

116TH CONGRESS
2D SESSION

S. 4199

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

JULY 2, 2020

Mr. GRASSLEY (for himself, Mr. PORTMAN, Mr. CASSIDY, Mr. DAINES, Ms. COLLINS, Ms. ERNST, Ms. MCSALLY, Mr. BRAUN, Mrs. HYDE-SMITH, and Ms. MURKOWSKI) introduced the following bill; which was read twice and referred to the Committee on Finance

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,*

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Prescription Drug Pricing Reduction Act of 2020”.

1 (b) TABLE OF CONTENTS.—The table of contents of
 2 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. HHS Inspector General study and report on bona fide service fees.
- 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. 121A. Maximum monthly cap on cost-sharing payments under prescription drug plans and MA–PD plans.
- Sec. 121B. Requiring pharmacy-negotiated price concessions, payment, and fees to be included in negotiated prices at the point-of-sale under part D of the medicare program.
- 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. Fairness in the calculation of the part D premium.
- Sec. 134. 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 DRUG PRICING REFORMS

- 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. Applying Medicaid drug rebate requirement to drugs provided as part of outpatient hospital services.
- 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.

TITLE I—MEDICARE

Subtitle A—Part B

SEC. 101. IMPROVING MANUFACTURERS' REPORTING OF AVERAGE SALES PRICES TO SET ACCURATE PAYMENT RATES.

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

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

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

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

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

“(A) IN GENERAL.—For calendar quarters beginning with the second calendar quarter after the date of the enactment of this paragraph, the following provisions shall apply with respect to a manufacturer of an applicable drug or biological (as defined in subparagraph (B)) that has not entered into and does not have in effect a rebate agreement described in subsection (b) of section 1927 in the same manner and to the same extent as such provisions apply

with respect to a manufacturer that has entered
into and has in effect such a rebate agreement:

“(i) Section 1927(b)(3)(A)(iii).

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

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

(b) CONFORMING AMENDMENTS.—

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

(A) in paragraph (2)(A), by inserting “or
subsection (f)(2), as applicable” after “under
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, 2022, 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

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

“(J) VALUE.—The term ‘value’ means, with respect to a coupon (as defined in subparagraph (K)), the difference, if any, between—

“(i) the amount of any reduction or elimination of cost-sharing or other out-of-pocket costs described in such subparagraph to a patient as a result of the use of such coupon; and

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

“(K) COUPON.—The term ‘coupon’ means any financial support that is provided to a patient, either directly to the patient or indirectly to the patient through a physician, prescriber, pharmacy, or other provider, under a drug coupon program of a manufacturer (as defined in subparagraph (L)) that is used to reduce or eliminate cost-sharing or other out-of-pocket costs of the patient, including costs related to a deductible, coinsurance, or copayment, with respect to a drug or biological, including a biosimilar 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 2
 4 ems to the right;

5 (2) by redesignating subparagraphs (A) and
 6 (B) as clauses (i) and (ii) and moving such clauses
 7 2 ems 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 January 1, 2021, in lieu of applying subpara-
 19 graph (A) during the initial period described in
 20 such subparagraph with respect to the bio-
 21 similar biological product, the amount payable
 22 under this section for the biosimilar biological
 23 product is 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, 2021, 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 2020, the 5-year period beginning on
22 January 1, 2021; 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 2022 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 2022, 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 2022, 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, 2022, 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, 2022.

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.

“(C) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this subparagraph for a rebatable drug for a rebate period is—

“(i) the amount determined under subsection (b)(4) for such rebatable drug in the payment amount benchmark quarter (as defined in subparagraph (D)); increased by

“(ii) the percentage by which the rebate period CPI-U (as defined in subparagraph (F)) for the rebate period exceeds the benchmark period CPI-U (as defined in subparagraph (E)).

“(D) PAYMENT AMOUNT BENCHMARK QUARTER.—The term ‘payment amount benchmark quarter’ means the calendar quarter beginning July 1, 2019.

“(E) BENCHMARK PERIOD CPI-U.—The term ‘benchmark period CPI-U’ means the consumer price index for all urban consumers (United States city average) for July 2019.

“(F) REBATE PERIOD CPI-U.—The term ‘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 January 1, 2022,
 16 the Secretary shall, with respect to a refundable
 17 single-dose container or single-use package drug
 18 (as defined in paragraph (8)), report to each
 19 manufacturer (as defined in subsection
 20 (c)(6)(A)) of such refundable single-dose con-
 21 tainer or single-use package drug the following
 22 for the calendar quarter:

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

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

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

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

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

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

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

12 “(3) REFUND AMOUNT.—

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

21 “(i) the product of—

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

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

3 “(II)(aa) in the case of a refund-
 4 able single-dose container or single-
 5 use package drug that is a single
 6 source drug or biological, the amount
 7 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. HHS INSPECTOR GENERAL STUDY AND REPORT**
19 **ON BONA FIDE SERVICE FEES.**

20 (a) STUDY.—The Inspector General of the Depart-
21 ment of Health and Human Services (in this section re-
22 ferred to as the “Inspector General”) shall conduct a
23 study on the effect of the use of bona fide service fee con-
24 tracting arrangements by drug manufacturers and other
25 entities on Medicare payments for drugs and biologicals

1 furnished under part B of title XVIII of the Social Secu-
2 rity Act (42 U.S.C. 1395j et seq.). Such study shall in-
3 clude an analysis of—

4 (1) the various types of entities that enter into
5 contracting arrangements that use bona fide service
6 fees, such as group purchasing organizations, whole-
7 salers, providers, and pharmacies;

8 (2) the various types of bona fide service fee
9 contracting arrangements used by such entities;

10 (3) the types of services that are paid for
11 through such arrangements;

12 (4) whether manufacturers define bona fide
13 service fees differently across different entities;

14 (5) how such arrangements are structured;

15 (6) whether the structure or use of such ar-
16 rangements has changed over time;

17 (7) the extent, if any, to which there is consist-
18 ency across manufacturers in what they consider to
19 be a bona fide service fee as opposed to a discount
20 or rebate that should be excluded from the deter-
21 mination of average sales price pursuant to the
22 methodology under section 1847A of the Social Se-
23 curity Act (42 U.S.C. 1395w–3a);

24 (8) the overall magnitude of bona fide service
25 fees;

(11) whether and, if so, how much, the magnitude of bona fide service fees has grown over time and how such growth compares to growth in the magnitude of other fees and rebates; and

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Inspector General shall submit to Congress a report containing the results of the study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Inspector General determines appropriate.

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

(A) in paragraph (1), in the matter pre-
ceding subparagraph (A), by striking “para-

graph (7)” and inserting “paragraphs (7) and (9)”;

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

“(9) MAXIMUM ADD-ON PAYMENT AMOUNT.—

“(A) IN GENERAL.—In determining the payment amount under the provisions of subparagraph (A), (B), or (C) of paragraph (1) of this subsection, subsection (c)(4)(A)(ii), or subsection (d)(3)(C) for a drug or biological furnished on or after January 1, 2022, if the applicable add-on payment (as defined in subparagraph (B)) for each drug or biological on a claim for a date of service exceeds the maximum add-on payment amount specified under subparagraph (C) for the drug or biological, then the payment amount otherwise determined for the drug or biological under those provisions, as applicable, shall be reduced by the amount of such excess.

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

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

4 “(I) the amount that would oth-
5 erwise be applied under paragraph
6 (1)(A); 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 “(ii) In the case of a single source
12 drug or biological, an amount equal to the
13 difference between—

14 “(I) the amount that would oth-
15 erwise be applied under paragraph
16 (1)(B); and

17 “(II) the amount that would be
18 applied under such paragraph if ‘100
19 percent’ were substituted for ‘106 per-
20 cent’.

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

24 “(iv) In the case of a drug or biologi-
25 cal during the initial period described in

1 subsection (c)(4)(A), an amount equal to
2 the difference between—

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

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

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

12 “(bb) any percent in excess
13 of 100 percent applied under
14 subclause (II) of such subsection.

15 “(v) In the case of a drug or biologi-
16 cal to which subsection (d)(3)(C) applies,
17 an amount equal to the difference be-
18 tween—

19 “(I) the amount that would oth-
20 erwise be applied under such sub-
21 section; and

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

1 “(aa) any percent in excess
 2 of 100 percent applied under
 3 clause (i) of such subsection; or
 4 “(bb) ‘103 percent’ in clause
 5 (ii) of such subsection.

6 “(C) MAXIMUM ADD-ON PAYMENT AMOUNT
 7 SPECIFIED.—For purposes of subparagraph
 8 (A), the maximum add-on payment amount
 9 specified in this subparagraph is—

10 “(i) for each of 2022 through 2029,
 11 \$1,000; and

12 “(ii) for a subsequent year, the
 13 amount specified in this subparagraph for
 14 the preceding year increased by the per-
 15 centage increase in the consumer price
 16 index for all urban consumers (all items;
 17 United States city average) for the 12-
 18 month period ending with June of the pre-
 19 vious year.

20 Any amount determined under this subpara-
 21 graph that is not a multiple of \$10 shall be
 22 rounded to the nearest multiple of \$10.”; and
 23 (2) in subsection (c)(4)(A)(ii), by striking “in
 24 the case” and inserting “subject to subsection
 25 (b)(9), in the case”.

1 (b) CONFORMING AMENDMENTS RELATING TO SEPA-
2 RATELY PAYABLE DRUGS.—

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

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

8 (B) by adding at the end the following new
9 subparagraph:

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

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

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

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

7 (C) by inserting after clause (v) the fol-
 8 lowing new clause:

9 “(vi) If there is a separate payment under the system
 10 described in clause (i) for a drug or biological furnished
 11 on or after January 1, 2022, the provisions of subsection
 12 (t)(14)(I) shall apply to the establishment of the amount
 13 of payment for the drug or biological under such system
 14 in the same manner in which such provisions apply to the
 15 establishment of the amount of payment under subsection
 16 (t)(14)(A).”.

