

117TH CONGRESS
1ST SESSION

S. 2164

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

JUNE 22, 2021

Mr. CRAPO (for himself, Mr. BURR, Mr. SCOTT of South Carolina, Mr. DAINES, Mr. RISCH, Ms. ERNST, Mr. MARSHALL, and Mr. TILLIS) 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 2021”.

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 AND MEDICAID PROVISIONS

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. Credit under the Medicare Merit-Based Incentive Payment System for completion of a clinical medical education program on biosimilar biological 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. Allowing the offering of additional prescription drug plans under Medicare part D.
- Sec. 113. Allowing certain enrollees of prescription drug plans and MA–PD plans under the Medicare program to spread out cost-sharing under certain circumstances.
- Sec. 114. Continuation of Part D Senior Savings Model.
- Sec. 115. Requiring prescription drug plans and MA–PD plans to report potential fraud, waste, and abuse to the Secretary of HHS.
- Sec. 116. Establishment of pharmacy quality measures under Medicare part D.

Subtitle C—Medicaid Provisions

- Sec. 121. Price reporting clarifications for gene therapy outcomes-based agreements.
- Sec. 122. Anti-kickback statute and physician self-referral safe harbors.
- Sec. 123. GAO study and report on use of outcomes-based agreements.

TITLE II—DRUG PRICE TRANSPARENCY PROVISIONS

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

TITLE III—REVENUE PROVISION

- Sec. 301. Inclusion of insulin and other treatments for chronic conditions as preventive care.

TITLE IV—MISCELLANEOUS PROVISIONS

- 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. Authority to require 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.

**TITLE I—MEDICARE AND
MEDICAID PROVISIONS**

**Subtitle A—Medicare Part B
Provisions**

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

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

(1) in paragraph (1)—

(A) in the heading, by striking “IN GENERAL” and inserting “SITE PAYMENT”;

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

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

(ii) by inserting “, or to a physician for services furnished in a physician’s office” after “surgical center under this title”; and

1 (iii) by inserting “(or 2022 with re-
 2 spect to a physician for services furnished
 3 in a physician’s office)” after “2018”; and
 4 (C) in subparagraph (A)—

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

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

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

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

16 “(2) PHYSICIAN PAYMENT.—Beginning in
 17 2022, the Secretary shall expand the information in-
 18 cluded on the internet website described in para-
 19 graph (1) to include—

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

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

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

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

9 (1) by redesignating subsection (h) as sub-
 10 section (i); and

11 (2) by inserting after subsection (g) the fol-
 12 lowing new subsection:

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

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

17 “(A) IN GENERAL.—For each calendar
 18 quarter beginning on or after July 1, 2022, the
 19 Secretary shall, with respect to a refundable
 20 single-dose container or single-use package drug
 21 (as defined in paragraph (8)), report to each
 22 manufacturer (as defined in subsection
 23 (c)(6)(A)) of such refundable single-dose con-
 24 tainer or single-use package drug the following
 25 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 2022, 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, 2022, 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, 2022, 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, 2022, 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, 2022, 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, 2022, 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(i) of the Social Security Act (42
U.S.C. 1395w–3a(i)), as redesignated by section 102, 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, 2022, 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 2022 through
5 2029, \$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 2022 through
18 2029, \$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, 2022, if such
 25 payment is determined based on the average

price for the year established under section 1847A pursuant to clause (iii)(II) of such subparagraph, the provisions of subsection (b)(10) of section 1847A shall apply to the amount of payment so established in the same manner as such provisions apply to the amount of payment under section 1847A.”.

(2) ASC.—Section 1833(i)(2)(D) of the Social Security Act (42 U.S.C. 1395l(i)(2)(D)) is amended—

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

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

(C) by inserting after clause (v) the following new clause:

“(vi) If there is a separate payment under the system described in clause (i) for a drug or biological furnished on or after January 1, 2022, the provisions of subsection (t)(14)(I) shall apply to the establishment of the amount of payment for the drug or biological under such system in the same manner in which such provisions apply to the establishment of the amount 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, 2022, 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 January 1, 2022, 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. CREDIT UNDER THE MEDICARE MERIT-BASED INCENTIVE PAYMENT SYSTEM FOR COMPLETION OF A CLINICAL MEDICAL EDUCATION PROGRAM ON BIOSIMILAR BIOLOGICAL PRODUCTS.

Section 1848(q)(5)(C) of the Social Security Act (42 U.S.C. 1395w-4(q)(5)(C)) is amended by adding at the end the following new clause:

“(iv) CLINICAL MEDICAL EDUCATION PROGRAM ON BIOSIMILAR BIOLOGICAL PRODUCTS.—Completion of a clinical medical education program developed or im-

1 proved under section 352A(b) of the Public
 2 Health Service Act by a MIPS eligible pro-
 3 fessional during a performance period shall
 4 earn such eligible professional one-half of
 5 the highest potential score for the perform-
 6 ance category described in paragraph
 7 (2)(A)(iii) for such performance period. A
 8 MIPS eligible professional may only count
 9 the completion of such a program for pur-
 10 poses of such category one time during the
 11 eligible professional’s lifetime.”.

12 **SEC. 108. GAO STUDY AND REPORT ON AVERAGE SALES**
 13 **PRICE.**

14 (a) STUDY.—

15 (1) IN GENERAL.—The Comptroller General of
 16 the United States (in this section referred to as the
 17 “Comptroller General”) shall conduct a study on
 18 spending for applicable drugs under part B of title
 19 XVIII of the Social Security Act.

20 (2) APPLICABLE DRUGS DEFINED.—In this sec-
 21 tion, the term “applicable drugs” means drugs and
 22 biologicals—

23 (A) for which reimbursement under such
 24 part B is based on the average sales price of
 25 the drug or biological; and

1 (B) that account for the largest percentage
2 of total spending on drugs and biologicals under
3 such part B (as determined by the Comptroller
4 General, but in no case less than 25 drugs or
5 biologicals).

6 (3) REQUIREMENTS.—The study under para-
7 graph (1) shall include an analysis of the following:

8 (A) The extent to which each applicable
9 drug is paid for—

10 (i) under such part B for Medicare
11 beneficiaries; or

12 (ii) by private payers in the commer-
13 cial market.

14 (B) Any change in Medicare spending or
15 Medicare beneficiary cost-sharing that would
16 occur if the average sales price of an applicable
17 drug was based solely on payments by private
18 payers in the commercial market.

19 (C) The extent to which drug manufactur-
20 ers provide rebates, discounts, or other price
21 concessions to private payers in the commercial
22 market for applicable drugs, which the manu-
23 facturer includes in its average sales price cal-
24 culation, for—

25 (i) formulary placement;

1 (ii) utilization management consider-
 2 ations; or

3 (iii) other purposes.

4 (D) Barriers to drug manufacturers pro-
 5 viding such price concessions for applicable
 6 drugs.

7 (E) Other areas determined appropriate by
 8 the Comptroller General.

9 (b) REPORT.—Not later than 2 years after the date
 10 of the enactment of this Act, the Comptroller General shall
 11 submit to Congress a report on the study conducted under
 12 subsection (a), together with recommendations for such
 13 legislation and administrative action as the Secretary de-
 14 termines appropriate.

