”;
 19 (ii) in clause (i), by inserting after
 20 “25 percent” the following: “(or, for 2022
 21 and each subsequent year, 15 percent)”;
 22 and

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

1 (B) in subparagraph (C)—

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

6 (ii) in clause (ii)(III), by striking
 7 “and each subsequent year” and inserting
 8 “and 2021”; and

9 (C) in subparagraph (D)—

10 (i) in clause (i)—

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

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

19 (ii) in clause (ii)(V), by striking
 20 “2019 and each subsequent year” and in-
 21 serting “each of years 2019 through
 22 2021”;

23 (2) in paragraph (3)(A)—

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

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

7 (3) in paragraph (4)—

8 (A) in subparagraph (A)—

9 (i) in clause (i)—

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

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

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

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

24 (IV) by adding at the end the fol-
 25 lowing:

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

3 (ii) in clause (ii)—

4 (I) by striking “clause (i)(I)” and
 5 inserting “clause (i)(I)(aa)”;

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

13 (B) in subparagraph (B)—

14 (i) in clause (i)—

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

17 (II) in subclause (VI)—

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

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

24 (III) by adding at the end the
 25 following new subclauses:

1 “(VII) for 2022, is equal to
2 \$3,100; or

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

9 (ii) in clause (ii), by striking “clause
10 (i)(II)” and inserting “clause (i)”;

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

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

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

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

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

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

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

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

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

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

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

5 (c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

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

21 “(b) TERMS OF AGREEMENT.—

22 “(1) IN GENERAL.—

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

1 counted prices for applicable drugs of the man-
2 ufacturer that are dispensed on or after Janu-
3 ary 1, 2022.

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

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

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

25 “(4) LENGTH OF AGREEMENT.—

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

7 “(B) TERMINATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 “(2) MONITORING COMPLIANCE.—

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

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

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

7 “(d) ADMINISTRATION.—

8 “(1) IN GENERAL.—Subject to paragraph (2),
 9 the Secretary shall provide for the implementation of
 10 this section, including the performance of the duties
 11 described in subsection (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 one or
 18 more third parties to administer the requirements
 19 established by the Secretary in order to carry out
 20 this section. At a minimum, the contract with a
 21 third party under the preceding sentence shall re-
 22 quire 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 (4) CLARIFICATION REGARDING EXCLUSION OF
23 MANUFACTURER DISCOUNTS FROM TROOP.—Section
24 1860D–2(b)(4) of the Social Security Act (42
25 U.S.C. 1395w–102(b)(4)) is amended—

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

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

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

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

14 (1) in paragraph (2)—

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

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

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

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

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

6 (2) in paragraph (3)—

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

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

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

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

1 suant to the amendments made by section 121 of
 2 the Lower Costs, More Cures Act of 2019.”.

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

6 (1) in subsection (a)—

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

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

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

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

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

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

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

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

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

9 “(2) the Secretary determines that in the period
 10 beginning on January 1, 2011, and ending on De-
 11 cember 31, 2011 (with respect to paragraphs (1)
 12 through (3) of subsection (a)), or the period begin-
 13 ning on January 1, 2022, and ending December 31,
 14 2022 (with respect to paragraphs (4) through (6) of
 15 such subsection), there were extenuating cir-
 16 cumstances.”.

17 (g) CONFORMING AMENDMENTS.—

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

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

24 (B) in subsection (c)(1)(C)—

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

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

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

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

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

19 (A) in paragraph (1)—

20 (i) in subparagraph (C), by striking
 21 “The continuation” and inserting “For a
 22 year preceding 2022, the continuation”;

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

1 (iii) in subparagraph (E), by striking
 2 “The elimination” and inserting “For a
 3 year preceding 2022, the elimination”; and
 4 (B) in paragraph (2)—

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

9 (ii) in subparagraph (E)—
 10 (I) by inserting “for a year pre-
 11 ceding 2022,” after “subsection (c)”;
 12 and

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

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

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

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

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

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

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

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

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

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

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

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

20 **SEC. 112. TRANSITIONAL COVERAGE AND RETROACTIVE**
21 **MEDICARE PART D COVERAGE FOR CERTAIN**
22 **LOW-INCOME BENEFICIARIES.**

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

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

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

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

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

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

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

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

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

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

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

20 “(i) begins on the date that is the
21 later of—

22 “(I) the date that such individual
23 was first eligible for a low-income sub-
24 sidy under this part; or

1 “(II) the date that is 36 months
 2 prior to the date such individual en-
 3 rolls in a prescription drug plan or
 4 MA–PD plan; and

5 “(ii) ends on the date that coverage
 6 under such plan takes effect.

7 “(4) PROGRAM ADMINISTRATION.—

8 “(A) SINGLE POINT OF CONTACT.—The
 9 Secretary shall, to the extent feasible, admin-
 10 ister the program under this subsection through
 11 a contract with a single program administrator.

12 “(B) BENEFIT DESIGN.—The Secretary
 13 shall ensure that the transitional coverage pro-
 14 vided to LI NET eligible individuals under this
 15 subsection—

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

18 “(ii) permits all pharmacies deter-
 19 mined by the Secretary to be in good
 20 standing to process claims under the pro-
 21 gram;

22 “(iii) is consistent with such require-
 23 ments as the Secretary considers necessary
 24 to improve patient safety and ensure ap-
 25 propriate dispensing of medication; and

1 “(iv) meets such other requirements
2 as the Secretary may establish.

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

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

8 “(i) Paragraphs (1) and (3)(B) of sec-
9 tion 1860D–4(a) (dissemination of general
10 information; availability of information on
11 changes in formulary through the inter-
12 net).

13 “(ii) Subparagraphs (A) and (B) of
14 section 1860D–4(b)(3) (development and
15 revision by a pharmacy and therapeutic
16 committee; formulary development).

17 “(iii) Paragraphs (1)(C) and (2) of
18 section 1860D–4(c) (medication therapy
19 management program).