17 **SEC. 110. TREATMENT OF DRUG ADMINISTRATION SERV-**
 18 **ICES FURNISHED BY CERTAIN EXCEPTED**
 19 **OFF-CAMPUS OUTPATIENT DEPARTMENTS OF**
 20 **A PROVIDER.**

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

1 “(G) SPECIAL PAYMENT RULE FOR DRUG
2 ADMINISTRATION SERVICES FURNISHED BY AN
3 EXCEPTED DEPARTMENT OF A PROVIDER.—

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

17 “(ii) APPLICATION WITHOUT REGARD
18 TO BUDGET NEUTRALITY.—The reductions
19 made under this subparagraph—

20 “(I) shall not be considered an
21 adjustment under paragraph (2)(E);
22 and

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

1 **SEC. 111. GAO STUDY AND REPORT ON AVERAGE SALES**

2 **PRICE.**

3 (a) STUDY.—

4 (1) IN GENERAL.—The Comptroller General of
5 the United States (in this section referred to as the
6 “Comptroller General”) shall conduct a study on
7 spending for applicable drugs under part B of title
8 XVIII of the Social Security Act.

9 (2) APPLICABLE DRUGS DEFINED.—In this sec-
10 tion, the term “applicable drugs” means drugs and
11 biologicals—

12 (A) for which reimbursement under such
13 part B is based on the average sales price of
14 the drug or biological; and

15 (B) that account for the largest percentage
16 of total spending on drugs and biologicals under
17 such part B (as determined by the Comptroller
18 General, but in no case less than 25 drugs or
19 biologicals).

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

22 (A) The extent to which each applicable
23 drug is paid for—

24 (i) under such part B for Medicare
25 beneficiaries; or

1 (ii) by private payers in the commer-
2 cial market.

3 (B) Any change in Medicare spending or
4 Medicare beneficiary cost-sharing that would
5 occur if the average sales price of an applicable
6 drug was based solely on payments by private
7 payers in the commercial market.

8 (C) The extent to which drug manufactur-
9 ers provide rebates, discounts, or other price
10 concessions to private payers in the commercial
11 market for applicable drugs, which the manu-
12 facturer includes in its average sales price cal-
13 culation, for—

14 (i) formulary placement;

15 (ii) utilization management consider-
16 ations; or

17 (iii) other purposes.

18 (D) Barriers to drug manufacturers pro-
19 viding such price concessions for applicable
20 drugs.

21 (E) Other areas determined appropriate by
22 the Comptroller General.

23 (b) REPORT.—Not later than 2 years after the date
24 of the enactment of this Act, the Comptroller General shall
25 submit to Congress a report on the study conducted under

1 subsection (a), together with recommendations for such
 2 legislation and administrative action as the Secretary de-
 3 termines appropriate.

4 **SEC. 112. AUTHORITY TO USE ALTERNATIVE PAYMENT FOR**
 5 **DRUGS AND BIOLOGICALS TO PREVENT PO-**
 6 **TENTIAL DRUG SHORTAGES.**

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

9 (1) by striking “PAYMENT IN RESPONSE TO
 10 PUBLIC HEALTH EMERGENCY.—In the case” and
 11 inserting “PAYMENTS.—

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

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

16 “(2) PREVENTING POTENTIAL DRUG SHORT-
 17 AGES.—

18 “(A) IN GENERAL.—In the case of a drug
 19 or biological that the Secretary determines is
 20 described in subparagraph (B) for one or more
 21 quarters beginning on or after January 1,
 22 2021, the Secretary may use wholesale acquisi-
 23 tion cost (or other reasonable measure of a
 24 drug or biological price) instead of the manu-
 25 facturer’s average sales price for such quarters

1 and for subsequent quarters until the end of
2 the quarter in which such drug or biological is
3 removed from the drug shortage list under sec-
4 tion 506E of the Federal Food, Drug, and Cos-
5 metic Act, or in the case of a drug or biological
6 described in subparagraph (B)(ii), the date on
7 which the Secretary determines that the total
8 manufacturing capacity or the total number of
9 manufacturers of such drug or biological is suf-
10 ficient to mitigate a potential shortage of the
11 drug or biological.

12 “(B) DRUG OR BIOLOGICAL DESCRIBED.—

13 For purposes of subparagraph (A), a drug or
14 biological described in this subparagraph is a
15 drug or biological—

16 “(i) that is listed on the drug shortage
17 list maintained by the Food and Drug Ad-
18 ministration pursuant to section 506E of
19 the Federal Food, Drug, and Cosmetic
20 Act, and with respect to which any manu-
21 facturer of such drug or biological notifies
22 the Secretary of a permanent discontinu-
23 ance or an interruption that is likely to
24 lead to a meaningful disruption in the

1 manufacturer's supply of that drug pursu-
2 ant to section 506C(a) of such Act; or

3 “(ii) that—

4 “(I) is described in section
5 506C(a) of such Act;

6 “(II) was listed on the drug
7 shortage list maintained by the Food
8 and Drug Administration pursuant to
9 section 506E of such Act within the
10 preceding 5 years; and

11 “(III) for which the total manu-
12 facturing capacity of all manufactur-
13 ers with an approved application for
14 such drug or biological that is cur-
15 rently marketed or total number of
16 manufacturers with an approved ap-
17 plication for such drug or biological
18 that is currently marketed declines
19 during a 6-month period, as deter-
20 mined by the Secretary.

21 “(C) PROVISION OF ADDITIONAL INFORMA-
22 TION.—For each quarter in which the amount
23 of payment for a drug or biological described in
24 subparagraph (B) pursuant to subparagraph
25 (A) exceeds the amount of payment for the

1 drug or biological otherwise applicable under
 2 this section, each manufacturer of such drug or
 3 biological shall provide to the Secretary infor-
 4 mation related to the potential cause or causes
 5 of the shortage and the expected duration of
 6 the shortage with respect to such drug.”.

7 (b) TRACKING SHORTAGE DRUGS THROUGH
 8 CLAIMS.—The Secretary of Health and Human Services
 9 (referred to in this section as the “Secretary”) shall estab-
 10 lish a mechanism (such as a modifier) for purposes of
 11 tracking utilization under title XVIII of the Social Secu-
 12 rity Act (42 U.S.C. 1395 et seq.) of drugs and biologicals
 13 listed on the drug shortage list maintained by the Food
 14 and Drug Administration pursuant to section 506E of the
 15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e).

16 (c) HHS REPORT AND RECOMMENDATIONS.—

17 (1) IN GENERAL.—Not later than 18 months
 18 after the date of the enactment of this Act, the Sec-
 19 retary shall submit to Congress a report on short-
 20 ages of drugs within the Medicare program under
 21 title XVIII of the Social Security Act (42 U.S.C.
 22 1395 et seq.). The report shall include—

23 (A) an analysis of—

1 (i) the effect of drug shortages on
2 Medicare beneficiary access, quality, safe-
3 ty, and out-of-pocket costs;

4 (ii) the effect of drug shortages on
5 health providers, including hospitals and
6 physicians, across the Medicare program;

7 (iii) the current role of the Centers for
8 Medicare & Medicaid Services (CMS) in
9 addressing drug shortages, including
10 CMS's working relationship and commu-
11 nication with other Federal agencies and
12 stakeholders;

13 (iv) the role of all actors in the drug
14 supply chain (including drug manufactur-
15 ers, distributors, wholesalers, secondary
16 wholesalers, group purchasing organiza-
17 tions, hospitals, and physicians) on drug
18 shortages within the Medicare program;
19 and

20 (v) payment structures and incentives
21 under parts A, B, C, and D of the Medi-
22 care program and their effect, if any, on
23 drug shortages; and

24 (B) relevant findings and recommendations
25 to Congress.

9 **Subtitle B—Part D**

11 (a) BENEFIT STRUCTURE REDESIGN.—Section
12 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
13 102(b)) is amended—

(A) in subparagraph (A), in the matter preceding clause (i), by inserting “for a year preceding 2023 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2023 and each subsequent year” after “paragraph (3)”;

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

1 year preceding 2023,” after “paragraph
2 (4),”; and

3 (ii) in clause (ii)(III), by striking
4 “and each subsequent year” and inserting
5 “, 2021, and 2022”; and

6 (C) in subparagraph (D)—

7 (i) in clause (i)—

8 (I) in the matter preceding sub-
9 clause (I), by inserting “for a year
10 preceding 2023,” after “paragraph
11 (4),”; and

12 (II) in subclause (I)(bb), by
13 striking “a year after 2018” and in-
14 serting “each of years 2018 through
15 2022”; and

16 (ii) in clause (ii)(V), by striking
17 “2019 and each subsequent year” and in-
18 serting “each of years 2019 through
19 2022”;

20 (2) in paragraph (3)(A)—

21 (A) in the matter preceding clause (i), by
22 inserting “for a year preceding 2023,” after
23 “and (4),”; and

(B) in clause (ii), by striking “for a subsequent year” and inserting “for each of years 2007 through 2022”;

(3) in paragraph (4)—

(A) in subparagraph (A)—

(i) in clause (i)—

(I) by redesignating subclauses (I) and (II) as items (aa) and (bb), respectively, and indenting appropriately;

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

“(I) for a year preceding 2023, the greater of—”;

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

(IV) by adding at the end the following:

“(II) for 2023 and each succeeding year, \$0.”; and

(ii) in clause (ii)—

1 (I) by striking “clause (i)(I)” and
2 inserting “clause (i)(I)(aa)”; and

3 (II) by adding at the end the fol-
4 lowing new sentence: “The Secretary
5 shall continue to calculate the dollar
6 amounts specified in clause (i)(I)(aa),
7 including with the adjustment under
8 this clause, after 2022 for purposes of
9 section 1860D–14(a)(1)(D)(iii).”;

10 (B) in subparagraph (B)—

11 (i) in clause (i)—

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

14 (II) in subclause (VI)—

15 (aa) by striking “for a sub-
16 sequent year” and inserting “for
17 2021 and 2022”; and

18 (bb) by striking the period
19 at the end and inserting a semi-
20 colon; and

21 (III) by adding at the end the
22 following new subclauses:

23 “(VII) for 2023, is equal to
24 \$3,100; or

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

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

9 (C) in subparagraph (C)(i), by striking
 10 “and for amounts” and inserting “and for a
 11 year preceding 2023 for amounts”; and

12 (D) in subparagraph (E), by striking “In
 13 applying” and inserting “For each of 2011
 14 through 2022, in applying”.

