

Calendar No. 225116TH CONGRESS
1ST SESSION**S. 2543****[Report No. 116-120]**

To amend titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices in the Medicare and Medicaid programs, to improve transparency related to pharmaceutical prices and transactions, to lower patients' out-of-pocket costs, and to ensure accountability to taxpayers, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 25, 2019

Mr. GRASSLEY, from the Committee on Finance, reported the following original bill; which was read twice and placed on the calendar

A BILL

To amend titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices in the Medicare and Medicaid programs, to improve transparency related to pharmaceutical prices and transactions, to lower patients' out-of-pocket costs, and to ensure accountability to taxpayers, 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,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
3 “Prescription Drug Pricing Reduction Act of 2019”.

4 (b) **TABLE OF CONTENTS.**—The table of contents of
5 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—MEDICARE

Subtitle A—Part B

Sec. 101. Improving manufacturers’ reporting of average sales prices to set accurate payment rates.

Sec. 102. Inclusion of value of coupons in determination of average sales price for drugs and biologicals under Medicare part B.

Sec. 103. Payment for biosimilar biological products during initial period.

Sec. 104. Temporary increase in Medicare part B payment for biosimilar biological products.

Sec. 105. Improvements to Medicare site-of-service transparency.

Sec. 106. Medicare part B rebate by manufacturers for drugs or biologicals with prices increasing faster than inflation.

Sec. 107. 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. 108. Clarification of Medicare average sales price payment methodology.

Sec. 109. Establishment of maximum add-on payment for drugs and biologicals.

Sec. 110. Treatment of drug administration services furnished by certain excepted off-campus outpatient departments of a provider.

Sec. 111. GAO study and report on average sales price.

Sec. 112. Authority to use alternative payment for drugs and biologicals to prevent potential drug shortages.

Subtitle B—Part D

Sec. 121. Medicare part D modernization redesign.

Sec. 122. Providing the Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission with access to certain drug payment information, including certain rebate information.

Sec. 123. Public disclosure of drug discounts and other pharmacy benefit manager (PBM) provisions.

Sec. 124. Public disclosure of direct and indirect remuneration review and audit results.

Sec. 125. Increasing the use of real-time benefit tools to lower beneficiary costs.

Sec. 126. Improvements to provision of parts A and B claims data to prescription drug plans.

Sec. 127. Permanently authorize a successful pilot on retroactive Medicare part D coverage for low-income beneficiaries.

- Sec. 128. Medicare part D rebate by manufacturers for certain drugs with prices increasing faster than inflation.
- Sec. 129. Prohibiting branding on part D benefit cards.
- Sec. 130. Requiring prescription drug plans and MA–PD plans to report potential fraud, waste, and abuse to the Secretary of HHS.
- Sec. 131. Establishment of pharmacy quality measures under Medicare part D.
- Sec. 132. Addition of new measures based on access to biosimilar biological products to the 5-star rating system under Medicare Advantage.
- Sec. 133. HHS study and report on the influence of pharmaceutical manufacturer third-party reimbursement hubs on health care providers who prescribe their drugs and biologicals.

Subtitle C—Miscellaneous

- Sec. 141. Drug manufacturer price transparency.
- Sec. 142. Strengthening and expanding pharmacy benefit managers transparency requirements.
- Sec. 143. Prescription drug pricing dashboards.
- Sec. 144. Improving coordination between the Food and Drug Administration and the Centers for Medicare & Medicaid Services.
- Sec. 145. Patient consultation in Medicare national and local coverage determinations in order to mitigate barriers to inclusion of such perspectives.
- Sec. 146. GAO study on increases to Medicare and Medicaid spending due to copayment coupons and other patient assistance programs.
- Sec. 147. MedPAC report on shifting coverage of certain Medicare part B drugs to Medicare part D.
- Sec. 148. Taking steps to fulfill treaty obligations to tribal communities.

TITLE II—MEDICAID

- Sec. 201. Medicaid pharmacy and therapeutics committee improvements.
- Sec. 202. Improving reporting requirements and developing standards for the use of drug use review boards in State Medicaid programs.
- Sec. 203. GAO report on conflicts of interest in State Medicaid program drug use review boards and pharmacy and therapeutics (P&T) committees.
- Sec. 204. Ensuring the accuracy of manufacturer price and drug product information under the Medicaid drug rebate program.
- Sec. 205. Excluding authorized generic drugs from calculation of average manufacturer price under the Medicaid drug rebate program.
- Sec. 206. Improving transparency and preventing the use of abusive spread pricing and related practices in Medicaid.
- Sec. 207. T–MSIS drug data analytics reports.
- Sec. 208. Risk-sharing value-based payment agreements for covered outpatient drugs under Medicaid.
- Sec. 209. Modification of maximum rebate amount under Medicaid drug rebate program.
- Sec. 210. Applying Medicaid drug rebate requirement to drugs provided as part of outpatient hospital services.

TITLE I—MEDICARE**Subtitle A—Part B**

1
2
3 **SEC. 101. IMPROVING MANUFACTURERS' REPORTING OF**
4 **AVERAGE SALES PRICES TO SET ACCURATE**
5 **PAYMENT RATES.**

6 (a) IN GENERAL.—Section 1847A(f) of the Social Se-
7 curity Act (42 U.S.C. 1395w-3a(f)) is amended—

8 (1) by striking “PRICE.—For requirements”
9 and inserting “PRICE.—

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

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

13 “(2) MANUFACTURERS THAT DO NOT HAVE A
14 REBATE AGREEMENT.—

15 “(A) IN GENERAL.—For calendar quarters
16 beginning with the first calendar quarter after
17 the date of the enactment of this paragraph,
18 the following provisions shall apply with respect
19 to a manufacturer of an applicable drug or bio-
20 logical (as defined in subparagraph (B)) that
21 has not entered into and does not have in effect
22 a rebate agreement described in subsection (b)
23 of section 1927 in the same manner and to the
24 same extent as such provisions apply with re-

1 spect to a manufacturer that has entered into
2 and has in effect such a rebate agreement:

3 “(i) Section 1927(b)(3)(A)(iii).

4 “(ii) Subparagraphs (B) and (C)
5 (other than the rebate agreement suspen-
6 sion described in such subparagraph (C))
7 of section 1927(b)(3).

8 “(B) APPLICABLE DRUG OR BIOLOGICAL
9 DEFINED.—For purposes of subparagraph (A),
10 the term ‘applicable drug or biological’ means a
11 drug or biological described in subparagraph
12 (C), (E), or (G) of section 1842(o)(1) or in sec-
13 tion 1881(b)(14)(B) that is payable under this
14 part. For purposes of applying this paragraph,
15 a drug or biological described in the previous
16 sentence includes an item, service, supply, or
17 product that is payable under this part as a
18 drug or biological.”.

19 (b) CONFORMING AMENDMENTS.—

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

23 (A) in paragraph (2)(A), by inserting “or
24 subsection (f)(2), as applicable” after “under
25 section 1927(b)(3)(A)(iii)”; and

1 (B) in each of paragraphs (3) and (6)(A),
2 in the matter preceding subparagraph (A) and
3 clause (i), respectively, by inserting “or sub-
4 section (f)(2), as applicable,” after “under sec-
5 tion 1927(b)(3)(A)(iii)”.

6 (2) TITLE XIX.—Section 1927(b)(3) of the So-
7 cial Security Act (42 U.S.C. 1396r–8(b)(3)) is
8 amended—

9 (A) in subparagraph (A), in the flush mat-
10 ter following clause (iv), by inserting “or sec-
11 tion 1847A(f)(2)” after “Information reported
12 under this subparagraph”; and

13 (B) in subparagraph (D), in the matter
14 preceding clause (i), by striking “or wholesalers
15 under this paragraph or under” and inserting
16 “or wholesalers under this paragraph, under
17 section 1847A(f)(2), or under”.

18 (3) TECHNICAL CORRECTION.—Section
19 1927(b)(3)(A)(iii) of such Act (42 U.S.C. 1396r–
20 8(b)(3)(A)(iii)) is amended by striking “section
21 1881(b)(13)(A)(ii)” and inserting “section
22 1881(b)(14)(B)”.

1 **SEC. 102. INCLUSION OF VALUE OF COUPONS IN DETER-**
2 **MINATION OF AVERAGE SALES PRICE FOR**
3 **DRUGS AND BIOLOGICALS UNDER MEDICARE**
4 **PART B.**

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

7 (1) in paragraph (3)—

8 (A) by striking “DISCOUNTS.—In calcu-
9 lating” and inserting “DISCOUNTS TO PUR-
10 CHASERS AND COUPONS PROVIDED TO PRI-
11 VATELY INSURED INDIVIDUALS.—

12 “(A) DISCOUNTS TO PURCHASERS.—In
13 calculating”; and

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

16 “(B) COUPONS PROVIDED TO REDUCE
17 COST-SHARING.—For calendar quarters begin-
18 ning on or after July 1, 2021, in calculating the
19 manufacturer’s average sales price under this
20 subsection, such price shall include the value
21 (as defined in paragraph (6)(J)) of any coupons
22 provided under a drug coupon program of a
23 manufacturer (as those terms are defined in
24 subparagraphs (K) and (L), respectively, of
25 paragraph (6)).”; and

1 (2) in paragraph (6), by adding at the end the
2 following new subparagraphs:

3 “(J) VALUE.—The term ‘value’ means,
4 with respect to a coupon (as defined in sub-
5 paragraph (K)), the difference, if any, be-
6 tween—

7 “(i) the amount of any reduction or
8 elimination of cost-sharing or other out-of-
9 pocket costs described in such subpara-
10 graph to a patient as a result of the use
11 of such coupon; and

12 “(ii) any charge to the patient for the
13 use of such coupon.

14 “(K) COUPON.—The term ‘coupon’ means
15 any financial support that is provided to a pa-
16 tient, either directly to the patient or indirectly
17 to the patient through a physician, prescriber,
18 pharmacy, or other provider, under a drug cou-
19 pon program of a manufacturer (as defined in
20 subparagraph (L)) that is used to reduce or
21 eliminate cost-sharing or other out-of-pocket
22 costs of the patient, including costs related to
23 a deductible, coinsurance, or copayment, with
24 respect to a drug or biological, including a bio-
25 similar biological product, of the manufacturer.

1 “(L) DRUG COUPON PROGRAM.—

2 “(i) IN GENERAL.—Subject to clause
3 (ii), the term ‘drug coupon program’
4 means, with respect to a manufacturer, a
5 program through which the manufacturer
6 provides coupons to patients as described
7 in subparagraph (K).

8 “(ii) EXCLUSIONS.—Such term does
9 not include—

10 “(I) a patient assistance program
11 operated by a manufacturer that pro-
12 vides free or discounted drugs or
13 biologicals, including biosimilar bio-
14 logical products, (through in-kind do-
15 nations) to patients of low income; or

16 “(II) a contribution by a manu-
17 facturer to a nonprofit or Foundation
18 that provides free or discounted drugs
19 or biologicals, including biosimilar bio-
20 logical products, (through in-kind do-
21 nations) to patients of low income.”.

22 **SEC. 103. PAYMENT FOR BIOSIMILAR BIOLOGICAL PROD-**
23 **UCTS DURING INITIAL PERIOD.**

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

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

5 (2) by redesignating subparagraphs (A) and
6 (B) as clauses (i) and (ii) and moving such clauses
7 to the right;

8 (3) by striking “UNAVAILABLE.—In the case”
9 and inserting “UNAVAILABLE.—

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

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

14 “(B) LIMITATION ON PAYMENT AMOUNT
15 FOR BIOSIMILAR BIOLOGICAL PRODUCTS DUR-
16 ING INITIAL PERIOD.—In the case of a bio-
17 similar biological product furnished on or after
18 July 1, 2020, in lieu of applying subparagraph
19 (A) during the initial period described in such
20 subparagraph with respect to the biosimilar bio-
21 logical product, the amount payable under this
22 section for the biosimilar biological product is
23 the lesser of the following:

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

4 “(ii) The amount determined under
5 subsection (b)(1)(B) for the reference bio-
6 logical product.”.

7 **SEC. 104. TEMPORARY INCREASE IN MEDICARE PART B**
8 **PAYMENT FOR BIOSIMILAR BIOLOGICAL**
9 **PRODUCTS.**

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

12 (1) by redesignating subparagraphs (A) and
13 (B) as clauses (i) and (ii), respectively, and indent-
14 ing appropriately;

15 (2) by striking “PRODUCT.—The amount” and
16 inserting the following: “PRODUCT.—

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

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

21 “(B) TEMPORARY PAYMENT INCREASE FOR
22 BIOSIMILAR BIOLOGICAL PRODUCTS.—

23 “(i) IN GENERAL.—Beginning Janu-
24 ary 1, 2020, in the case of a biosimilar bio-
25 logical product described in paragraph

1 (1)(C) that is furnished during the applica-
2 ble 5-year period for such product, the
3 amount specified in this paragraph for
4 such product is an amount equal to the
5 lesser of the following:

6 “(I) The amount specified in sub-
7 paragraph (A) for such product if
8 clause (ii) of such subparagraph was
9 applied by substituting ‘8 percent’ for
10 ‘6 percent’.

11 “(II) The amount determined
12 under subsection (b)(1)(B) for the
13 reference biological product.

14 “(ii) APPLICABLE 5-YEAR PERIOD.—
15 For purposes of clause (i), the applicable
16 5-year period for a biosimilar biological
17 product is—

18 “(I) in the case of such a product
19 for which payment was made under
20 this paragraph as of December 31,
21 2019, the 5-year period beginning on
22 January 1, 2020; and

23 “(II) in the case of such a prod-
24 uct that is not described in subclause
25 (I), the 5-year period beginning on the

1 first day of the first calendar quarter
2 in which payment was made for such
3 product under this paragraph.”.

4 **SEC. 105. IMPROVEMENTS TO MEDICARE SITE-OF-SERVICE**
5 **TRANSPARENCY.**

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

8 (1) in paragraph (1)—

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

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

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

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

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

21 (C) in subparagraph (A)—

22 (i) by striking “and the” and insert-
23 ing “, the”; and

24 (ii) by inserting “, and the physician
25 fee schedule under section 1848 (with re-

1 spect to the practice expense component of
2 such payment amount)” after “such sec-
3 tion”;

4 (2) by redesignating paragraphs (2) through
5 (4) and paragraphs (3) through (5), respectively;
6 and

7 (3) by inserting after paragraph (1) the fol-
8 lowing new paragraph:

9 “(2) PHYSICIAN PAYMENT.—Beginning in
10 2021, the Secretary may expand the information in-
11 cluded on the Internet website described in para-
12 graph (1) to include—

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

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

18 **SEC. 106. MEDICARE PART B REBATE BY MANUFACTURERS**
19 **FOR DRUGS OR BIOLOGICALS WITH PRICES**
20 **INCREASING FASTER THAN INFLATION.**

21 (a) IN GENERAL.—Section 1847A of the Social Secu-
22 rity Act (42 U.S.C. 1395w–3a) is amended by adding at
23 the end the following new subsection:

1 “(h) REBATE BY MANUFACTURERS FOR DRUGS OR
2 BIOLOGICALS WITH PRICES INCREASING FASTER THAN
3 INFLATION.—

4 “(1) REQUIREMENTS.—

5 “(A) SECRETARIAL PROVISION OF INFOR-
6 MATION.—Not later than 6 months after the
7 end of each rebate period (as defined in para-
8 graph (2)(A)) beginning on or after January 1,
9 2021, the Secretary shall, for each rebatable
10 drug (as defined in paragraph (2)(B)), report
11 to each manufacturer of such rebatable drug
12 the following for such rebate period:

13 “(i) Information on the total number
14 of units of the billing and payment code
15 described in subparagraph (A)(i) of para-
16 graph (3) with respect to such rebatable
17 drug and rebate period.

18 “(ii) Information on the amount (if
19 any) of the excess average sales price in-
20 crease described in subparagraph (A)(ii) of
21 such paragraph for such rebatable drug
22 and rebate period.

23 “(iii) The rebate amount specified
24 under such paragraph for such rebatable
25 drug and rebate period.

1 “(B) MANUFACTURER REBATE.—

2 “(i) IN GENERAL.—Subject to clause
3 (ii), for each rebate period beginning on or
4 after January 1, 2021, the manufacturer
5 of a rebatable drug shall, for such drug,
6 not later than 30 days after the date of re-
7 ceipt from the Secretary of the information
8 and rebate amount pursuant to subpara-
9 graph (A) for such rebate period, provide
10 to the Secretary a rebate that is equal to
11 the amount specified in paragraph (3) for
12 such drug for such rebate period.

13 “(ii) EXEMPTION FOR SHORTAGES.—
14 The Secretary may reduce or waive the re-
15 bate under this subparagraph with respect
16 to a rebatable drug that is listed on the
17 drug shortage list maintained by the Food
18 and Drug Administration pursuant to sec-
19 tion 506E of the Federal Food, Drug, and
20 Cosmetic Act .

21 “(C) REQUEST FOR RECONSIDERATION.—

22 The Secretary shall establish procedures under
23 which a manufacturer of a rebatable drug may
24 request a reconsideration by the Secretary of
25 the rebate amount specified under paragraph

1 (3) for such rebatable drug and rebate period,
2 as reported to the manufacturer pursuant to
3 subparagraph (A)(iii).

4 “(2) REBATE PERIOD AND REBATABLE DRUG
5 DEFINED.—In this subsection:

6 “(A) REBATE PERIOD.—The term ‘rebate
7 period’ means a calendar quarter beginning on
8 or after January 1, 2021.

9 “(B) REBATABLE DRUG.—The term
10 ‘rebatable drug’ means a single source drug or
11 biological (other than a biosimilar biological
12 product)—

13 “(i) described in section
14 1842(o)(1)(C) for which the payment
15 amount is provided under this section; or

16 “(ii) for which payment is made sepa-
17 rately under section 1833(i) or section
18 1833(t) and for which the payment
19 amount is calculated based on the payment
20 amount under this section.

21 “(3) REBATE AMOUNT.—

22 “(A) IN GENERAL.—For purposes of para-
23 graph (1)(B), the amount specified in this para-
24 graph for a rebatable drug assigned to a billing
25 and payment code for a rebate period is, subject

1 to paragraph (4), the amount equal to the prod-
2 uct of—

3 “(i) subject to subparagraph (B), the
4 total number of units of the billing and
5 payment code for such rebatable drug fur-
6 nished during the rebate period; and

7 “(ii) the amount (if any) by which—

8 “(I) the amount determined
9 under subsection (b)(4) for such
10 rebatable drug during the rebate pe-
11 riod; exceeds

12 “(II) the inflation-adjusted base
13 payment amount determined under
14 subparagraph (C) of this paragraph
15 for such rebatable drug during the re-
16 bate period.

17 “(B) EXCLUDED UNITS.—For purposes of
18 subparagraph (A)(i), the total number of units
19 of the billing and payment code for rebatable
20 drugs furnished during a rebate period shall not
21 include units with respect to which the manu-
22 facturer provides a discount under the program
23 under section 340B of the Public Health Serv-
24 ice Act or a rebate under section 1927.

1 “(C) DETERMINATION OF INFLATION-AD-
 2 JUSTED PAYMENT AMOUNT.—The inflation-ad-
 3 justed payment amount determined under this
 4 subparagraph for a rebatable drug for a rebate
 5 period is—

6 “(i) the amount determined under
 7 subsection (b)(4) for such rebatable drug
 8 in the payment amount benchmark quarter
 9 (as defined in subparagraph (D)); in-
 10 creased by

11 “(ii) the percentage by which the re-
 12 bate period CPI–U (as defined in subpara-
 13 graph (F)) for the rebate period exceeds
 14 the benchmark period CPI–U (as defined
 15 in subparagraph (E)).