15 **Subtitle B—Medicare Part D** 16 **Provisions**

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

18 (a) BENEFIT STRUCTURE REDESIGN.—Section
 19 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
 20 102(b)) is amended—

21 (1) in paragraph (2)—

22 (A) in subparagraph (A)—

23 (i) in the matter preceding clause (i),
 24 by inserting “for a year preceding 2022
 25 and for costs above the annual deductible

specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2022 and each subsequent year” after “paragraph (3)”;

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

and

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

(B) in subparagraph (C)—

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

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

(C) in subparagraph (D)—

(i) in clause (i)—

(I) in the matter preceding subclause (I), by inserting “for a year preceding 2022,” after “paragraph (4),”; and

1 (II) in subclause (I)(bb), by
 2 striking “a year after 2018” and in-
 3 serting “each of years 2018 through
 4 2021”; and

5 (ii) in clause (ii)(V), by striking
 6 “2019 and each subsequent year” and in-
 7 serting “each of years 2019 through
 8 2021”;

9 (2) in paragraph (3)(A)—

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

13 (B) in clause (ii), by striking “for a subse-
 14 quent year” and inserting “for each of years
 15 2007 through 2021”; and

16 (3) in paragraph (4)—

17 (A) in subparagraph (A)—

18 (i) in clause (i)—

19 (I) by redesignating subclauses
 20 (I) and (II) as items (aa) and (bb),
 21 respectively, and indenting appro-
 22 priately;

23 (II) in the matter preceding item
 24 (aa), as redesignated by subclause (I),

1 by striking “is equal to the greater
2 of—” and inserting “is equal to—

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

5 (III) by striking the period at the
6 end of item (bb), as redesignated by
7 subclause (I), and inserting “; and”;
8 and

9 (IV) by adding at the end the fol-
10 lowing:

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

13 (ii) in clause (ii)—

14 (I) by striking “clause (i)(I)” and
15 inserting “clause (i)(I)(aa)”;

16 (II) by adding at the end the fol-
17 lowing new sentence: “The Secretary
18 shall continue to calculate the dollar
19 amounts specified in clause (i)(I)(aa),
20 including with the adjustment under
21 this clause, after 2021 for purposes of
22 section 1860D–14(a)(1)(D)(iii).”;

23 (B) in subparagraph (B)—

24 (i) in clause (i)—

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

3 (II) in subclause (VI)—

4 (aa) by striking “for a sub-
5 sequent year” and inserting “for
6 2021”; and

7 (bb) by striking the period
8 at the end and inserting a semi-
9 colon; and

10 (III) by adding at the end the
11 following new subclauses:

12 “(VII) for 2022, is equal to
13 \$3,100; or

14 “(VIII) for a subsequent year, is
15 equal to the amount specified in this
16 subparagraph for the previous year,
17 increased by the annual percentage in-
18 crease described in paragraph (6) for
19 the year involved.”; and

20 (ii) in clause (ii), by striking “clause
21 (i)(II)” and inserting “clause (i)”;

22 (C) in subparagraph (C)(i), by striking
23 “and for amounts” and inserting “and for a
24 year preceding 2022 for amounts”; and

1 (D) in subparagraph (E), by striking “In
 2 applying” and inserting “For each of 2011
 3 through 2021, in applying”.

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

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

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

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

14 (3) by adding at the end the following new sub-
 15 paragraph:

16 “(B) for 2022 and each subsequent year,
 17 the sum of—

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

1 section 1860D–2(b)(4)(B) with respect to
 2 applicable drugs (as defined in section
 3 1860D–14B(g)(2)); and

4 “(ii) an amount equal to 30 percent of
 5 the allowable reinsurance costs (as speci-
 6 fied in paragraph (2)) attributable to that
 7 portion of gross covered prescription drug
 8 costs as specified in paragraph (3) in-
 9 curred in the coverage year after such indi-
 10 vidual has incurred costs that exceed the
 11 annual out-of-pocket threshold specified in
 12 section 1860D–2(b)(4)(B) with respect to
 13 covered part D drugs that are not applica-
 14 ble drugs (as so defined).”.

15 (c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

21 “(a) ESTABLISHMENT.—The Secretary shall estab-
 22 lish a manufacturer discount program (in this section re-
 23 ferred to as the ‘program’). Under the program, the Sec-
 24 retary shall enter into agreements described in subsection
 25 (b) with manufacturers and provide for the performance

1 of the duties described in subsection (c). The Secretary
2 shall establish a model agreement for use under the pro-
3 gram by not later than January 1, 2023, in consultation
4 with manufacturers, and allow for comment on such model
5 agreement.

6 “(b) TERMS OF AGREEMENT.—

7 “(1) IN GENERAL.—

8 “(A) AGREEMENT.—An agreement under
9 this section shall require the manufacturer to
10 provide applicable beneficiaries access to dis-
11 counted prices for applicable drugs of the man-
12 ufacturer that are dispensed on or after Janu-
13 ary 1, 2022.

14 “(B) PROVISION OF DISCOUNTED PRICES
15 AT THE POINT-OF-SALE.—The discounted prices
16 described in subparagraph (A) shall be provided
17 to the applicable beneficiary at the pharmacy or
18 by the mail order service at the point-of-sale of
19 an applicable drug.

20 “(2) PROVISION OF APPROPRIATE DATA.—Each
21 manufacturer with an agreement in effect under this
22 section shall collect and have available appropriate
23 data, as determined by the Secretary, to ensure that
24 it can demonstrate to the Secretary compliance with
25 the requirements under the program.

1 “(3) COMPLIANCE WITH REQUIREMENTS FOR
2 ADMINISTRATION OF PROGRAM.—Each manufac-
3 turer with an agreement in effect under this section
4 shall comply with requirements imposed by the Sec-
5 retary or a third party with a contract under sub-
6 section (d)(3), as applicable, for purposes of admin-
7 istering the program, including any determination
8 under subparagraph (A) of subsection (c)(1) or pro-
9 cedures established under such subsection (c)(1).

10 “(4) LENGTH OF AGREEMENT.—

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

17 “(B) TERMINATION.—

18 “(i) BY THE SECRETARY.—The Sec-
19 retary may provide for termination of an
20 agreement under this section for a knowing
21 and willful violation of the requirements of
22 the agreement or other good cause shown.
23 Such termination shall not be effective ear-
24 lier than 30 days after the date of notice
25 to the manufacturer of such termination.

1 The Secretary shall provide, upon request,
2 a manufacturer with a hearing concerning
3 such a termination, and such hearing shall
4 take place prior to the effective date of the
5 termination with sufficient time for such
6 effective date to be repealed if the Sec-
7 retary determines appropriate.

8 “(ii) BY A MANUFACTURER.—A man-
9 ufacturer may terminate an agreement
10 under this section for any reason. Any
11 such termination shall be effective, with re-
12 spect to a plan year—

13 “(I) if the termination occurs be-
14 fore January 30 of a plan year, as of
15 the day after the end of the plan year;
16 and

17 “(II) if the termination occurs on
18 or after January 30 of a plan year, as
19 of the day after the end of the suc-
20 ceeding plan year.