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

1 **SEC. 113. ALLOWING THE OFFERING OF ADDITIONAL PRE-**
 2 **SCRIPTION DRUG PLANS UNDER MEDICARE**
 3 **PART D.**

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

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

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

23 (b) OFFERING OF ADDITIONAL PLANS.—Section
 24 1860D–11(d) of the Social Security Act (42 U.S.C.
 25 1395w–111(d)) is amended by adding at the end the fol-
 26 lowing new paragraph:

1 “(4) OFFERING OF ADDITIONAL PLANS.—

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

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

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

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

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

19 (c) RULE OF CONSTRUCTION.—Nothing in the provi-
20 sions of, or amendments made by, this section shall be
21 construed as limiting the ability of the Secretary to in-
22 crease any limit otherwise applicable on the number of
23 prescription drug plans that a PDP sponsor may offer,
24 at the discretion of the PDP sponsor, in a PDP region

1 under part D of title XVIII of the Social Security Act (42
2 U.S.C. 1395w–101 et seq.).

3 **SEC. 114. ALLOWING CERTAIN ENROLLEES OF PRESCRIP-**
4 **TION DRUG PLANS AND MA-PD PLANS UNDER**
5 **THE MEDICARE PROGRAM TO SPREAD OUT**
6 **COST-SHARING UNDER CERTAIN CIR-**
7 **CUMSTANCES.**

8 (a) STANDARD PRESCRIPTION DRUG COVERAGE.—
9 Section 1860D–2(b)(2) of the Social Security Act (42
10 U.S.C. 1395w–102(b)(2)), as amended by section 111, is
11 amended—

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

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

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

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

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

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

22 (b) ALTERNATIVE PRESCRIPTION DRUG COV-
23 ERAGE.—Section 1860D–2(c) of the Social Security Act
24 (42 U.S.C. 1395w–102(c)) is amended by adding at the
25 end the following new paragraph:

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

7 **SEC. 115. ESTABLISHING A MONTHLY CAP ON BENEFICIARY**
 8 **INCURRED COSTS FOR INSULIN PRODUCTS**
 9 **AND SUPPLIES UNDER A PRESCRIPTION**
 10 **DRUG PLAN OR MA-PD PLAN.**

11 (a) IN GENERAL.—Section 1860D–2 of the Social
 12 Security Act (42 U.S.C. 1395w–102), as amended by sec-
 13 tions 111 and 114, is amended—

14 (1) in subsection (b)(2)—

15 (A) in subparagraph (A), by striking “and
 16 (E)” and inserting “(E), and (F)”;

17 (B) in subparagraph (B), by striking “and
 18 (D)” and inserting “(D), and (F)”;

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

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

23 “(i) IN GENERAL.—The coverage pro-
 24 vides benefits, for costs above the annual
 25 deductible specified in paragraph (1) and

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

10 “(I) for months occurring in
11 2022, \$50; or

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

21 “(ii) APPLICATION.—The provisions
22 of clauses (i) through (iii) of paragraph
23 (4)(C) shall apply with respect to the de-
24 termination of the incurred costs for speci-
25 fied covered part D drugs for purposes of

1 clause (i) in the same manner as such pro-
 2 visions apply with respect to the deter-
 3 mination of incurred costs for covered part
 4 D drugs for purposes of paragraph (4)(A).

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

10 “(I) insulin; or

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

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

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

22 (b) CONFORMING AMENDMENTS.—

23 (1) IN GENERAL.—Section 1860D–14(a)(1)(D)
 24 of the Social Security Act (42 U.S.C. 1395w–

1 114(a)(1)(D)), as amended by section 111, is
 2 amended—

3 (A) in clause (ii), by striking “section
 4 1860D–2(b)(2)” and inserting “section 1860D–
 5 2(b)(2)(A)”; and

6 (B) in clause (iii), by striking “section
 7 1860D–2(b)(2)” and inserting “section 1860D–
 8 2(b)(2)(A)”.

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

12 **SEC. 116. GROWTH RATE OF MEDICARE PART D OUT-OF-**
 13 **POCKET COST THRESHOLD.**

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

19 “(F) 2020 OFFSET PAYMENTS.—

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

24 “(I) In the case of a specified in-
 25 dividual (as defined in clause (ii)(I))

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

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

24 “(ii) DEFINITIONS.—For purposes of
25 this subparagraph:

1 “(I) SPECIFIED INDIVIDUAL.—

2 The term ‘specified individual’ means
3 an individual who—

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

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

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

13 “(II) TARGET THRESHOLD FOR
14 2020.—The term ‘target threshold for
15 2020’ means the annual out-of-pocket
16 threshold that would have been ap-
17 plied under subparagraph (B)(i) for
18 2020 if such threshold had been de-
19 termined in accordance with subclause
20 (IV) of such subparagraph instead of
21 subclause (V) of such subparagraph.

22 “(iii) NOTIFICATION.—In the case of
23 any specified individual who during 2020
24 has incurred costs for covered part D
25 drugs so that the individual has exceeded

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

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

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

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

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

21 (2) by redesignating subclause (VI) as sub-
 22 clause (VIII); and

23 (3) by inserting after subclause (V) the fol-
 24 lowing new subclauses:

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

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

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

15 “(VII) for 2022, is equal to the
16 amount that would have been applied
17 under this subparagraph for 2022 if
18 the amendments made by section
19 1101(d)(1) of the Health Care and
20 Education Reconciliation Act of 2010
21 and by section 135 of the Lower
22 Costs, More Cures Act of 2019 had
23 not been enacted; or”.

1 **SEC. 117. REQUIRING PRESCRIPTION DRUG PLAN SPON-**
 2 **SORS TO INCLUDE REAL-TIME BENEFIT IN-**
 3 **FORMATION AS PART OF SUCH SPONSOR'S**
 4 **ELECTRONIC PRESCRIPTION PROGRAM**
 5 **UNDER THE MEDICARE PROGRAM.**

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

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

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

13 “(F) REAL-TIME BENEFIT INFORMA-
 14 TION.—

15 “(i) IN GENERAL.—Not later than
 16 January 1, 2021, the program shall imple-
 17 ment real-time benefit tools that are capa-
 18 ble of integrating with a prescribing health
 19 care professional’s electronic prescribing or
 20 electronic health record system for the
 21 transmission of formulary and benefit in-
 22 formation in real time to prescribing health
 23 care professionals. With respect to a cov-
 24 ered part D drug, such tools shall be capa-
 25 ble of transmitting such information spe-
 26 cific to an individual enrolled in a prescrip-

tion drug plan. Such information shall include the following:

“(I) A list of any clinically appropriate alternatives to such drug included in the formulary of such plan.