15 (b) REDUCTION IN BENEFICIARY COINSURANCE.—

16 (1) IN GENERAL.—Section 1860D–2(b)(2)(A)
 17 of the Social Security Act (42 U.S.C. 1395w–
 18 102(b)(2)(A)), as amended by subsection (a), is
 19 amended—

20 (A) by redesignating clauses (i) and (ii) as
 21 subclauses (I) and (II) and moving such sub-
 22 clauses 2 ems to the right;

23 (B) by striking “25 PERCENT COINSUR-
 24 ANCE.—Subject to” and inserting “COINSUR-
 25 ANCE.—

1 “(i) IN GENERAL.—Subject to”;

2 (C) in each of subclauses (I) and (II), as
 3 redesignated by subparagraph (A), by striking
 4 “25 percent” and inserting “the applicable per-
 5 centage (as defined in clause (ii))”; and

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

8 “(ii) APPLICABLE PERCENTAGE DE-
 9 FINED.—For purposes of clause (i), the
 10 term ‘applicable percentage’ means—

11 “(I) for a year preceding 2023,
 12 25 percent; and

13 “(II) for 2023 and each subse-
 14 quent year, 20 percent.”.

15 (2) CONFORMING AMENDMENT.—Section
 16 1860D–14(a)(2)(D) of the Social Security Act (42
 17 U.S.C. 1395w–114(a)(2)(D)) is amended by striking
 18 “25 percent” and inserting “the applicable percent-
 19 age”.

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

23 (1) in paragraph (1)—

24 (A) by striking “equal to 80 percent” and
 25 inserting “equal to—

1 “(A) for a year preceding 2023, 80 per-
2 cent”;

3 (B) in subparagraph (A), as added by
4 paragraph (1), by striking the period at the end
5 and inserting “; and”; and

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

8 “(B) for 2023 and each subsequent year,
9 the sum of—

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

21 “(ii) an amount equal to the applica-
22 ble percentage specified in paragraph
23 (5)(B) of allowable reinsurance costs at-
24 tributable to that portion of gross prescrip-
25 tion drug costs as specified in paragraph

1 (3) incurred in the coverage year after
 2 such individual has incurred costs that ex-
 3 ceed the annual out-of-pocket threshold
 4 specified in section 1860D–2(b)(4)(B) with
 5 respect to covered part D drugs that are
 6 not applicable drugs (as so defined).”; and

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

9 “(5) APPLICABLE PERCENTAGE SPECIFIED.—
 10 For purposes of paragraph (1)(B), the applicable
 11 percentage specified in this paragraph is—

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

14 “(i) for 2023, 60 percent;

15 “(ii) for 2024, 40 percent; and

16 “(iii) for 2025 and each subsequent
 17 year, 20 percent; and

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

20 “(i) for 2023, 80 percent;

21 “(ii) for 2024, 60 percent; and

22 “(iii) for 2025 and each subsequent
 23 year, 40 percent.”.

24 (d) MANUFACTURER DISCOUNT PROGRAM DURING
 25 INITIAL AND CATASTROPHIC PHASES OF COVERAGE.—

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

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

6 “(a) ESTABLISHMENT.—The Secretary shall estab-
 7 lish a manufacturer discount program (in this section re-
 8 ferred to as the ‘program’). Under the program, the Sec-
 9 retary shall enter into agreements described in subsection
 10 (b) with manufacturers and provide for the performance
 11 of the duties described in subsection (c). The Secretary
 12 shall establish a model agreement for use under the pro-
 13 gram by not later than January 1, 2022, in consultation
 14 with manufacturers, and allow for comment on such model
 15 agreement.

16 “(b) TERMS OF AGREEMENT.—

17 “(1) IN GENERAL.—

18 “(A) AGREEMENT.—An agreement under
 19 this section shall require the manufacturer to
 20 provide applicable beneficiaries access to dis-
 21 counted prices for applicable drugs of the man-
 22 ufacturer that are dispensed on or after Janu-
 23 ary 1, 2023.

24 “(B) PROVISION OF DISCOUNTED PRICES
 25 AT THE POINT-OF-SALE.—The discounted prices

1 described in subparagraph (A) shall be provided
2 to the applicable beneficiary at the pharmacy or
3 by the mail order service at the point-of-sale of
4 an applicable drug.

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

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

20 “(4) LENGTH OF AGREEMENT.—

21 “(A) IN GENERAL.—An agreement under
22 this section shall be effective for an initial pe-
23 riod of not less than 12 months and shall be
24 automatically renewed for a period of not less

1 than 1 year unless terminated under subpara-
2 graph (B).

3 “(B) TERMINATION.—

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

19 “(ii) BY A MANUFACTURER.—A man-
20 ufacturer may terminate an agreement
21 under this section for any reason. Any
22 such termination shall be effective, with re-
23 spect to a plan year—

24 “(I) if the termination occurs be-
25 fore January 30 of a plan year, as of

1 the day after the end of the plan year;
2 and

3 “(II) if the termination occurs on
4 or after January 30 of a plan year, as
5 of the day after the end of the suc-
6 ceeding plan year.

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

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

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

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

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

3 “(A) the determination of the amount of
4 the discounted price of an applicable drug of a
5 manufacturer;

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

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

18 “(i) the negotiated price of the appli-
19 cable drug; and

20 “(ii) the discounted price of the appli-
21 cable drug;

22 “(D) the establishment of procedures to
23 ensure that the discounted price for an applica-
24 ble drug under this section is applied before any
25 coverage or financial assistance under other

1 health benefit plans or programs that provide
 2 coverage or financial assistance for the pur-
 3 chase or provision of prescription drug coverage
 4 on behalf of applicable beneficiaries as the Sec-
 5 retary may specify; and

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

11 “(2) MONITORING COMPLIANCE.—

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

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

21 “(3) COLLECTION OF DATA FROM PRESCRIP-
 22 TION DRUG PLANS AND MA–PD PLANS.—The Sec-
 23 retary may collect appropriate data from prescrip-
 24 tion drug plans and MA–PD plans in a timeframe

1 that allows for discounted prices to be provided for
2 applicable drugs under this section.

3 “(d) ADMINISTRATION.—

4 “(1) IN GENERAL.—Subject to paragraph (2),
5 the Secretary shall provide for the implementation of
6 this section, including the performance of the duties
7 described in subsection (c).

8 “(2) LIMITATION.—In providing for the imple-
9 mentation of this section, the Secretary shall not re-
10 ceive or distribute any funds of a manufacturer
11 under the program.

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

19 “(A) receive and transmit information be-
20 tween the Secretary, manufacturers, and other
21 individuals or entities the Secretary determines
22 appropriate;

23 “(B) receive, distribute, or facilitate the
24 distribution of funds of manufacturers to ap-
25 propriate individuals or entities in order to

1 meet the obligations of manufacturers under
2 agreements under this section;

3 “(C) provide adequate and timely informa-
4 tion to manufacturers, consistent with the
5 agreement with the manufacturer under this
6 section, as necessary for the manufacturer to
7 fulfill its obligations under this section; and

8 “(D) permit manufacturers to conduct
9 periodic audits, directly or through contracts, of
10 the data and information used by the third
11 party to determine discounts for applicable
12 drugs of the manufacturer under the program.

13 “(4) PERFORMANCE REQUIREMENTS.—The
14 Secretary shall establish performance requirements
15 for a third party with a contract under paragraph
16 (3) and safeguards to protect the independence and
17 integrity of the activities carried out by the third
18 party under the program under this section.

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

22 “(6) FUNDING.—For purposes of carrying out
23 this section, the Secretary shall provide for the
24 transfer, from the Federal Supplementary Medical
25 Insurance Trust Fund under section 1841 to the

Centers for Medicare & Medicaid Services Program Management Account, of \$4,000,000 for each of fiscal years 2020 through 2023, to remain available until expended.”.

“(e) ENFORCEMENT.—

“(1) AUDITS.—Each manufacturer with an agreement in effect under this section shall be subject to periodic audit by the Secretary.

“(2) CIVIL MONEY PENALTY.—

“(A) IN GENERAL.—The Secretary shall impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with such agreement for each such failure in an amount the Secretary determines is commensurate with the sum of—

“(i) the amount that the manufacturer would have paid with respect to such discounts under the agreement, which will then be used to pay the discounts which the manufacturer had failed to provide; and

“(ii) 25 percent of such amount.

“(B) APPLICATION.—The provisions of section 1128A (other than subsections (a) and

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

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

12 “(g) DEFINITIONS.—In this section:

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

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

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

20 “(C) has incurred costs for covered part D
 21 drugs in the year that are above the annual de-
 22 ductible specified in section 1860D–2(b)(1) for
 23 such year.

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

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

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

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

23 “(iii) is provided through an exception or
24 appeal.

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

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

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

8 “(4) DISCOUNTED PRICE.—

9 “(A) IN GENERAL.—The term ‘discounted
10 price’ means—

11 “(i) with respect to an applicable drug
12 dispensed for an applicable beneficiary who
13 has incurred costs that are below the an-
14 nual out-of-pocket threshold specified in
15 section 1860D–2(b)(4)(B) for the year, 93
16 percent of the negotiated price of the ap-
17 plicable drug of a manufacturer; and

18 “(ii) with respect to an applicable
19 drug dispensed for an applicable bene-
20 ficiary who has incurred costs for covered
21 part D drugs in the year that are equal to
22 or exceed the annual out-of-pocket thresh-
23 old specified in section 1860D–2(b)(4)(B)
24 for the year, 86 percent of the negotiated

1 price of the applicable drug of a manufac-
2 turer.

3 “(B) CLARIFICATION.—Nothing in this
4 section shall be construed as affecting the re-
5 sponsibility of an applicable beneficiary for pay-
6 ment of a dispensing fee for an applicable drug.