21 “(iii) EFFECTIVENESS OF TERMI-
22 NATION.—Any termination under this sub-
23 paragraph shall not affect discounts for
24 applicable drugs of the manufacturer that

1 are due under the agreement before the ef-
2 fective date of its termination.

3 “(iv) NOTICE TO THIRD PARTY.—The
4 Secretary shall provide notice of such ter-
5 mination to a third party with a contract
6 under subsection (d)(3) within not less
7 than 30 days before the effective date of
8 such termination.

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

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

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

17 “(A) the determination of the amount of
18 the discounted price of an applicable drug of a
19 manufacturer;

20 “(B) the establishment of procedures
21 under which discounted prices are provided to
22 applicable beneficiaries at pharmacies or by
23 mail order service at the point-of-sale of an ap-
24 plicable drug;

1 “(C) the establishment of procedures to
2 ensure that, not later than the applicable num-
3 ber of calendar days after the dispensing of an
4 applicable drug by a pharmacy or mail order
5 service, the pharmacy or mail order service is
6 reimbursed for an amount equal to the dif-
7 ference between—

8 “(i) the negotiated price of the appli-
9 cable drug; and

10 “(ii) the discounted price of the appli-
11 cable drug;

12 “(D) the establishment of procedures to
13 ensure that the discounted price for an applica-
14 ble drug under this section is applied before any
15 coverage or financial assistance under other
16 health benefit plans or programs that provide
17 coverage or financial assistance for the pur-
18 chase or provision of prescription drug coverage
19 on behalf of applicable beneficiaries as the Sec-
20 retary may specify; and

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

1 “(2) MONITORING COMPLIANCE.—

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

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

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

17 “(d) ADMINISTRATION.—

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

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

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

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

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

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

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

1 party to determine discounts for applicable
2 drugs of the manufacturer under the program.

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

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

12 “(e) ENFORCEMENT.—

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

16 “(2) CIVIL MONEY PENALTY.—

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

24 “(i) the amount that the manufac-
25 turer would have paid with respect to such

1 discounts under the agreement, which will
 2 then be used to pay the discounts which
 3 the manufacturer had failed to provide;
 4 and

5 “(ii) 25 percent of such amount.

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

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

18 “(g) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

21 “(ii) if the PDP sponsor of the prescrip-
22 tion drug plan or the MA organization offering
23 the MA–PD plan does not use a formulary, for
24 which benefits are available under the prescrip-

1 tion drug plan or MA–PD plan that the appli-
2 cable beneficiary is enrolled in; or

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

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

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

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

12 “(4) DISCOUNTED PRICE.—

13 “(A) IN GENERAL.—The term ‘discounted
14 price’ means, with respect to an applicable drug
15 of a manufacturer furnished during a year to
16 an applicable beneficiary, 90 percent of the ne-
17 gotiated price of such drug.

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

22 “(C) SPECIAL CASE FOR CLAIMS SPANNING
23 DEDUCTIBLE.—In the case where the entire
24 amount of the negotiated price of an individual
25 claim for an applicable drug with respect to an

1 applicable beneficiary does not fall at or above
2 the annual deductible specified in section
3 1860D–2(b)(1) for the year, the manufacturer
4 of the applicable drug shall provide the dis-
5 counted price under this section on only the
6 portion of the negotiated price of the applicable
7 drug that falls at or above such annual deduct-
8 ible.

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

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

24 “(7) QUALIFIED RETIREE PRESCRIPTION DRUG
25 PLAN.—The term ‘qualified retiree prescription drug

1 plan’ has the meaning given such term in section
 2 11860D–22(a)(2).”.

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

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

10 (B) by adding at the end the following new
 11 subsection:

12 “(h) SUNSET OF PROGRAM.—

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

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

24 (3) INCLUSION OF ACTUARIAL VALUE OF MANU-
 25 FACTURER DISCOUNTS IN BIDS.—Section 1860D–11

1 of the Social Security Act (42 U.S.C. 1395w–111)
2 is amended—

3 (A) in subsection (b)(2)(C)(iii)—

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

7 “(I) the reinsurance”; and

8 (ii) by adding at the end the fol-
9 lowing:

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

15 (B) in subsection (c)(1)(C)—

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

19 “(i) the reinsurance”;

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

23 (iii) by adding at the end the fol-
24 lowing:

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

4 (4) CLARIFICATION REGARDING EXCLUSION OF
 5 MANUFACTURER DISCOUNTS FROM TROOP.—Section
 6 1860D–2(b)(4) of the Social Security Act (42
 7 U.S.C. 1395w–102(b)(4)) is amended—

8 (A) in subparagraph (C), by inserting “and
 9 subject to subparagraph (F)” after “subpara-
 10 graph (E)”; and

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

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

18 (d) DETERMINATION OF ALLOWABLE REINSURANCE
 19 COSTS.—Section 1860D–15(b) of the Social Security Act
 20 (42 U.S.C. 1395w–115(b)) is amended—

21 (1) in paragraph (2)—

22 (A) by striking “COSTS.—For purposes”
 23 and inserting “COSTS.—

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

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

3 “(B) INCLUSION OF MANUFACTURER DIS-
 4 COUNTS ON APPLICABLE DRUGS.—For purposes
 5 of applying subparagraph (A), the term ‘allow-
 6 able reinsurance costs’ shall include the portion
 7 of the negotiated price (as defined in section
 8 1860D–14B(g)(6)) of an applicable drug (as
 9 defined in section 1860D–14(g)(2)) that was
 10 paid by a manufacturer under the manufacturer
 11 discount program under section 1860D–14B.”;
 12 and
 13 (2) in paragraph (3)—

14 (A) in the first sentence, by striking “For
 15 purposes” and inserting “Subject to paragraph
 16 (2)(B), for purposes”; and

17 (B) in the second sentence, by inserting
 18 “or, in the case of an applicable drug, by a
 19 manufacturer” after “by the individual or
 20 under the plan”.

21 (e) UPDATING RISK ADJUSTMENT METHODOLOGIES
 22 TO ACCOUNT FOR PART D MODERNIZATION REDE-
 23 SIGN.—Section 1860D–15(c) of the Social Security Act
 24 (42 U.S.C. 1395w–115(c)) is amended by adding at the
 25 end the following new paragraph:

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

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

12 (1) in subsection (a)—

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

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

17 (C) by adding at the end the following new
 18 paragraphs:

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

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

24 “(6) have entered into and have in effect, under
 25 terms and conditions specified by the Secretary, a

1 contract with a third party that the Secretary has
 2 entered into a contract with under subsection (d)(3)
 3 of such section 1860D–14B.”;

4 (2) by striking subsection (b) and inserting the
 5 following:

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

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

14 “(2) the Secretary determines that in the period
 15 beginning on January 1, 2011, and ending on De-
 16 cember 31, 2011 (with respect to paragraphs (1)
 17 through (3) of subsection (a)), or the period begin-
 18 ning on January 1, 2022, and ending December 31,
 19 2022 (with respect to paragraphs (4) through (6) of
 20 such subsection), there were extenuating cir-
 21 cumstances.”.