“(II) Cost-sharing information for such drug and such alternatives, including a description of any variance in cost-sharing based on the pharmacy dispensing of such drug or such alternatives.

“(III) Information relating to whether such drug is included in the formulary of such plan and any prior authorization or other utilization management requirements applicable to such drug and such alternatives so included.

“(ii) ELECTRONIC TRANSMISSION.—
The provisions of subclauses (I) and (II) of clause (ii) of subparagraph (E) shall apply to an electronic transmission described in clause (i) in the same manner as such provisions apply with respect to an electronic

transmission described in clause (i) of such subparagraph.

“(iii) SPECIAL RULE FOR 2021.—The program shall be deemed to be in compliance with clause (i) for 2021 if the program complies with the provisions of section 423.160(b)(7) of title 42, Code of Federal Regulations (or a successor regulation), for such year.

“(iv) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed as to allow a real-time benefits tool to steer an individual, without the consent of the individual, to a particular pharmacy or pharmacy setting over their preferred pharmacy setting nor prohibit the designation of a preferred pharmacy under such tool.”.

SEC. 118. REQUIRING PRESCRIPTION DRUG PLANS AND MA-PD PLANS TO REPORT POTENTIAL FRAUD, WASTE, AND ABUSE TO THE SECRETARY OF HHS.

Section 1860D–4 of the Social Security Act (42 U.S.C. 1395w–104) is amended by adding at the end the following new subsection:

1 “(p) REPORTING POTENTIAL FRAUD, WASTE, AND
 2 ABUSE.—Beginning January 1, 2021, the PDP sponsor
 3 of a prescription drug plan shall report to the Secretary,
 4 as specified by the Secretary—

5 “(1) any substantiated or suspicious activities
 6 (as defined by the Secretary) with respect to the
 7 program under this part as it relates to fraud,
 8 waste, and abuse; and

9 “(2) any steps made by the PDP sponsor after
 10 identifying such activities to take corrective ac-
 11 tions.”.

12 **SEC. 119. ESTABLISHMENT OF PHARMACY QUALITY MEAS-**
 13 **URES UNDER MEDICARE PART D.**

14 Section 1860D–4(c) of the Social Security Act (42
 15 U.S.C. 1395w–104(c)) is amended by adding at the end
 16 the following new paragraph:

17 “(8) APPLICATION OF PHARMACY QUALITY
 18 MEASURES.—

19 “(A) IN GENERAL.—A PDP sponsor that
 20 implements incentive payments to a pharmacy
 21 or price concessions paid by a pharmacy based
 22 on quality measures shall use measures estab-
 23 lished or approved by the Secretary under sub-
 24 paragraph (B) with respect to payment for cov-
 25 ered part D drugs dispensed by such pharmacy.

“(B) STANDARD PHARMACY QUALITY MEASURES.—The Secretary shall establish or approve standard quality measures from a consensus and evidence-based organization for payments described in subparagraph (A). Such measures shall focus on patient health outcomes and be based on proven criteria measuring pharmacy performance.

“(C) EFFECTIVE DATE.—The requirement under subparagraph (A) shall take effect for plan years beginning on or after January 1, 2023, or such earlier date specified by the Secretary if the Secretary determines there are sufficient measures established or approved under subparagraph (B) to meet the requirement under subparagraph (A).”.

TITLE II—DRUG PRICE TRANSPARENCY

SEC. 201. REPORTING ON EXPLANATION FOR DRUG PRICE INCREASES.

(a) IN GENERAL.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1128K the following new section:

“SEC. 1128L. DRUG PRICE REPORTING.

“(a) DEFINITIONS.—In this section:

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

3 “(A) that holds the application for a drug
4 approved under section 505 of the Federal
5 Food, Drug, and Cosmetic Act or licensed
6 under section 351 of the Public Health Service
7 Act; or

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

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

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

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

24 “(ii) administered or otherwise dis-
25 pensed to treat a disease or condition af-

1 fecting more than 200,000 persons in the
2 United States; and

3 “(iii) not a vaccine; and

4 “(B) for which, during the previous cal-
5 endar year, at least 1 dollar of the total amount
6 of sales were for individuals enrolled under the
7 Medicare program under title XVIII or under a
8 State Medicaid plan under title XIX or under
9 a waiver of such plan.

10 “(3) WHOLESALE ACQUISITION COST.—The
11 term ‘wholesale acquisition cost’ has the meaning
12 given that term in section 1847A(c)(6)(B).

13 “(b) REPORT.—

14 “(1) REPORT REQUIRED.—The manufacturer of
15 a qualifying drug shall submit a report to the Sec-
16 retary—

17 “(A) for each increase in the price of a
18 qualifying drug that results in an increase in
19 the wholesale acquisition cost of that drug that
20 is equal to—

21 “(i) 10 percent or more within a sin-
22 gle calendar year beginning on or after
23 January 1, 2019; or

24 “(ii) 25 percent or more within three
25 consecutive calendar years for which the

1 first such calendar year begins on or after
2 January 1, 2019; and

3 “(B) in the case that the qualifying drug
4 is first covered under title XVIII with respect
5 to an applicable year, if the estimated cost or
6 spending under such title per individual or per
7 user of such drug (as estimated by the Sec-
8 retary) for such applicable year (or per course
9 of treatment in such applicable year, as defined
10 by the Secretary) is at least \$26,000.