7 “(C) CLARIFICATION FOR CERTAIN
8 CLAIMS.—With respect to the amount of the ne-
9 gotiated price of an individual claim for an ap-
10 plicable drug with respect to an applicable bene-
11 ficiary, the manufacturer of the applicable drug
12 shall provide—

13 “(i) the discounted price under clause
14 (i) of subparagraph (A) only on the portion
15 of the negotiated price of the applicable
16 drug that falls above the deductible speci-
17 fied in section 1860D–2(b)(1) for the year
18 and below the annual out-of-pocket thresh-
19 old specified in section 1860D–2(b)(4)(B)
20 for the year; and

21 “(ii) the discounted price under clause
22 (ii) of subparagraph (A) only on the por-
23 tion of the negotiated price of the applica-
24 ble drug that falls at or above such annual
25 out-of-pocket threshold.

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

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

16 “(7) QUALIFIED RETIREE PRESCRIPTION DRUG
17 PLAN.—The term ‘qualified retiree prescription drug
18 plan’ has the meaning given such term in section
19 1860D–22(a)(2).”.

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

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

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

6 “(h) SUNSET OF PROGRAM.—

7 “(1) IN GENERAL.—The program shall not
 8 apply to applicable drugs dispensed on or after Jan-
 9 uary 1, 2023, and, subject to paragraph (2), agree-
 10 ments under this section shall be terminated as of
 11 such date.

12 “(2) CONTINUED APPLICATION FOR APPLICA-
 13 BLE DRUGS DISPENSED PRIOR TO SUNSET.—The
 14 provisions of this section (including all responsibil-
 15 ities and duties) shall continue to apply after Janu-
 16 ary 1, 2023, with respect to applicable drugs dis-
 17 pensed prior to such date.”.

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

22 (A) in subsection (b)(2)(C)(iii)—

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

1 “(I) the reinsurance”; and

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

4 “(II) for 2023 and each subse-
5 quent year, the manufacturer dis-
6 counts provided under section 1860D–
7 14B subtracted from the actuarial
8 value to produce such bid; and”; and

9 (B) in subsection (c)(1)(C)—

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

13 “(i) the reinsurance”;

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

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

19 “(ii) for 2023 and each subsequent
20 year, the manufacturer discounts provided
21 under section 1860D–14B;”.

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

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

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

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

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

14 (1) in paragraph (2)—

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

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

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

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

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

6 (2) in paragraph (3)—

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

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

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

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

1 121 of the Prescription Drug Pricing Reduction Act
2 of 2020.”.

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

6 (1) in subsection (a)—

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

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

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

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

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

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

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

1 “(b) EFFECTIVE DATE.—Paragraphs (1) through (3)
 2 of subsection (a) shall apply to covered part D drugs dis-
 3 pensed under this part on or after January 1, 2011, and
 4 before January 1, 2023, and paragraphs (4) through (6)
 5 of such subsection shall apply to covered part D drugs
 6 dispensed on or after January 1, 2023.”; and

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

9 “(2) the Secretary determines that in the period
 10 beginning on January 1, 2011, and ending on De-
 11 cember 31, 2011 (with respect to paragraphs (1)
 12 through (3) of subsection (a)), or the period begin-
 13 ning on January 1, 2023, and ending December 31,
 14 2023 (with respect to paragraphs (4) through (6) of
 15 such subsection), there were extenuating cir-
 16 cumstances.”.

17 (h) CONFORMING AMENDMENTS.—

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

20 (A) in subsection (a)(2)(A)(i)(I), by strik-
 21 ing “, or an increase in the initial” and insert-
 22 ing “or for a year preceding 2023 an increase
 23 in the initial”;

24 (B) in subsection (c)(1)(C)—

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

4 (ii) by inserting “for a year preceding
 5 2023 or the annual out-of-pocket threshold
 6 specified in subsection (b)(4)(B) for the
 7 year for 2023 and each subsequent year”
 8 after “subsection (b)(3) for the year” each
 9 place it appears; and

10 (C) in subsection (d)(1)(A), by striking “or
 11 an initial” and inserting “or for a year pre-
 12 ceding 2023 an initial”.

13 (2) Section 1860D–4(a)(4)(B)(i) of the Social
 14 Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is
 15 amended by striking “the initial” and inserting “for
 16 a year preceding 2023, the initial”.

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

19 (A) in paragraph (1)—

20 (i) in subparagraph (C), by striking
 21 “The continuation” and inserting “For a
 22 year preceding 2023, the continuation”;

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

1 (iii) in subparagraph (E), by striking
 2 “The elimination” and inserting “For a
 3 year preceding 2023, the elimination”; and
 4 (B) in paragraph (2)—

5 (i) in subparagraph (C), by striking
 6 “The continuation” and inserting “For a
 7 year preceding 2023, the continuation”;
 8 and

9 (ii) in subparagraph (E)—
 10 (I) by inserting “for a year pre-
 11 ceding 2023,” after “subsection (c)”;
 12 and

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

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

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

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

1 “(i) for years prior to 2023, any dis-
2 count”;

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

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

8 “(ii) for 2023 and each subsequent
9 year, any discount provided pursuant to
10 section 1860D–14B.”.

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

13 (A) by inserting “for a year before 2023”
14 after “1860D–2(b)(3)”; and

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

17 (i) EFFECTIVE DATE.—The amendments made by
18 this section shall apply to plan year 2023 and subsequent
19 plan years.

20 **SEC. 121A. MAXIMUM MONTHLY CAP ON COST-SHARING**
21 **PAYMENTS UNDER PRESCRIPTION DRUG**
22 **PLANS AND MA-PD PLANS.**

23 (a) IN GENERAL.—Section 1860D–2(b) of the Social
24 Security Act (42 U.S.C. 1395w–102(b)), as amended by
25 section 121, is amended—

1 (1) in paragraph (2)—

2 (A) in subparagraph (A), by striking “and
3 (D)” and inserting “, (D), and (E)”; and

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

6 “(E) MAXIMUM MONTHLY CAP ON COST-
7 SHARING PAYMENTS.—

8 “(i) IN GENERAL.—For plan years be-
9 ginning on or after January 1, 2023, the
10 Secretary shall, through notice and com-
11 ment rulemaking, establish a process under
12 which each PDP sponsor offering a pre-
13 scription drug plan and each MA organiza-
14 tion offering an MA–PD plan shall provide
15 to any enrollee, including an enrollee who
16 is a subsidy eligible individual (as defined
17 in paragraph (3) of section 1860D–14(a)),
18 the option to elect with respect to a plan
19 year to have their monthly cost-sharing
20 payments under the plan capped in accord-
21 ance with this subparagraph.

22 “(ii) DETERMINATION OF MAXIMUM
23 MONTHLY CAP.—For each month in the
24 plan year after an enrollee in a prescrip-
25 tion drug plan or an MA–PD plan has

made an election pursuant to clause (i), the PDP sponsor or MA organization shall determine a maximum monthly cap (as defined in clause (iv)) for such enrollee.

“(iii) BENEFICIARY MONTHLY PAYMENTS.—With respect to an enrollee who has made an election pursuant to clause (i), for each month described in clause (ii), the PDP sponsor or MA organization shall bill such enrollee an amount (not to exceed the maximum monthly cap) for the out-of-pocket costs of such enrollee in such month.

“(iv) MAXIMUM MONTHLY CAP DEFINED.—In this subparagraph, the term ‘maximum monthly cap’ means, with respect to an enrollee—

“(I) for the first month in which this subparagraph applies, an amount determined by calculating—

“(aa) the annual out-of-pocket threshold specified in paragraph (4)(B) minus the incurred costs of the enrollee as de-

1 scribed in paragraph (4)(C); di-
2 vided by

3 “(bb) the number of months
4 remaining in the plan year; and

5 “(II) for a subsequent month, an
6 amount determined by calculating—

7 “(aa) the sum of any re-
8 maining out-of-pocket costs owed
9 by the enrollee from a previous
10 month that have not yet been
11 billed to the enrollee and any ad-
12 ditional costs incurred by the en-
13 rollee; divided by

14 “(bb) the number of months
15 remaining in the plan year.

16 “(v) ADDITIONAL REQUIREMENTS.—
17 The following requirements shall apply
18 with respect to the option to make an elec-
19 tion pursuant to clause (i) under this sub-
20 paragraph:

21 “(I) SECRETARIAL RESPONSIBIL-
22 ITIES.—The Secretary shall provide
23 information to part D eligible individ-
24 uals on the option to make such elec-
25 tion through educational materials, in-

cluding through the notices provided
under section 1804(a).

“(II) TIMING OF ELECTION.—An
enrollee in a prescription drug plan or
an MA–PD plan may make such an
election—

“(aa) prior to the beginning
of the plan year; or

“(bb) in any month during
the plan year.

“(III) PDP SPONSOR AND MA
ORGANIZATION RESPONSIBILITIES.—
Each PDP sponsor offering a pre-
scription drug plan or MA organiza-
tion offering an MA–PD plan—

“(aa) may not limit the op-
tion for an enrollee to make such
an election to certain covered
part D drugs;

“(bb) shall, prior to the plan
year, notify prospective enrollees
of the option to make such an
election in promotional materials;

1 “(cc) shall include informa-
2 tion on such option in enrollee
3 educational materials;

4 “(dd) shall have in place a
5 mechanism to notify a pharmacy
6 during the plan year when an en-
7 rollee incurs out-of-pocket costs
8 with respect to covered part D
9 drugs that make it likely the en-
10 rollee may benefit from making
11 such an election;

12 “(ee) shall provide that a
13 pharmacy, after receiving a noti-
14 fication described in item (dd)
15 with respect to an enrollee, in-
16 forms the enrollee of such notifi-
17 cation;

18 “(ff) shall ensure that such
19 an election by an enrollee has no
20 effect on the amount paid to
21 pharmacies (or the timing of
22 such payments) with respect to
23 covered part D drugs dispensed
24 to the enrollee; and

1 “(gg) shall have in place a
2 financial reconciliation process to
3 correct inaccuracies in payments
4 made by an enrollee under this
5 subparagraph with respect to
6 covered part D drugs during the
7 plan year.