22 (g) CONFORMING AMENDMENTS.—

23 (1) Section 1860D–2 of the Social Security Act
 24 (42 U.S.C. 1395w–102) is amended—

(A) in subsection (a)(2)(A)(i)(I), by striking “, or an increase in the initial” and inserting “or for a year preceding 2022 an increase in the initial”;

(B) in subsection (c)(1)(C)—

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

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

(C) in subsection (d)(1)(A), by striking “or an initial” and inserting “or for a year preceding 2022, an initial”.

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

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

(A) in paragraph (1)—

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

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

7 (iii) in subparagraph (E), by striking
 8 “The elimination” and inserting “For a
 9 year preceding 2022, the elimination”; and
 10 (B) in paragraph (2)—

11 (i) in subparagraph (C), by striking
 12 “The continuation” and inserting “For a
 13 year preceding 2022, the continuation”;
 14 and

15 (ii) in subparagraph (E)—

16 (I) by inserting “for a year pre-
 17 ceding 2022,” after “subsection (c)”;
 18 and

19 (II) by striking “1860D–
 20 2(b)(4)(A)(i)(I)” and inserting
 21 “1860D–2(b)(4)(A)(i)(I)(aa)”.

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

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

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

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

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

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

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

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

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

20 (B) by inserting “for such year” before the
 21 period.

22 (h) EFFECTIVE DATE.—The amendments made by
 23 this section shall apply to plan year 2022 and subsequent
 24 plan years.

1 **SEC. 112. 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. 113. 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. 114. CONTINUATION OF PART D SENIOR SAVINGS**
 8 **MODEL.**

9 Section 1115A of the Social Security Act (42 U.S.C.
 10 1315a) is amended by adding at the end the following new
 11 subsection:

12 “(h) PART D SENIOR SAVINGS MODEL.—Notwith-
 13 standing any other provision of law, the Secretary shall
 14 provide for the continued implementation on a permanent
 15 basis of the Part D Senior Savings Model under this sec-
 16 tion, under the same parameters under which such model
 17 was implemented for plan year 2021.”.

18 **SEC. 115. REQUIRING PRESCRIPTION DRUG PLANS AND**
 19 **MA-PD PLANS TO REPORT POTENTIAL**
 20 **FRAUD, WASTE, AND ABUSE TO THE SEC-**
 21 **RETARY OF HHS.**

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

1 “(p) REPORTING POTENTIAL FRAUD, WASTE, AND
 2 ABUSE.—Beginning January 1, 2022, 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. 116. 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).”.

Subtitle C—Medicaid Provisions

SEC. 121. PRICE REPORTING CLARIFICATIONS FOR GENE THERAPY OUTCOMES-BASED AGREEMENTS.

(a) QUARTERLY PRICE REPORTING OBLIGATION.—Section 1927(b)(3) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)) is amended by adding at the end the following new subparagraph:

“(E) OUTCOMES-BASED AGREEMENTS.—

1 “(i) IN GENERAL.—Beginning Janu-
2 ary 1, 2022, in the case of a covered out-
3 patient drug that is a single course trans-
4 formative therapy (as defined in subsection
5 (k)(12)) and is sold under an outcomes-
6 based agreement (as defined in subsection
7 (k)(13)) during a rebate period, the manu-
8 facturer of such drug shall report (in addi-
9 tion to any other information required
10 under this paragraph) the pricing struc-
11 ture for such drug based on pre-defined
12 outcomes or measures specified in such
13 outcomes-based agreement.

14 “(ii) ACCESS TO OUTCOMES-BASED
15 AGREEMENTS FOR STATE PLANS.—As a
16 condition of excluding a refund, rebate, re-
17 imbursement, free item, withholding, or re-
18 payment made under an outcomes-based
19 agreement with respect to a covered out-
20 patient drug from the best price or average
21 manufacturer price of the drug for a re-
22 bate period (as described in subsection
23 (c)(1)(C)(i)(VII) or (k)(1)(B)(i)(VI), as
24 applicable), the manufacturer shall—

1 “(I) make available to each State
2 plan the opportunity to enter into an
3 outcomes-based agreement for such
4 drug and rebate period; and

5 “(II) certify to the Secretary that
6 the manufacturer has made such op-
7 portunity so available to each State
8 plan.

9 “(iii) RULES OF CONSTRUCTION.—
10 Nothing in this subparagraph shall be con-
11 strued as—

12 “(I) requiring a manufacturer to
13 execute an outcomes-based agreement
14 with a State for a covered outpatient
15 drug that is a single course trans-
16 formative therapy (as defined in sub-
17 section (k)(12)); ;

18 “(II) precluding the execution of
19 a rebate agreement under this section
20 for such a drug; or

21 “(III) limiting States’ ability to
22 join together for a multi-State con-
23 tract with a single manufacturer to
24 establish an outcomes-based agree-
25 ment for such a drug.”.

1 (b) DEFINITION OF BEST PRICE.—Section
2 1927(c)(1)(C) of the Social Security Act (42 U.S.C.
3 1396–8(c)(1)(C)) is amended—

4 (1) in clause (i)—

5 (A) in subclause (V), by striking “and”;

6 (B) in subclause (VI), by striking the pe-
7 riod at the end and inserting “; and”; and

8 (C) by adding at the end the following new
9 subclause:

10 “(VII) subject to subsection
11 (b)(3)(E)(ii), with respect to a covered
12 outpatient drug that is a single course
13 transformative therapy (as defined in
14 subsection (k)(12)) and is sold under
15 an outcomes-based agreement (as de-
16 fined in subsection (k)(13)) during
17 the rebate period, any prices resulting
18 from—

19 “(aa) a refund, rebate, reim-
20 bursement, or free goods from
21 the manufacturer or third party
22 on behalf of the manufacturer; or

23 “(bb) the withholding or re-
24 duction of a payment to the man-

1 ufacturer or third party on behalf
 2 of the manufacturer,
 3 that is triggered by a patient who
 4 fails to achieve outcomes or measures
 5 defined under the terms of such out-
 6 comes-based agreement during the pe-
 7 riod for which such agreement is ef-
 8 fective.”; and

9 (2) in clause (ii)—

10 (A) in subclause (I), by striking the semi-
 11 colon at the end and inserting “, except any
 12 price adjustment described in clause (i)(VII);”;

13 (B) in subclause (III), by striking “and”;

14 (C) in subclause (IV)—

15 (i) by moving the left margin of such
 16 subclause 2 ems to the right; and

17 (ii) by striking the period at the end
 18 and inserting “; and”; and

19 (D) by adding at the end the following new
 20 subclause:

21 “(V) in the case of a covered out-
 22 patient drug that is a single course
 23 transformative therapy (as defined in
 24 subsection (k)(12)) and is sold under
 25 an outcomes-based agreement (as de-

1 fined in subsection (k)(13)) that pro-
 2 vides that payment for such drug is
 3 made in installments over the course
 4 of such agreement, shall be deter-
 5 mined as if the aggregate price per
 6 the terms of the agreement was paid
 7 in full in the first installment during
 8 the rebate period.”.