16 “(D) PAYMENT AMOUNT BENCHMARK
 17 QUARTER.—The term ‘payment amount bench-
 18 mark quarter’ means the calendar quarter be-
 19 ginning July 1, 2019.

20 “(E) BENCHMARK PERIOD CPI–U.—The
 21 term ‘benchmark period CPI–U’ means the con-
 22 sumer price index for all urban consumers
 23 (United States city average) for July 2019.

24 “(F) REBATE PERIOD CPI–U.—The term
 25 ‘rebate period CPI–U’ means, with respect to a

1 rebate period, the consumer price index for all
2 urban consumers (United States city average)
3 for the last month of the calendar quarter that
4 is two calendar quarters prior to the rebate pe-
5 riod.

6 “(4) APPLICATION TO NEW DRUGS.—In the
7 case of a rebatable drug first approved or licensed
8 by the Food and Drug Administration after July 1,
9 2019, the following shall apply:

10 “(A) DURING INITIAL PERIOD.—For quar-
11 ters during the initial period in which the pay-
12 ment amount for such drug is determined using
13 the methodology described in subsection
14 (c)(4)—

15 “(i) clause (ii)(I) of paragraph (3)(A)
16 shall be applied as if the reference to ‘the
17 amount determined under subsection
18 (b)(4),’ were a reference to ‘the wholesale
19 acquisition cost applicable under subsection
20 (c)(4)’;

21 “(ii) clause (i) of paragraph (3)(C)
22 shall be applied—

23 “(I) as if the reference to ‘the
24 amount determined under subsection
25 (b)(4),’ were a reference to ‘the whole-

1 sale acquisition cost applicable under
2 subsection (c)(4)'; and

3 “(II) as if the term ‘payment
4 amount benchmark quarter’ were de-
5 fined under paragraph (3)(D) as the
6 first full calendar quarter after the
7 day on which the drug was first mar-
8 keted; and

9 “(iii) clause (ii) of paragraph (3)(C)
10 shall be applied as if the term ‘benchmark
11 period CPI-U’ were defined under para-
12 graph (4)(E) as if the reference to ‘July
13 2019’ under such paragraph were a ref-
14 erence to ‘the first month of the first full
15 calendar quarter after the day on which
16 the drug was first marketed’.

17 “(B) AFTER INITIAL PERIOD.—For quar-
18 ters beginning after such initial period—

19 “(i) clause (i) of paragraph (3)(C)
20 shall be applied as if the term ‘payment
21 amount benchmark quarter’ were defined
22 under paragraph (3)(D) as the first full
23 calendar quarter for which the Secretary is
24 able to compute an average sales price for
25 the rebatable drug; and

1 “(ii) clause (ii) of paragraph (3)(C)
2 shall be applied as if the term ‘benchmark
3 period CPI–U’ were defined under para-
4 graph (4)(E) as if the reference to ‘July
5 2019’ under such paragraph were a ref-
6 erence to ‘the first month of the first full
7 calendar quarter for which the Secretary is
8 able to compute an average sales price for
9 the rebatable drug’.

10 “(5) REBATE DEPOSITS.—Amounts paid as re-
11 bates under paragraph (1)(B) shall be deposited into
12 the Federal Supplementary Medical Insurance Trust
13 Fund established under section 1841.

14 “(6) ENFORCEMENT.—

15 “(A) CIVIL MONEY PENALTY.—

16 “(i) IN GENERAL.—The Secretary
17 shall impose a civil money penalty on a
18 manufacturer that fails to comply with the
19 requirements under paragraph (1)(B) with
20 respect to providing a rebate for a
21 rebatable drug for a rebate period for each
22 such failure in an amount equal to the sum
23 of—

1 “(I) the rebate amount specified
2 pursuant to paragraph (3) for such
3 drug for such rebate period; and

4 “(II) 25 percent of such amount.

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

13 “(B) NO PAYMENT FOR MANUFACTURERS
14 WHO FAIL TO PAY PENALTY.—If the manufac-
15 turer of a rebatable drug fails to pay a civil
16 money penalty under subparagraph (A) with re-
17 spect to the failure to provide a rebate for a
18 rebatable drug for a rebate period by a date
19 specified by the Secretary after the imposition
20 of such penalty, no payment shall be available
21 under this part for such rebatable drug for cal-
22 endar quarters beginning on or after such date
23 until the Secretary determines the manufac-
24 turer has paid the penalty due under such sub-
25 paragraph.”.

1 (b) IMPLEMENTATION.—Section 1847A(g) of the So-
2 cial Security Act (42 U.S.C. 1395w–3(g)) is amended—

3 (1) in paragraph (4), by striking “and” at the
4 end;

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

7 (3) by adding at the end the following new
8 paragraph:

9 “(6) determination of the rebate amount for a
10 rebatable drug under paragraph (3) of subsection
11 (h), including with respect to a new drug pursuant
12 to paragraph (4) of such subsection, including—

13 “(A) a decision by the Secretary with re-
14 spect to a request for reconsideration under
15 paragraph (1)(C); and

16 “(B) the determination of—

17 “(i) the total number of units of the
18 billing and payment code under paragraph
19 (3)(A)(i); and

20 “(ii) the inflation-adjusted payment
21 amount under paragraph (3)(C).”.

22 (c) CONFORMING AMENDMENT TO PART B ASP CAL-
23 CULATION.—Section 1847A(c)(3) of the Social Security
24 Act (42 U.S.C. 1395w–3a(c)(3)) is amended by inserting
25 “or subsection (h)” after “section 1927”.

1 **SEC. 107. 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), as amended by section 106, is amended by add-
 9 ing at the end the following new subsection:

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

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

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

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

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

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

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

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

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

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

12 “(3) REFUND AMOUNT.—

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

21 “(i) the product of—

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

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

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

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

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

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

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

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

1 “(II) in the case of a refundable
2 single-dose container or single-use
3 package drug described in subclause
4 (I) of clause (iii) and, if applicable, a
5 refundable single-dose container or
6 single-use package drug described in
7 subclause (II) of such clause, a per-
8 centage specified by the Secretary
9 pursuant to clause (ii).

10 “(ii) TREATMENT OF DRUGS THAT
11 REQUIRE FILTRATION OR OTHER UNIQUE
12 CIRCUMSTANCES.—The Secretary, through
13 notice and comment rulemaking—

14 “(I) in the case of a refundable
15 single-dose container or single-use
16 package drug described in subclause
17 (I) of clause (iii), shall increase the
18 applicable percentage otherwise appli-
19 cable under clause (i)(I) as deter-
20 mined appropriate by the Secretary;
21 and

22 “(II) in the case of a refundable
23 single-dose container or single-use
24 package drug described in subclause
25 (II) of clause (iii), may increase the

1 applicable percentage otherwise appli-
2 cable under clause (i)(I) as deter-
3 mined appropriate by the Secretary.

4 “(iii) DRUG DESCRIBED.—For pur-
5 poses of clause (ii), a refundable single-
6 dose container or single-use package drug
7 described in this clause is either of the fol-
8 lowing:

9 “(I) A refundable single-dose
10 container or single-use package drug
11 for which preparation instructions re-
12 quired and approved by the Commis-
13 sioner of the Food and Drug Adminis-
14 tration include filtration during the
15 drug preparation process, prior to di-
16 lution and administration, and require
17 that any unused portion of such drug
18 after the filtration process be dis-
19 carded after the completion of such
20 filtration process.

21 “(II) Any other refundable sin-
22 gle-dose container or single-use pack-
23 age drug that has unique cir-
24 cumstances involving similar loss of
25 product.

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

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

9 “(6) ENFORCEMENT.—

10 “(A) AUDITS.—

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

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

1 “(B) CIVIL MONEY PENALTY.—

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

10 “(I) the amount that the manu-
11 facturer would have paid under such
12 paragraph with respect to such drug
13 for such quarter; and

14 “(II) 25 percent of such amount.

15 “(ii) APPLICATION.—The provisions
16 of section 1128A (other than subsections
17 (a) and (b)) shall apply to a civil money
18 penalty under this subparagraph in the
19 same manner as such provisions apply to a
20 penalty or proceeding under section
21 1128A(a).

22 “(7) IMPLEMENTATION.—The Secretary shall
23 implement this subsection through notice and com-
24 ment rulemaking.

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

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

13 “(B) EXCLUSIONS.—The term ‘refundable
14 single-dose container or single-use package
15 drug’ does not include a drug or biological that
16 is either a radiopharmaceutical or an imaging
17 agent.”.

18 **SEC. 108. CLARIFICATION OF MEDICARE AVERAGE SALES**

19 **PRICE PAYMENT METHODOLOGY.**

20 (a) IN GENERAL.—Section 1847A(c) of the Social
21 Security Act (42 U.S.C. 1395w–3a(c)), as amended by
22 section 102, is amended—

23 (1) in paragraph (3)(A), in the first sentence—

24 (A) by striking “and rebates” and insert-
25 ing “rebates”; and

1 (B) by inserting “, and fees (other than
2 bona fide service fees)” before the period at the
3 end; and

4 (2) in paragraph (6), by adding at the end the
5 following new subparagraph:

6 “(M) BONA FIDE SERVICE FEE.—The
7 term ‘bona fide service fee’ means a fee paid by
8 a manufacturer to an entity that—

9 “(i) represents fair market value for a
10 bona fide, itemized service that—

11 “(I) is actually performed on be-
12 half of the manufacturer; and

13 “(II) the manufacturer would
14 otherwise perform (or contract for) in
15 the absence of the service arrange-
16 ment;

17 “(ii) is not passed on, in whole or in
18 part, to a client or customer of the entity,
19 whether or not the entity takes title to the
20 drug or biological;

21 “(iii) is a fixed payment and not
22 based on a percentage of sales; and

23 “(iv) is not determined in a manner
24 that takes into account the volume or value

1 of any referrals or business otherwise gen-
 2 erated between the parties.”.

3 (b) **EFFECTIVE DATE.**—The amendments made by
 4 subsection (a) shall apply to drugs and biologicals fur-
 5 nished on or after the first day of the first calendar quar-
 6 ter that begins on or after the date that is 180 days after
 7 the date of the enactment of this Act.

8 **SEC. 109. ESTABLISHMENT OF MAXIMUM ADD-ON PAYMENT**
 9 **FOR DRUGS AND BIOLOGICALS.**

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

12 (1) in subsection (b)—

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

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

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

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

1 applicable add-on payment (as defined in subpara-
2 graph (B)) for each drug or biological on a
3 claim for a date of service exceeds the max-
4 imum add-on payment amount specified under
5 subparagraph (C) for the drug or biological,
6 then the payment amount otherwise determined
7 for the drug or biological under those provi-
8 sions, as applicable, shall be reduced by the
9 amount of such excess.

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

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

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

21 “(II) the amount that would be
22 applied under such paragraph if ‘100
23 percent’ were substituted for ‘106 per-
24 cent’.

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 ‘106 per-
10 cent’.

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

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

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

21 “(II) the amount that would be
22 applied under such subsection if ‘100
23 percent’ were substituted, as applica-
24 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) for each of 2021 through 2028,
2 \$1,000; and

3 “(ii) for a subsequent year, the
4 amount specified in this subparagraph for
5 the preceding year increased by the per-
6 centage increase in the consumer price
7 index for all urban consumers (all items;
8 United States city average) for the 12-
9 month period ending with June of the pre-
10 vious year.

11 Any amount determined under this subpara-
12 graph that is not a multiple of \$10 shall be
13 rounded to the nearest multiple of \$10.”; and
14 (2) in subsection (c)(4)(A)(ii), by striking “in
15 the case” and inserting “subject to subsection
16 (b)(9), in the case”.

17 (b) CONFORMING AMENDMENTS RELATING TO SEPA-
18 RATELY PAYABLE DRUGS.—

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

21 (A) in subparagraph (A)(iii)(II), by insert-
22 ing “, subject to subparagraph (I)” after “are
23 not available”; and

24 (B) by adding at the end the following new
25 subparagraph:

1 “(I) APPLICATION OF MAXIMUM ADD-ON
2 PAYMENT FOR SEPARATELY PAYABLE DRUGS
3 AND BIOLOGICALS.—In establishing the amount
4 of payment under subparagraph (A) for a speci-
5 fied covered outpatient drug that is furnished
6 as part of a covered OPD service (or group of
7 services) on or after January 1, 2021, if such
8 payment is determined based on the average
9 price for the year established under section
10 1847A pursuant to clause (iii)(II) of such sub-
11 paragraph, the provisions of subsection (b)(9)
12 of section 1847A shall apply to the amount of
13 payment so established in the same manner as
14 such provisions apply to the amount of payment
15 under section 1847A.”.

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

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

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

22 (C) by inserting after clause (v) the fol-
23 lowing new clause:

24 “(vi) If there is a separate payment under the system
25 described in clause (i) for a drug or biological furnished

1 on or after January 1, 2021, the provisions of subsection
 2 (t)(14)(I) shall apply to the establishment of the amount
 3 of payment for the drug or biological under such system
 4 in the same manner in which such provisions apply to the
 5 establishment of the amount of payment under subsection
 6 (t)(14)(A).”.

7 **SEC. 110. TREATMENT OF DRUG ADMINISTRATION SERV-**
 8 **ICES FURNISHED BY CERTAIN EXCEPTED**
 9 **OFF-CAMPUS OUTPATIENT DEPARTMENTS OF**
 10 **A PROVIDER.**

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

14 “(G) SPECIAL PAYMENT RULE FOR DRUG
 15 ADMINISTRATION SERVICES FURNISHED BY AN
 16 EXCEPTED DEPARTMENT OF A PROVIDER.—

17 “(i) IN GENERAL.—In the case of a
 18 covered OPD service that is a drug admin-
 19 istration service (as defined by the Sec-
 20 retary) furnished by a department of a
 21 provider described in clause (ii) or (iv) of
 22 paragraph (21)(B), the payment amount
 23 for such service furnished on or after Jan-
 24 uary 1, 2021, shall be the same payment
 25 amount (as determined in paragraph

1 (21)(C)) that would apply if the drug ad-
 2 ministration service was furnished by an
 3 off-campus outpatient department of a pro-
 4 vider (as defined in paragraph (21)(B)).

5 “(ii) APPLICATION WITHOUT REGARD
 6 TO BUDGET NEUTRALITY.—The reductions
 7 made under this subparagraph—

8 “(I) shall not be considered an
 9 adjustment under paragraph (2)(E);
 10 and

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

13 **SEC. 111. GAO STUDY AND REPORT ON AVERAGE SALES**
 14 **PRICE.**

15 (a) STUDY.—

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

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

1 (A) for which reimbursement under such
2 part B is based on the average sales price of
3 the drug or biological; and

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

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

11 (A) The extent to which each applicable
12 drug is paid for—

13 (i) under such part B for Medicare
14 beneficiaries; or

15 (ii) by private payers in the commer-
16 cial market.

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

22 (C) The extent to which drug manufactur-
23 ers provide rebates, discounts, or other price
24 concessions to private payers in the commercial
25 market for applicable drugs, which the manu-

1 factorer includes in its average sales price cal-
2 culation, for—

3 (i) formulary placement;

4 (ii) utilization management consider-
5 ations; or

6 (iii) other purposes.

7 (D) Barriers to drug manufacturers pro-
8 viding such price concessions for applicable
9 drugs.

10 (E) Other areas determined appropriate by
11 the Comptroller General.

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

18 **SEC. 112. AUTHORITY TO USE ALTERNATIVE PAYMENT FOR**
19 **DRUGS AND BIOLOGICALS TO PREVENT PO-**
20 **TENTIAL DRUG SHORTAGES.**

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

23 (1) by striking “PAYMENT IN RESPONSE TO
24 PUBLIC HEALTH EMERGENCY.—In the case” and
25 inserting “PAYMENTS.—

1 “(1) IN RESPONSE TO PUBLIC HEALTH EMER-
2 GENCY.—In the case”; and

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

5 “(2) PREVENTING POTENTIAL DRUG SHORT-
6 AGES.—

7 “(A) IN GENERAL.—In the case of a drug
8 or biological that the Secretary determines is
9 described in subparagraph (B) for one or more
10 quarters beginning on or after January 1,
11 2021, the Secretary may use wholesale acquisi-
12 tion cost (or other reasonable measure of a
13 drug or biological price) instead of the manu-
14 facturer’s average sales price for such quarters
15 and for subsequent quarters until the end of
16 the quarter in which such drug or biological is
17 removed from the drug shortage list under sec-
18 tion 506E of the Federal Food, Drug, and Cos-
19 metic Act, or in the case of a drug or biological
20 described in subparagraph (B)(ii), the date on
21 which the Secretary determines that the total
22 manufacturing capacity or the total number of
23 manufacturers of such drug or biological is suf-
24 ficient to mitigate a potential shortage of the
25 drug or biological.

1 “(B) DRUG OR BIOLOGICAL DESCRIBED.—

2 For purposes of subparagraph (A), a drug or
3 biological described in this subparagraph is a
4 drug or biological—

5 “(i) that is listed on the drug shortage
6 list maintained by the Food and Drug Ad-
7 ministration pursuant to section 506E of
8 the Federal Food, Drug, and Cosmetic
9 Act, and with respect to which any manu-
10 facturer of such drug or biological notifies
11 the Secretary of a permanent discontinu-
12 ance or an interruption that is likely to
13 lead to a meaningful disruption in the
14 manufacturer’s supply of that drug pursu-
15 ant to section 506C(a) of such Act; or

16 “(ii) that—

17 “(I) is described in section
18 506C(a) of such Act;

19 “(II) was listed on the drug
20 shortage list maintained by the Food
21 and Drug Administration pursuant to
22 section 506E of such Act within the
23 preceding 5 years; and

24 “(III) for which the total manu-
25 facturing capacity of all manufactur-

1 ers with an approved application for
2 such drug or biological that is cur-
3 rently marketed or total number of
4 manufacturers with an approved ap-
5 plication for such drug or biological
6 that is currently marketed declines
7 during a 6-month period, as deter-
8 mined by the Secretary.

9 “(C) PROVISION OF ADDITIONAL INFORMA-
10 TION.—For each quarter in which the amount
11 of payment for a drug or biological described in
12 subparagraph (B) pursuant to subparagraph
13 (A) exceeds the amount of payment for the
14 drug or biological otherwise applicable under
15 this section, each manufacturer of such drug or
16 biological shall provide to the Secretary infor-
17 mation related to the potential cause or causes
18 of the shortage and the expected duration of
19 the shortage with respect to such drug.”.

20 (b) TRACKING SHORTAGE DRUGS THROUGH
21 CLAIMS.—The Secretary of Health and Human Services
22 (referred to in this section as the “Secretary”) shall estab-
23 lish a mechanism (such as a modifier) for purposes of
24 tracking utilization under title XVIII of the Social Secu-
25 rity Act (42 U.S.C. 1395 et seq.) of drugs and biologicals

1 listed on the drug shortage list maintained by the Food
2 and Drug Administration pursuant to section 506E of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e).

4 (c) HHS REPORT AND RECOMMENDATIONS.—

5 (1) IN GENERAL.—Not later than July 1, 2021,
6 the Secretary shall submit to Congress a report on
7 shortages of drugs within the Medicare program
8 under title XVIII of the Social Security Act (42
9 U.S.C. 1395 et seq.). The report shall include—

10 (A) an analysis of—

11 (i) the effect of drug shortages on
12 Medicare beneficiary access, quality, safe-
13 ty, and out-of-pocket costs;

14 (ii) the effect of drug shortages on
15 health providers, including hospitals and
16 physicians, across the Medicare program;

17 (iii) the current role of the Centers for
18 Medicare & Medicaid Services (CMS) in
19 addressing drug shortages, including
20 CMS's working relationship and commu-
21 nication with other Federal agencies and
22 stakeholders;

23 (iv) the role of all actors in the drug
24 supply chain (including drug manufactur-
25 ers, distributors, wholesalers, secondary

1 wholesalers, group purchasing organiza-
 2 tions, hospitals, and physicians) on drug
 3 shortages within the Medicare program;
 4 and

5 (v) payment structures and incentives
 6 under parts A, B, C, and D of the Medi-
 7 care program and their effect, if any, on
 8 drug shortages; and

9 (B) relevant findings and recommendations
 10 to Congress.