8 “(IV) FAILURE TO PAY AMOUNT
9 BILLED.—If an enrollee fails to pay
10 the amount billed for a month as re-
11 quired under this subparagraph, the
12 election of the enrollee pursuant to
13 clause (i) shall be terminated and en-
14 rollee shall pay the cost-sharing other-
15 wise applicable for any covered part D
16 drugs subsequently dispensed to the
17 enrollee up to the annual out-of-pock-
18 et threshold specified in paragraph
19 (4)(B).

20 “(V) CLARIFICATION REGARDING
21 PAST DUE AMOUNTS.—Nothing in this
22 subparagraph shall be construed as
23 prohibiting a PDP sponsor or an MA
24 organization from billing an enrollee

1 for an amount owed under this sub-
 2 paragraph.

3 “(VI) TREATMENT OF UNSET-
 4 TLED BALANCES.—Any unsettled bal-
 5 ances with respect to amounts owed
 6 under this subparagraph shall be
 7 treated as plan losses and the Sec-
 8 retary shall not be liable for any such
 9 balances outside of those assumed as
 10 losses estimated in plan bids.”; and

11 (2) in paragraph (4)—

12 (A) in subparagraph (C), by striking “and
 13 subject to subparagraph (F)” and inserting
 14 “and subject to subparagraphs (F) and (G)”;
 15 and

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

18 “(G) INCLUSION OF COSTS PAID UNDER
 19 MAXIMUM MONTHLY CAP OPTION.—In applying
 20 subparagraph (A), with respect to an enrollee
 21 who has made an election pursuant to clause (i)
 22 of paragraph (2)(E), costs shall be treated as
 23 incurred if such costs are paid by a PDP spon-
 24 sor or an MA organization under the process
 25 provided under such paragraph.”.

1 (b) APPLICATION TO ALTERNATIVE PRESCRIPTION
 2 DRUG COVERAGE.—Section 1860D–2(c) of the Social Se-
 3 curity Act (42 U.S.C. 1395w–102(c)) is amended by add-
 4 ing at the end the following new paragraph:

5 “(4) SAME MAXIMUM MONTHLY CAP ON COST-
 6 SHARING.—For plan years beginning on or after
 7 January 1, 2023, the maximum monthly cap on
 8 cost-sharing payments under the process provided
 9 under subsection (b)(2)(E) shall apply to such cov-
 10 erage.”.

11 **SEC. 121B. REQUIRING PHARMACY-NEGOTIATED PRICE**
 12 **CONCESSIONS, PAYMENT, AND FEES TO BE**
 13 **INCLUDED IN NEGOTIATED PRICES AT THE**
 14 **POINT-OF-SALE UNDER PART D OF THE MEDI-**
 15 **CARE PROGRAM.**

16 Section 1860D–2(d)(1)(B) of the Social Security Act
 17 (42 U.S.C. 1395w–102(d)(1)(B)) is amended—

18 (1) by striking “PRICES.—For purposes” and
 19 inserting “PRICES.—

20 “(i) IN GENERAL.—For purposes”;
 21 and

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

24 “(ii) PRICES NEGOTIATED WITH
 25 PHARMACY AT POINT-OF-SALE.—For plan

1 years beginning on or after January 1,
 2 2022, a negotiated price for a covered part
 3 D drug described in clause (i) shall be the
 4 approximate lowest possible reimbursement
 5 for such drug negotiated with the phar-
 6 macy dispensing such drug, and shall in-
 7 clude all contingent and noncontingent
 8 price concessions, payments, and fees nego-
 9 tiated with such pharmacy, but shall not
 10 include positive incentive payments paid or
 11 to be paid to such pharmacy. Such nego-
 12 tiated price shall be provided at the point-
 13 of-sale of such drug.”.

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

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

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

23 (1) in paragraph (2)—

24 (A) in subparagraph (A)(ii), by striking

25 “and” at the end;

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

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

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

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

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

1 “(A) The specific amounts or the identity
 2 of the source of any rebates, price concessions,
 3 or other forms of direct or indirect remunera-
 4 tion under such prescription drug plan or such
 5 MA–PD plan.

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

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

16 (b) ACCESS TO CERTAIN REBATE AND PAYMENT
 17 DATA UNDER MEDICARE AND MEDICAID.—Section
 18 1927(b)(3)(D) of the Social Security Act (42 U.S.C.
 19 1396r–8(b)(3)(D)) is amended—

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

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

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

1 (4) by inserting after clause (vi) the following
 2 new clause:

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

9 (5) in the matter at the end, by striking
 10 “1860D–4(c)(2)(E)” and inserting “1860D–
 11 4(c)(2)(G)”; and

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

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

25 (a) PUBLIC DISCLOSURE OF DRUG DISCOUNTS.—

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

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

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

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

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

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

1 “(3) CONFIDENTIALITY.—The Secretary shall
 2 ensure that such information is displayed in a man-
 3 ner that prevents the disclosure of information on
 4 rebates, discounts, and price concessions with re-
 5 spect to an individual drug or an individual PDP
 6 sponsor, MA organization, or qualified health bene-
 7 fits plan.”.

8 (2) EFFECTIVE DATE.—The amendment made
 9 by paragraph (1)(A) shall take effect on January 1,
 10 2022.

11 (b) PLAN AUDIT OF PHARMACY BENEFIT MANAGER
 12 DATA.—Section 1860D–2(d)(3) of the Social Security Act
 13 (42 U.S.C. 1395w–102(d)(3)) is amended—

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

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

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

20 “(B) AUDITS OF PHARMACY BENEFIT
 21 MANAGERS BY PDP SPONSORS AND MA ORGANI-
 22 ZATIONS.—

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

1 “(I) contracting terms between a
 2 PDP sponsor offering a prescription
 3 drug plan or an MA organization of-
 4 fering an MA–PD plan and its con-
 5 tracted or owned pharmacy benefit
 6 manager are met; and

7 “(II) the PDP sponsor and MA
 8 organization can account for the cost
 9 of each covered part D drug net of all
 10 direct and indirect remuneration;
 11 the PDP sponsor or MA organization shall
 12 conduct financial audits.

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

15 “(I) be conducted by an inde-
 16 pendent third party; and

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

23 “(iii) REBATE AGREEMENTS.—A PDP
 24 sponsor and an MA organization shall re-
 25 quire pharmacy benefit managers to make

1 rebate contracts with drug manufacturers
2 made on their behalf available under audits
3 described in clause (i).

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

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

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

23 “(vii) SUBMISSION OF AUDIT REPORTS
24 TO THE SECRETARY.—

1 “(I) IN GENERAL.—A PDP spon-
2 sor and an MA organization shall sub-
3 mit to the Secretary the final report
4 on any audit conducted under clause
5 (i) within 30 days of the PDP sponsor
6 or MA organization receiving the re-
7 port from the independent third party
8 conducting the audit.

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

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

23 “(viii) NOTICE OF NONCOMPLI-
24 ANCE.—A PDP sponsor and an MA orga-
25 nization shall notify the Secretary if any

1 pharmacy benefit manager is not com-
2 plying with requests for access to informa-
3 tion required under an audit under clause
4 (i).

5 “(ix) CIVIL MONETARY PENALTIES.—

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

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

23 (c) DISCLOSURE TO PHARMACY OF POST-POINT-OF-

24 SALE PHARMACY PRICE CONCESSIONS AND INCENTIVE

1 PAYMENTS.—Section 1860D–2(d)(2) of the Social Secu-
 2 rity Act (42 U.S.C. 1395w–102(d)(2)) is amended—

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

5 “(A) TO THE SECRETARY.—A PDP spon-
 6 sor”; and

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

9 “(B) TO PHARMACIES.—

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

22 “(ii) TIMING.—The reporting of price
 23 concessions and incentive payments to a
 24 pharmacy under clause (i) shall be made

on a periodic basis (but in no case less frequently than annually).

“(iii) CLAIM LEVEL.—The reporting of price concessions and incentive payments to a pharmacy under clause (i) shall be at the claim level or approximated at the claim level if the price concession or incentive payment was applied at a level other than at the claim level.”.

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

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

“(iii) DISCLOSURE OF CONFLICTS OF INTEREST.—With respect to plan year 2022 and subsequent plan years, a PDP sponsor of a prescription drug plan and an MA organization offering an MA–PD plan shall, as part of its bid submission under section 1860D–11(b), provide the Secretary with a completed statement of financial conflicts of interest, including with manufacturers, from each member of any

1 pharmacy and therapeutic committee used
2 by the sponsor or organization pursuant to
3 this paragraph.”.

4 (2) INCLUSION IN BID.—Section 1860D–
5 11(b)(2) of the Social Security Act (42 U.S.C.
6 1395w–111(b)(2)) is amended—

7 (A) by redesignating subparagraph (F) as
8 subparagraph (G); and

9 (B) by inserting after subparagraph (E)
10 the following new subparagraph:

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

14 (e) INFORMATION ON DIRECT AND INDIRECT REMU-
15 NERATION REQUIRED TO BE INCLUDED IN BID.—Section
16 1860D–11(b) of the Social Security Act (42 U.S.C.
17 1395w–111(b)) is amended—

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

24 (2) in paragraph (2)(C)—

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

3 (B) in clause (iv), by striking the period at
4 the end and inserting the following: “, and, with
5 respect to plan year 2022 and subsequent plan
6 years, actual and projected administrative ex-
7 penses assumed in the bid, categorized by the
8 type of such expense, including actual and pro-
9 jected price concessions retained by a pharmacy
10 benefit manager; and”; and

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

13 “(v) with respect to plan year 2022
14 and subsequent plan years, actual and pro-
15 jected direct and indirect remuneration,
16 categorized as received from each of the
17 following:

18 “(I) A pharmacy.

19 “(II) A manufacturer.

20 “(III) A pharmacy benefit man-
21 ager.