9 (c) DEFINITION OF AVERAGE MANUFACTURER
 10 PRICE.—Section 1927(k)(1) of the Social Security Act (42
 11 U.S.C. 1396r–8(k)(1)) is amended—

12 (1) in subparagraph (B)(i)—

13 (A) in subclause (IV), by striking at the
 14 end “and”;

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

17 (C) by adding at the end the following new
 18 subclause:

19 “(VI) subject to subsection
 20 (b)(3)(E)(ii), with respect to a covered
 21 outpatient drug that is a single course
 22 transformative therapy (as defined in
 23 paragraph (12)) and is sold under an
 24 outcomes-based agreement (as defined

1 in paragraph (13)) during the rebate
2 period—

3 “(aa) a refund, rebate, reim-
4 bursement, or free goods from
5 the manufacturer or third party
6 on behalf of the manufacturer; or

7 “(bb) the withholding or re-
8 duction of a payment to the man-
9 ufacturer or third party on behalf
10 of the manufacturer,

11 that is triggered by a patient who
12 fails to achieve outcomes or measures
13 defined under the terms of such out-
14 comes-based agreement during the pe-
15 riod for which such agreement is ef-
16 fective.”; and

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

19 “(D) SPECIAL RULE FOR CERTAIN OUT-
20 COMES-BASED AGREEMENTS.—For the purpose
21 of subparagraph (A), in determining the aver-
22 age price paid to the manufacturer for a cov-
23 ered outpatient drug that is a single course
24 transformative therapy (as defined in para-
25 graph (12)) and is sold under an outcomes-

1 based agreement (as defined in paragraph (13))
 2 that provides that payment for such drug is
 3 made in installments over the course of such
 4 agreement, such price shall be determined as if
 5 the aggregate price per the terms of the agree-
 6 ment was paid in full in the first installment
 7 during the rebate period.”.

8 (d) OTHER DEFINITIONS.—Section 1927(k) of the
 9 Social Security Act (42 U.S.C. 1396r–8(k)) is amended
 10 by adding at the end the following paragraphs:

11 “(12) SINGLE COURSE TRANSFORMATIVE THER-
 12 APY.—The term ‘single course transformative ther-
 13 apy’ means a treatment that consists of the adminis-
 14 tration of a covered outpatient drug that—

15 “(A) is a form of gene therapy, as defined
 16 by the Commissioner of Food and Drugs, that
 17 is—

18 “(i) designated under section 526 of
 19 the Federal Food, Drug, and Cosmetics
 20 Act; and

21 “(ii) licensed under subsection (a) or
 22 (k) of section 351 of the Public Health
 23 Service Act for a serious or life-threatening
 24 rare disease or condition;

1 “(B) if administered in accordance with
2 the ‘Indications and Usage’ section of its label,
3 is expected to result in—

4 “(i) the cure of such disease or condi-
5 tion;

6 “(ii) a reduction in the symptoms of
7 such disease or condition to the extent that
8 it is expected to—

9 “(I) extend life expectancy for
10 those individuals with such disease or
11 condition;

12 “(II) prevent, eliminate, or halt
13 progression of comorbidities related to
14 such disease or condition in such indi-
15 viduals; or

16 “(III) allow such individuals to
17 achieve or maintain maximum func-
18 tional capacity in performing daily ac-
19 tivities; or

20 “(iii) prevention or elimination of epi-
21 sodes, illnesses, injuries, or disabilities re-
22 lated to such disease or condition; and

23 “(C) is expected to achieve a result de-
24 scribed in subparagraph (B), which may be

1 achieved over an extended period of time, fol-
 2 lowing a single prescribed course of treatment.

3 “(13) OUTCOMES-BASED AGREEMENT.—The
 4 term ‘outcomes-based agreement’ means a written
 5 contract between a manufacturer and purchaser in
 6 which the aggregate price over the course of the con-
 7 tract of the covered outpatient drug is based on the
 8 achievement of pre-defined outcomes or measures
 9 and adjusted accordingly.”.

10 (e) EFFECTIVE DATE.—The amendments made by
 11 this section shall take effect on January 1, 2022.

12 **SEC. 122. ANTI-KICKBACK STATUTE AND PHYSICIAN SELF-**
 13 **REFERRAL SAFE HARBORS.**

14 (a) EXCLUSION FROM ANTICKICKBACK PROHIBI-
 15 TION.—Section 1128B(b)(3) of the Social Security Act
 16 (42 U.S.C. 1320a–7b(b)(3)) is amended—

17 (1) in subclause (J)—

18 (A) by moving the left margin of such sub-
 19 paragraph 2 ems to the left; and

20 (B) by striking “and” after the semicolon
 21 at the end;

22 (2) in subclause (K)—

23 (A) by moving the left margin of such sub-
 24 paragraph 2 ems to the left; and

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

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

5 “(L) any remuneration provided by a manufac-
6 turer or third party on behalf of a manufacturer to
7 a plan under an outcomes-based agreement (as de-
8 fined in section 1927(k)(13)) in the event a patient
9 fails to achieve outcomes or measures defined in
10 such agreement following the administration of a
11 covered outpatient drug that is a single course
12 transformative therapy (as defined in section
13 1927(k)(12)).”.

14 (b) EXCLUSION FROM PHYSICIAN SELF-REFERRAL
15 PROHIBITION.—Section 1877(h)(1)(C) of the Social Secu-
16 rity Act (42 U.S.C. 1395nn(h)(1)(C)) is amended by add-
17 ing at the end the following new clause:

18 “(iv) Any amounts paid under an out-
19 comes-based agreement (as defined in section
20 1927(k)(13)).”.

21 (c) EFFECTIVE DATE.—The amendments made by
22 this section shall take effect on January 1, 2022.

1 **SEC. 123. GAO STUDY AND REPORT ON USE OF OUTCOMES-**
2 **BASED AGREEMENTS.**

3 (a) STUDY.—The Comptroller General of the United
4 States shall conduct a study on the extent to which out-
5 comes-based agreements (as defined in section
6 1927(k)(13) of the Social Security Act (42 U.S.C. 1396r-
7 8(k)(13)) for rare disease gene therapies facilitate patient
8 access to such therapies, improve patient outcomes, lower
9 overall health system costs, and lower costs for patients
10 in Federal health care programs. In conducting such
11 study, the Comptroller General shall—

12 (1) study the impact of this subtitle on—

13 (A) mitigating socioeconomic disparities in
14 accessing rare disease gene therapies through
15 its requirement that State Medicaid programs
16 have access to the same outcomes-based agree-
17 ment remedy terms that are available in the
18 commercial market for the gene therapy; and

19 (B) the Medicaid Drug Rebate Program,
20 the 340B Drug Pricing Program, and the Medi-
21 care Part B program, including compliance with
22 such programs; and

23 (2) with respect to rare disease gene therapies
24 sold under an outcomes-based agreement (as so de-
25 fined), conduct an audit of manufacturers offering
26 State Medicaid programs the same remedy terms for

1 non-responding patients as offered to commercial in-
 2 surance plans during a particular rebate period, as
 3 described in subsections (c)(1)(C)(i)(VII) and
 4 (k)(1)(B)(i)(VI) of section 1927 of the Social Secu-
 5 rity Act (42 U.S.C. 1396r–8), as added by this sub-
 6 title.

7 (b) REPORT.—Not later than June 30, 2027, the
 8 Comptroller General of the United States shall submit to
 9 Congress a report containing the results of the study con-
 10 ducted under subsection (a).