11 (2) PUBLIC AVAILABILITY.—The report under
 12 this subsection shall be made available to the public.

13 (3) CONSULTATION.—The Secretary shall con-
 14 sult with the drug shortage task force authorized
 15 under section 506D(a)(1)(A) of the Federal Food,
 16 Drug, and Cosmetic Act (21 U.S.C. 356d(a)(1)(A))
 17 in preparing the report under this subsection, as ap-
 18 propriate.

19 **Subtitle B—Part D**

20 **SEC. 121. MEDICARE PART D MODERNIZATION REDESIGN.**

21 (a) BENEFIT STRUCTURE REDESIGN.—Section
 22 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
 23 102(b)) is amended—

24 (1) in paragraph (2)—

1 (A) in subparagraph (A), in the matter
2 preceding clause (i), by inserting “for a year
3 preceding 2022 and for costs above the annual
4 deductible specified in paragraph (1) and up to
5 the annual out-of-pocket threshold specified in
6 paragraph (4)(B) for 2022 and each subsequent
7 year” after “paragraph (3)”;

8 (B) in subparagraph (C)—

9 (i) in clause (i), in the matter pre-
10 ceding subclause (I), by inserting “for a
11 year preceding 2022,” after “paragraph
12 (4),”; and

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

16 (C) in subparagraph (D)—

17 (i) in clause (i)—

18 (I) in the matter preceding sub-
19 clause (I), by inserting “for a year
20 preceding 2022,” after “paragraph
21 (4),”; and

22 (II) in subclause (I)(bb), by
23 striking “a year after 2018” and in-
24 serting “each of years 2018 through
25 2021”; and

1 (ii) in clause (ii)(V), by striking
2 “2019 and each subsequent year” and in-
3 serting “each of years 2019 through
4 2021”;

5 (2) in paragraph (3)(A)—

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

9 (B) in clause (ii), by striking “for a subse-
10 quent year” and inserting “for each of years
11 2007 through 2021”;

12 (3) in paragraph (4)—

13 (A) in subparagraph (A)—

14 (i) in clause (i)—

15 (I) by redesignating subclauses
16 (I) and (II) as items (aa) and (bb),
17 respectively, and indenting appro-
18 priately;

19 (II) in the matter preceding item
20 (aa), as redesignated by subclause (I),
21 by striking “is equal to the greater
22 of—” and inserting “is equal to—

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

1 (III) by striking the period at the
2 end of item (bb), as redesignated by
3 subclause (I), and inserting “; and”;
4 and

5 (IV) by adding at the end the fol-
6 lowing:

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

9 (ii) in clause (ii)—

10 (I) by striking “clause (i)(I)” and
11 inserting “clause (i)(I)(aa)”; and

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

19 (B) in subparagraph (B)—

20 (i) in clause (i)—

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

23 (II) in subclause (VI)—

1 (aa) by striking “for a sub-
2 sequent year” and inserting “for
3 2021”; and

4 (bb) by striking the period
5 at the end and inserting a semi-
6 colon; and

7 (III) by adding at the end the
8 following new subclauses:

9 “(VII) for 2022, is equal to
10 \$3,100; or

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

17 (ii) in clause (ii), by striking “clause
18 (i)(II)” and inserting “clause (i)”;

19 (C) in subparagraph (C)(i), by striking
20 “and for amounts” and inserting “and for a
21 year preceding 2022 for amounts”; and

22 (D) in subparagraph (E), by striking “In
23 applying” and inserting “For each of 2011
24 through 2021, in applying”

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

4 (1) in paragraph (1)—

5 (A) by striking “equal to 80 percent” and
6 inserting “equal to—

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

9 (B) in subparagraph (A), as added by
10 paragraph (1), by striking the period at the end
11 and inserting “; and”; and

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

14 “(B) for a subsequent year, the sum of—

15 “(i) an amount equal to the applicable
16 percentage specified in paragraph (5)(A) of
17 such allowable reinsurance costs attrib-
18 utable to that portion of gross prescription
19 drug costs as specified in paragraph (3) in-
20 curred in the coverage year after such indi-
21 vidual has incurred costs that exceed the
22 annual out-of-pocket threshold specified in
23 section 1860D–2(b)(4)(B) with respect to
24 applicable drugs (as defined in section
25 1860D–14B(g)(2)); and

1 “(ii) an amount equal to the applica-
2 ble percentage specified in paragraph
3 (5)(B) of allowable reinsurance costs at-
4 tributable to that portion of gross prescrip-
5 tion drug costs as specified in paragraph
6 (3) incurred in the coverage year after
7 such individual has incurred costs that ex-
8 ceed the annual out-of-pocket threshold
9 specified in section 1860D–2(b)(4)(B) with
10 respect to covered part D drugs that are
11 not applicable drugs (as so defined).”;

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

14 “(5) APPLICABLE PERCENTAGE SPECIFIED.—
15 For purposes of paragraph (1)(B), the applicable
16 percentage specified in this paragraph is—

17 “(A) with respect to applicable drugs (as
18 defined in section 1860D–14B(g)(2))—

19 “(i) for 2022, 60 percent;

20 “(ii) for 2023, 40 percent; and

21 “(iii) for 2024 and each subsequent
22 year, 20 percent; and

23 “(B) with respect to covered part D drugs
24 that are not applicable drugs (as so defined)—

25 “(i) for 2022, 80 percent;

1 “(ii) for 2023, 60 percent; and
 2 “(iii) for 2024 and each subsequent
 3 year, 40 percent.”.

4 (c) MANUFACTURER CATASTROPHIC DISCOUNT PRO-
 5 GRAM.—

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

10 **“SEC. 1860D–14B. MANUFACTURER CATASTROPHIC DIS-**
 11 **COUNT PROGRAM.**

12 “(a) ESTABLISHMENT.—The Secretary shall estab-
 13 lish a manufacturer catastrophic discount program (in this
 14 section referred to as the ‘program’). Under the program,
 15 the Secretary shall enter into agreements described in sub-
 16 section (b) with manufacturers and provide for the per-
 17 formance of the duties described in subsection (c). The
 18 Secretary shall establish a model agreement for use under
 19 the program by not later than January 1, 2021, in con-
 20 sultation with manufacturers, and allow for comment on
 21 such model agreement.

22 “(b) TERMS OF AGREEMENT.—

23 “(1) IN GENERAL.—

24 “(A) AGREEMENT.—An agreement under
 25 this section shall require the manufacturer to

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

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

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

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

1 “(4) LENGTH OF AGREEMENT.—

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

8 “(B) TERMINATION.—

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

24 “(ii) BY A MANUFACTURER.—A man-
25 ufacturer may terminate an agreement

1 under this section for any reason. Any
2 such termination shall be effective, with re-
3 spect to a plan year—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 “(2) MONITORING COMPLIANCE.—

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

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

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

7 “(d) ADMINISTRATION.—

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

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

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

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

1 individuals or entities the Secretary determines
2 appropriate;

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

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

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

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

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

4 “(6) FUNDING.—For purposes of carrying out
5 this section, the Secretary shall provide for the
6 transfer, from the Federal Supplementary Medical
7 Insurance Trust Fund under section 1841 to the
8 Centers for Medicare & Medicaid Services Program
9 Management Account, of \$4,000,000 for each of fis-
10 cal years 2020 through 2023, to remain available
11 until expended.”.

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 an applicable
16 drug (including a generic drug or a drug that is not on
17 the formulary of the prescription drug plan or MA–PD
18 plan that the applicable beneficiary is enrolled in).

19 “(g) DEFINITIONS.—In this section:

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

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

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

3 “(C) has incurred costs for covered part D
4 drugs in the year that are equal to or exceed
5 the annual out-of-pocket threshold specified in
6 section 1860D–2(b)(4)(B).

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

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

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

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

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

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

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

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

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

13 “(4) DISCOUNTED PRICE.—

14 “(A) IN GENERAL.—The term ‘discounted
15 price’ means 80 percent of the negotiated price
16 of the applicable drug of a manufacturer.

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

21 “(C) SPECIAL CASE FOR CERTAIN
22 CLAIMS.—In the case where the entire amount
23 of the negotiated price of an individual claim
24 for an applicable drug with respect to an appli-
25 cable beneficiary does not fall at or above the

1 annual out-of-pocket threshold specified in sec-
2 tion 1860D–2(b)(4)(B) for the year, the manu-
3 facturer of the applicable drug shall provide the
4 discounted price under this section on only the
5 portion of the negotiated price of the applicable
6 drug that falls at or above such annual out-of-
7 pocket threshold.

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

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

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

1 plan' has the meaning given such term in section
2 1860D-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 (d) DETERMINATION OF ALLOWABLE REINSURANCE
5 COSTS.—Section 1860D–15(b) of the Social Security Act
6 (42 U.S.C. 1395w–115(b)) is amended—

7 (1) in paragraph (2)—

8 (A) by striking “COSTS.—For purposes”
9 and inserting “COSTS.—

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

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

14 “(B) INCLUSION OF MANUFACTURER DIS-
15 COUNTS ON APPLICABLE DRUGS.—For purposes
16 of applying subparagraph (A), the term ‘allow-
17 able reinsurance costs’ shall include the portion
18 of the negotiated price (as defined in section
19 1860D–14B(g)(6)) of an applicable drug (as
20 defined in section 1860D–14(g)(2)) that was
21 paid by a manufacturer under the manufacturer
22 catastrophic discount program under section
23 1860D–14B.”; and

24 (2) in paragraph (3)—

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

4 (B) in the second sentence, by inserting
5 “or, in the case of an applicable drug, by a
6 manufacturer” after “by the individual or
7 under the plan”.

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

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

22 (f) CONFORMING AMENDMENTS.—

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

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

5 (B) in subsection (c)(1)(C)—

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

9 (ii) by inserting “for a year preceding
10 2022 or the annual out-of-pocket threshold
11 specified in subsection (b)(4)(B) for the
12 year for 2022 and each subsequent year”
13 after “subsection (b)(3) for the year” each
14 place it appears;

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

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

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

24 (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 (E), by striking
5 “The elimination” and inserting “For a
6 year preceding 2022, the elimination”; and

7 (iii) in subparagraph (D)(iii), by strik-
8 ing “1860D–2(b)(4)(A)(i)(I)” and insert-
9 ing “1860D–2(b)(4)(A)(i)(I)(aa)”; 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 (e)”;
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)(B)(4)(B)(i)” and
25 inserting “section 1860D–2(b)(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 (7) Section 1860D–43(a)(1) of the Social Secu-
23 rity Act (42 U.S.C. 1395w–153(a)(1)) is amended to
24 read as follows:

25 “(1) participate in—

1 “(A) for 2011 through 2021, the Medicare
2 coverage gap discount program under section
3 1860D–14A; and

4 “(B) for 2022 and each subsequent year,
5 the manufacturer catastrophic discount pro-
6 gram under section 1860D–14B;”.

7 (g) EFFECTIVE DATE.—The amendments made by
8 this section shall apply to plan year 2022 and subsequent
9 plan years.

10 **SEC. 122. PROVIDING THE MEDICARE PAYMENT ADVISORY**
11 **COMMISSION AND MEDICAID AND CHIP PAY-**
12 **MENT AND ACCESS COMMISSION WITH AC-**
13 **CESS TO CERTAIN DRUG PAYMENT INFORMA-**
14 **TION, INCLUDING CERTAIN REBATE INFOR-**
15 **MATION.**

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

19 (1) in paragraph (2)—

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

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

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

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

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

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

22 “(A) The specific amounts or the identity
23 of the source of any rebates, price concessions,
24 or other forms of direct or indirect remunera-

1 tion under such prescription drug plan or such
2 MA–PD plan.

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

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

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

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

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

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

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

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

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

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

20 **SEC. 123. PUBLIC DISCLOSURE OF DRUG DISCOUNTS AND**
 21 **OTHER PHARMACY BENEFIT MANAGER (PBM)**
 22 **PROVISIONS.**

23 (a) PUBLIC DISCLOSURE OF DRUG DISCOUNTS.—

24 (1) IN GENERAL.—Section 1150A of the Social
 25 Security Act (42 U.S.C. 1320b-23) is amended—

1 (A) in subsection (c), in the matter pre-
2 ceding paragraph (1), by striking “this section”
3 and inserting “subsection (b)(1)”; and

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

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

8 “(1) IN GENERAL.—Subject to paragraphs (2)
9 and (3), in order to allow patients and employers to
10 compare PBMs’ ability to negotiate rebates, dis-
11 counts, and price concessions and the amount of
12 such rebates, discounts, and price concessions that
13 are passed through to plan sponsors, not later than
14 July 1, 2022, the Secretary shall make available on
15 the Internet website of the Department of Health
16 and Human Services the information provided to the
17 Secretary and described in paragraphs (2) and (3)
18 of subsection (b) with respect to each PBM.

19 “(2) LAG IN DATA.—The information made
20 available in a plan year under paragraph (1) shall
21 not include information with respect to such plan
22 year or the two preceding plan years.

23 “(3) CONFIDENTIALITY.—The Secretary shall
24 ensure that such information is displayed in a man-
25 ner that prevents the disclosure of information on

1 rebates, discounts, and price concessions with re-
2 spect to an individual drug or an individual PDP
3 sponsor, MA organization, or qualified health bene-
4 fits plan.”.

5 (2) EFFECTIVE DATE.—The amendment made
6 by paragraph (1)(A) shall take effect on January 1,
7 2022.

8 (b) PLAN AUDIT OF PHARMACY BENEFIT MANAGER
9 DATA.—Section 1860D–2(d)(3) of the Social Security Act
10 (42 U.S.C. 1395w–102(d)(3)) is amended—

11 (1) by striking “AUDITS.—To protect” and in-
12 serting the following: “AUDITS.—

13 “(A) AUDITS OF PLANS BY THE SEC-
14 RETARY.—To protect”; and

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

17 “(B) AUDITS OF PHARMACY BENEFIT
18 MANAGERS BY PDP SPONSORS AND MA ORGANI-
19 ZATIONS.—

20 “(i) IN GENERAL.—Beginning Janu-
21 ary 1, 2022, in order to ensure that—

22 “(I) contracting terms between a
23 PDP sponsor offering a prescription
24 drug plan or an MA organization of-
25 fering an MA–PD plan and its con-

1 tracted or owned pharmacy benefit
2 manager are met; and

3 “(II) the PDP sponsor and MA
4 organization can account for the cost
5 of each covered part D drug net of all
6 direct and indirect remuneration;

7 the PDP sponsor or MA organization shall
8 conduct financial audits.

9 “(ii) INDEPENDENT THIRD PARTY.—
10 An audit described in clause (i) shall—

11 “(I) be conducted by an inde-
12 pendent third party; and

13 “(II) account and reconcile flows
14 of funds that determine the net cost
15 of covered part D drugs, including di-
16 rect and indirect remuneration from
17 drug manufacturers and pharmacies
18 or provided to pharmacies.

19 “(iii) REBATE AGREEMENTS.—A PDP
20 sponsor and an MA organization shall re-
21 quire pharmacy benefit managers to make
22 rebate contracts with drug manufacturers
23 made on their behalf available under audits
24 described in clause (i).

1 “(iv) CONFIDENTIALITY AGREE-
2 MENTS.—Audits described in clause (i)
3 shall be subject to confidentiality agree-
4 ments to prevent, except as required under
5 clause (vii), the redisclosure of data trans-
6 mitted under the audit.

7 “(v) FREQUENCY.—A financial audit
8 under clause (i) shall be conducted periodi-
9 cally (but in no case less frequently than
10 once every 2 years).

11 “(vi) TIMEFRAME FOR PBM TO PRO-
12 VIDE INFORMATION.—A PDP sponsor and
13 an MA organization shall require that a
14 pharmacy benefit manager that is being
15 audited under clause (i) provide (as part of
16 their contracting agreement) the requested
17 information to the independent third party
18 conducting the audit within 45 days of the
19 date of the request.

20 “(vii) SUBMISSION OF AUDIT REPORTS
21 TO THE SECRETARY.—

22 “(I) IN GENERAL.—A PDP spon-
23 sor and an MA organization shall sub-
24 mit to the Secretary the final report
25 on any audit conducted under clause

1 (i) within 30 days of the PDP sponsor
2 or MA organization receiving the re-
3 port from the independent third party
4 conducting the audit.

5 “(II) REVIEW.—The Secretary
6 shall review final reports submitted
7 under clause (i) to determine the ex-
8 tent to which the goals specified in
9 subclauses (I) and (II) of subpara-
10 graph (B)(i) are met.

11 “(III) CONFIDENTIALITY.—Not-
12 withstanding any other provision of
13 law, information disclosed in a report
14 submitted under clause (i) related to
15 the net cost of a covered part D drug
16 is confidential and shall not be dis-
17 closed by the Secretary or a Medicare
18 contractor.

19 “(viii) NOTICE OF NONCOMPLI-
20 ANCE.—A PDP sponsor and an MA orga-
21 nization shall notify the Secretary if any
22 pharmacy benefit manager is not com-
23 plying with requests for access to informa-
24 tion required under an audit under clause
25 (i).

1 “(ix) CIVIL MONETARY PENALTIES.—

2 “(I) IN GENERAL.—Subject to
3 subclause (II), if the Secretary deter-
4 mines that a PDP sponsor or an MA
5 organization has failed to conduct an
6 audit under clause (i), the Secretary
7 may impose a civil monetary penalty
8 of not more than \$10,000 for each
9 day of such noncompliance.

10 “(II) PROCEDURE.—The provi-
11 sions of section 1128A, other than
12 subsections (a) and (b) and the first
13 sentence of subsection (c)(1) of such
14 section, shall apply to civil monetary
15 penalties under this clause in the
16 same manner as such provisions apply
17 to a penalty or proceeding under sec-
18 tion 1128A.”.

19 (c) DISCLOSURE TO PHARMACY OF POST-POINT-OF-
20 SALE PHARMACY PRICE CONCESSIONS AND INCENTIVE
21 PAYMENTS.—Section 1860D–2(d)(2) of the Social Secu-
22 rity Act (42 U.S.C. 1395w–102(d)(2)) is amended—

23 (1) by striking “DISCLOSURE.—A PDP spon-
24 sor” and inserting the following: “DISCLOSURE.—

1 “(A) TO THE SECRETARY.—A PDP spon-
2 sor”;

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

5 “(B) TO PHARMACIES.—

6 “(i) IN GENERAL.—For plan year
7 2022 and subsequent plan years, a PDP
8 sponsor offering a prescription drug plan
9 and an MA organization offering an MA-
10 PD plan shall report any pharmacy price
11 concession or incentive payment that oc-
12 curs with respect to a pharmacy after pay-
13 ment for covered part D drugs at the
14 point-of-sale, including by an intermediary
15 organization with which a PDP sponsor or
16 MA organization has contracted, to the
17 pharmacy.

18 “(ii) TIMING.—The reporting of price
19 concessions and incentive payments to a
20 pharmacy under clause (i) shall be made
21 on a periodic basis (but in no case less fre-
22 quently than annually).

23 “(iii) CLAIM LEVEL.—The reporting
24 of price concessions and incentive pay-
25 ments to a pharmacy under clause (i) shall

1 be at the claim level or approximated at
2 the claim level if the price concession or in-
3 centive payment was applied at a level
4 other than at the claim level.”.