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

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

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

1 the planned effective date of such price increase
 2 for such qualifying drug; and

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

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

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

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

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

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

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

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

13 “(II) for licensure of the drug
14 under section 351 of the Public
15 Health Service Act; and

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

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

1 license for the drug under section 351 of the
2 Public Health Service Act, or since the manu-
3 facturer acquired such approved application or
4 license, if applicable;

5 “(E) the current wholesale acquisition cost
6 of the drug;

7 “(F) the total expenditures of the manu-
8 facturer on—

9 “(i) materials and manufacturing for
10 such drug; and

11 “(ii) acquiring patents and licensing
12 for such drug;

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

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

1 “(I) the total expenditures of the manufac-
2 turer on pursuing new or expanded indications
3 or dosage changes for such drug under section
4 505 of the Federal Food, Drug, and Cosmetic
5 Act or section 351 of the Public Health Service
6 Act;

7 “(J) the total expenditures of the manufac-
8 turer on carrying out postmarket requirements
9 related to such drug, including under section
10 505(o)(3) of the Federal Food, Drug, and Cos-
11 metic Act;

12 “(K) the total revenue and the net profit
13 generated from the qualifying drug for each cal-
14 endar year since the approval of the application
15 for the drug under section 505 of the Federal
16 Food, Drug, and Cosmetic Act or the issuance
17 of the license for the drug under section 351 of
18 the Public Health Service Act, or since the
19 manufacturer acquired such approved applica-
20 tion or license; and

21 “(L) the total costs associated with mar-
22 keting and advertising for the qualifying drug;
23 “(2) with respect to the manufacturer—

24 “(A) the total revenue and the net profit
25 of the manufacturer for each of the 1-year pe-

1 riod described in subsection (b)(1)(A) or the 3-
 2 year period described in subsection (b)(1)(B),
 3 as applicable;

4 “(B) all stock-based performance metrics
 5 used by the manufacturer to determine execu-
 6 tive compensation for each of the 1-year period
 7 described in subsection (b)(1)(A) or the 3-year
 8 period described in subsection (b)(1)(B), as ap-
 9 plicable; and

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

13 “(i) drug research and development;

14 or

15 “(ii) clinical trials, including on drugs
 16 that failed to receive approval by the Food
 17 and Drug Administration; and

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

21 “(d) INFORMATION PROVIDED.—The manufacturer
 22 of a qualifying drug that is required to submit a report
 23 under subsection (b), shall ensure that such report and
 24 any explanation for, and description of, each price increase

1 described in subsection (c)(1)(B) shall be truthful, not
2 misleading, and accurate.

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

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

15 “(g) PUBLIC POSTING.—

16 “(1) IN GENERAL.—Subject to paragraph (3),
17 the Secretary shall post each report submitted under
18 subsection (b) on the public website of the Depart-
19 ment of Health and Human Services the day the
20 price increase of a qualifying drug is scheduled to go
21 into effect.

22 “(2) FORMAT.—In developing the format in
23 which reports will be publicly posted under para-
24 graph (1), the Secretary shall consult with stake-
25 holders, including beneficiary groups, and shall seek

1 feedback from consumer advocates and readability
2 experts on the format and presentation of the con-
3 tent of such reports to ensure that such reports
4 are—

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

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

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

15 “(h) ANNUAL REPORT TO CONGRESS.—

16 “(1) IN GENERAL.—Subject to paragraph (2),
17 the Secretary shall submit to Congress, and post on
18 the public website of the Department of Health and
19 Human Services in a way that is user-friendly to the
20 public and written in plain language that consumers
21 can readily understand, an annual report—

22 “(A) summarizing the information re-
23 ported pursuant to this section;

1 “(B) including copies of the reports and
 2 supporting detailed economic analyses sub-
 3 mitted pursuant to this section;

4 “(C) detailing the costs and expenditures
 5 incurred by the Department of Health and
 6 Human Services in carrying out this section;
 7 and

8 “(D) explaining how the Department of
 9 Health and Human Services is improving con-
 10 sumer and provider information about drug
 11 value and drug price transparency.

12 “(2) PROTECTED INFORMATION.—Nothing in
 13 this subsection shall be construed to authorize the
 14 public disclosure of information submitted by a man-
 15 ufacturer that is prohibited from disclosure by appli-
 16 cable laws concerning the protection of trade secrets,
 17 commercial information, and other information cov-
 18 ered under such laws.”.

19 (b) EFFECTIVE DATE.—The amendment made by
 20 subsection (a) shall take effect on the date of enactment
 21 of this Act.

22 **SEC. 202. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.**

23 Section 1150A of the Social Security Act (42 U.S.C.
 24 1320b–23) is amended—

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

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

7 “(e) PUBLIC AVAILABILITY OF CERTAIN INFORMA-
 8 TION.—

9 “(1) IN GENERAL.—In order to allow the com-
 10 parison of PBMs’ ability to negotiate rebates, dis-
 11 counts, direct and indirect remuneration fees, ad-
 12 ministrative fees, and price concessions and the
 13 amount of such rebates, discounts, direct and indi-
 14 rect remuneration fees, administrative fees, and
 15 price concessions that are passed through to plan
 16 sponsors, beginning January 1, 2020, the Secretary
 17 shall make available on the Internet website of the
 18 Department of Health and Human Services the in-
 19 formation with respect to the second preceding cal-
 20 endar year provided to the Secretary on generic dis-
 21 pensing rates (as described in paragraph (1) of sub-
 22 section (b)) and information provided to the Sec-
 23 retary under paragraphs (2) and (3) of such sub-
 24 section that, as determined by the Secretary, is with
 25 respect to each PBM.

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

4 “(A) CONFIDENTIALITY.—The information
5 described in such paragraph is displayed in a
6 manner that prevents the disclosure of informa-
7 tion, with respect to an individual drug or an
8 individual plan, on rebates, discounts, direct
9 and indirect remuneration fees, administrative
10 fees, and price concessions.

11 “(B) CLASS OF DRUG.—The information
12 described in such paragraph is made available
13 by class of drug, using an existing classification
14 system, but only if the class contains such num-
15 ber of drugs, as specified by the Secretary (but
16 not fewer than three drugs), to ensure confiden-
17 tiality of proprietary information or other infor-
18 mation that is prevented to be disclosed under
19 subparagraph (A).”.