11 **TITLE II—DRUG PRICE** 12 **TRANSPARENCY PROVISIONS**

13 **SEC. 201. REPORTING ON EXPLANATION FOR DRUG PRICE** 14 **INCREASES.**

15 (a) IN GENERAL.—Title XI of the Social Security Act
 16 (42 U.S.C. 1301 et seq.) is amended by inserting after
 17 section 1128K the following new section:

18 **“SEC. 1128L. DRUG PRICE REPORTING.**

19 “(a) DEFINITIONS.—In this section:

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

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

1 under section 351 of the Public Health Service
2 Act; or

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

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

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

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

19 “(ii) administered or otherwise dis-
20 pensed to treat a disease or condition af-
21 fecting more than 200,000 persons in the
22 United States; and

23 “(iii) not a vaccine; and

24 “(B) for which, during the previous cal-
25 endar year, at least 1 dollar of the total amount

1 of sales were for individuals enrolled under the
2 Medicare program under title XVIII or under a
3 State Medicaid plan under title XIX or under
4 a waiver of such plan.

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

8 “(b) REPORT.—

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

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

16 “(i) 10 percent or more within a sin-
17 gle calendar year beginning on or after
18 January 1, 2021; or

19 “(ii) 25 percent or more within three
20 consecutive calendar years for which the
21 first such calendar year begins on or after
22 January 1, 2021; and

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

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

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

9 “(A) in the case of a report with respect
10 to an increase in the price of a qualifying drug
11 that occurs during the period beginning on Jan-
12 uary 1, 2021, and ending on the day that is 60
13 days after the date of enactment of this section,
14 not later than 90 days after such date of enact-
15 ment;

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

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

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

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

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

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

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

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

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

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

6 “(II) for licensure of the drug
7 under section 351 of the Public
8 Health Service Act; and

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

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

23 “(E) the current wholesale acquisition cost
24 of the drug;

1 “(F) the total expenditures of the manu-
2 facturer on—

3 “(i) materials and manufacturing for
4 such drug; and

5 “(ii) acquiring patents and licensing
6 for such drug;

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

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

19 “(I) the total expenditures of the manufac-
20 turer on pursuing new or expanded indications
21 or dosage changes for such drug under section
22 505 of the Federal Food, Drug, and Cosmetic
23 Act or section 351 of the Public Health Service
24 Act;

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

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

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

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

23 “(B) all stock-based performance metrics
24 used by the manufacturer to determine execu-
25 tive compensation for each of the 1-year period

1 described in subsection (b)(1)(A) or the 3-year
2 period described in subsection (b)(1)(B), as ap-
3 plicable; and

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

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

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

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

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

21 “(e) CIVIL MONETARY PENALTY.—Any manufac-
22 turer of a qualifying drug that fails to submit a report
23 for the drug as required by this section, following notifica-
24 tion by the Secretary to the manufacturer that the manu-
25 facturer is not in compliance with this section, shall be

1 subject to a civil monetary penalty of \$75,000 for each
 2 day on which the violation continues.

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

8 “(g) PUBLIC POSTING.—

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

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

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

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

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

8 “(h) ANNUAL REPORT TO CONGRESS.—

9 “(1) IN GENERAL.—Subject to paragraph (2),
 10 the Secretary shall submit to Congress, and post on
 11 the public website of the Department of Health and
 12 Human Services in a way that is user-friendly to the
 13 public and written in plain language that consumers
 14 can readily understand, an annual report—

15 “(A) summarizing the information re-
 16 ported pursuant to this section;

17 “(B) including copies of the reports and
 18 supporting detailed economic analyses sub-
 19 mitted pursuant to this section;

20 “(C) detailing the costs and expenditures
 21 incurred by the Department of Health and
 22 Human Services in carrying out this section;
 23 and

24 “(D) explaining how the Department of
 25 Health and Human Services is improving con-

1 sumer and provider information about drug
2 value and drug price transparency.

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

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

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

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

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

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

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

24 “(1) IN GENERAL.—In order to allow the com-
25 parison of PBMs’ ability to negotiate rebates, dis-

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

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

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

“(B) CLASS OF DRUG.—The information described in such paragraph is made available by class of drug, using an existing classification system, but only if the class contains such number of drugs, as specified by the Secretary (but not fewer than three drugs), to ensure confidentiality of proprietary information or other information that is prevented to be disclosed under subparagraph (A).”.

SEC. 203. MAKING PRESCRIPTION DRUG MARKETING SAMPLE INFORMATION REPORTED BY MANUFACTURERS AVAILABLE TO CERTAIN INDIVIDUALS AND ENTITIES.

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

(1) by redesignating subsection (b) as subsection (e); and

(2) by inserting after subsection (a) the following new subsections:

“(b) DATA SHARING AGREEMENTS.—

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

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

6 “(B) such individual or entity agrees to
 7 not disclose publicly or to another individual or
 8 entity any information that identifies a par-
 9 ticular practitioner or health care facility.

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

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

24 “(B) RESEARCHERS.—Individuals who
 25 conduct scientific research (as defined in sec-

1 tion 164.501 of title 45, Code of Federal Regu-
 2 lations) in relevant areas as determined by the
 3 Secretary.

4 “(C) PAYERS.—Private and public health
 5 care payers, including group health plans,
 6 health insurance coverage offered by health in-
 7 surance issuers, Federal health programs, and
 8 State health programs.

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

18 “(c) PENALTIES.—

19 “(1) DATA SHARING AGREEMENTS.—Subject to
 20 paragraph (3), any specified data sharing individual
 21 or entity described in subsection (b)(2) that violates
 22 the terms of a data sharing agreement the individual
 23 or entity has with the Secretary under subsection
 24 (b)(1) shall be subject to a civil money penalty of
 25 not less than \$1,000, but not more than \$10,000,

1 for each such violation. Such penalty shall be im-
2 posed and collected in the same manner as civil
3 money penalties under subsection (a) of section
4 1128A are imposed and collected under that section.

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

17 “(3) LIMITATION.—The total amount of civil
18 money penalties imposed under paragraph (1) or (2)
19 with respect to a year and an individual or entity de-
20 scribed in paragraph (1) or a manufacturer or dis-
21 tributor described in paragraph (2), respectively,
22 shall not exceed \$150,000.

23 “(d) DRUG SAMPLE DISTRIBUTION INFORMATION.—

24 “(1) IN GENERAL.—Not later than January 1
25 of each year (beginning with 2022), the Secretary

1 shall maintain a list containing information related
2 to the distribution of samples of applicable drugs.
3 Such list shall provide the following information with
4 respect to the preceding year:

5 “(A) The name of the manufacturer or au-
6 thorized distributor of record of an applicable
7 drug for which samples were requested or dis-
8 tributed under this section.

9 “(B) The quantity and class of drug sam-
10 ples requested.

11 “(C) The quantity and class of drug sam-
12 ples distributed.

13 “(2) PUBLIC AVAILABILITY.—The Secretary
14 shall make the information in such list available to
15 the public on the internet website of the Food and
16 Drug Administration.”.