5 (d) DISCLOSURE OF P&T COMMITTEE CONFLICTS OF
6 INTEREST.—

7 (1) IN GENERAL.—Section 1860D–4(b)(3)(A)
8 of the Social Security Act (42 U.S.C. 1395w–
9 104(b)(3)(A)) is amended by adding at the end the
10 following new clause:

11 “(iii) DISCLOSURE OF CONFLICTS OF
12 INTEREST.—With respect to plan year
13 2022 and subsequent plan years, a PDP
14 sponsor of a prescription drug plan and an
15 MA organization offering an MA–PD plan
16 shall, as part of its bid submission under
17 section 1860D–11(b), provide the Sec-
18 retary with a completed statement of fi-
19 nancial conflicts of interest, including with
20 manufacturers, from each member of any
21 pharmacy and therapeutic committee used
22 by the sponsor or organization pursuant to
23 this paragraph.”.

1 (2) INCLUSION IN BID.—Section 1860D–
2 11(b)(2) of the Social Security Act (42 U.S.C.
3 1395w–111(b)(2)) is amended—

4 (A) by redesignating subparagraph (F) as
5 subparagraph (G); and

6 (B) by inserting after subparagraph (E)
7 the following new subparagraph:

8 “(F) P&T COMMITTEE CONFLICTS OF IN-
9 TEREST.—The information required to be dis-
10 closed under section 1860D–4(b)(3)(A)(iii).”.

11 (e) INFORMATION ON DIRECT AND INDIRECT REMU-
12 NERATION REQUIRED TO BE INCLUDED IN BID.—Section
13 1860D–11(b) of the Social Security Act (42 U.S.C.
14 1395w–111(b)) is amended—

15 (1) in paragraph (1), by adding at the end the
16 following new sentence: “With respect to actual
17 amounts of direct and indirect remuneration sub-
18 mitted pursuant to clause (v) of paragraph (2), such
19 amounts shall be consistent with data reported to
20 the Secretary in a prior year.”; and

21 (2) in paragraph (2)(C)—

22 (A) in clause (iii), by striking “and” at the
23 end;

24 (B) in clause (iv), by striking the period at
25 the end and inserting the following: “, and, with

1 respect to plan year 2022 and subsequent plan
 2 years, actual and projected administrative ex-
 3 penses assumed in the bid, categorized by the
 4 type of such expense, including actual and pro-
 5 jected price concessions retained by a pharmacy
 6 benefit manager; and”;

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

9 “(v) with respect to plan year 2022
 10 and subsequent plan years, actual and pro-
 11 jected direct and indirect remuneration,
 12 categorized as received from each of the
 13 following:

14 “(I) A pharmacy.

15 “(II) A manufacturer.

16 “(III) A pharmacy benefit man-
 17 ager.

18 “(IV) Other entities, as deter-
 19 mined by the Secretary.”.

20 **SEC. 124. PUBLIC DISCLOSURE OF DIRECT AND INDIRECT**
 21 **REMUNERATION REVIEW AND AUDIT RE-**
 22 **SULTS.**

23 Section 1860D–42 of the Social Security Act (42
 24 U.S.C. 1395w–152) is amended by adding at the end the
 25 following new subsection:

1 “(e) PUBLIC DISCLOSURE OF DIRECT AND INDIRECT
2 REMUNERATION REVIEW AND FINANCIAL AUDIT RE-
3 SULTS.—

4 “(1) DIR REVIEW RESULTS.—

5 “(A) IN GENERAL.—Except as provided in
6 subparagraph (B), in 2020 and each subse-
7 quent year, the Secretary shall make available
8 to the public on the Internet website of the
9 Centers for Medicare & Medicaid Services infor-
10 mation on discrepancies related to summary
11 and detailed DIR reports submitted by PDP
12 sponsors pursuant to section 1860D–15 across
13 all prescription drug plans based on the most
14 recent data available. Information made avail-
15 able under this subparagraph shall include the
16 following:

17 “(i) The number of potential errors
18 identified by the Secretary for PDP spon-
19 sors to review.

20 “(ii) The extent to which PDP spon-
21 sors resubmitted DIR reports to make
22 changes for previous contract years.

23 “(iii) The extent to which resubmitted
24 DIR reports resulted in an increase or de-
25 crease in DIR in a previous contract year.

1 “(B) EXCLUSION OF CERTAIN SUBMIS-
2 SIONS IN CALCULATION.—The Secretary shall
3 exclude any information in DIR reports sub-
4 mitted with respect to PACE programs under
5 section 1894 (pursuant to section 1860D–21(f))
6 and qualified retiree prescription drug plans (as
7 defined in section 1860D–22(a)(2)) from the
8 information that is made available to the public
9 under subparagraph (A).

10 “(2) FINANCIAL AUDIT RESULTS.—In 2020 and
11 each subsequent year, the Secretary shall make
12 available to the public on the Internet website of the
13 Centers for Medicare & Medicaid Services the results
14 of DIR audits required under section 1860D–
15 12(b)(3)(C). Information made available under this
16 paragraph shall include the following:

17 “(A) With respect to the year, the number
18 of PDP sponsors that received each of the fol-
19 lowing:

20 “(i) A notice of observations or find-
21 ings that required the sponsor to make
22 DIR report corrections.

23 “(ii) An unqualified audit opinion that
24 renders the audit closed.

1 “(iii) A qualified audit opinion that
2 requires the sponsor to submit a corrective
3 action plan to the Secretary.

4 “(iv) An adverse opinion, with a de-
5 scription of the types of actions that the
6 Secretary takes when issuing an adverse
7 opinion.

8 “(B) With respect to a preceding year:

9 “(i) The number of PDP sponsors
10 that reopened a previously closed reconcili-
11 ation as a result of an audit, including as
12 a result of DIR changes.

13 “(ii) The extent to which the Sec-
14 retary recouped an overpayment or made
15 an underpayment as a result of a reopen-
16 ing of a previously closed reconciliation.

17 “(3) DEFINITION OF DIR.—For purposes of
18 this subsection, the term ‘DIR’ means direct and in-
19 direct remuneration as defined in section 423.308 of
20 title 42, Code of Federal Regulations, or any suc-
21 cessor regulation.”.

22 **SEC. 125. INCREASING THE USE OF REAL-TIME BENEFIT**
23 **TOOLS TO LOWER BENEFICIARY COSTS.**

24 (a) REQUIRING PRESCRIPTION DRUG PLAN SPON-
25 SORS AND MEDICARE ADVANTAGE ORGANIZATIONS TO IN-

1 CLUDE REAL-TIME BENEFIT INFORMATION UNDER
2 MEDICARE PART D.—Section 1860D–4 of the Social Se-
3 curity Act (42 U.S.C. 1395w–104) is amended—

4 (1) by redesignating subsection (m) (relating to
5 program integrity transparency measures), as added
6 by section 6063(c) of the Substance Use-Disorder
7 Prevention that Promotes Opioid Recovery and
8 Treatment for Patients and Communities Act (Pub-
9 lic Law 115–271), as subsection (n); and

10 (2) by adding at the end the following new sub-
11 section:

12 “(o) REAL-TIME BENEFIT INFORMATION.—

13 “(1) IN GENERAL.—After the Secretary has
14 adopted a standard under paragraph (3) for elec-
15 tronic real-time benefit tools, and at a time deter-
16 mined appropriate by the Secretary, a PDP sponsor
17 of a prescription drug plan shall implement one or
18 more of such tools that meet the requirements de-
19 scribed in paragraph (2).

20 “(2) REQUIREMENTS.—For purposes of para-
21 graph (1), the requirements described in this para-
22 graph, with respect to an electronic real-time benefit
23 tool, are that the tool is capable of—

24 “(A) integrating with electronic prescribing
25 and electronic health record systems of pre-

1 scribing health care professionals for the trans-
2 mission of eligibility and formulary and benefit
3 information in real time to such professionals;
4 and

5 “(B) with respect to a covered part D
6 drug, transmitting such information specific to
7 an individual enrolled in a prescription drug
8 plan, including the following:

9 “(i) A list of any clinically-appropriate
10 alternatives to such drug included in the
11 formulary of such plan.

12 “(ii) Cost-sharing information and the
13 negotiated price for such drug and such al-
14 ternatives at—

15 “(I) multiple pharmacy options,
16 including the individual’s preferred
17 pharmacy and, as applicable, other re-
18 tail pharmacies and a mail order
19 pharmacy; and

20 “(II) the formulary status of
21 such drug and such alternatives and
22 any prior authorization or other utili-
23 zation management requirements ap-
24 plicable to such drug and such alter-

1 natives included in the formulary of
2 such plan.

3 “(3) STANDARDS.—In order to be treated (for
4 purposes of this subsection) as an electronic real-
5 time benefit tool described in paragraph (1), such
6 tool shall comply with technical standards adopted
7 by the Secretary in consultation with the National
8 Coordinator for Health Information Technology, the
9 National Council for Prescription Drug Programs,
10 other standard setting organizations determined ap-
11 propriate by the Secretary, and stakeholders includ-
12 ing PDP sponsors, Medicare Advantage organiza-
13 tions, health care professionals, and health informa-
14 tion technology software vendors.

15 “(4) RULE OF CONSTRUCTION.—Nothing in
16 this subsection shall be construed to prohibit the ap-
17 plication of paragraph (b)(7) of section 423.160 of
18 title 42, Code of Federal Regulations, as is to be
19 added to such section pursuant to the final rule pub-
20 lished in the Federal Register on May 23, 2019, and
21 titled ‘Modernizing Part D and Medicare Advantage
22 To Lower Drug Prices and Reduce Out-of-Pocket
23 Expenses’ (84 Fed. Reg. 23832 through 23884).”.

24 (b) REQUIRING QUALIFIED ELECTRONIC HEALTH
25 RECORDS TO INCLUDE REAL-TIME BENEFIT TOOLS.—

1 Section 3000(13) of the Public Health Service Act (42
2 U.S.C. 300jj(13)) is amended—

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

5 (2) in subparagraph (B), by striking the period
6 and inserting “; and”; and

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

8 “(C) includes, or is capable of including, a
9 real-time benefit tool that conveys patient-spe-
10 cific real-time cost and coverage information
11 with respect to prescription drugs that, with re-
12 spect to any health information technology cer-
13 tified for electronic prescribing, the technology
14 shall be capable of incorporating the informa-
15 tion described in clauses (i) and (ii) of para-
16 graph (2)(B) of section 1860D–4(o) of the So-
17 cial Security Act at a time specified by the Sec-
18 retary but not before the Secretary adopts a
19 standard for such tools as described in para-
20 graph (1) of such section.”.

21 (c) INCLUSION OF USE OF REAL-TIME ELECTRONIC
22 INFORMATION IN SHARED DECISION-MAKING UNDER
23 MIPS.—Section 1848(q)(2)(B)(iii)(IV) of the Social Se-
24 curity Act (42 U.S.C. 1395w–4(q)(2)(B)(iii)(IV)) is
25 amended by adding at the end the following new sentence:

1 “This subcategory shall include as an activity option, be-
 2 ginning with the performance period starting on January
 3 1, 2021, use of a real-time benefit tool as described in
 4 1860D–4(o).”.

5 **SEC. 126. IMPROVEMENTS TO PROVISION OF PARTS A AND**
 6 **B CLAIMS DATA TO PRESCRIPTION DRUG**
 7 **PLANS.**

8 (a) DATA USE.—

9 (1) IN GENERAL.—Paragraph (6) of section
 10 1860D–4(c) of the Social Security Act (42 U.S.C.
 11 1395w–104(c)), as added by section 50354 of divi-
 12 sion E of the Bipartisan Budget Act of 2018 (Public
 13 Law 115–123), relating to providing prescription
 14 drug plans with parts A and B claims data to pro-
 15 mote the appropriate use of medications and im-
 16 prove health outcomes, is amended—

17 (A) in subparagraph (B)—

18 (i) by redesignating clauses (i), (ii),
 19 and (iii) as subclauses (I), (II), and (III),
 20 respectively, and moving such subclauses 2
 21 ems to the right;

22 (ii) by striking “PURPOSES.—A PDP
 23 sponsor” and inserting PURPOSES—

24 “(i) IN GENERAL.—A PDP sponsor.”;

25 and

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

3 “(ii) CLARIFICATION.—The limitation
 4 on data use under subparagraph (C)(i)
 5 shall not apply to the extent that the PDP
 6 sponsor is using the data provided to carry
 7 out any of the purposes described in clause
 8 (i).”; and

9 (B) in subparagraph (C)(i), by striking
 10 “To inform” and inserting “Subject to subpara-
 11 graph (B)(ii), to inform”.

12 (2) EFFECTIVE DATE.—The amendments made
 13 by this subsection shall apply to plan years begin-
 14 ning on or after January 1, 2022.

15 (b) MANNER OF PROVISION.—Subparagraph (D) of
 16 such paragraph (6) is amended—

17 (1) by striking “DESCRIBED.—The data de-
 18 scribed in this clause” and inserting “DESCRIBED.—

19 “(i) IN GENERAL.—The data de-
 20 scribed in this subparagraph”; and

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

23 “(ii) MANNER OF PROVISION.—

24 “(I) IN GENERAL.—Such data
 25 may be provided pursuant to this

1 paragraph in the same manner as
 2 data under the Part D Enhanced
 3 Medication Therapy Management
 4 model tested under section 1115A,
 5 through Application Programming
 6 Interface, or in another manner as de-
 7 termined by the Secretary.

8 “(II) IMPLEMENTATION.—Not-
 9 withstanding any other provision of
 10 law, the Secretary may implement this
 11 clause by program instruction or oth-
 12 erwise.”.

13 (c) TECHNICAL CORRECTION.—Such paragraph (6)
 14 is redesignated as paragraph (7).

15 **SEC. 127. PERMANENTLY AUTHORIZE A SUCCESSFUL PILOT**
 16 **ON RETROACTIVE MEDICARE PART D COV-**
 17 **ERAGE FOR LOW-INCOME BENEFICIARIES.**

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

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

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

24 “(e) LIMITED INCOME NEWLY ELIGIBLE TRANSI-
 25 TION (LI NET) PROGRAM.—

1 “(1) IN GENERAL.—By not later than 2022,
2 the Secretary shall establish a program to provide
3 transitional coverage for covered part D drugs for
4 LI NET eligible individuals in accordance with this
5 subsection.

6 “(2) LI NET ELIGIBLE INDIVIDUAL DEFINED.—
7 For purposes of this subsection, the term ‘LI NET
8 eligible individual’ means a part D eligible individual
9 who—

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

12 “(B) has not yet enrolled in a prescription
13 drug plan or an MA-PD plan, or, who has so
14 enrolled, but with respect to whom coverage
15 under such plan has not yet taken effect.

16 “(3) TRANSITIONAL COVERAGE DEFINED.—For
17 purposes of this subsection, the term ‘transitional
18 coverage’ means the following with respect to a LI
19 NET eligible individual:

20 “(A) ALL LI NET ELIGIBLE INDIVID-
21 UALS.—Immediate access to covered part D
22 drugs at the point of sale during the period
23 that begins on the first day of the month such
24 individual is determined to meet the require-
25 ments of clauses (ii) and (iii) of subsection

1 (a)(3)(A) and ends on the date that coverage
2 under a prescription drug plan or an MA–PD
3 plan takes effect with respect to such indi-
4 vidual.

5 “(B) FULL-BENEFIT DUAL ELIGIBLES AND
6 SSI RECIPIENTS.—In the case of a LI NET eli-
7 gible individual who is a full-benefit dual eligi-
8 ble individual (as defined in section 1935(c)(6))
9 or recipient of supplemental security income
10 benefits under title XVI, retroactive coverage
11 (in the form of reimbursement of the amounts
12 that would have been paid under this part had
13 such individual been enrolled in a prescription
14 drug plan or an MA–PD plan) of covered part
15 D drugs purchased by such individual during
16 the period that—

17 “(i) begins on the date that is the
18 later of the date that—

19 “(I) such individual was first eli-
20 gible for a low income subsidy under
21 this part; or

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

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

3 “(4) PROGRAM ADMINISTRATION.—

4 “(A) SINGLE POINT OF CONTACT.—The
5 Secretary shall, to the extent feasible, admin-
6 ister the program under this subsection through
7 a contract with a single program administrator
8 who will provide for a single point of contact for
9 LI NET eligible individuals.

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

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

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

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

24 “(iv) meets such other requirements
25 as the Secretary may establish.

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

3 “(A) IN GENERAL.—The following provi-
4 sions shall not apply to the program under this
5 subsection:

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

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

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

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

1 **SEC. 128. MEDICARE PART D REBATE BY MANUFACTURERS**
2 **FOR CERTAIN DRUGS WITH PRICES INCREAS-**
3 **ING FASTER THAN INFLATION.**

4 (a) IN GENERAL.—Subpart 2 of part D of title XVIII
5 of the Social Security Act is amended by inserting after
6 section 1860D–14B, as added by section 121, the fol-
7 lowing new section:

8 **“SEC. 1860D–14C. MANUFACTURER REBATE FOR CERTAIN**
9 **DRUGS WITH PRICES INCREASING FASTER**
10 **THAN INFLATION.**

11 “(a) REQUIREMENTS.—

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

14 “(A) IN GENERAL.—Subject to subpara-
15 graph (B), not later than 6 months after the
16 end of each rebate period (as defined in para-
17 graph (4)(A)) beginning on or after January 1,
18 2022, the Secretary shall, for each rebatable
19 covered part D drug (as defined in paragraph
20 (4)(B)), report to each manufacturer (as de-
21 fined in paragraph (4)(C)) of such rebatable
22 covered part D drug the following for the rebate
23 period:

24 “(i) Information on the total number
25 of units (as defined in paragraph (4)(D))
26 of each dosage form and strength de-

1 scribed in paragraph (1)(A) of subsection
2 (b) for such rebatable covered part D drug
3 and rebate period.

4 “(ii) Information on the amount (if
5 any) of the excess price described in para-
6 graph (1)(B) of such subsection for such
7 rebatable covered part D drug and rebate
8 period.

9 “(iii) The rebate amount specified
10 under such subsection for such rebatable
11 covered part D drug and rebate period.

12 “(iv) Other information determined
13 appropriate by the Secretary.

14 “(B) TRANSITION RULE FOR INFORMATION
15 IN 2022.—Notwithstanding subparagraph (A),
16 the Secretary may, for each rebatable covered
17 part D drug, delay the timeframe for reporting
18 the information and rebate amount described in
19 clauses (i), (ii), (iii), and (iv) of such subpara-
20 graph for rebate periods in 2022 until not later
21 than December 31, 2023.

22 “(2) MANUFACTURER REBATE.—

23 “(A) IN GENERAL.—Subject to subpara-
24 graph (B), for each rebate period beginning on
25 or after January 1, 2022, each manufacturer of

1 a rebatable covered part D drug shall, not later
2 than 30 days after the date of receipt from the
3 Secretary of the information and rebate amount
4 pursuant to paragraph (1), provide to the Sec-
5 retary a rebate that is equal to the amount
6 specified in subsection (b) for such drug for
7 such rebate period.

8 “(B) EXEMPTION FOR SHORTAGES.—The
9 Secretary may reduce or waive the rebate under
10 this paragraph with respect to a rebatable cov-
11 ered part D drug that is listed on the drug
12 shortage list maintained by the Food and Drug
13 Administration pursuant to section 506E of the
14 Federal Food, Drug, and Cosmetic Act.

15 “(3) REQUEST FOR RECONSIDERATION.—The
16 Secretary shall establish procedures under which a
17 manufacturer of a rebatable covered part D drug
18 may request a reconsideration by the Secretary of
19 the rebate amount specified under subsection (b) for
20 such drug and rebate period, as reported to the
21 manufacturer pursuant to paragraph (1). Timing for
22 a reconsideration shall be coordinated with the tim-
23 ing of reconciliation, as described in subsection
24 (b)(6) and as determined appropriate by the Sec-
25 retary.