20 **SEC. 203. REQUIRING CERTAIN MANUFACTURERS TO RE-**
21 **PORT DRUG PRICING INFORMATION WITH**
22 **RESPECT TO DRUGS UNDER THE MEDICARE**
23 **PROGRAM.**

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 (2)(A), by inserting “or
3 subsection (f)(2), as applicable” before the pe-
4 riod at the end;

5 (B) in paragraph (3), in the matter pre-
6 ceding subparagraph (A), by inserting “or sub-
7 section (f)(2), as applicable,” before “deter-
8 mined by”; and

9 (C) in paragraph (6)(A), in the matter
10 preceding clause (i), by inserting “or subsection
11 (f)(2), as applicable,” before “determined by”;
12 and

13 (2) in subsection (f)—

14 (A) by striking “For requirements” and
15 inserting the following:

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

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

19 “(2) MANUFACTURERS WITHOUT A REBATE
20 AGREEMENT UNDER TITLE XIX.—

21 “(A) IN GENERAL.—If the manufacturer
22 of a drug or biological described in subpara-
23 graph (C), (E), or (G) of section 1842(o)(1) or
24 in section 1881(b)(14)(B) that is payable under
25 this part has not entered into and does not

1 have in effect a rebate agreement described in
2 subsection (b) of section 1927, for calendar
3 quarters beginning on or after January 1,
4 2020, such manufacturer shall report to the
5 Secretary the information described in sub-
6 section (b)(3)(A)(iii) of such section 1927 with
7 respect to such drug or biological in a time and
8 manner specified by the Secretary. For pur-
9 poses of applying this paragraph, a drug or bio-
10 logical described in the previous sentence in-
11 cludes items, services, supplies, and products
12 that are payable under this part as a drug or
13 biological.

14 “(B) AUDIT.—Information reported under
15 subparagraph (A) is subject to audit by the In-
16 spector General of the Department of Health
17 and Human Services.

18 “(C) VERIFICATION.—The Secretary may
19 survey wholesalers and manufacturers that di-
20 rectly distribute drugs described in subpara-
21 graph (A), when necessary, to verify manufac-
22 turer prices and manufacturer’s average sales
23 prices (including wholesale acquisition cost) if
24 required to make payment reported under sub-
25 paragraph (A). The Secretary may impose a

1 civil monetary penalty in an amount not to ex-
2 ceed \$100,000 on a wholesaler, manufacturer,
3 or direct seller, if the wholesaler, manufacturer,
4 or direct seller of such a drug refuses a request
5 for information about charges or prices by the
6 Secretary in connection with a survey under
7 this subparagraph or knowingly provides false
8 information. The provisions of section 1128A
9 (other than subsections (a) (with respect to
10 amounts of penalties or additional assessments)
11 and (b)) shall apply to a civil money penalty
12 under this subparagraph in the same manner as
13 such provisions apply to a penalty or proceeding
14 under section 1128A(a).

15 “(D) CONFIDENTIALITY.—Notwith-
16 standing any other provision of law, information
17 disclosed by manufacturers or wholesalers
18 under this paragraph (other than the wholesale
19 acquisition cost for purposes of carrying out
20 this section) is confidential and shall not be dis-
21 closed by the Secretary in a form which dis-
22 closes the identity of a specific manufacturer or
23 wholesaler or prices charged for drugs by such
24 manufacturer or wholesaler, except—

1 “(i) as the Secretary determines to be
 2 necessary to carry out this section (includ-
 3 ing the determination and implementation
 4 of the payment amount), or to carry out
 5 section 1847B;

6 “(ii) to permit the Comptroller Gen-
 7 eral of the United States to review the in-
 8 formation provided; and

9 “(iii) to permit the Director of the
 10 Congressional Budget Office to review the
 11 information provided.”.

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

14 (1) in subsection (d)(4)—

15 (A) in subparagraph (A), by striking “IN
 16 GENERAL” and inserting “MISREPRESENTA-
 17 TION”;

18 (B) in subparagraph (B), by striking “sub-
 19 paragraph (B)” and inserting “subparagraph
 20 (A), (B), or (C)”;

21 (C) by redesignating subparagraph (B) as
 22 subparagraph (D); and

23 (D) by inserting after subparagraph (A)
 24 the following new subparagraphs:

1 “(B) FAILURE TO PROVIDE TIMELY INFOR-
 2 MATION.—If the Secretary determines that a
 3 manufacturer described in subsection (f)(2) has
 4 failed to report on information described in sec-
 5 tion 1927(b)(3)(A)(iii) with respect to a drug or
 6 biological in accordance with such subsection,
 7 the Secretary shall apply a civil money penalty
 8 in an amount of \$10,000 for each day the man-
 9 ufacturer has failed to report such information
 10 and such amount shall be paid to the Treasury.

11 “(C) FALSE INFORMATION.—Any manu-
 12 facturer required to submit information under
 13 subsection (f)(2) that knowingly provides false
 14 information is subject to a civil money penalty
 15 in an amount not to exceed \$100,000 for each
 16 item of false information. Such civil money pen-
 17 alties are in addition to other penalties as may
 18 be prescribed by law.”; and

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

24 (c) MANUFACTURERS WITH A REBATE AGREE-
 25 MENT.—

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

9 (2) TECHNICAL AMENDMENT.—Section
10 1927(b)(3)(A)(iii) of the Social Security Act (42
11 U.S.C. 1396r–8(b)(3)(A)(iii)) is amended by striking
12 “section 1881(b)(13)(A)(ii)” and inserting “section
13 1881(b)(14)(B)”.

14 (d) REPORT.—Not later than January 1, 2021, the
15 Inspector General of the Department of Health and
16 Human Services shall assess and submit to Congress a
17 report on the accuracy of average sales price information
18 submitted by manufacturers under section 1847A of the
19 Social Security Act (42 U.S.C. 1395w–3a). Such report
20 shall include any recommendations on how to improve the
21 accuracy of such information.