17 (b) FDA MAINTENANCE OF INFORMATION.—The
18 Food and Drug Administration shall maintain information
19 available to affected reporting companies to ensure their
20 ability to fully comply with the requirements of section
21 1128H of the Social Security Act.

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

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

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

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

6 “(A) an applicable drug (as defined in section
 7 1128H(e) of the Social Security Act);

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

12 “(C) approved under section 505 for use in the
 13 management or treatment of pain (other than for
 14 the management or treatment of a substance use
 15 disorder).”.

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

22 **SEC. 204. SENSE OF THE SENATE REGARDING THE NEED TO**
 23 **EXPAND COMMERCIALLY AVAILABLE DRUG**
 24 **PRICING COMPARISON PLATFORMS.**

25 It is the sense of the Senate that—

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

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

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

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

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

16 **TITLE III—REVENUE PROVISION**

17 **SEC. 301. INCLUSION OF INSULIN AND OTHER TREAT-** 18 **MENTS FOR CHRONIC CONDITIONS AS PRE-** 19 **VENTIVE CARE.**

20 (a) IN GENERAL.—Subparagraph (C) of section
 21 223(c)(2) of the Internal Revenue Code of 1986 is amend-
 22 ed—

23 (1) by striking “DEDUCTIBLE.—A plan” and
 24 inserting “DEDUCTIBLE.—

25 “(i) IN GENERAL.—A plan”, and

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

3 “(ii) SPECIAL RULE.—The term ‘pre-
4 ventive care’ includes such drugs (includ-
5 ing insulin), devices, supplies, and medical
6 services or screenings prescribed for the
7 prevention or avoidance of a disease or
8 condition, or the regular treatment and
9 maintenance of a chronic disease or condi-
10 tion, as are determined by the Secretary,
11 in consultation with the Secretary of
12 Health and Human Services, to be—

13 “(I) low in cost,

14 “(II) supported by medical evi-
15 dence to have a high cost efficiency in
16 preventing exacerbation of a chronic
17 condition or the development of a sec-
18 ondary condition, and

19 “(III) likely (as documented by
20 clinical evidence), when prescribed for
21 a class of individuals, to prevent exac-
22 erbation of the chronic condition of
23 such individuals or the development of
24 a secondary condition requiring sig-
25 nificantly higher cost treatments.”.

1 (b) EFFECTIVE DATE.—

2 (1) IN GENERAL.—The amendments made by
3 this section shall apply to taxable years beginning
4 after the date of the enactment of this Act.

5 (2) TREASURY GUIDANCE IN EFFECT ON DATE
6 OF ENACTMENT.—

7 (A) IN GENERAL.—No inference shall be
8 drawn by reason of the amendments made by
9 this Act with respect to the effectiveness of the
10 provisions of Internal Revenue Service Notice
11 2019-45 on the date of the enactment of this
12 Act, and such notice shall continue to apply as
13 in effect on July 17, 2019, unless amended by
14 the Secretary of the Treasury (or the Sec-
15 retary's delegate) pursuant to the amendments
16 made by this Act or pursuant to subparagraph
17 (B).

18 (B) CONTINUED PUBLICATION AND UP-
19 DATE OF LIST.—

20 (i) IN GENERAL.—The Secretary of
21 the Treasury (or the Secretary's delegate)
22 may publish, and update from time to time
23 as such Secretary (or delegate) deems ap-
24 propriate, a list of the drugs, devices, sup-
25 plies, and services identified under section

223(c)(2)(C)(ii) of the Internal Revenue Code of 1986, in consultation with the Secretary of Health and Human Services (or such Secretary’s delegate), as preventive care.

(ii) INCLUSION OF CERTAIN DIABETIC SUPPLIES.—As soon as practicable after the date of the enactment of this Act, the list in effect under Internal Revenue Service Notice 2019-45 shall be amended to include insulin delivery devices and related supplies, and continuous glucose monitoring systems and related supplies.

TITLE IV—MISCELLANEOUS PROVISIONS

SEC. 401. IMPROVING COORDINATION BETWEEN THE FOOD AND DRUG ADMINISTRATION AND THE CENTERS FOR MEDICARE & MEDICAID SERVICES.

(a) IN GENERAL.—

(1) PUBLIC MEETING.—

(A) IN GENERAL.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall convene a public meeting for the

1 purposes of discussing and providing input on
2 improvements to coordination between the Food
3 and Drug Administration and the Centers for
4 Medicare & Medicaid Services in preparing for
5 the availability of novel medical products de-
6 scribed in subsection (c) on the market in the
7 United States.

8 (B) ATTENDEES.—The public meeting
9 shall include—

10 (i) representatives of relevant Federal
11 agencies, including representatives from
12 each of the medical product centers within
13 the Food and Drug Administration and
14 representatives from the coding, coverage,
15 and payment offices within the Centers for
16 Medicare & Medicaid Services;

17 (ii) stakeholders with expertise in the
18 research and development of novel medical
19 products, including manufacturers of such
20 products;

21 (iii) representatives of commercial
22 health insurance payers;

23 (iv) stakeholders with expertise in the
24 administration and use of novel medical
25 products, including physicians; and

1 (v) stakeholders representing patients
2 and with expertise in the utilization of pa-
3 tient experience data in medical product
4 development.

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

7 (i) the status of the drug and medical
8 device development pipeline related to the
9 availability of novel medical products;

10 (ii) the anticipated expertise necessary
11 to review the safety and effectiveness of
12 such products at the Food and Drug Ad-
13 ministration and current gaps in such ex-
14 pertise, if any;

15 (iii) the expertise necessary to make
16 coding, coverage, and payment decisions
17 with respect to such products within the
18 Centers for Medicare & Medicaid Services,
19 and current gaps in such expertise, if any;

20 (iv) trends in the differences in the
21 data necessary to determine the safety and
22 effectiveness of a novel medical product
23 and the data necessary to determine
24 whether a novel medical product meets the
25 reasonable and necessary requirements for

1 coverage and payment under title XVIII of
 2 the Social Security Act pursuant to section
 3 1862(a)(1)(A) of such Act (42 U.S.C.
 4 1395y(a)(1)(A));

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

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

14 (D) TRADE SECRETS AND CONFIDENTIAL
 15 INFORMATION.—No information discussed as a
 16 part of the public meeting under this paragraph
 17 shall be construed as authorizing the Secretary
 18 to disclose any information that is a trade se-
 19 cret or confidential information subject to sec-
 20 tion 552(b)(4) of title 5, United States Code.

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

23 (A) DRAFT GUIDANCE.—Not later than 18
 24 months after the public meeting under para-
 25 graph (1), the Secretary shall update the final

1 guidance titled “National Coverage Determina-
2 tions with Data Collection as a Condition of
3 Coverage: Coverage with Evidence Develop-
4 ment” to address any opportunities to improve
5 the availability and coordination of information
6 as described in clauses (iv) through (vi) of para-
7 graph (1)(C).

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

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

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

4 (2) Recommendations to—

5 (A) incorporate patient experience data
6 (such as the impact of a disease or condition on
7 the lives of patients and patient treatment pref-
8 erences) into the coverage and payment proc-
9 esses within the Centers for Medicare & Med-
10 icaid Services;

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

17 (C) streamline the coverage process under
18 the Medicare program and incorporate input
19 from relevant stakeholders into such coverage
20 determinations; and

21 (D) identify potential mechanisms to incor-
22 porate novel payment designs similar to those
23 in development in commercial insurance plans
24 and State plans under title XIX of such Act

1 (42 U.S.C. 1396 et seq.) into the Medicare pro-
 2 gram.