1 “(4) DEFINITIONS.—In this section:

2 “(A) REBATE PERIOD.—

3 “(i) IN GENERAL.—Subject to clause
4 (ii), the term ‘rebate period’ means, with
5 respect to a year, each of the six month
6 periods that begin on January 1 and July
7 1 of the year.

8 “(ii) INITIAL REBATE PERIOD FOR
9 SUBSEQUENTLY APPROVED DRUGS.—In
10 the case of a rebatable covered part D
11 drug described in subsection (c), the initial
12 rebate period for which a rebate amount is
13 determined for such rebatable covered part
14 D drug pursuant to such subsection shall
15 be the period beginning with the first
16 month after the last day of the six month
17 period that begins on the day on which the
18 drug was first marketed and ending on the
19 last day of the first full rebate period
20 under clause (i) that begins after the last
21 day of such six month period.

22 “(B) REBATABLE COVERED PART D
23 DRUG.—The term ‘rebatable covered part D
24 drug’ means a covered part D drug approved
25 under a new drug application under section

1 505(c) of the Federal Food, Drug, and Cos-
2 metic Act or, in the case of a biologic product,
3 licensed under section 351(a) of the Public
4 Health Service Act.

5 “(C) MANUFACTURER.—The term ‘manu-
6 facturer’ has the meaning given such term in
7 section 1860D—14A(g).

8 “(D) UNITS.—The term ‘units’ means,
9 with respect to a rebatable covered part D
10 drug, the lowest common quantity (such as the
11 number of capsules or tablets, milligrams of
12 molecules, or grams) of such drug dispensed to
13 individuals under this part.

14 “(E) PRICE.—The term ‘price’ means,
15 with respect to a rebatable covered part D
16 drug, the wholesale acquisition cost (as defined
17 in section 1847A(e)(6)(B)) for such drug.

18 “(b) REBATE AMOUNT.—

19 “(1) IN GENERAL.—Subject to subsection
20 (e)(2), the amount of the rebate specified in this
21 subsection for a rebate period, with respect to each
22 dosage form and strength of a rebatable covered
23 part D drug, is the amount equal to the product
24 of—

1 “(A) the total number of units of such dos-
2 age form and strength for each rebatable cov-
3 ered part D drug during the rebate period; and

4 “(B) the amount (if any) by which—

5 “(i) the unit-weighted average price
6 for such dosage form and strength of the
7 drug determined under paragraph (2) for
8 the rebate period; exceeds

9 “(ii) the inflation-adjusted price for
10 such dosage form and strength determined
11 under paragraph (3) for the rebate period.

12 “(2) DETERMINATION OF UNIT-WEIGHTED AV-
13 ERAGE PRICE.—

14 “(A) IN GENERAL.—The unit-weighted av-
15 erage price determined under this paragraph
16 for a rebate period, with respect to each dosage
17 form and strength of a rebatable covered Part
18 D drug, is the sum of the products of—

19 “(i) the weighted average price deter-
20 mined under subparagraph (B) with re-
21 spect to each package size of such dosage
22 form and strength dispensed during the re-
23 bate period; and

24 “(ii) the ratio of—

1 “(I) the total number of units of
2 such package size dispensed during
3 the rebate period; to

4 “(II) the total number of units of
5 such dosage form and strength of
6 such drug dispensed during such re-
7 bate period.

8 “(B) COMPUTATION OF WEIGHTED AVER-
9 AGE PRICE.—The weighted average price, with
10 respect to each package size of such dosage
11 form and strength of a rebatable covered part
12 D drug dispensed during a rebate period, is the
13 sum of the products of—

14 “(i) each price, as calculated for a
15 unit of such drug, applicable to each pack-
16 age size of such dosage form and strength
17 of such drug during the rebate period; and

18 “(ii) the ratio of—

19 “(I) the number of days for
20 which each such price is applicable
21 during the rebate period; to

22 “(II) the total number of days in
23 such rebate period.

24 “(3) DETERMINATION OF INFLATION-ADJUSTED
25 PRICE.—

1 “(A) IN GENERAL.—The inflation-adjusted
2 price determined under this paragraph for a re-
3 bate period, with respect to each dosage form
4 and strength of a rebatable covered part D
5 drug, is—

6 “(i) the benchmark unit-weighted
7 price determined under subparagraph (B)
8 for the rebate period; increased by

9 “(ii) the percentage by which the re-
10 bate period CPI-U (as defined in para-
11 graph (4)) for the rebate period exceeds
12 the benchmark CPI-U (as defined in para-
13 graph (5)).

14 “(B) DETERMINATION OF BENCHMARK
15 UNIT-WEIGHTED PRICE.—The benchmark unit-
16 weighted price determined under this subpara-
17 graph for a rebate period, with respect to each
18 dosage form and strength of a rebatable cov-
19 ered part D drug, is the sum of the products
20 of—

21 “(i) each price, as calculated for a
22 unit of such drug, applicable to each pack-
23 age size of such dosage form and strength
24 of such drug on July 1, 2019; and

25 “(ii) the ratio of—

1 “(I) the total number of units of
2 such package size dispensed on July
3 1, 2019; to

4 “(II) the total number of units of
5 such dosage form and strength dis-
6 pensed on July 1, 2019.

7 “(4) BENCHMARK CPI-U.—The term ‘bench-
8 mark CPI-U’ means the consumer price index for
9 all urban consumers (United States city average) for
10 July 2019.

11 “(5) REBATE PERIOD CPI-U.—The term ‘rebate
12 period CPI-U’ means, with respect to a rebate pe-
13 riod, the consumer price index for all urban con-
14 sumers (United States city average) for the last
15 month of the rebate period.

16 “(6) ANNUAL RECONCILIATION OF REBATE
17 AMOUNT.—The Secretary shall, on an annual basis,
18 conduct a one-time reconciliation of the rebate
19 amounts owed by a manufacturer under this section
20 based on any changes submitted by a PDP sponsor
21 of a prescription drug plan or an MA organization
22 offering an MA-PD plan to the number of units of
23 a rebatable covered part D drug dispensed during
24 the preceding year. Such reconciliation shall be com-
25 pleted not later than 6 months after the date by

1 which the Secretary reconciles payment for covered
2 part D drugs with PDP sponsors of prescription
3 drug plans or MA organizations offering MA–PD
4 plans.

5 “(c) TREATMENT OF SUBSEQUENTLY APPROVED
6 DRUGS.—Subject to subsection (e)(2), in the case of a
7 rebatable covered part D drug first approved or licensed
8 by the Food and Drug Administration after July 1,
9 2019—

10 “(1) subparagraph (A)(ii) of subsection (b)(3)
11 shall be applied as if the term ‘benchmark CPI–U’
12 were defined under subsection (b)(4) as if the ref-
13 erence to ‘July 2019’ under such subsection were a
14 reference to ‘the first month after the last day of the
15 six month period that begins on the day on which
16 the drug was first marketed’; and

17 “(2) subsection (b)(3) shall be applied by sub-
18 stituting, for the benchmark unit-weighted price oth-
19 erwise determined under subparagraph (B) of such
20 subsection, the benchmark unit-weighted average
21 price determined under paragraph (3) for the rebate
22 period;

23 “(3) the benchmark unit-weighted average price
24 determined under this paragraph for a rebate period,
25 with respect to each dosage form and strength of a

1 rebatable covered part D drug, is the sum of the
2 products of—

3 “(A) the new drug weighted average price
4 determined under paragraph (4) with respect to
5 each package size of such dosage form and
6 strength of such drug dispensed during the six
7 month period that begins on the day on which
8 the drug was first marketed; and

9 “(B) the ratio of—

10 “(i) the total number of units of such
11 package size dispensed during the six
12 month period that begins on the day on
13 which the drug was first marketed; to

14 “(ii) the total number of units of such
15 dosage form and strength of such drug dis-
16 pensed during such six month period; and

17 “(4) the new drug weighted average price, with
18 respect to each package size of such dosage form
19 and strength of such rebatable covered part D drug
20 dispensed during the six month period that begins
21 on the day on which the drug was first marketed,
22 is the sum of the products of—

23 “(A) each price, as calculated for a unit of
24 such drug, applicable to each package size of
25 such dosage form and strength of such drug

1 during the six month period that begins on the
2 day on which the drug was first marketed; and

3 “(B) the ratio of—

4 “(i) the number of days for which
5 each such price is applicable during such
6 six month period; to

7 “(ii) the total number of days in such
8 six month period.

9 “(d) REBATE DEPOSITS.—Amounts paid as rebates
10 under subsection (b) shall be deposited into the Federal
11 Supplementary Medical Insurance Trust Fund established
12 under section 1841.

13 “(e) ADMINISTRATION.—

14 “(1) PERIODIC AUDITS.—The Secretary shall
15 permit a manufacturer of a rebatable covered part
16 D drug to conduct periodic audits, directly or
17 through contracts, of the data and information used
18 to determine the rebate amount for such drug under
19 this section.

20 “(2) SPECIAL RULES FOR CALCULATION OF
21 BENCHMARK UNIT-WEIGHTED PRICE AND BENCH-
22 MARK-UNIT-WEIGHTED AVERAGE PRICE.—

23 “(A) BENCHMARK UNIT-WEIGHTED
24 PRICE.—In the case that the benchmark unit-
25 weighted price of a dosage form and strength of

1 a rebatable covered part D drug is determined
2 under subsection (b)(3)(B) to be \$0 due to no
3 units of such dosage form and strength of such
4 drug being dispensed on July 1, 2019, the Sec-
5 retary may use a calculation, as determined ap-
6 propriate by the Secretary, to determine the
7 benchmark-unit weighted price for such dosage
8 form and strength of such drug that is different
9 than the calculation described in such sub-
10 section.

11 “(B) BENCHMARK UNIT-WEIGHTED AVER-
12 AGE PRICE.—In the case that the benchmark
13 unit-weighted average price of a dosage form
14 and strength of a rebatable covered part D
15 drug described under subsection (c) is deter-
16 mined under paragraph (3) of such subsection
17 to be \$0 due to no units of such dosage form
18 and strength of such drug being dispensed dur-
19 ing the six month period that begins on the day
20 on which the drug was first marketed, the Sec-
21 retary may use a calculation, as determined ap-
22 propriate by the Secretary, to determine the
23 benchmark-unit weighted average price for such
24 dosage form and strength of such drug that is

1 different than the calculation described in such
2 paragraph.

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

6 “(4) JUDICIAL REVIEW.—There shall be no ad-
7 ministrative or judicial review under section 1869,
8 section 1878, or otherwise of the determination of
9 the rebate amount under subsection (b), including
10 with respect to a subsequently approved drug pursu-
11 ant to subsection (c), including—

12 “(A) the determination of—

13 “(i) the total number of units of each
14 rebatable covered part D drug under sub-
15 section (b)(1)(A);

16 “(ii) the unit-weighted average price
17 under subsection (b)(2);

18 “(iii) the inflation-adjusted price
19 under subsection (b)(3);

20 “(iv) the benchmark unit-weighted av-
21 erage price under subsection (c)(3); and

22 “(v) the new drug weighted average
23 price under subsection (c)(4); and

24 “(B) the application of special rules for
25 calculation of benchmark unit-weighted price

1 and benchmark unit-weighted average price
2 under paragraph (2) of this subsection.

3 “(f) CIVIL MONEY PENALTY.—

4 “(1) IN GENERAL.—The Secretary shall impose
5 a civil money penalty on a manufacturer that fails
6 to comply with the requirements under subsection
7 (a)(2) with respect to providing a rebate for a
8 rebtable covered part D drug for a rebate period
9 for each such failure in an amount equal to the sum
10 of—

11 “(A) the rebate amount determined pursu-
12 ant to subsection (b) for such drug for such re-
13 bate period; and

14 “(B) 25 percent of such amount.

15 “(2) APPLICATION.—The provisions of section
16 1128A (other than subsections (a) and (b)) shall
17 apply to a civil money penalty under this subsection
18 in the same manner as such provisions apply to a
19 penalty or proceeding under section 1128A(a).

20 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-
21 tion shall be construed as having any effect on—

22 “(1) any formulary design under section
23 1860D–4(b)(3); or

24 “(2) any discounts provided under the coverage
25 gap discount program under section 1860D–14A or

1 the manufacturer catastrophic discount program
2 under section 1860D–14B.

3 “(h) REBATE AGREEMENT.—

4 “(1) IN GENERAL.—The Secretary shall enter
5 into agreements described in paragraph (2) with
6 manufacturers.

7 “(2) TERMS OF AGREEMENT.—

8 “(A) IN GENERAL.—A rebate agreement
9 under this paragraph shall require the manu-
10 facturer to provide to the Secretary rebates re-
11 quired under subsection (a)(2)(A) with respect
12 to a rebate period.

13 “(B) MANUFACTURER PROVISION OF
14 PRICE AND DRUG PRODUCT INFORMATION.—
15 Each manufacturer with an agreement in effect
16 under this subsection shall report to the Sec-
17 retary, with respect to each rebatable covered
18 part D drug of the manufacturer, at a time
19 specified by the Secretary—

20 “(i) for each calendar month under
21 the rebate agreement—

22 “(I) each wholesale acquisition
23 cost (as defined in section
24 1847A(c)(6)) applicable during the
25 month, applicable to each National

1 Drug Code for the dosage form and
2 strength of such rebatable covered
3 part D drug; and

4 “(II) the number of days with re-
5 spect to which each wholesale acquisi-
6 tion cost reported was applicable;

7 “(ii) the wholesale acquisition cost (as
8 so defined) applicable on July 1, 2019, ap-
9 plicable to each National Drug Code for
10 the dosage form and strength of such
11 rebatable covered part D drug (or, in the
12 case of a rebatable covered part D drug
13 first approved or licensed by the Food and
14 Drug Administration after July 1, 2019,
15 each wholesale acquisition cost applicable
16 to each National Drug Code of each dos-
17 age form and strength of the rebatable
18 covered part D drug of the manufacturer
19 during the six month period that begins on
20 the day on which the drug was first mar-
21 keted); and

22 “(iii) such other information as the
23 Secretary shall require.

1 Information reported under this subparagraph
2 is subject to audit by the Inspector General of
3 the Department of Health and Human Services.

4 “(3) CIVIL MONEY PENALTIES.—The provisions
5 of subparagraph (C) of section 1927(b)(3) shall
6 apply with respect to information required pursuant
7 to paragraph (2)(B) of this subsection and the fail-
8 ure to provide such information in the same manner
9 and to the same extent as such provisions apply with
10 respect to information required under subparagraph
11 (A) of such section 1927(b)(3) and the failure to
12 provide such information.

13 “(4) COORDINATION.—The Secretary may co-
14 ordinate rebate agreements required under this sub-
15 section with agreements required under section
16 1860D–14B.

17 “(i) FUNDING.—

18 “(1) IN GENERAL.—There are appropriated to
19 the Secretary, from the Federal Supplementary
20 Medical Insurance Trust Fund established under
21 section 1841—

22 “(A) for each of calendar years 2020
23 through 2025, \$4,000,000; and

1 “(B) for each subsequent calendar year,
2 such sums as are necessary to carry out this
3 section.

4 “(2) AVAILABILITY.—Amounts appropriated
5 under paragraph (1) shall remain available until ex-
6 pended.”.

7 (b) CONFORMING AMENDMENTS.—

8 (1) Section 1860D–43(a) of the Social Security
9 Act (42 U.S.C. 1395w–153(a)), as amended by sec-
10 tion 121(f)(7), is amended—

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

13 (B) in paragraph (3), by striking the pe-
14 riod at the end and inserting “; and”; and

15 (C) by adding at the end the following new
16 paragraph:

17 “(4) for 2022 and each subsequent year, have
18 entered into and have in effect an agreement de-
19 scribed in section 1860D–14C(h)(2) with the Sec-
20 retary”.

21 (2) Section 1927(c)(1)(C)(VI) of the Social Se-
22 curity Act (42 U.S.C. 1396r–8(c)(1)(C)(VI)) is
23 amended—

24 (A) by striking “or any discounts” and in-
25 serting “any discounts”; and

1 (B) by inserting “, or any rebates under
2 section 1860D–14C” before the period.

3 **SEC. 129. PROHIBITING BRANDING ON PART D BENEFIT**
4 **CARDS.**

5 (a) IN GENERAL.—Section 1851(j)(2)(B) of the So-
6 cial Security Act (42 U.S.C. 1395w–21(j)(2)(B)) is
7 amended by striking “co-branded network provider” and
8 inserting “co-branded, co-owned, or affiliated network pro-
9 vider, pharmacy, or pharmacy benefit manager”.

10 (b) EFFECTIVE DATE.—The amendment made by
11 subsection (a) shall apply to plan years beginning on or
12 after January 1, 2022.

13 **SEC. 130. REQUIRING PRESCRIPTION DRUG PLANS AND**
14 **MA-PD PLANS TO REPORT POTENTIAL**
15 **FRAUD, WASTE, AND ABUSE TO THE SEC-**
16 **RETARY OF HHS.**

17 Section 1860D–4 of the Social Security Act (42
18 U.S.C. 1395w–104), as amended by section 125, is
19 amended by adding at the end the following new sub-
20 section:

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

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

5 “(2) any steps made by the PDP sponsor after
6 identifying such activities to take corrective ac-
7 tions.”.

8 **SEC. 131. ESTABLISHMENT OF PHARMACY QUALITY MEAS-**
9 **URES UNDER MEDICARE PART D.**

10 Section 1860D–4(c) of the Social Security Act (42
11 U.S.C. 1395w–104(c)), as amended by section 126, is
12 amended by adding at the end the following new para-
13 graph:

14 “(8) APPLICATION OF PHARMACY QUALITY
15 MEASURES.—

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

23 “(B) STANDARD PHARMACY QUALITY
24 MEASURES.—The Secretary shall establish or
25 approve standard quality measures from a con-

1 sensus and evidence-based organization for pay-
 2 ments described in subparagraph (A). Such
 3 measures shall focus on patient health outcomes
 4 and be based on proven criteria measuring
 5 pharmacy performance.

6 “(C) EFFECTIVE DATE.—The requirement
 7 under subparagraph (A) shall take effect for
 8 plan years beginning on or after January 1,
 9 2023, or such earlier date specified by the Sec-
 10 retary if the Secretary determines there are suf-
 11 ficient measures established or approved under
 12 subparagraph (B) to meet the requirement
 13 under subparagraph (A).”.

14 **SEC. 132. ADDITION OF NEW MEASURES BASED ON ACCESS**
 15 **TO BIOSIMILAR BIOLOGICAL PRODUCTS TO**
 16 **THE 5-STAR RATING SYSTEM UNDER MEDI-**
 17 **CARE ADVANTAGE.**

18 (a) IN GENERAL.—Section 1853(o)(4) of the Social
 19 Security Act (42 U.S.C. 1395w–23(o)(4)) is amended by
 20 adding at the end the following new subparagraph:

21 “(E) ADDITION OF NEW MEASURES BASED
 22 ON ACCESS TO BIOSIMILAR BIOLOGICAL PROD-
 23 UCTS.—

24 “(i) IN GENERAL.—For 2025 and
 25 subsequent years, the Secretary shall add a

1 new set of measures to the 5-star rating
2 system based on access to biosimilar bio-
3 logical products covered under part B and,
4 in the case of MA–PD plans, such prod-
5 ucts that are covered part D drugs. Such
6 measures shall assess the impact a plan’s
7 benefit structure may have on enrollees’
8 utilization of or ability to access biosimilar
9 biological products, including in compari-
10 son to the reference biological product, and
11 shall include measures, as applicable, with
12 respect to the following:

13 “(I) COVERAGE.—Assessing
14 whether a biosimilar biological prod-
15 uct is on the plan formulary in lieu of
16 or in addition to the reference biologi-
17 cal product.

18 “(II) PREFERENCING.—Assess-
19 ing tier placement or cost-sharing for
20 a biosimilar biological product relative
21 to the reference biological product.