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

1 **SEC. 124. PUBLIC DISCLOSURE OF DIRECT AND INDIRECT**
 2 **REMUNERATION REVIEW AND AUDIT RE-**
 3 **SULTS.**

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

7 “(e) PUBLIC DISCLOSURE OF DIRECT AND INDIRECT
 8 REMUNERATION REVIEW AND FINANCIAL AUDIT RE-
 9 SULTS.—

10 “(1) DIRECT AND INDIRECT REMUNERATION
 11 REVIEW RESULTS.—

12 “(A) IN GENERAL.—Except as provided in
 13 subparagraph (B), in 2021 and each subse-
 14 quent year, the Secretary shall make available
 15 to the public on the Internet website of the
 16 Centers for Medicare & Medicaid Services infor-
 17 mation on discrepancies related to summary
 18 and detailed direct and indirect remuneration
 19 reports submitted by PDP sponsors pursuant to
 20 section 1860D–15 across all prescription drug
 21 plans based on the most recent data available.
 22 Information made available under this subpara-
 23 graph shall include the following:

24 “(i) The number of potential discrep-
 25 ancies in summary and detailed direct and

1 indirect remuneration identified by the
2 Secretary for PDP sponsors to review.

3 “(ii) The extent to which PDP spon-
4 sors resubmitted summary direct and indi-
5 rect remuneration reports to make changes
6 for previous contract years.

7 “(iii) The extent to which resubmitted
8 summary direct and indirect remuneration
9 reports resulted in an increase or decrease
10 in direct and indirect remuneration in a
11 previous contract year.

12 “(B) EXCLUSION OF CERTAIN SUBMIS-
13 SIONS IN CALCULATION.—The Secretary shall
14 exclude any information in direct and indirect
15 remuneration reports submitted with respect to
16 PACE programs under section 1894 (pursuant
17 to section 1860D–21(f)) and qualified retiree
18 prescription drug plans (as defined in section
19 1860D–22(a)(2)) from the information that is
20 made available to the public under subpara-
21 graph (A).

22 “(2) FINANCIAL AUDIT RESULTS.—In 2021 and
23 each subsequent year, the Secretary shall make
24 available to the public on the Internet website of the
25 Centers for Medicare & Medicaid Services data on

1 the results of financial audits required under section
2 1860D–12(b)(3)(C). Information made available
3 under this paragraph shall include the following:

4 “(A) With respect to a year, the number of
5 PDP sponsors that received each of the fol-
6 lowing (or successor categories), with an indica-
7 tion of the number that pertain to direct and
8 indirect remuneration:

9 “(i) A notice of observations or find-
10 ings.

11 “(ii) An unqualified audit opinion that
12 renders the audit closed.

13 “(iii) A qualified audit opinion that
14 requires the sponsor to submit a corrective
15 action plan to the Secretary.

16 “(iv) An adverse opinion, with a de-
17 scription of the types of actions that the
18 Secretary takes when issuing an adverse
19 opinion.

20 “(v) A disclaimed opinion.

21 “(B) With respect to a year, the number of
22 PDP sponsors—

23 “(i) that reopened a previously closed
24 reconciliation as a result of an audit, indi-

1 cating those that pertain to direct and in-
 2 direct remuneration changes; and

3 “(ii) for which the Secretary recouped
 4 a payment or made a payment as a result
 5 of a reopening of a previously closed rec-
 6 onciliation, indicating when such
 7 recoupment or payment pertains to direct
 8 and indirect remuneration.

9 “(3) NO IDENTIFICATION OF SPECIFIC PDP
 10 SPONSORS.—The information to be made available
 11 on the Internet website of the Centers for Medicare
 12 & Medicaid Services described in paragraph (1) and
 13 paragraph (2) shall not identify the specific PDP
 14 sponsor to which any determination or action per-
 15 tains.

16 “(4) DEFINITION OF DIRECT AND INDIRECT
 17 REMUNERATION.—For purposes of this subsection,
 18 the term ‘direct and indirect remuneration’ means
 19 direct and indirect remuneration as described in sec-
 20 tion 423.308 of title 42, Code of Federal Regula-
 21 tions, or any successor 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

1 INCLUDE 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

paragraph in the same manner as data under the Part D Enhanced Medication Therapy Management model tested under section 1115A, through Application Programming Interface, or in another manner as determined by the Secretary.

“(II) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this clause by program instruction or otherwise.”.

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

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

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

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

(2) by inserting after subsection (d) the following new subsection:

“(e) LIMITED INCOME NEWLY ELIGIBLE TRANSITION (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

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

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

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

“(I) such individual was first eligible for a low income subsidy under this part; or

“(II) is 36 months prior to the date such individual enrolls in a prescription drug plan or an MA–PD 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 2023, 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-

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

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

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

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

“(B) TRANSITION RULE FOR INFORMATION
IN 2023.—Notwithstanding subparagraph (A),
the Secretary may, for each rebatable covered
part D drug, delay the timeframe for reporting
the information and rebate amount described in
clauses (i), (ii), (iii), and (iv) of such subpara-
graph for rebate periods in 2023 until not later
than December 31, 2024.

“(2) MANUFACTURER REBATE.—

“(A) IN GENERAL.—Subject to subpara-
graph (B), for each rebate period beginning on
or after January 1, 2023, 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 follows the last day of
21 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(c)(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.—

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

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

“(ii) the percentage by which the rebate period CPI–U (as defined in paragraph (4)) for the rebate period exceeds the benchmark CPI–U (as defined in paragraph (5)).

“(B) DETERMINATION OF BENCHMARK UNIT-WEIGHTED PRICE.—The benchmark unit-weighted price determined under this subparagraph for a rebate period, with respect to each dosage form and strength of a rebatable covered part D drug, is the sum of the products of—

“(i) each price, as calculated for a unit of such drug, applicable to each package size of such dosage form and strength of such drug on July 1, 2019; and

“(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 subsequently rebatable drug
4 weighted average price determined under para-
5 graph (4) with respect to each package size of
6 such dosage form and strength of such drug
7 dispensed during the six month period that be-
8 gins on the day on which the drug was first
9 marketed; and

10 “(B) the ratio of—

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

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

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

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

1 such dosage form and strength of such drug
 2 during the six month period that begins on the
 3 day on which the drug was first marketed; and

4 “(B) the ratio of—

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

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

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

14 “(e) ADMINISTRATION.—

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

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

24 “(A) BENCHMARK UNIT-WEIGHTED
 25 PRICE.—In the case that the benchmark unit-

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

12 “(B) BENCHMARK UNIT-WEIGHTED AVER-
13 AGE PRICE.—In the case that the benchmark
14 unit-weighted average price of a dosage form
15 and strength of a rebatable covered part D
16 drug described under subsection (c) is deter-
17 mined under paragraph (3) of such subsection
18 to be \$0 due to no units of such dosage form
19 and strength of such drug being dispensed dur-
20 ing the six month period that begins on the day
21 on which the drug was first marketed, the Sec-
22 retary may use a calculation, as determined ap-
23 propriate by the Secretary, to determine the
24 benchmark-unit weighted average price for such
25 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 subsequently rebatable drug
23 weighted average price under subsection
24 (c)(4); and

1 “(B) the application of special rules for
 2 calculation of benchmark unit-weighted price
 3 and benchmark unit-weighted average price
 4 under paragraph (2) of this subsection.

5 “(f) CIVIL MONEY PENALTY.—

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

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

16 “(B) 25 percent of such amount.

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

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

24 “(1) any formulary design under section
 25 1860D–4(b)(3); or

1 “(2) any discounts provided under the coverage
 2 gap discount program under section 1860D–14A or
 3 the manufacturer catastrophic discount program
 4 under section 1860D–14B.

5 “(h) REBATE AGREEMENT.—

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

9 “(2) TERMS OF AGREEMENT.—

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

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

22 “(i) for each calendar month under
 23 the rebate agreement—

24 “(I) each wholesale acquisition
 25 cost (as defined in section

1 1847A(c)(6)) applicable during the
2 month, applicable to each National
3 Drug Code for the dosage form and
4 strength of such rebatable covered
5 part D drug; and

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

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

24 “(iii) such other information as the
25 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 of the Social Security
9 Act (42 U.S.C. 1395w–153), as amended by section
10 121(g), is amended—

11 (A) in subsection (a)—

12 (i) in paragraph (5), by striking
13 “and” at the end;

14 (ii) in paragraph (6), by striking the
15 period at the end and inserting “; and”;
16 and

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

19 “(7) have entered into and have in effect an
20 agreement described in section 1860D–14C(h)(2)
21 with the Secretary.”;

22 (B) in subsection (b), by striking “(6)”
23 and inserting “(7)”; and

24 (C) in subsection (c), by striking “(6)” and
25 inserting “(7)”.

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

4 (A) by striking “or any discounts” and in-
 5 serting “any discounts”; and

6 (B) by inserting “, or any rebates under
 7 section 1860D-14C” before the period.

8 **SEC. 129. PROHIBITING BRANDING ON PART D BENEFIT**
 9 **CARDS.**

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

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

18 **SEC. 130. REQUIRING PRESCRIPTION DRUG PLANS AND**
 19 **MA-PD PLANS TO REPORT POTENTIAL**
 20 **FRAUD, WASTE, AND ABUSE TO THE SEC-**
 21 **RETARY OF HHS.**

22 Section 1860D-4 of the Social Security Act (42
 23 U.S.C. 1395w-104), as amended by section 125, is
 24 amended by adding at the end the following new sub-
 25 section:

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

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

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

12 **SEC. 131. ESTABLISHMENT OF PHARMACY QUALITY MEAS-**
 13 **URES UNDER MEDICARE PART D.**

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

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

20 “(A) IN GENERAL.—A PDP sponsor that
 21 makes incentive payments to a pharmacy or re-
 22 ceives price concessions paid by a pharmacy
 23 based on quality measures shall, for the pur-
 24 poses of such incentive payments or price con-
 25 cessions with respect to covered part D drugs

dispensed by such pharmacy, only use measures—

“(i) established or adopted by the Secretary under subparagraph (B), as listed under clause (ii) of such subparagraph; and

“(ii) that are relevant to the performance of such pharmacy with respect to areas that the pharmacy can impact.