1 **SEC. 204. MAKING PRESCRIPTION DRUG MARKETING SAM-**
 2 **PLE INFORMATION REPORTED BY MANUFAC-**
 3 **TURERS AVAILABLE TO CERTAIN INDIVID-**
 4 **UALS AND ENTITIES.**

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

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

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

11 “(b) DATA SHARING AGREEMENTS.—

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

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

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

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

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

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

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

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

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

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

7 “(c) PENALTIES.—

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

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

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

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

12 “(d) DRUG SAMPLE DISTRIBUTION INFORMATION.—

13 “(1) IN GENERAL.—Not later than January 1
14 of each year (beginning with 2021), the Secretary
15 shall maintain a list containing information related
16 to the distribution of samples of applicable drugs.
17 Such list shall provide the following information with
18 respect to the preceding year:

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

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

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

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

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

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

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

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

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

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

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

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

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

11 **SEC. 205. PROVIDING THE MEDICARE PAYMENT ADVISORY**
 12 **COMMISSION AND MEDICAID AND CHIP PAY-**
 13 **MENT AND ACCESS COMMISSION WITH AC-**
 14 **CESS TO CERTAIN DRUG PAYMENT INFORMA-**
 15 **TION, INCLUDING CERTAIN REBATE INFOR-**
 16 **MATION.**

17 (a) ACCESS TO CERTAIN PART D PAYMENT DATA.—
 18 Section 1860D–15(f) of the Social Security Act (42
 19 U.S.C. 1395w–115(f)) is amended—

20 (1) in paragraph (2)—

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

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

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

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

14 (2) by adding at the end the following new
15 paragraph:

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

24 “(A) The specific amounts or the identity
25 of the source of any rebates, price concessions,

1 or other forms of direct or indirect remunera-
 2 tion under such prescription drug plan or such
 3 MA–PD plan.

4 “(B) Information submitted with the bid
 5 submitted under section 1860D–11 by such
 6 PDP sponsor or section 1854 by such MA orga-
 7 nization.

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

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

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

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

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

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

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

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

20 **SEC. 206. SENSE OF THE SENATE REGARDING THE NEED TO**
 21 **EXPAND COMMERCIALLY AVAILABLE DRUG**
 22 **PRICING COMPARISON PLATFORMS.**

23 It is the sense of the Senate that—

24 (1) commercially available drug pricing com-
 25 parison platforms can, at no cost, help patients find

1 the lowest price for their medications at their local
2 pharmacy;

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

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

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

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

14 **TITLE III—REVENUE** 15 **PROVISIONS**

16 **SEC. 301. PERMANENT EXTENSION OF REDUCTION IN MED-** 17 **ICAL EXPENSE DEDUCTION FLOOR.**

18 (a) IN GENERAL.—Section 213(a) of the Internal
19 Revenue Code of 1986 is amended by striking “10 per-
20 cent” and inserting “7.5 percent”.

21 (b) CONFORMING AMENDMENTS.—

22 (1) Section 213 of such Code is amended by
23 striking subsection (f).

24 (2) Section 56(b)(1) of such Code is amended
25 by striking subparagraph (B) and by redesignating

1 subparagraphs (C), (D), (E), and (F), as subpara-
 2 graphs (B), (C), (D), and (E), respectively.

3 (c) EFFECTIVE DATE.—The amendment made by
 4 this section shall apply to taxable years ending after De-
 5 cember 31, 2018.

6 **SEC. 302. SAFE HARBOR FOR HIGH DEDUCTIBLE HEALTH**
 7 **PLANS WITHOUT DEDUCTIBLE FOR INSULIN.**

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

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

15 **SEC. 303. INCLUSION OF CERTAIN OVER-THE-COUNTER**
 16 **MEDICAL PRODUCTS AS QUALIFIED MEDICAL**
 17 **EXPENSES.**

18 (a) HSAs.—Section 223(d)(2) of the Internal Rev-
 19 enue Code of 1986 is amended—

20 (1) by striking the last sentence of subpara-
 21 graph (A) and inserting the following: “For pur-
 22 poses of this subparagraph, amounts paid for men-
 23 strual care products shall be treated as paid for
 24 medical care.”; and

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

3 “(D) MENSTRUAL CARE PRODUCT.—For
4 purposes of this paragraph, the term ‘menstrual
5 care product’ means a tampon, pad, liner, cup,
6 sponge, or similar product used by individuals
7 with respect to menstruation or other genital-
8 tract secretions.”.

9 (b) ARCHER MSAS.—Section 220(d)(2)(A) of such
10 Code is amended by striking the last sentence and insert-
11 ing the following: “For purposes of this subparagraph,
12 amounts paid for menstrual care products (as defined in
13 section 223(d)(2)(D)) shall be treated as paid for medical
14 care.”.

15 (c) HEALTH FLEXIBLE SPENDING ARRANGEMENTS
16 AND HEALTH REIMBURSEMENT ARRANGEMENTS.—Sec-
17 tion 106 of such Code is amended by striking subsection
18 (f) and inserting the following new subsection:

19 “(f) REIMBURSEMENTS FOR MENSTRUAL CARE
20 PRODUCTS.—For purposes of this section and section
21 105, expenses incurred for menstrual care products (as
22 defined in section 223(d)(2)(D)) shall be treated as in-
23 curred for medical care.”.

24 (d) EFFECTIVE DATES.—

1 (1) DISTRIBUTIONS FROM SAVINGS AC-
 2 COUNTS.—The amendment made by subsections (a)
 3 and (b) shall apply to amounts paid after December
 4 31, 2019.

5 (2) REIMBURSEMENTS.—The amendment made
 6 by subsection (c) shall apply to expenses incurred
 7 after December 31, 2019.

8 **TITLE IV—MISCELLANEOUS**

9 **SEC. 401. IMPROVING COORDINATION BETWEEN THE FOOD** 10 **AND DRUG ADMINISTRATION AND THE CEN-** 11 **TERS FOR MEDICARE & MEDICAID SERVICES.**

12 (a) IN GENERAL.—

13 (1) PUBLIC MEETING.—

14 (A) IN GENERAL.—Not later than 12
 15 months after the date of the enactment of this
 16 Act, the Secretary of Health and Human Serv-
 17 ices (referred to in this section as the “Sec-
 18 retary”) shall convene a public meeting for the
 19 purposes of discussing and providing input on
 20 improvements to coordination between the Food
 21 and Drug Administration and the Centers for
 22 Medicare & Medicaid Services in preparing for
 23 the availability of novel medical products de-
 24 scribed in subsection (c) on the market in the
 25 United States.

1 (B) ATTENDEES.—The public meeting
2 shall include—

3 (i) representatives of relevant Federal
4 agencies, including representatives from
5 each of the medical product centers within
6 the Food and Drug Administration and
7 representatives from the coding, coverage,
8 and payment offices within the Centers for
9 Medicare & Medicaid Services;

10 (ii) stakeholders with expertise in the
11 research and development of novel medical
12 products, including manufacturers of such
13 products;

14 (iii) representatives of commercial
15 health insurance payers;

16 (iv) stakeholders with expertise in the
17 administration and use of novel medical
18 products, including physicians; and

19 (v) stakeholders representing patients
20 and with expertise in the utilization of pa-
21 tient experience data in medical product
22 development.