22 “(III) UTILIZATION MANAGE-
23 MENT TOOLS.—Assessing whether and
24 how utilization management tools are
25 used with respect to a biosimilar bio-

1 logical product relative to the ref-
2 erence biological product.

3 “(IV) UTILIZATION.—Assessing
4 the percentage of enrollees prescribed
5 the biosimilar biological product and
6 the percentage of enrollees prescribed
7 the reference biological product when
8 the reference biological product is also
9 on the plan formulary.

10 “(ii) DEFINITIONS.—In this subpara-
11 graph, the terms ‘biosimilar biological
12 product’ and ‘reference biological product’
13 have the meaning given those terms in sec-
14 tion 1847A(c)(6).

15 “(iii) PROTECTING PATIENT INTER-
16 ESTS.—In developing such measures, the
17 Secretary shall ensure that each measure
18 developed to address coverage,
19 preferencing, or utilization management is
20 constructed such that patients retain ac-
21 cess to appropriate therapeutic options
22 without undue administrative burden.”.

23 (b) CLARIFICATION REGARDING APPLICATION TO
24 PRESCRIPTION DRUG PLANS.—To the extent the Sec-
25 retary of Health and Human Services applies the 5-star

1 rating system under section 1853(o)(4) of the Social Secu-
2 rity Act (42 U.S.C. 1395w-23(o)(4)), or a similar system,
3 to prescription drug plans under part D of title XVIII of
4 such Act, the provisions of subparagraph (E) of such sec-
5 tion, as added by subsection (a) of this section, shall apply
6 under the system with respect to such plans in the same
7 manner as such provisions apply to the 5-star rating sys-
8 tem under such section 1853(o)(4).

9 **SEC. 133. HHS STUDY AND REPORT ON THE INFLUENCE OF**
10 **PHARMACEUTICAL MANUFACTURER THIRD-**
11 **PARTY REIMBURSEMENT HUBS ON HEALTH**
12 **CARE PROVIDERS WHO PRESCRIBE THEIR**
13 **DRUGS AND BIOLOGICALS.**

14 (a) STUDY.—

15 (1) IN GENERAL.—The Secretary of Health and
16 Human Services (in this section referred to as the
17 “Secretary”) shall conduct a study on the influence
18 of pharmaceutical manufacturer distribution models
19 that provide third-party reimbursement hub services
20 on health care providers who prescribe the manufac-
21 turer’s drugs and biologicals, including for Medicare
22 part D beneficiaries.

23 (2) REQUIREMENTS.—The study under para-
24 graph (1) shall include an analysis of the following:

1 (A) The influence of pharmaceutical manu-
2 facturer distribution models that provide third-
3 party reimbursement hub services to health care
4 providers who prescribe the manufacturer's
5 drugs and biologicals, including—

6 (i) the operations of pharmaceutical
7 manufacturer distribution models that pro-
8 vide reimbursement hub services for health
9 care providers who prescribe the manufac-
10 turer's products;

11 (ii) Federal laws affecting these phar-
12 maceutical manufacturer distribution mod-
13 els; and

14 (iii) whether hub services could im-
15 properly incentivize health care providers
16 to deem a drug or biological as medically
17 necessary under section 423.578 of title
18 42, Code of Federal Regulations.

19 (B) Other areas determined appropriate by
20 the Secretary.

21 (b) REPORT.—Not later than January 1, 2021, the
22 Secretary shall submit to Congress a report on the study
23 conducted under subsection (a), together with rec-
24 ommendations for such legislation and administrative ac-
25 tion as the Secretary determines appropriate.

1 (c) CONSULTATION.—In conducting the study under
 2 subsection (a) and preparing the report under subsection
 3 (b), the Secretary shall consult with the Attorney General.

4 **Subtitle C—Miscellaneous**

5 **SEC. 141. DRUG MANUFACTURER PRICE TRANSPARENCY.**

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

9 **“SEC. 1128L. DRUG MANUFACTURER PRICE TRANS-** 10 **PARENCY.**

11 “(a) IN GENERAL.—

12 “(1) DETERMINATIONS.—Beginning July 1,
 13 2022, the Secretary shall make determinations as to
 14 whether a drug is an applicable drug as described in
 15 subsection (b).

16 “(2) REQUIRED JUSTIFICATION.—If the Sec-
 17 retary determines under paragraph (1) that an ap-
 18 plicable drug is described in subsection (b), the man-
 19 ufacturer of the applicable drug shall submit to the
 20 Secretary the justification described in subsection (c)
 21 in accordance with the timing described in sub-
 22 section (d).

23 “(b) APPLICABLE DRUG DESCRIBED.—

1 “(1) IN GENERAL.—An applicable drug is de-
2 scribed in this subsection if it meets any of the fol-
3 lowing at the time of the determination:

4 “(A) LARGE INCREASE.—The drug (per
5 dose)—

6 “(i) has a wholesale acquisition cost of
7 at least \$10; and

8 “(ii) had an increase in the wholesale
9 acquisition cost, with respect to determina-
10 tions made—

11 “(I) during 2020, of at least 100
12 percent since the date of the enact-
13 ment of this section;

14 “(II) during 2021, of at least
15 100 percent in the preceding 12
16 months or of at least 150 percent in
17 the preceding 24 months;

18 “(III) during 2022, of at least
19 100 percent in the preceding 12
20 months or of at least 200 percent in
21 the preceding 36 months;

22 “(IV) during 2023, of at least
23 100 percent in the preceding 12
24 months or of at least 250 percent in
25 the preceding 48 months; or

1 “(V) on or after January 1,
2 2024, of at least 100 percent in the
3 preceding 12 months or of at least
4 300 percent in the preceding 60
5 months.

6 “(B) HIGH SPENDING WITH INCREASE.—

7 The drug—

8 “(i) was in the top 50th percentile of
9 net spending under title XVIII or XIX (to
10 the extent data is available) during any 12-
11 month period in the preceding 60 months;
12 and

13 “(ii) per dose, had an increase in the
14 wholesale acquisition cost, with respect to
15 determinations made—

16 “(I) during 2020, of at least 15
17 percent since the date of the enact-
18 ment of this section;

19 “(II) during 2021, of at least 15
20 percent in the preceding 12 months or
21 of at least 20 percent in the preceding
22 24 months;

23 “(III) during 2022, of at least 15
24 percent in the preceding 12 months or

1 of at least 30 percent in the preceding
2 36 months;

3 “(IV) during 2023, of at least 15
4 percent in the preceding 12 months or
5 of at least 40 percent in the preceding
6 48 months; or

7 “(V) on or after January 1,
8 2024, of at least 15 percent in the
9 preceding 12 months or of at least 50
10 percent in the preceding 60 months.

11 “(C) HIGH LAUNCH PRICE FOR NEW
12 DRUGS.—In the case of a drug that is marketed
13 for the first time on or after January 1, 2020,
14 and for which the manufacturer has established
15 the first wholesale acquisition cost on or after
16 such date, such wholesale acquisition cost for a
17 year’s supply or a course of treatment for such
18 drug exceeds the gross spending for covered
19 part D drugs at which the annual out-of-pocket
20 threshold under section 1860D–2(b)(4)(B)
21 would be met for the year.

22 “(2) SPECIAL RULES.—

23 “(A) AUTHORITY OF SECRETARY TO SUB-
24 STITUTE PERCENTAGES WITHIN A DE MINIMIS
25 RANGE.—For purposes of applying paragraph

1 (1), the Secretary may substitute for each per-
2 centage described in subparagraph (A) or (B)
3 of such paragraph (other than the percentile de-
4 scribed subparagraph (B)(i) of such paragraph)
5 a percentage within a de minimis range speci-
6 fied by the Secretary below the percentage so
7 described.

8 “(B) DRUGS WITH HIGH LAUNCH PRICES
9 ANNUALLY REPORT UNTIL A THERAPEUTIC
10 EQUIVALENT IS AVAILABLE.—In the case of a
11 drug that the Secretary determines is an appli-
12 cable drug described in subparagraph (C) of
13 paragraph (1), such drug shall remain de-
14 scribed in such subparagraph (C) (and the
15 manufacturer of such drug shall annually re-
16 port the justification under subsection (c)(2))
17 until the Secretary determines that there is a
18 therapeutic equivalent (as defined in section
19 314.3 of title 21, Code of Federal Regulations,
20 or any successor regulation) for such drug.

21 “(3) DOSE.—For purposes of applying para-
22 graph (1), the Secretary shall establish a definition
23 of the term ‘dose’.

24 “(c) JUSTIFICATION DESCRIBED.—

1 “(1) INCREASE IN WAC.—In the case of a drug
2 that the Secretary determines is an applicable drug
3 described in subparagraph (A) or (B) of subsection
4 (b)(1), the justification described in this subsection
5 is all relevant, truthful, and nonmisleading informa-
6 tion and supporting documentation necessary to jus-
7 tify the increase in the wholesale acquisition cost of
8 the applicable drug of the manufacturer, as deter-
9 mined appropriate by the Secretary and which may
10 include the following:

11 “(A) The individual factors that have con-
12 tributed to the increase in the wholesale acqui-
13 sition cost.

14 “(B) An explanation of the role of each
15 factor in contributing to such increase.

16 “(C) Total expenditures of the manufac-
17 turer on—

18 “(i) materials and manufacturing for
19 such drug;

20 “(ii) acquiring patents and licensing
21 for each drug of the manufacturer; and

22 “(iii) costs to purchase or acquire the
23 drug from another company, if applicable.

24 “(D) The percentage of total expenditures
25 of the manufacturer on research and develop-

1 ment for such drug that was derived from Fed-
2 eral funds.

3 “(E) The total expenditures of the manu-
4 facturer on research and development for such
5 drug.

6 “(F) The total revenue and net profit gen-
7 erated from the applicable drug for each cal-
8 endar year since drug approval.

9 “(G) The total expenditures of the manu-
10 facturer that are associated with marketing and
11 advertising for the applicable drug.

12 “(H) Additional information specific to the
13 manufacturer of the applicable drug, such as—

14 “(i) the total revenue and net profit of
15 the manufacturer for the period of such in-
16 crease, as determined by the Secretary;

17 “(ii) metrics used to determine execu-
18 tive compensation;

19 “(iii) any additional information re-
20 lated to drug pricing decisions of the man-
21 ufacturer, such as total expenditures on—

22 “(I) drug research and develop-
23 ment; or

1 “(II) clinical trials on drugs that
2 failed to receive approval by the Food
3 and Drug Administration.

4 “(2) HIGH LAUNCH PRICE.—In the case of a
5 drug that the Secretary determines is an applicable
6 drug described in subparagraph (C) of subsection
7 (b)(1), the justification described in this subsection
8 is all relevant, truthful, and nonmisleading informa-
9 tion and supporting documentation necessary to jus-
10 tify the wholesale acquisition cost of the applicable
11 drug of the manufacturer, as determined by the Sec-
12 retary and which may include the items described in
13 subparagraph (C) through (H) of paragraph (1).

14 “(d) TIMING.—

15 “(1) NOTIFICATION.—Not later than 60 days
16 after the date on which the Secretary makes the de-
17 termination that a drug is an applicable drug under
18 subsection (b), the Secretary shall notify the manu-
19 facturer of the applicable drug of such determina-
20 tion.

21 “(2) SUBMISSION OF JUSTIFICATION.—Not
22 later than 180 days after the date on which a manu-
23 facturer receives a notification under paragraph (1),
24 the manufacturer shall submit to the Secretary the
25 justification required under subsection (a).

1 “(3) POSTING ON INTERNET WEBSITE.—

2 “(A) IN GENERAL.—Subject to subpara-
3 graph (B), not later than 30 days after receiv-
4 ing the justification under paragraph (2), the
5 Secretary shall post on the Internet website of
6 the Centers for Medicare & Medicaid Services
7 the justification, together with a summary of
8 such justification that is written and formatted
9 using language that is easily understandable by
10 beneficiaries under titles XVIII and XIX.

11 “(B) EXCLUSION OF PROPRIETARY INFOR-
12 MATION.—The Secretary shall exclude propri-
13 etary information, such as trade secrets and in-
14 tellectual property, submitted by the manufac-
15 turer in the justification under paragraph (2)
16 from the posting described in subparagraph
17 (A).

18 “(e) EXCEPTION TO REQUIREMENT FOR SUBMIS-
19 SION.—In the case of a drug that the Secretary deter-
20 mines is an applicable drug described in subparagraph (A)
21 or (B) of subsection (b)(1), the requirement to submit a
22 justification under subsection (a) shall not apply where the
23 manufacturer, after receiving the notification under sub-
24 section (d)(1) with respect to the applicable drug of the
25 manufacturer, reduces the wholesale acquisition cost of a

1 drug so that it no longer is described in such subpara-
2 graph (A) or (B) for at least a 4-month period, as deter-
3 mined by the Secretary.

4 “(f) PENALTIES.—

5 “(1) FAILURE TO SUBMIT TIMELY JUSTIFICA-
6 TION.—If the Secretary determines that a manufac-
7 turer has failed to submit a justification as required
8 under this section, including in accordance with the
9 timing and form required, with respect to an appli-
10 cable drug, the Secretary shall apply a civil mone-
11 tary penalty in an amount of \$10,000 for each day
12 the manufacturer has failed to submit such justifica-
13 tion as so required.

14 “(2) FALSE INFORMATION.—Any manufacturer
15 that submits a justification under this section and
16 knowingly provides false information in such jus-
17 tification is subject to a civil monetary penalty in an
18 amount not to exceed \$100,000 for each item of
19 false information.

20 “(3) APPLICATION OF PROCEDURES.—The pro-
21 visions of section 1128A (other than subsections (a)
22 and (b)) shall apply to a civil monetary penalty
23 under this subsection in the same manner as such
24 provisions apply to a penalty or proceeding under
25 section 1128A(a). Civil monetary penalties imposed

1 under this subsection are in addition to other pen-
2 alties as may be prescribed by law.

3 “(g) DEFINITIONS.—In this section:

4 “(1) DRUG.—The term ‘drug’ means a drug, as
5 defined in section 201(g) of the Federal Food, Drug,
6 and Cosmetic Act, that is intended for human use
7 and subject to section 503(b)(1) of such Act, includ-
8 ing a product licensed under section 351 of the Pub-
9 lic health Service Act.

10 “(2) MANUFACTURER.—The term ‘manufac-
11 turer’ has the meaning given that term in section
12 1847A(c)(6)(A).

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

16 **SEC. 142. STRENGTHENING AND EXPANDING PHARMACY**
17 **BENEFIT MANAGERS TRANSPARENCY RE-**
18 **QUIREMENTS.**

19 Section 1150A of the Social Security Act (42 U.S.C.
20 1320b–23), as amended by section 123, is amended—

21 (1) in subsection (a)—

22 (A) in paragraph (1), by striking “or” at
23 then end;

24 (B) in paragraph (2), by striking the
25 comma at the end and inserting “; or”; and

1 (C) by inserting after paragraph (2) the
2 following new paragraph:

3 “(3) a State plan under title XIX, including a
4 managed care entity (as defined in section
5 1932(a)(1)(B)),”;

6 (2) in subsection (b)—

7 (A) in paragraph (2)—

8 (i) by striking “(excluding bona fide”
9 and all that follows through “patient edu-
10 cation programs))”; and

11 (ii) by striking “aggregate amount of”
12 and inserting “aggregate amount and per-
13 centage of”;

14 (B) in paragraph (3), by striking “aggre-
15 gate amount of” and inserting “aggregate
16 amount and percentage (defined as a share of
17 gross drug costs) of”; and

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

20 “(4) The aggregate amount of bona fide service
21 fees (which include distribution service fees, inven-
22 tory management fees, product stocking allowances,
23 and fees associated with administrative services
24 agreements and patient care programs (such as

1 medication compliance programs and patient edu-
2 cation programs)) the PBM received from—

3 “(A) PDP sponsors;

4 “(B) qualified health benefit plans;

5 “(C) managed care entities (as defined in
6 section 1932(a)(1)(b)); and

7 “(D) drug manufacturers.”;

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

10 “(5) To States to carry out their administration
11 and oversight of the State plan under title XIX.

12 “(6) To the Federal Trade Commission to carry
13 out section 5(a) of the Federal Trade Commission
14 Act (15 U.S.C. 45a) and any other relevant con-
15 sumer protection or antitrust authorities enforced by
16 such Commission, including reviewing proposed
17 mergers in the prescription drug sector.

18 “(7) To assist the Department of Justice to
19 carry out its antitrust authorities, including review-
20 ing proposed mergers in the prescription drug sec-
21 tor.”; and

22 (4) by adding at the end the following new sub-
23 section:

24 “(f) ANNUAL OIG EVALUATION AND REPORT.—

1 “(1) ANALYSIS.—The Inspector General of the
2 Department of Health and Human Services shall
3 conduct an annual evaluation of the information pro-
4 vided to the Secretary under this section. Such eval-
5 uation shall include an analysis of—

6 “(A) PBM rebates;

7 “(B) administrative fees;

8 “(C) the difference between what plans pay
9 PBMs and what PBMs pay pharmacies;

10 “(D) generic dispensing rates; and

11 “(E) other areas determined appropriate
12 by the Inspector General.

13 “(2) REPORT.—Not later than July 1, 2020,
14 and annually thereafter, the Inspector General of the
15 Department of Health and Human Services shall
16 submit to Congress a report containing the results
17 of the evaluation conducted under paragraph (1), to-
18 gether with recommendations for such legislation
19 and administrative action as the Inspector General
20 determines appropriate. Such report shall not dis-
21 close the identity of a specific PBM, plan, or price
22 charged for a drug.”.

23 **SEC. 143. PRESCRIPTION DRUG PRICING DASHBOARDS.**

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. 1150C. PRESCRIPTION DRUG PRICING DASHBOARDS.**

2 “(a) IN GENERAL.—Beginning not later than Janu-
3 ary 1, 2020, the Secretary shall establish, and annually
4 update, internet website-based dashboards, through which
5 beneficiaries, clinicians, researchers, and the public can re-
6 view information on spending for, and utilization of, pre-
7 scription drugs and biologicals (and related supplies and
8 mechanisms of delivery) covered under each of parts B
9 and D of title XVIII and under a State program under
10 title XIX, including information on trends of such spend-
11 ing and utilization over time.

12 “(b) MEDICARE PART B DRUG AND BIOLOGICAL
13 DASHBOARD.—

14 “(1) IN GENERAL.—The dashboard established
15 under subsection (a) for part B of title XVIII shall
16 provide the information described in paragraph (2).

17 “(2) INFORMATION DESCRIBED.—The informa-
18 tion described in this paragraph is the following in-
19 formation with respect to drug or biologicals covered
20 under such part B:

21 “(A) The brand name and, if applicable,
22 the generic names of the drug or biological.

23 “(B) Consumer-friendly information on the
24 uses and clinical indications of the drug or bio-
25 logical.

1 “(C) The manufacturer or labeler of the
2 drug or biological.

3 “(D) To the extent feasible, the following
4 information:

5 “(i) Average total spending per dos-
6 age unit of the drug or biological in the
7 most recent 2 calendar years for which
8 data is available.

9 “(ii) The percentage change in aver-
10 age spending on the drug or biological per
11 dosage unit between the most recent cal-
12 endar year for which data is available
13 and—

14 “(I) the preceding calendar year;
15 and

16 “(II) the preceding 5 and 10 cal-
17 endar years.

18 “(iii) The annual growth rate in aver-
19 age spending per dosage unit of the drug
20 or biological in the most recent 5 or 10
21 calendar years for which data is available.

22 “(iv) Total spending for the drug or
23 biological for the most recent calendar year
24 for which data is available.

1 “(v) The number of beneficiaries re-
2 ceiving the drug or biological in the most
3 recent calendar year for which data is
4 available.