“(B) STANDARD PHARMACY QUALITY MEASURES.—

“(i) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall establish or adopt quality measures from one or more multi-stakeholder, consensus organizations to be used by a PDP sponsor for the purposes of determining incentive payments and price concessions described in subparagraph (A). Such measures shall be evidence-based and focus on pharmacy performance on patient health outcomes and other areas, as determined by the Secretary, that the pharmacy can impact.

1 “(ii) MAINTENANCE OF LIST.—The
 2 Secretary shall maintain a single list of
 3 measures established or adopted under this
 4 subparagraph.

5 “(C) EFFECTIVE DATE.—The requirement
 6 under subparagraph (A) shall take effect for
 7 plan years beginning on January 1, 2022, or
 8 such earlier date specified by the Secretary if
 9 the Secretary determines there are sufficient
 10 measures established or adopted under subpara-
 11 graph (B) for the purposes of the requirement
 12 under subparagraph (A).”.

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

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

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

23 “(i) IN GENERAL.—For 2026 and
 24 subsequent years, the Secretary shall add a
 25 new set of measures to the 5-star rating

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

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

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

21 “(III) UTILIZATION MANAGE-
22 MENT TOOLS.—Assessing whether and
23 how utilization management tools are
24 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. FAIRNESS IN THE CALCULATION OF THE PART D**
 10 **PREMIUM.**

11 (a) IN GENERAL.—Section 1860D-13(a) of the So-
 12 cial Security Act (42 U.S.C. 1395w-113(a)) is amended—

13 (1) in paragraph (3)(A), by striking “25.5 per-
 14 cent” and inserting “the applicable percent (as spec-
 15 ified in paragraph (8))”; and

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

18 “(8) APPLICABLE PERCENT.—For purposes of
 19 paragraph (3)(A), the applicable percent specified in
 20 this paragraph is—

21 “(A) for years prior to 2022, 25.5 percent;

22 and

23 “(B) for 2022 and subsequent years, 24.5
 24 percent.”.

25 (b) CONFORMING AMENDMENTS.—

1 (1) SUBSIDY.—Section 1860D–15(a) of the So-
 2 cial Security Act (42 U.S.C. 1395w–115(a)) is
 3 amended, in the matter preceding paragraph (1), by
 4 inserting “(or, for 2020 and subsequent years, 75.5
 5 percent)” after “74.5 percent”.

6 (2) FALLBACK AREA MONTHLY BENEFICIARY
 7 PREMIUM.—Section 1860D–11(g)(6) of the Social
 8 Security Act (42 U.S.C. 1395w–111(g)(6)) is
 9 amended by striking “25.5 percent” and inserting
 10 “the applicable percent (as specified in section
 11 1860D–13(a)(8))”.

12 (3) INCOME-RELATED MONTHLY ADJUSTMENT
 13 AMOUNT (IRMAA).—Section 1860D–
 14 13(a)(7)(B)(i)(II) of the Social Security Act (42
 15 U.S.C. 1395w–113(a)(7)(B)(i)(II)) is amended by
 16 striking “25.5 percent” and inserting “the applica-
 17 ble percent (as specified in paragraph (8))”.

18 **SEC. 134. HHS STUDY AND REPORT ON THE INFLUENCE OF**
 19 **PHARMACEUTICAL MANUFACTURER THIRD-**
 20 **PARTY REIMBURSEMENT HUBS ON HEALTH**
 21 **CARE PROVIDERS WHO PRESCRIBE THEIR**
 22 **DRUGS AND BIOLOGICALS.**

23 (a) STUDY.—

24 (1) IN GENERAL.—The Secretary of Health and
 25 Human Services (in this section referred to as the

1 “Secretary”) shall conduct a study on the influence
2 of pharmaceutical manufacturer distribution models
3 that provide third-party reimbursement hub services
4 on health care providers who prescribe the manufac-
5 turer’s drugs and biologicals, including for Medicare
6 part D beneficiaries.

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

9 (A) The influence of pharmaceutical manu-
10 facturer distribution models that provide third-
11 party reimbursement hub services to health care
12 providers who prescribe the manufacturer’s
13 drugs and biologicals, including—

14 (i) the operations of pharmaceutical
15 manufacturer distribution models that pro-
16 vide reimbursement hub services for health
17 care providers who prescribe the manufac-
18 turer’s products;

19 (ii) Federal laws affecting these phar-
20 maceutical manufacturer distribution mod-
21 els; and

22 (iii) whether hub services could im-
23 properly incentivize health care providers
24 to deem a drug or biological as medically

1 necessary under section 423.578 of title
2 42, Code of Federal Regulations.

3 (B) Other areas determined appropriate by
4 the Secretary.

5 (b) REPORT.—Not later than July 1, 2022, the Sec-
6 retary shall submit to Congress a report on the study con-
7 ducted under subsection (a), together with recommenda-
8 tions for such legislation and administrative action as the
9 Secretary determines appropriate.

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

13 **Subtitle C—Miscellaneous**

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

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

18 **“SEC. 1128L. DRUG MANUFACTURER PRICE TRANS-** 19 **PARENCY.**

20 “(a) IN GENERAL.—

21 “(1) DETERMINATIONS.—Beginning July 1,
22 2022, the Secretary shall make determinations as to
23 whether a drug is an applicable drug as described in
24 subsection (b).

1 “(2) REQUIRED JUSTIFICATION.—If the Sec-
 2 retary determines under paragraph (1) that an ap-
 3 plicable drug is described in subsection (b), the man-
 4 ufacturer of the applicable drug shall submit to the
 5 Secretary the justification described in subsection (c)
 6 in accordance with the timing described in sub-
 7 section (d).

8 “(b) APPLICABLE DRUG DESCRIBED.—

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

12 “(A) LARGE INCREASE.—The drug (per
 13 dose)—

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

16 “(ii) had an increase in the wholesale
 17 acquisition cost, with respect to determina-
 18 tions made—

19 “(I) during 2020, of at least 100
 20 percent since the date of the enact-
 21 ment of this section;

22 “(II) during 2021, of at least
 23 100 percent in the preceding 12
 24 months or of at least 150 percent in
 25 the preceding 24 months;

1 “(III) during 2022, of at least
2 100 percent in the preceding 12
3 months or of at least 200 percent in
4 the preceding 36 months;

5 “(IV) during 2023, of at least
6 100 percent in the preceding 12
7 months or of at least 250 percent in
8 the preceding 48 months; or

9 “(V) on or after January 1,
10 2024, of at least 100 percent in the
11 preceding 12 months or of at least
12 300 percent in the preceding 60
13 months.

14 “(B) HIGH SPENDING WITH INCREASE.—

15 The drug—

16 “(i) was in the top 50th percentile of
17 net spending under title XVIII or XIX (to
18 the extent data is available) during any 12-
19 month period in the preceding 60 months;
20 and

21 “(ii) per dose, had an increase in the
22 wholesale acquisition cost, with respect to
23 determinations made—

1 “(I) during 2020, of at least 15
2 percent since the date of the enact-
3 ment of this section;

4 “(II) during 2021, of at least 15
5 percent in the preceding 12 months or
6 of at least 20 percent in the preceding
7 24 months;

8 “(III) during 2022, of at least 15
9 percent in the preceding 12 months or
10 of at least 30 percent in the preceding
11 36 months;

12 “(IV) during 2023, of at least 15
13 percent in the preceding 12 months or
14 of at least 40 percent in the preceding
15 48 months; or

16 “(V) on or after January 1,
17 2024, of at least 15 percent in the
18 preceding 12 months or of at least 50
19 percent in the preceding 60 months.

20 “(C) HIGH LAUNCH PRICE FOR NEW
21 DRUGS.—In the case of a drug that is marketed
22 for the first time on or after January 1, 2020,
23 and for which the manufacturer has established
24 the first wholesale acquisition cost on or after
25 such date, such wholesale acquisition cost for a

year's supply or a course of treatment for such drug exceeds the gross spending for covered part D drugs at which the annual out-of-pocket threshold under section 1860D-2(b)(4)(B) would be met for the year.

“(2) SPECIAL RULES.—

“(A) AUTHORITY OF SECRETARY TO SUBSTITUTE PERCENTAGES WITHIN A DE MINIMIS RANGE.—For purposes of applying paragraph (1), the Secretary may substitute for each percentage described in subparagraph (A) or (B) of such paragraph (other than the percentile described subparagraph (B)(i) of such paragraph) a percentage within a de minimis range specified by the Secretary below the percentage so described.

“(B) DRUGS WITH HIGH LAUNCH PRICES ANNUALLY REPORT UNTIL A THERAPEUTIC EQUIVALENT IS AVAILABLE.—In the case of a drug that the Secretary determines is an applicable drug described in subparagraph (C) of paragraph (1), such drug shall remain described in such subparagraph (C) (and the manufacturer of such drug shall annually report the justification under subsection (c)(2))

1 until the Secretary determines that there is a
2 therapeutic equivalent (as defined in section
3 314.3 of title 21, Code of Federal Regulations,
4 or any successor regulation) for such drug.

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

8 “(c) JUSTIFICATION DESCRIBED.—

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

19 “(A) The individual factors that have con-
20 tributed to the increase in the wholesale acqui-
21 sition cost.

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

24 “(C) Total expenditures of the manufac-
25 turer on—

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

3 “(ii) acquiring patents and licensing
4 for each drug of the manufacturer; and

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

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

11 “(E) The total expenditures of the manu-
12 facturer on research and development for such
13 drug.

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

17 “(G) The total expenditures of the manu-
18 facturer that are associated with marketing and
19 advertising for the applicable drug.

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

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

1 “(ii) metrics used to determine execu-
 2 tive compensation;

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

6 “(I) drug research and develop-
 7 ment; or

8 “(II) clinical trials on drugs that
 9 failed to receive approval by the Food
 10 and Drug Administration.