23 (C) TOPICS.—The public meeting shall in-
24 clude a discussion of—

1 (i) the status of the drug and medical
2 device development pipeline related to the
3 availability of novel medical products;

4 (ii) the anticipated expertise necessary
5 to review the safety and effectiveness of
6 such products at the Food and Drug Ad-
7 ministration and current gaps in such ex-
8 pertise, if any;

9 (iii) the expertise necessary to make
10 coding, coverage, and payment decisions
11 with respect to such products within the
12 Centers for Medicare & Medicaid Services,
13 and current gaps in such expertise, if any;

14 (iv) trends in the differences in the
15 data necessary to determine the safety and
16 effectiveness of a novel medical product
17 and the data necessary to determine
18 whether a novel medical product meets the
19 reasonable and necessary requirements for
20 coverage and payment under title XVIII of
21 the Social Security Act pursuant to section
22 1862(a)(1)(A) of such Act (42 U.S.C.
23 1395y(a)(1)(A));

(v) the availability of information for sponsors of such novel medical products to meet each of those requirements; and

(vi) the coordination of information related to significant clinical improvement over existing therapies for patients between the Food and Drug Administration and the Centers for Medicare & Medicaid Services with respect to novel medical products.

(D) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—No information discussed as a part of the public meeting under this paragraph shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code.

(2) IMPROVING TRANSPARENCY OF CRITERIA FOR MEDICARE COVERAGE.—

(A) DRAFT GUIDANCE.—Not later than 18 months after the public meeting under paragraph (1), the Secretary shall update the final guidance titled “National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development” to address any opportunities to improve

1 the availability and coordination of information
2 as described in clauses (iv) through (vi) of para-
3 graph (1)(C).

4 (B) FINAL GUIDANCE.—Not later than 12
5 months after issuing draft guidance under sub-
6 paragraph (A), the Secretary shall finalize the
7 updated guidance to address any such opportu-
8 nities.

9 (b) REPORT ON CODING, COVERAGE, AND PAYMENT
10 PROCESSES UNDER MEDICARE FOR NOVEL MEDICAL
11 PRODUCTS.—Not later than 12 months after the date of
12 the enactment of this Act, the Secretary shall publish a
13 report on the Internet website of the Department of
14 Health and Human Services regarding processes under
15 the Medicare program under title XVIII of the Social Se-
16 curity Act (42 U.S.C. 1395 et seq.) with respect to the
17 coding, coverage, and payment of novel medical products
18 described in subsection (c). Such report shall include the
19 following:

20 (1) A description of challenges in the coding,
21 coverage, and payment processes under the Medicare
22 program for novel medical products.

23 (2) Recommendations to—

24 (A) incorporate patient experience data
25 (such as the impact of a disease or condition on

1 the lives of patients and patient treatment pref-
 2 erences) into the coverage and payment proc-
 3 esses within the Centers for Medicare & Med-
 4 icaid Services;

5 (B) decrease the length of time to make
 6 national and local coverage determinations
 7 under the Medicare program (as those terms
 8 are defined in subparagraph (A) and (B), re-
 9 spectively, of section 1862(l)(6) of the Social
 10 Security Act (42 U.S.C. 1395y(l)(6)));

11 (C) streamline the coverage process under
 12 the Medicare program and incorporate input
 13 from relevant stakeholders into such coverage
 14 determinations; and

15 (D) identify potential mechanisms to incor-
 16 porate novel payment designs similar to those
 17 in development in commercial insurance plans
 18 and State plans under title XIX of such Act
 19 (42 U.S.C. 1396 et seq.) into the Medicare pro-
 20 gram.

21 (c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For
 22 purposes of this section, a novel medical product described
 23 in this subsection is a medical product, including a drug,
 24 biological (including gene and cell therapy), or medical de-
 25 vice, that has been designated as a breakthrough therapy

1 under section 506(a) of the Federal Food, Drug, and Cos-
 2 metic Act (21 U.S.C. 356(a)), a breakthrough device
 3 under section 515B of such Act (21 U.S.C. 360e–3), or
 4 a regenerative advanced therapy under section 506(g) of
 5 such Act (21 U.S.C. 356(g)).

6 **SEC. 402. PATIENT CONSULTATION IN MEDICARE NA-**
 7 **TIONAL AND LOCAL COVERAGE DETERMINA-**
 8 **TIONS IN ORDER TO MITIGATE BARRIERS TO**
 9 **INCLUSION OF SUCH PERSPECTIVES.**

10 Section 1862(l) of the Social Security Act (42 U.S.C.
 11 1395y(l)) is amended by adding at the end the following
 12 new paragraph:

13 “(7) PATIENT CONSULTATION IN NATIONAL
 14 AND LOCAL COVERAGE DETERMINATIONS.—The Sec-
 15 retary may consult with patients and organizations
 16 representing patients in making national and local
 17 coverage determinations.”.

18 **SEC. 403. MEDPAC REPORT ON SHIFTING COVERAGE OF**
 19 **CERTAIN MEDICARE PART B DRUGS TO MEDI-**
 20 **CARE PART D.**

21 (a) STUDY.—The Medicare Payment Advisory Com-
 22 mission (in this section referred to as the “Commission”)
 23 shall conduct a study on shifting coverage of certain drugs
 24 and biologicals for which payment is currently made under
 25 part B of title XVIII of the Social Security Act (42 U.S.C.

1 1395j et seq.) to part D of such title (42 U.S.C. 1395w–
 2 21 et seq.). Such study shall include an analysis of—

3 (1) differences in program structures and pay-
 4 ment methods for drugs and biologicals covered
 5 under such parts B and D, including effects of such
 6 a shift on program spending, beneficiary cost-shar-
 7 ing liability, and utilization management techniques
 8 for such drugs and biologicals; and

9 (2) the feasibility and policy implications of
 10 shifting coverage of drugs and biologicals for which
 11 payment is currently made under such part B to
 12 such part D.