5 “(vi) Average spending on the drug
6 per beneficiary for the most recent cal-
7 endar year for which data is available.

8 “(E) The average sales price of the drug
9 or biological (as determined under section
10 1847A) for the most recent quarter.

11 “(F) Consumer-friendly information about
12 the coinsurance amount for the drug or biologi-
13 cal for beneficiaries for the most recent quarter.
14 Such information shall not include coinsurance
15 amounts for qualified medicare beneficiaries (as
16 defined in section 1905(p)(1)).

17 “(G) For the most recent calendar year for
18 which data is available—

19 “(i) the 15 drugs and biologicals with
20 the highest total spending under such part;
21 and

22 “(ii) any drug or biological for which
23 the average annual per beneficiary spend-
24 ing exceeds the gross spending for covered
25 part D drugs at which the annual out-of-

1 pocket threshold under section 1860D–
2 2(b)(4)(B) would be met for the year.

3 “(H) Other information (not otherwise
4 prohibited in law from being disclosed) that the
5 Secretary determines would provide bene-
6 ficiaries, clinicians, researchers, and the public
7 with helpful information about drug and bio-
8 logical spending and utilization (including
9 trends of such spending and utilization).

10 “(c) MEDICARE COVERED PART D DRUG DASH-
11 BOARD.—

12 “(1) IN GENERAL.—The dashboard established
13 under subsection (a) for part D of title XVIII shall
14 provide the information described in paragraph (2).

15 “(2) INFORMATION DESCRIBED.—The informa-
16 tion described in this paragraph is the following in-
17 formation with respect to covered part D drugs
18 under such part D:

19 “(A) The information described in sub-
20 paragraphs (A) through (D) of subsection
21 (b)(2).

22 “(B) Information on average annual bene-
23 ficiary out-of-pocket costs below and above the
24 annual out-of-pocket threshold under section
25 1860D–2(b)(4)(B) for the current plan year.

1 Such information shall not include out-of-pocket
2 costs for subsidy eligible individuals under sec-
3 tion 1860D–14.

4 “(C) Information on how to access re-
5 sources as described in sections 1860D–1(e)
6 and 1851(d).

7 “(D) For the most recent calendar year for
8 which data is available—

9 “(i) the 15 covered part D drugs with
10 the highest total spending under such part;
11 and

12 “(ii) any covered part D drug for
13 which the average annual per beneficiary
14 spending exceeds the gross spending for
15 covered part D drugs at which the annual
16 out-of-pocket threshold under section
17 1860D–2(b)(4)(B) would be met for the
18 year.

19 “(E) Other information (not otherwise pro-
20 hibited in law from being disclosed) that the
21 Secretary determines would provide bene-
22 ficiaries, clinicians, researchers, and the public
23 with helpful information about covered part D
24 drug spending and utilization (including trends
25 of such spending and utilization).

1 “(d) MEDICAID COVERED OUTPATIENT DRUG DASH-
2 BOARD.—

3 “(1) IN GENERAL.—The dashboard established
4 under subsection (a) for title XIX shall provide the
5 information described in paragraph (2).

6 “(2) INFORMATION DESCRIBED.—The informa-
7 tion described in this paragraph is the following in-
8 formation with respect to covered outpatient drugs
9 under such title:

10 “(A) The information described in sub-
11 paragraphs (A) through (D) of subsection
12 (b)(2).

13 “(B) For the most recent calendar year for
14 which data is available, the 15 covered out-
15 patient drugs with the highest total spending
16 under such title.

17 “(C) Other information (not otherwise pro-
18 hibited in law from being disclosed) that the
19 Secretary determines would provide bene-
20 ficiaries, clinicians, researchers, and the public
21 with helpful information about covered out-
22 patient drug spending and utilization (including
23 trends of such spending and utilization).

1 “(e) DATA FILES.—The Secretary shall make avail-
2 able the underlying data for each dashboard established
3 under subsection (a) in a machine-readable format.”.

4 **SEC. 144. IMPROVING COORDINATION BETWEEN THE FOOD**
5 **AND DRUG ADMINISTRATION AND THE CEN-**
6 **TERS FOR MEDICARE & MEDICAID SERVICES.**

7 (a) IN GENERAL.—

8 (1) PUBLIC MEETING.—

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

21 (B) ATTENDEES.—The public meeting
22 shall include—

23 (i) representatives of relevant Federal
24 agencies, including representatives from
25 each of the medical product centers within

1 the Food and Drug Administration and
2 representatives from the coding, coverage,
3 and payment offices within the Centers for
4 Medicare & Medicaid Services;

5 (ii) stakeholders with expertise in the
6 research and development of novel medical
7 products, including manufacturers of such
8 products;

9 (iii) representatives of commercial
10 health insurance payers;

11 (iv) stakeholders with expertise in the
12 administration and use of novel medical
13 products, including physicians; and

14 (v) stakeholders representing patients
15 and with expertise in the utilization of pa-
16 tient experience data in medical product
17 development.

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

20 (i) the status of the drug and medical
21 device development pipeline related to the
22 availability of novel medical products;

23 (ii) the anticipated expertise necessary
24 to review the safety and effectiveness of
25 such products at the Food and Drug Ad-

1 ministration and current gaps in such ex-
2 pertise, if any;

3 (iii) the expertise necessary to make
4 coding, coverage, and payment decisions
5 with respect to such products within the
6 Centers for Medicare & Medicaid Services,
7 and current gaps in such expertise, if any;

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

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

21 (vi) the coordination of information
22 related to significant clinical improvement
23 over existing therapies for patients between
24 the Food and Drug Administration and the

1 Centers for Medicare & Medicaid Services
2 with respect to novel medical products.

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

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

12 (A) DRAFT GUIDANCE.—Not later than 18
13 months after the public meeting under para-
14 graph (1), the Secretary shall update the final
15 guidance titled “National Coverage Determina-
16 tions with Data Collection as a Condition of
17 Coverage: Coverage with Evidence Develop-
18 ment” to address any opportunities to improve
19 the availability and coordination of information
20 as described in clauses (iv) through (vi) of para-
21 graph (1)(C).

22 (B) FINAL GUIDANCE.—Not later than 12
23 months after issuing draft guidance under sub-
24 paragraph (A), the Secretary shall finalize the

1 updated guidance to address any such opportu-
2 nities.

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

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

17 (2) Recommendations to—

18 (A) incorporate patient experience data
19 (such as the impact of a disease or condition on
20 the lives of patients and patient treatment pref-
21 erences) into the coverage and payment proc-
22 esses within the Centers for Medicare & Med-
23 icaid Services;

24 (B) decrease the length of time to make
25 national and local coverage determinations

1 under the Medicare program (as those terms
2 are defined in subparagraph (A) and (B), re-
3 spectively, of section 1862(l)(6) of the Social
4 Security Act (42 U.S.C. 1395y(l)(6));

5 (C) streamline the coverage process under
6 the Medicare program and incorporate input
7 from relevant stakeholders into such coverage
8 determinations; and

9 (D) identify potential mechanisms to incor-
10 porate novel payment designs similar to those
11 in development in commercial insurance plans
12 and State plans under title XIX of such Act
13 (42 U.S.C. 1396 et seq.) into the Medicare pro-
14 gram.

15 (c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For
16 purposes of this section, a novel medical product described
17 in this subsection is a medical product, including a drug,
18 biological (including gene and cell therapy), or medical de-
19 vice, that has been designated as a breakthrough therapy
20 under section 506(a) of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 356(a)), a breakthrough device
22 under section 515B of such Act (21 U.S.C. 360e–3), or
23 a regenerative advanced therapy under section 506(g) of
24 such Act (21 U.S.C. 356(g)).

1 **SEC. 145. PATIENT CONSULTATION IN MEDICARE NA-**
2 **TIONAL AND LOCAL COVERAGE DETERMINA-**
3 **TIONS IN ORDER TO MITIGATE BARRIERS TO**
4 **INCLUSION OF SUCH PERSPECTIVES.**

5 Section 1862(l) of the Social Security Act (42 U.S.C.
6 1395y(l)) is amended by adding at the end the following
7 new paragraph:

8 “(7) PATIENT CONSULTATION IN NATIONAL
9 AND LOCAL COVERAGE DETERMINATIONS.—The Sec-
10 retary may consult with patients and organizations
11 representing patients in making national and local
12 coverage determinations.”.

13 **SEC. 146. GAO STUDY ON INCREASES TO MEDICARE AND**
14 **MEDICAID SPENDING DUE TO COPAYMENT**
15 **COUPONS AND OTHER PATIENT ASSISTANCE**
16 **PROGRAMS.**

17 (a) STUDY.—The Comptroller General of the United
18 States shall conduct a study on the impact of copayment
19 coupons and other patient assistance programs on pre-
20 scription drug pricing and expenditures within the Medi-
21 care and Medicaid programs. The study shall assess the
22 following:

23 (1) The extent to which copayment coupons and
24 other patient assistance programs contribute to in-
25 flated prescription drug prices under such programs.

1 (2) The impact copayment coupons and other
2 patient assistance programs have in the Medicare
3 Part D program established under part D of title
4 XVIII of the Social Security Act (42 U.S.C. 1395w–
5 101 et seq.) on utilization of higher-cost brand drugs
6 and lower utilization of generic drugs in that pro-
7 gram.

8 (3) The extent to which manufacturers report
9 or obtain tax benefits, including deductions of busi-
10 ness expenses and charitable contributions, for any
11 of the following:

12 (A) Offering copayment coupons or other
13 patient assistance programs.

14 (B) Sponsoring manufacturer patient as-
15 sistance programs.

16 (C) Paying for sponsorships at outreach
17 and advocacy events organized by patient as-
18 sistance programs.

19 (4) The efficacy of oversight conducted to en-
20 sure that independent charity patient assistance pro-
21 grams adhere to guidance from the Office of the In-
22 spector General of the Department of Health and
23 Human Services on avoiding waste, fraud, and
24 abuse.

25 (b) DEFINITIONS.—In this section:

1 (1) INDEPENDENT CHARITY PATIENT ASSIST-
2 ANCE PROGRAM.—The term “independent charity
3 patient assistance program” means any organization
4 described in section 501(c)(3) of the Internal Rev-
5 enue Code of 1986 and exempt from taxation under
6 section 501(a) of such Code and which is not a pri-
7 vate foundation (as defined in section 509(a) of such
8 Code) that offers patient assistance.

9 (2) MANUFACTURER.—The term “manufac-
10 turer” has the meaning given that term in section
11 1927(k)(5) of the Social Security Act (42 U.S.C.
12 1396r–8(k)(5)).

13 (3) MANUFACTURER PATIENT ASSISTANCE PRO-
14 GRAM.—The term “manufacturer patient assistance
15 program” means an organization, including a private
16 foundation (as so defined), that is sponsored by, or
17 receives funding from, a manufacturer and that of-
18 fers patient assistance. Such term does not include
19 an independent charity patient assistance program.

20 (4) PATIENT ASSISTANCE.—The term “patient
21 assistance” means assistance provided to offset the
22 cost of drugs for individuals. Such term includes free
23 products, coupons, rebates, copay or discount cards,
24 and other means of providing assistance to individ-

1 uals related to drug costs, as determined by the Sec-
2 retary of Health and Human Services.

3 (c) REPORT.—Not later than 24 months after the
4 date of the enactment of this Act, the Comptroller General
5 of the United States shall submit to Congress a report
6 describing the findings of the study required under sub-
7 section (a).

8 **SEC. 147. MEDPAC REPORT ON SHIFTING COVERAGE OF**
9 **CERTAIN MEDICARE PART B DRUGS TO MEDI-**
10 **CARE PART D.**

11 (a) STUDY.—The Medicare Payment Advisory Com-
12 mission (in this section referred to as the “Commission”)
13 shall conduct a study on shifting coverage of certain drugs
14 and biologicals for which payment is currently made under
15 part B of title XVIII of the Social Security Act (42 U.S.C.
16 1395j et seq.) to part D of such title (42 U.S.C. 1395w-
17 21 et seq.). Such study shall include an analysis of—

18 (1) differences in program structures and pay-
19 ment methods for drugs and biologicals covered
20 under such parts B and D, including effects of such
21 a shift on program spending, beneficiary cost-shar-
22 ing liability, and utilization management techniques
23 for such drugs and biologicals; and

24 (2) the feasibility and policy implications of
25 shifting coverage of drugs and biologicals for which

1 payment is currently made under such part B to
2 such part D.

3 (b) REPORT.—

4 (1) IN GENERAL.—Not later than June 30,
5 2021, the Commission shall submit to Congress a re-
6 port containing the results of the study conducted
7 under subsection (a).

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

11 (A) formulary design under such part D;

12 (B) the ability of the benefit structure
13 under such part D to control total spending on
14 drugs and biologicals for which payment is cur-
15 rently made under such part B;

16 (C) changes to the bid process under such
17 part D, if any, that may be necessary to inte-
18 grate coverage of such drugs and biologicals
19 into such part D; and

20 (D) any other changes to the program that
21 Congress should consider in determining wheth-
22 er to shift coverage of such drugs and
23 biologicals from such part B to such part D.

1 **SEC. 148. TAKING STEPS TO FULFILL TREATY OBLIGATIONS**
2 **TO TRIBAL COMMUNITIES.**

3 (a) GAO STUDY.—The Comptroller General shall
4 conduct a study regarding access to, and the cost of, pre-
5 scription drugs among Indians. The study shall include—

6 (1) a review of what Indian health programs
7 pay for prescription drugs on reservations and in
8 urban centers relative to other consumers;

9 (2) recommendations to align the value of pre-
10 scription drug discounts available under the Med-
11 icaid drug rebate program established under section
12 1927 of the Social Security Act (42 U.S.C. 1396r-
13 8) with prescription drug discounts available to
14 Tribal communities through the purchased/referred
15 care program of the Indian Health Service for physi-
16 cian administered drugs; and

17 (3) an examination of how Tribal communities
18 and urban Indian organizations utilize the Medicare
19 part D program established under title XVIII of the
20 Social Security Act (42 U.S.C. 1395w-101 et seq.)
21 and recommendations to improve enrollment among
22 Indians in that program.

23 (b) REPORT.—Not later than 18 months after the
24 date of the enactment of this Act, the Comptroller General
25 shall submit to Congress a report containing the results
26 of the study conducted under subsection (a), together with

1 recommendations for such legislation and administrative
2 action as the Comptroller General determines appropriate.

3 (c) DEFINITIONS.—In this section:

4 (1) COMPTROLLER GENERAL.—The term
5 “Comptroller General” means the Comptroller Gen-
6 eral of the United States.

7 (2) INDIAN; INDIAN HEALTH PROGRAM; INDIAN
8 TRIBE.—The terms “Indian”, “Indian health pro-
9 gram”, and “Indian tribe” have the meanings given
10 those terms in section 4 of the Indian Health Care
11 Improvement Act (25 U.S.C. 1603).

12 **TITLE II—MEDICAID**

13 **SEC. 201. MEDICAID PHARMACY AND THERAPEUTICS COM- 14 MITTEE IMPROVEMENTS.**

15 (a) IN GENERAL.—Subparagraph (A) of section
16 1927(d)(4) of the Social Security Act (42 U.S.C. 1396r-
17 8(d)(4)) is amended to read as follows:

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

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

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

3 “(I) is publicly accessible;

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

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

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

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

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

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

7 “(II) is made publicly available.

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

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

17 “(vi) If the Secretary determines it appro-
18 priate or necessary based on the findings and
19 recommendations of the Comptroller General of
20 the United States in the report submitted to
21 Congress under section 203 of the Prescription
22 Drug Pricing Reduction Act of 2019, the Sec-
23 retary shall issue guidance that States must fol-
24 low for establishing conflict of interest policies
25 for the pharmacy and therapeutics committee in

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

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

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

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

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

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

1 **SEC. 202. IMPROVING REPORTING REQUIREMENTS AND DE-**
2 **VELOPING STANDARDS FOR THE USE OF**
3 **DRUG USE REVIEW BOARDS IN STATE MED-**
4 **ICAID PROGRAMS.**

5 (a) IN GENERAL.—Section 1927(g)(3) of the Social
6 Security Act (42 U.S.C. 1396r–8(g)(3)) is amended—

7 (1) by amending subparagraph (B) to read as
8 follows:

9 “(B) MEMBERSHIP.—

10 “(i) IN GENERAL.—The membership
11 of the DUR Board shall include health
12 care professionals who have recognized
13 knowledge and expertise in one or more of
14 the following:

15 “(I) The clinically appropriate
16 prescribing of covered outpatient
17 drugs.

18 “(II) The clinically appropriate
19 dispensing and monitoring of covered
20 outpatient drugs.

21 “(III) Drug use review, evalua-
22 tion, and intervention.

23 “(IV) Medical quality assurance.

24 “(ii) MEMBERSHIP REQUIREMENTS.—
25 The membership of the DUR Board
26 shall—

1 “(I) be made up of at least $\frac{1}{3}$
2 but no more than 51 percent members
3 who are licensed and actively prac-
4 ticing physicians and at least $\frac{1}{3}$ mem-
5 bers who are licensed and actively
6 practicing pharmacists; and

7 “(II) include at least 1 licensed
8 and actively practicing physician and
9 at least 1 licensed and actively prac-
10 ticing pharmacist, each of whom—

11 “(aa) is independent and
12 free of any conflict, including
13 with respect to manufacturers,
14 medicaid managed care entities,
15 or pharmacy benefit managers;
16 and

17 “(bb) has expertise in the
18 care of 1 or more categories of
19 individuals who are likely to be
20 eligible for benefits under this
21 title, including elderly or disabled
22 individuals, children with complex
23 medical needs, or low-income in-
24 dividuals with chronic illnesses;
25 and

1 “(III) be made publicly available.

2 “(iii) CONFLICT OF INTEREST POL-
3 ICY.—The State shall establish and imple-
4 ment a conflict of interest policy for the
5 DUR Board that—

6 “(I) is publicly accessible;

7 “(II) requires all board members
8 to complete, on at least an annual
9 basis, a disclosure of relationships, as-
10 sociations, and financial dealings that
11 may affect their independence of
12 judgement in board matters; and

13 “(III) contains clear processes,
14 such as recusal from voting or discus-
15 sion, for those members who report a
16 conflict of interest, along with appro-
17 priate processes to address any in-
18 stance where a member fails to report
19 a conflict of interest.”; and

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

22 “(E) DUR BOARD MEMBERSHIP RE-
23 PORTS.—

24 “(i) DUR BOARD REPORTS.—Each
25 State shall require the DUR Board to pre-

1 pare and submit to the State an annual re-
2 port on the DUR Board membership. Each
3 such report shall include any conflicts of
4 interest with respect to members of the
5 DUR Board that the DUR Board recorded
6 or was aware of during the period that is
7 the subject of the report, and the process
8 applied to address such conflicts of inter-
9 est, in addition to any other information
10 required by the State.

11 “(ii) INCLUSION OF DUR BOARD MEM-
12 BERSHIP INFORMATION IN STATE RE-
13 PORTS.—Each annual State report to the
14 Secretary required under subparagraph
15 (D) shall include—

16 “(I) the number of individuals
17 serving on the State’s DUR Board;

18 “(II) the names and professions
19 of the individuals serving on such
20 DUR Board;

21 “(III) any conflicts of interest or
22 recusals with respect to members of
23 such DUR Board reported by the
24 DUR Board or that the State was

1 aware of during the period that is the
2 subject of the report; and

3 “(IV) whether the State has
4 elected for such DUR Board to serve
5 as the committee responsible for de-
6 veloping a State formulary under sub-
7 section (d)(4)(A).”.