3 (c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For
 4 purposes of this section, a novel medical product described
 5 in this subsection is a medical product, including a drug,
 6 biological (including gene and cell therapy), or medical de-
 7 vice, that has been designated as a breakthrough therapy
 8 under section 506(a) of the Federal Food, Drug, and Cos-
 9 metic Act (21 U.S.C. 356(a)), a breakthrough device
 10 under section 515B of such Act (21 U.S.C. 360e–3), or
 11 a regenerative advanced therapy under section 506(g) of
 12 such Act (21 U.S.C. 356(g)).

13 **SEC. 402. PATIENT CONSULTATION IN MEDICARE NA-**
 14 **TIONAL AND LOCAL COVERAGE DETERMINA-**
 15 **TIONS IN ORDER TO MITIGATE BARRIERS TO**
 16 **INCLUSION OF SUCH PERSPECTIVES.**

17 Section 1862(l) of the Social Security Act (42 U.S.C.
 18 1395y(l)) is amended by adding at the end the following
 19 new paragraph:

20 “(7) PATIENT CONSULTATION IN NATIONAL
 21 AND LOCAL COVERAGE DETERMINATIONS.—The Sec-
 22 retary may consult with patients and organizations
 23 representing patients in making national and local
 24 coverage determinations.”.

1 **SEC. 403. MEDPAC REPORT ON SHIFTING COVERAGE OF**
2 **CERTAIN MEDICARE PART B DRUGS TO MEDI-**
3 **CARE PART D.**

4 (a) STUDY.—The Medicare Payment Advisory Com-
5 mission (in this section referred to as the “Commission”)
6 shall conduct a study on shifting coverage of certain drugs
7 and biologicals for which payment is currently made under
8 part B of title XVIII of the Social Security Act (42 U.S.C.
9 1395j et seq.) to part D of such title (42 U.S.C. 1395w–
10 21 et seq.). Such study shall include an analysis of—

11 (1) differences in program structures and pay-
12 ment methods for drugs and biologicals covered
13 under such parts B and D, including effects of such
14 a shift on program spending, beneficiary cost-shar-
15 ing liability, and utilization management techniques
16 for such drugs and biologicals; and

17 (2) the feasibility and policy implications of
18 shifting coverage of drugs and biologicals for which
19 payment is currently made under such part B to
20 such part D.

21 (b) REPORT.—

22 (1) IN GENERAL.—Not later than June 30,
23 2023, the Commission shall submit to Congress a re-
24 port containing the results of the study conducted
25 under subsection (a).

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

4 (A) formulary design under such part D;

5 (B) the ability of the benefit structure
6 under such part D to control total spending on
7 drugs and biologicals for which payment is cur-
8 rently made under such part B;

9 (C) changes to the bid process under such
10 part D, if any, that may be necessary to inte-
11 grate coverage of such drugs and biologicals
12 into such part D;

13 (D) any other changes to the program that
14 Congress should consider in determining wheth-
15 er to shift coverage of such drugs and
16 biologicals from such part B to such part D;
17 and

18 (E) the feasibility and policy implications
19 of creating a methodology to preserve the
20 healthcare provider's ability to take title of the
21 drug, including a methodology under which—

22 (i) prescription drug plans negotiate
23 reimbursement rates and other arrange-
24 ments with drug manufacturers on behalf
25 of a wholesaler;

1 (ii) wholesalers purchase the drugs
 2 from the manufacturers at the negotiated
 3 rate and ship them through distributors to
 4 physicians to administer to patients;

5 (iii) physicians and hospitals purchase
 6 the drug from the wholesaler via the dis-
 7 tributor;

8 (iv) after administering the drug, the
 9 physician submits a claim to the MAC for
 10 their drug administration fee;

11 (v) to be reimbursed for the purchase
 12 of the drug from the distributor, the physi-
 13 cian furnishes the claim for the drug itself
 14 to the wholesaler and the wholesaler would
 15 refund the cost of the drug to the physi-
 16 cian; and

17 (vi) the wholesaler passes this claim to
 18 the PDP to receive reimbursement.

19 **SEC. 404. AUTHORITY TO REQUIRE THAT DIRECT-TO-CON-**
 20 **SUMER ADVERTISEMENTS FOR PRESCRIP-**
 21 **TION DRUGS AND BIOLOGICAL PRODUCTS IN-**
 22 **CLUDE TRUTHFUL AND NON-MISLEADING**
 23 **PRICING INFORMATION.**

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

1 **“SEC. 1150D. AUTHORITY TO REQUIRE THAT DIRECT-TO-**
 2 **CONSUMER ADVERTISEMENTS FOR PRE-**
 3 **SCRIPTION DRUGS AND BIOLOGICAL PROD-**
 4 **UCTS INCLUDE TRUTHFUL AND NON-MIS-**
 5 **LEADING PRICING INFORMATION.**

6 “(a) IN GENERAL.—The Secretary may require that
 7 each direct-to-consumer advertisement for a prescription
 8 drug or biological product for which payment is available
 9 under title XVIII or XIX includes an internet website ad-
 10 dress that provides an appropriate disclosure of truthful
 11 and non-misleading pricing information with respect to the
 12 drug or product.

13 “(b) DETERMINATION BY CMS.—The Secretary, act-
 14 ing through the Administrator of the Centers for Medicare
 15 & Medicaid Services, shall determine the components of
 16 the requirement under subsection (a), such as the forms
 17 of advertising, the manner of disclosure, the price point
 18 listing, and the price information for disclosure.”.

19 **SEC. 405. CHIEF PHARMACEUTICAL NEGOTIATOR AT THE**
 20 **OFFICE OF THE UNITED STATES TRADE REP-**
 21 **RESENTATIVE.**

22 (a) IN GENERAL.—Section 141 of the Trade Act of
 23 1974 (19 U.S.C. 2171) is amended—

24 (1) in subsection (b)(2)—

25 (A) by striking “and one Chief Innovation
 26 and Intellectual Property Negotiator” and in-

1 serting “one Chief Innovation and Intellectual
2 Property Negotiator, and one Chief Pharma-
3 ceutical Negotiator”;

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

9 (C) by striking “and the Chief Innovation
10 and Intellectual Property Negotiator” and in-
11 serting “the Chief Innovation and Intellectual
12 Property Negotiator, and the Chief Pharma-
13 ceutical Negotiator”; and

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

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

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

5 “Chief Innovation and Intellectual Property Ne-
6 gotiator, Office of the United States Trade Rep-
7 resentative.

8 “Chief Pharmaceutical Negotiator, Office of the
9 United States Trade Representative.”.

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

19 (1) enforcement actions taken by the United
20 States Trade Representative during the 1-year pe-
21 riod preceding the submission of the report to en-
22 sure the protection of United States pharmaceutical
23 products and services; and

- 1 (2) other actions taken by the United States
- 2 Trade Representative to advance United States
- 3 pharmaceutical products and services.