13 (b) REPORT.—

14 (1) IN GENERAL.—Not later than June 30,
 15 2021, the Commission shall submit to Congress a re-
 16 port containing the results of the study conducted
 17 under subsection (a).

18 (2) CONTENTS.—The report under paragraph
 19 (1) shall include information, and recommendations
 20 as the Commission deems appropriate, regarding—

21 (A) formulary design under such part D;

22 (B) the ability of the benefit structure
 23 under such part D to control total spending on
 24 drugs and biologicals for which payment is cur-
 25 rently made under such part B;

1 (C) changes to the bid process under such
2 part D, if any, that may be necessary to inte-
3 grate coverage of such drugs and biologicals
4 into such part D;

5 (D) any other changes to the program that
6 Congress should consider in determining wheth-
7 er to shift coverage of such drugs and
8 biologicals from such part B to such part D;
9 and

10 (E) the feasibility and policy implications
11 of creating a methodology to preserve the
12 healthcare provider's ability to take title of the
13 drug, including a methodology under which—

14 (i) prescription drug plans negotiate
15 reimbursement rates and other arrange-
16 ments with drug manufacturers on behalf
17 of a wholesaler;

18 (ii) wholesalers purchase the drugs
19 from the manufacturers at the negotiated
20 rate and ship them through distributors to
21 physicians to administer to patients;

22 (iii) physicians and hospitals purchase
23 the drug from the wholesaler via the dis-
24 tributor;

1 (iv) after administering the drug, the
 2 physician submits a claim to the MAC for
 3 their drug administration fee;

4 (v) to be reimbursed for the purchase
 5 of the drug from the distributor, the physi-
 6 cian furnishes the claim for the drug itself
 7 to the wholesaler and the wholesaler would
 8 refund the cost of the drug to the physi-
 9 cian; and

10 (vi) the wholesaler passes this claim to
 11 the PDP to receive reimbursement.

12 **SEC. 404. REQUIREMENT THAT DIRECT-TO-CONSUMER AD-**
 13 **VERTISEMENTS FOR PRESCRIPTION DRUGS**
 14 **AND BIOLOGICAL PRODUCTS INCLUDE**
 15 **TRUTHFUL AND NON-MISLEADING PRICING**
 16 **INFORMATION.**

17 Part A of title XI of the Social Security Act is
 18 amended by adding at the end the following new section:

19 **“SEC. 1150C. REQUIREMENT THAT DIRECT-TO-CONSUMER**
 20 **ADVERTISEMENTS FOR PRESCRIPTION**
 21 **DRUGS AND BIOLOGICAL PRODUCTS IN-**
 22 **CLUDE TRUTHFUL AND NON-MISLEADING**
 23 **PRICING INFORMATION.**

24 “(a) IN GENERAL.—The Secretary shall require that
 25 each direct-to-consumer advertisement for a prescription

1 drug or biological product for which payment is available
 2 under title XVIII or XIX includes an appropriate disclo-
 3 sure of truthful and non-misleading pricing information
 4 with respect to the drug or product.

5 “(b) DETERMINATION BY CMS.—The Secretary, act-
 6 ing through the Administrator of the Centers for Medicare
 7 & Medicaid Services, shall determine the components of
 8 the requirement under subsection (a), such as the forms
 9 of advertising, the manner of disclosure, the price point
 10 listing, and the price information for disclosure.”.

11 **SEC. 405. CHIEF PHARMACEUTICAL NEGOTIATOR AT THE**
 12 **OFFICE OF THE UNITED STATES TRADE REP-**
 13 **RESENTATIVE.**

14 (a) IN GENERAL.—Section 141 of the Trade Act of
 15 1974 (19 U.S.C. 2171) is amended—

16 (1) in subsection (b)(2)—

17 (A) by striking “and one Chief Innovation
 18 and Intellectual Property Negotiator” and in-
 19 serting “one Chief Innovation and Intellectual
 20 Property Negotiator, and one Chief Pharma-
 21 ceutical Negotiator”;

22 (B) by striking “or the Chief Innovation
 23 and Intellectual Property Negotiator” and in-
 24 serting “the Chief Innovation and Intellectual

1 Property Negotiator, or the Chief Pharma-
2 ceutical Negotiator”; and

3 (C) by striking “and the Chief Innovation
4 and Intellectual Property Negotiator” and in-
5 serting “the Chief Innovation and Intellectual
6 Property Negotiator, and the Chief Pharma-
7 ceutical Negotiator”; and

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

10 “(7) The principal function of the Chief Phar-
11 maceutical Negotiator shall be to conduct trade ne-
12 gotiations and to enforce trade agreements relating
13 to United States pharmaceutical products and serv-
14 ices. The Chief Pharmaceutical Negotiator shall be
15 a vigorous advocate on behalf of United States phar-
16 maceutical interests. The Chief Pharmaceutical Ne-
17 gotiator shall perform such other functions as the
18 United States Trade Representative may direct.”.

19 (b) COMPENSATION.—Section 5314 of title 5, United
20 States Code, is amended by striking “Chief Innovation
21 and Intellectual Property Negotiator, Office of the United
22 States Trade Representative.” and inserting the following:

23 “Chief Innovation and Intellectual Property Ne-
24 gotiator, Office of the United States Trade Rep-
25 resentative.

1 “Chief Pharmaceutical Negotiator, Office of the
2 United States Trade Representative.”.

3 (c) REPORT REQUIRED.—Not later than the date
4 that is one year after the appointment of the first Chief
5 Pharmaceutical Negotiator pursuant to paragraph (2) of
6 section 141(b) of the Trade Act of 1974, as amended by
7 subsection (a), and annually thereafter, the United States
8 Trade Representative shall submit to the Committee on
9 Finance of the Senate and the Committee on Ways and
10 Means of the House of Representatives a report describing
11 in detail—

12 (1) enforcement actions taken by the United
13 States Trade Representative during the 1-year pe-
14 riod preceding the submission of the report to en-
15 sure the protection of United States pharmaceutical
16 products and services; and

17 (2) other actions taken by the United States
18 Trade Representative to advance United States
19 pharmaceutical products and services.

○