8 (b) MANAGED CARE REQUIREMENTS.—Section
9 1932(i) of the Social Security Act (42 U.S.C. 1396u–2(i))
10 is amended—

11 (1) by striking “section 483.3(s)(4)” and in-
12 serting “section 438.3(s)(4)”;

13 (2) by striking “483.3(s)(5)” and inserting
14 “438.3(s)(5)”; and

15 (3) by adding at the end the following: “Such
16 a managed care entity shall not be considered to be
17 in compliance with the requirement of such section
18 438.3(s)(5) that the entity provide a detailed de-
19 scription of its drug utilization review activities un-
20 less the entity includes a description of the prospec-
21 tive drug review activities described in paragraph
22 (2)(A) of section 1927(g) and the activities listed in
23 paragraph (3)(C) of section 1927(g), makes the un-
24 derlying drug utilization review data available to the

1 State and the Secretary, and provides such other in-
2 formation as deemed appropriate by the Secretary.”.

3 (c) DEVELOPMENT OF NATIONAL STANDARDS FOR
4 MEDICAID DRUG USE REVIEW.—The Secretary of Health
5 and Human Services may promulgate regulations or guid-
6 ance establishing national standards for Medicaid drug
7 use review programs under section 1927(g) of the Social
8 Security Act (42 U.S.C. 1396r–8) and drug utilization re-
9 view activities and requirements under section 1932(i) of
10 such Act (42 U.S.C. 1396u–2(i)), for the purpose of align-
11 ing review criteria for prospective and retrospective drug
12 use review across all State Medicaid programs.

13 (d) CMS GUIDANCE.—Not later than 18 months
14 after the date of enactment of this Act, the Secretary of
15 Health and Human Services shall issue guidance—

16 (1) outlining steps that States must take to
17 come into compliance with statutory and regulatory
18 requirements for prospective and retrospective drug
19 use review under section 1927(g) of the Social Secu-
20 rity Act (42 U.S.C. 1396r–8(g)) and drug utilization
21 review activities and requirements under section
22 1932(i) of such Act (42 U.S.C. 1396u–2(i)) (includ-
23 ing with respect to requirements that were in effect
24 before the date of enactment of this Act); and

1 (2) describing the actions that the Secretary
2 will take to enforce such requirements.

3 (e) EFFECTIVE DATE.—The amendments made by
4 this section shall take effect on the date that is 1 year
5 after the date of enactment of this Act.

6 **SEC. 203. GAO REPORT ON CONFLICTS OF INTEREST IN**
7 **STATE MEDICAID PROGRAM DRUG USE RE-**
8 **VIEW BOARDS AND PHARMACY AND THERA-**
9 **PEUTICS (P&T) COMMITTEES.**

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

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

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

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

1 (B) States that operate separate P&T
2 Committees for their fee-for-service Medicaid
3 program and their Medicaid managed care or-
4 ganizations or other Medicaid managed care ar-
5 rangements (collectively referred to in this sec-
6 tion as “Medicaid MCOs”); and

7 (C) States that allow Medicaid MCOs to
8 have their own P&T Committees and the extent
9 to which pharmacy benefit managers administer
10 or participate in such P&T Committees.

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

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

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

1 (5) A description outlining how States, DUR
2 Boards, or P&T Committees define conflicts of inter-
3 est.

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

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

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

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

1 **SEC. 204. ENSURING THE ACCURACY OF MANUFACTURER**
2 **PRICE AND DRUG PRODUCT INFORMATION**
3 **UNDER THE MEDICAID DRUG REBATE PRO-**
4 **GRAM.**

5 (a) **AUDIT OF MANUFACTURER PRICE AND DRUG**
6 **PRODUCT INFORMATION.—**

7 (1) **IN GENERAL.—**Subparagraph (B) of section
8 1927(b)(3) of the Social Security Act (42 U.S.C.
9 1396r–8(b)(3)) is amended to read as follows:

10 “(B) **AUDITS AND SURVEYS OF MANUFAC-**
11 **TURER PRICE AND DRUG PRODUCT INFORMA-**
12 **TION.—**

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

23 “(ii) **VERIFICATIONS SURVEYS OF AV-**
24 **ERAGE MANUFACTURER PRICE AND MANU-**
25 **FACTURER’S AVERAGE SALES PRICE.—**In
26 addition to the audits required under

1 clause (i), the Secretary may survey whole-
2 salers and manufacturers (including manu-
3 facturers that directly distribute their cov-
4 ered outpatient drugs (in this subpara-
5 graph referred to as ‘direct sellers’)), when
6 necessary, to verify manufacturer prices
7 and manufacturer’s average sales prices
8 (including wholesale acquisition cost) to
9 make payment reported under subpara-
10 graph (A).

11 “(iii) PENALTIES.—In addition to
12 other penalties as may be prescribed by
13 law, including under subparagraph (C) of
14 this paragraph, the Secretary may impose
15 a civil monetary penalty in an amount not
16 to exceed \$185,000 on an annual basis on
17 a wholesaler, manufacturer, or direct sell-
18 er, if the wholesaler, manufacturer, or di-
19 rect seller of a covered outpatient drug re-
20 fuses a request for information about
21 charges or prices by the Secretary in con-
22 nection with an audit or survey under this
23 subparagraph or knowingly provides false
24 information. The provisions of section
25 1128A (other than subsections (a) (with

1 respect to amounts of penalties or addi-
2 tional assessments) and (b)) shall apply to
3 a civil money penalty under this clause in
4 the same manner as such provisions apply
5 to a penalty or proceeding under section
6 1128A(a).

7 “(iv) REPORTS.—

8 “(I) REPORT TO CONGRESS.—

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

1 reporting of price and drug product
2 information should be considered to
3 ensure the integrity of the drug rebate
4 program under this section.

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

15 “(III) CONTENT.—Each report
16 submitted under subclause (II) shall,
17 with respect to the period that is the
18 subject of the report, include sum-
19 maries of—

20 “(aa) error rates in the
21 price, drug product, and other
22 relevant information supplied by
23 manufacturers under subpara-
24 graph (A);

1 “(bb) the timeliness with
2 which manufacturers, whole-
3 salers, and direct sellers provide
4 information required under sub-
5 paragraph (A) or under clause (i)
6 or (ii) of this subparagraph;

7 “(cc) the number of manu-
8 facturers, wholesalers, and direct
9 sellers and drug products audited
10 under this subparagraph;

11 “(dd) the types of price and
12 drug product information re-
13 viewed under the audits con-
14 ducted under this subparagraph;

15 “(ee) the tools and meth-
16 odologies employed in such au-
17 dits;

18 “(ff) the findings of such
19 audits, including which manufac-
20 turers, if any, were penalized
21 under this subparagraph; and

22 “(gg) such other relevant in-
23 formation as the Secretary shall
24 deem appropriate.

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

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

14 (2) EFFECTIVE DATE.—The amendments made
15 by this subsection shall take effect on the first day
16 of the first fiscal quarter that begins after the date
17 of enactment of this Act.

18 (b) INCREASED PENALTIES FOR NONCOMPLIANCE
19 WITH REPORTING REQUIREMENTS.—

20 (1) INCREASED PENALTY FOR LATE REPORTING
21 OF INFORMATION.—Section 1927(b)(3)(C)(i) of the
22 Social Security Act (42 U.S.C. 1396r–8(b)(3)(C)(i))
23 is amended by striking “increased by \$10,000 for
24 each day in which such information has not been
25 provided and such amount shall be paid to the

1 Treasury” and inserting “, for each covered out-
2 patient drug with respect to which such information
3 is not provided, \$50,000 for the first day that such
4 information is not provided on a timely basis and
5 \$19,000 for each subsequent day that such informa-
6 tion is not provided”.

7 (2) INCREASED PENALTY FOR KNOWINGLY RE-
8 PORTING FALSE INFORMATION.—Section
9 1927(b)(3)(C)(ii) of the Social Security Act (42
10 U.S.C. 1396r–8(b)(3)(C)(ii)) is amended by striking
11 “\$100,000” and inserting “\$500,000”.

12 (3) EFFECTIVE DATE.—The amendments made
13 by this subsection shall take effect on the first day
14 of the first fiscal quarter that begins after the date
15 of enactment of this Act.

16 **SEC. 205. EXCLUDING AUTHORIZED GENERIC DRUGS FROM**
17 **CALCULATION OF AVERAGE MANUFACTURER**
18 **PRICE UNDER THE MEDICAID DRUG REBATE**
19 **PROGRAM.**

20 (a) IN GENERAL.—Subparagraph (C) of section
21 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r–
22 8(k)(1)) is amended—

23 (1) in the subparagraph heading, by striking
24 “INCLUSION” and inserting “EXCLUSION”;

1 (2) by striking “a new drug application” and
2 inserting “the manufacturer’s new drug applica-
3 tion”; and

4 (3) by striking “inclusive” and inserting “exclu-
5 sive”.

6 (b) **EXCLUDING MANUFACTURERS FROM DEFINI-**
7 **TION OF WHOLESALER.**—Section 1927(k)(11) of the So-
8 cial Security Act (42 U.S.C. 1396r–8(k)(11)) is amend-
9 ed—

10 (1) by striking “manufacturers,”;

11 (2) by striking “manufacturer’s and”; and

12 (3) by adding at the end the following: “Such
13 term does not include a manufacturer engaged in
14 wholesale distribution or a manufacturer’s ware-
15 houses.”.

16 (c) **EFFECTIVE DATE.**—The amendments made by
17 this section shall take effect on the first day of the first
18 fiscal quarter that begins after the date of enactment of
19 this Act.

20 **SEC. 206. IMPROVING TRANSPARENCY AND PREVENTING**
21 **THE USE OF ABUSIVE SPREAD PRICING AND**
22 **RELATED PRACTICES IN MEDICAID.**

23 (a) **PASS-THROUGH PRICING REQUIRED.**—

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

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

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

19 “(i) is limited to—

20 “(I) ingredient cost; and

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

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

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

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

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

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

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

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

15 (2) CONFORMING AMENDMENT.—Section
16 1903(m)(2)(A)(xiii) of such Act (42 U.S.C.
17 1396b(m)(2)(A)(xiii)) is amended—

18 (A) by striking “and (III)” and inserting
19 “(III)”;

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

1 macy benefit manager, shall comply with the re-
2 quirements of section 1927(e)(6)”; and

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

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

11 (b) SURVEY OF RETAIL PRICES.—

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

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

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

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

24 “(i) with respect to retail community
25 pharmacies, the determination on a month-

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

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

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

1 that has a contract with the State or a man-
2 aged care entity, shall respond to surveys of re-
3 tail prices conducted under this subsection.

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

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

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

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

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

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

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

1 “(H) PENALTIES.—

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

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

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

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

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

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

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

1 age drug acquisition costs capture drugs
2 sold at specialty pharmacies and how such
3 specialty pharmacies should be defined.”;

4 (C) in paragraph (2)—

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

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

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

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

19 (c) MANUFACTURER REPORTING OF WHOLESALE
20 ACQUISITION COST.—Section 1927(b)(3) of such Act (42
21 U.S.C. 1396r–8(b)(3)) is amended—

22 (1) in subparagraph (A)(i)—

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

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

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

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

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

17 (2) in subparagraph (D)—

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

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

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

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

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

13 **SEC. 207. T-MSIS DRUG DATA ANALYTICS REPORTS.**

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

22 (b) CONTENT OF REPORT.—

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

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

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

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

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

17 (iii) by episodes of care for—

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

25 (II) procedural groupings; and

- 1 (III) rare disease diagnosis codes;
2 (iv) by patient demographic character-
3 istics, including race (to the extent that
4 the Secretary determines that there is suf-
5 ficient data available with respect to such
6 characteristic in a majority of States), gen-
7 der, and age;
8 (v) by patient high-utilizer or risk sta-
9 tus; and
10 (vi) by high and low resource settings
11 by facility and place of service categories,
12 as determined by the Secretary.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 **SEC. 208. RISK-SHARING VALUE-BASED PAYMENT AGREE-**
 9 **MENTS FOR COVERED OUTPATIENT DRUGS**
 10 **UNDER MEDICAID.**

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

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

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

1 “(2) SECRETARIAL APPROVAL.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 “(i) TIMING OF FIRST PAYMENT.—

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

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

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

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

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

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

15 “(4) NOTICE OF INTENT.—

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

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

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

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

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

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

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

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

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

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

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

23 “(5) SPECIAL PAYMENT RULES.—

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

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

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

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

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

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

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

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

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

19 “(A) ASSESSMENTS.—

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

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

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

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

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

6 “(B) RESULTS OF ASSESSMENTS.—

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

23 “(ii) REPAYMENT REQUIRED.—

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

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

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

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

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

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

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

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

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

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

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

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

9 “(8) GUIDANCE AND REGULATIONS.—

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

19 “(B) MODEL AGREEMENTS.—

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

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

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

21 “(C) OIG CONSULTATION.—

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

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

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

15 “(9) RULES OF CONSTRUCTION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 “(D) RELEVANT CLINICAL PARAMETER.—

23 The term ‘relevant clinical parameter’ means,
24 with respect to a covered outpatient drug that

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

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

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

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

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

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

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

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

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

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

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

20 “(iv) which provides that—

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

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

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

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

13 “(i) the unit price of the drug charged
14 under the agreement; and

15 “(ii) the number of units of such drug
16 administered under the agreement during
17 such installment year.”.

18 (b) CONFORMING AMENDMENTS.—

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

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

3 (A) in paragraph (1)(A), by inserting “(ex-
4 cept for drugs for which payment is made by a
5 State under a risk-sharing value-based payment
6 agreement under subsection (l))” after “under
7 the State plan for such period”; and

8 (B) in paragraph (3)—

9 (i) in subparagraph (C)(i), by insert-
10 ing “or subsection (l)(2)(A)” after “sub-
11 paragraph (A)”; and

12 (ii) in subparagraph (D), in the mat-
13 ter preceding clause (i), by inserting “,
14 under subsection (l)(2)(A),” after “under
15 this paragraph”.

16 **SEC. 209. MODIFICATION OF MAXIMUM REBATE AMOUNT**
17 **UNDER MEDICAID DRUG REBATE PROGRAM.**

18 (a) IN GENERAL.—Subparagraph (D) of section
19 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r–
20 8(c)(2)) is amended to read as follows:

21 “(D) MAXIMUM REBATE AMOUNT.—

22 “(i) IN GENERAL.—Except as pro-
23 vided in clause (ii), in no case shall the
24 sum of the amounts applied under para-
25 graph (1)(A)(ii) and this paragraph with

1 respect to each dosage form and strength
2 of a single source drug or an innovator
3 multiple source drug for a rebate period
4 exceed—

5 “(I) for rebate periods beginning
6 after December 31, 2009, and before
7 September 30, 2022, 100 percent of
8 the average manufacturer price of the
9 drug; and

10 “(II) for rebate periods beginning
11 on or after October 1, 2022, 125 per-
12 cent of the average manufacturer
13 price of the drug.

14 “(ii) NO MAXIMUM AMOUNT FOR
15 DRUGS IF AMP INCREASES OUTPACE IN-
16 FLATION.—

17 “(I) IN GENERAL.—If the aver-
18 age manufacturer price with respect
19 to each dosage form and strength of
20 a single source drug or an innovator
21 multiple source drug increases on or
22 after October 1, 2021, and such in-
23 creased average manufacturer price
24 exceeds the inflation-adjusted average
25 manufacturer price determined with

1 respect to such drug under subclause
2 (II) for the rebate period, clause (i)
3 shall not apply and there shall be no
4 limitation on the sum of the amounts
5 applied under paragraph (1)(A)(ii)
6 and this paragraph for the rebate pe-
7 riod with respect to each dosage form
8 and strength of the single source drug
9 or innovator multiple source drug.

10 “(II) INFLATION-ADJUSTED AV-
11 ERAGE MANUFACTURER PRICE DE-
12 FINED.—In this clause, the term ‘in-
13 flation-adjusted average manufacturer
14 price’ means, with respect to a single
15 source drug or an innovator multiple
16 source drug and a rebate period, the
17 average manufacturer price for each
18 dosage form and strength of the drug
19 for the calendar quarter beginning
20 July 1, 1990 (without regard to
21 whether or not the drug has been sold
22 or transferred to an entity, including
23 a division or subsidiary of the manu-
24 facturer, after the 1st day of such
25 quarter), increased by the percentage

1 by which the consumer price index for
 2 all urban consumers (United States
 3 city average) for the month before the
 4 month in which the rebate period be-
 5 gins exceeds such index for September
 6 1990.”.

7 (b) TREATMENT OF SUBSEQUENTLY APPROVED
 8 DRUGS.—Section 1927(c)(2)(B) of the Social Security Act
 9 (42 U.S.C. 1396r–8(c)(2)(B)) is amended by inserting
 10 “and clause (ii)(II) of subparagraph (D)” after “clause
 11 (ii)(II) of subparagraph (A)”.

12 (c) TECHNICAL AMENDMENTS.—Section
 13 1927(c)(3)(C)(ii)(IV) of the Social Security Act (42
 14 U.S.C. 1396r–9(c)(3)(C)(ii)(IV)) is amended—

15 (1) by striking “subparagraph (A)” and insert-
 16 ing “paragraph (3)(A)”; and

17 (2) by striking “this subparagraph” and insert-
 18 ing “paragraph (3)(C)”.

19 **SEC. 210. APPLYING MEDICAID DRUG REBATE REQUIRE-**
 20 **MENT TO DRUGS PROVIDED AS PART OF OUT-**
 21 **PATIENT HOSPITAL SERVICES.**

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

25 “(3) LIMITING DEFINITION.—

1 “(A) IN GENERAL.—The term ‘covered
2 outpatient drug’ does not include any drug, bio-
3 logical product, or insulin provided as part of,
4 or as incident to and in the same setting as,
5 any of the following (and for which payment
6 may be made under this title as part of pay-
7 ment for the following and not as direct reim-
8 bursement for the drug):

9 “(i) Inpatient hospital services.

10 “(ii) Hospice services.

11 “(iii) Dental services, except that
12 drugs for which the State plan authorizes
13 direct reimbursement to the dispensing
14 dentist are covered outpatient drugs.

15 “(iv) Physicians’ services.

16 “(v) Outpatient hospital services.

17 “(vi) Nursing facility services and
18 services provided by an intermediate care
19 facility for the mentally retarded.

20 “(vii) Other laboratory and x-ray serv-
21 ices.

22 “(viii) Renal dialysis.

23 “(B) OTHER EXCLUSIONS.—Such term
24 also does not include any such drug or product
25 for which a National Drug Code number is not

1 required by the Food and Drug Administration
2 or a drug or biological used for a medical indi-
3 cation which is not a medically accepted indica-
4 tion.

5 “(C) STATE OPTION.—At the option of a
6 State, such term may include any drug, biologi-
7 cal product, or insulin provided on an out-
8 patient basis as part of, or as incident to and
9 in the same setting as, described in clause (iv)
10 or (v) of subparagraph (A) (such as a drug, bi-
11 ological product, or insulin being provided as
12 part of a bundled payment).

13 “(D) NO EFFECT ON BEST PRICE.—Any
14 drug, biological product, or insulin excluded
15 from the definition of such term as a result of
16 this paragraph shall be treated as a covered
17 outpatient drug for purposes of determining the
18 best price (as defined in subsection (c)(1)(C))
19 for such drug, biological product, or insulin.”.

20 (b) EFFECTIVE DATE; IMPLEMENTATION GUID-
21 ANCE.—

22 (1) IN GENERAL.—The amendment made by
23 subsection (a) shall take effect on the date that is
24 1 year after the date of enactment of this Act.

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

Calendar No. 225

116TH CONGRESS
1ST Session

S. 2543

[Report No. 116-120]

A BILL

To amend titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices in the Medicare and Medicaid programs, to improve transparency related to pharmaceutical prices and transactions, to lower patients' out-of-pocket costs, and to ensure accountability to taxpayers, and for other purposes.

SEPTEMBER 25, 2019

Read twice and placed on the calendar