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

21 “(d) TIMING.—

22 “(1) NOTIFICATION.—Not later than 60 days
 23 after the date on which the Secretary makes the de-
 24 termination that a drug is an applicable drug under
 25 subsection (b), the Secretary shall notify the manu-

1 manufacturer of the applicable drug of such determina-
2 tion.

3 “(2) SUBMISSION OF JUSTIFICATION.—Not
4 later than 180 days after the date on which a manu-
5 facturer receives a notification under paragraph (1),
6 the manufacturer shall submit to the Secretary the
7 justification required under subsection (a).

8 “(3) POSTING ON INTERNET WEBSITE.—

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

18 “(B) EXCLUSION OF PROPRIETARY INFOR-
19 MATION.—The Secretary shall exclude propri-
20 etary information, such as trade secrets and in-
21 tellectual property, submitted by the manufac-
22 turer in the justification under paragraph (2)
23 from the posting described in subparagraph
24 (A).

1 “(e) EXCEPTION TO REQUIREMENT FOR SUBMIS-
2 SION.—In the case of a drug that the Secretary deter-
3 mines is an applicable drug described in subparagraph (A)
4 or (B) of subsection (b)(1), the requirement to submit a
5 justification under subsection (a) shall not apply where the
6 manufacturer, after receiving the notification under sub-
7 section (d)(1) with respect to the applicable drug of the
8 manufacturer, reduces the wholesale acquisition cost of a
9 drug so that it no longer is described in such subpara-
10 graph (A) or (B) for at least a 4-month period, as deter-
11 mined by the Secretary.

12 “(f) PENALTIES.—

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

22 “(2) FALSE INFORMATION.—Any manufacturer
23 that submits a justification under this section and
24 knowingly provides false information in such jus-
25 tification is subject to a civil monetary penalty in an

1 amount not to exceed \$100,000 for each item of
2 false information.

3 “(3) APPLICATION OF PROCEDURES.—The pro-
4 visions of section 1128A (other than subsections (a)
5 and (b)) shall apply to a civil monetary penalty
6 under this subsection in the same manner as such
7 provisions apply to a penalty or proceeding under
8 section 1128A(a). Civil monetary penalties imposed
9 under this subsection are in addition to other pen-
10 alties as may be prescribed by law.

11 “(g) DEFINITIONS.—In this section:

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

18 “(2) MANUFACTURER.—The term ‘manufac-
19 turer’ has the meaning given that term in section
20 1847A(c)(6)(A).

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

1 **SEC. 142. STRENGTHENING AND EXPANDING PHARMACY**
 2 **BENEFIT MANAGERS TRANSPARENCY RE-**
 3 **QUIREMENTS.**

4 Section 1150A of the Social Security Act (42 U.S.C.
 5 1320b–23), as amended by section 123, is amended—

6 (1) in subsection (a)—

7 (A) in paragraph (1), by striking “or” at
 8 the end;

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

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

13 “(3) a State plan under title XIX, including a
 14 managed care entity (as defined in section
 15 1932(a)(1)(B)),”;

16 (2) in subsection (b)—

17 (A) in paragraph (2)—

18 (i) by striking “(excluding bona fide”
 19 and all that follows through “patient edu-
 20 cation programs))”; and

21 (ii) by striking “aggregate amount of”
 22 and inserting “aggregate amount and per-
 23 centage of”;

24 (B) in paragraph (3), by striking “aggre-
 25 gate amount of” and inserting “aggregate

1 amount and percentage (defined as a share of
2 gross drug costs) of”; and

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

5 “(4) The aggregate amount of bona fide service
6 fees (which include distribution service fees, inven-
7 tory management fees, product stocking allowances,
8 and fees associated with administrative services
9 agreements and patient care programs (such as
10 medication compliance programs and patient edu-
11 cation programs)) the PBM received from—

12 “(A) PDP sponsors;

13 “(B) qualified health benefit plans;

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

16 “(D) drug manufacturers.”;

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

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

21 “(6) To the Federal Trade Commission to carry
22 out section 5(a) of the Federal Trade Commission
23 Act (15 U.S.C. 45a) and any other relevant con-
24 sumer protection or antitrust authorities enforced by

1 such Commission, including reviewing proposed
2 mergers in the prescription drug sector.

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

7 (4) by adding at the end the following new sub-
8 section:

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

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

15 “(A) PBM rebates;

16 “(B) administrative fees;

17 “(C) the difference between what plans pay
18 PBMs and what PBMs pay pharmacies;

19 “(D) generic dispensing rates; and

20 “(E) other areas determined appropriate
21 by the Inspector General.

22 “(2) REPORT.—Not later than July 1, 2021,
23 and annually thereafter, the Inspector General of the
24 Department of Health and Human Services shall
25 submit to Congress a report containing the results

1 of the evaluation conducted under paragraph (1), to-
 2 gether with recommendations for such legislation
 3 and administrative action as the Inspector General
 4 determines appropriate. Such report shall not dis-
 5 close the identity of a specific PBM, plan, or price
 6 charged for a drug.”.

7 **SEC. 143. PRESCRIPTION DRUG PRICING DASHBOARDS.**

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

10 **“SEC. 1150C. PRESCRIPTION DRUG PRICING DASHBOARDS.**

11 “(a) IN GENERAL.—Beginning not later than Janu-
 12 ary 1, 2021, the Secretary shall establish, and annually
 13 update, internet website-based dashboards, through which
 14 beneficiaries, clinicians, researchers, and the public can re-
 15 view information on spending for, and utilization of, pre-
 16 scription drugs and biologicals (and related supplies and
 17 mechanisms of delivery) covered under each of parts B
 18 and D of title XVIII and under a State program under
 19 title XIX, including information on trends of such spend-
 20 ing and utilization over time.

21 “(b) MEDICARE PART B DRUG AND BIOLOGICAL
 22 DASHBOARD.—

23 “(1) IN GENERAL.—The dashboard established
 24 under subsection (a) for part B of title XVIII shall
 25 provide the information described in paragraph (2).

1 “(2) INFORMATION DESCRIBED.—The informa-
2 tion described in this paragraph is the following in-
3 formation with respect to drug or biologicals covered
4 under such part B:

5 “(A) The brand name and, if applicable,
6 the generic names of the drug or biological.

7 “(B) Consumer-friendly information on the
8 uses and clinical indications of the drug or bio-
9 logical.

10 “(C) The manufacturer or labeler of the
11 drug or biological.

12 “(D) To the extent feasible, the following
13 information:

14 “(i) Average total spending per dos-
15 age unit of the drug or biological in the
16 most recent 2 calendar years for which
17 data is available.

18 “(ii) The percentage change in aver-
19 age spending on the drug or biological per
20 dosage unit between the most recent cal-
21 endar year for which data is available
22 and—

23 “(I) the preceding calendar year;
24 and

1 “(II) the preceding 5 and 10 cal-
2 endar years.

3 “(iii) The annual growth rate in aver-
4 age spending per dosage unit of the drug
5 or biological in the most recent 5 or 10
6 calendar years for which data is available.

7 “(iv) Total spending for the drug or
8 biological for the most recent calendar year
9 for which data is available.

10 “(v) The number of beneficiaries re-
11 ceiving the drug or biological in the most
12 recent calendar year for which data is
13 available.

14 “(vi) Average spending on the drug
15 per beneficiary for the most recent cal-
16 endar year for which data is available.

17 “(E) The average sales price of the drug
18 or biological (as determined under section
19 1847A) for the most recent quarter.

20 “(F) Consumer-friendly information about
21 the coinsurance amount for the drug or biologi-
22 cal for beneficiaries for the most recent quarter.
23 Such information shall not include coinsurance
24 amounts for qualified medicare beneficiaries (as
25 defined in section 1905(p)(1)).

1 “(G) For the most recent calendar year for
2 which data is available—

3 “(i) the 15 drugs and biologicals with
4 the highest total spending under such part;
5 and

6 “(ii) any drug or biological for which
7 the average annual per beneficiary spend-
8 ing exceeds the gross spending for covered
9 part D drugs at which the annual out-of-
10 pocket threshold under section 1860D-
11 2(b)(4)(B) would be met for the year.

12 “(H) Other information (not otherwise
13 prohibited in law from being disclosed) that the
14 Secretary determines would provide bene-
15 ficiaries, clinicians, researchers, and the public
16 with helpful information about drug and bio-
17 logical spending and utilization (including
18 trends of such spending and utilization).

19 “(c) MEDICARE COVERED PART D DRUG DASH-
20 BOARD.—

21 “(1) IN GENERAL.—The dashboard established
22 under subsection (a) for part D of title XVIII shall
23 provide the information described in paragraph (2).

24 “(2) INFORMATION DESCRIBED.—The informa-
25 tion described in this paragraph is the following in-

1 formation with respect to covered part D drugs
2 under such part D:

3 “(A) The information described in sub-
4 paragraphs (A) through (D) of subsection
5 (b)(2).

6 “(B) Information on average annual bene-
7 ficiary out-of-pocket costs below and above the
8 annual out-of-pocket threshold under section
9 1860D–2(b)(4)(B) for the current plan year.
10 Such information shall not include out-of-pocket
11 costs for subsidy eligible individuals under sec-
12 tion 1860D–14.

13 “(C) Information on how to access re-
14 sources as described in sections 1860D–1(c)
15 and 1851(d).

16 “(D) For the most recent calendar year for
17 which data is available—

18 “(i) the 15 covered part D drugs with
19 the highest total spending under such part;
20 and

21 “(ii) any covered part D drug for
22 which the average annual per beneficiary
23 spending exceeds the gross spending for
24 covered part D drugs at which the annual
25 out-of-pocket threshold under section

1 1860D–2(b)(4)(B) would be met for the
2 year.

3 “(E) Other information (not otherwise pro-
4 hibited 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 covered part D
8 drug spending and utilization (including trends
9 of such spending and utilization).

10 “(d) MEDICAID COVERED OUTPATIENT DRUG DASH-
11 BOARD.—

12 “(1) IN GENERAL.—The dashboard established
13 under subsection (a) for title XIX shall provide the
14 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 outpatient drugs
18 under such title:

19 “(A) The information described in sub-
20 paragraphs (A) through (D) of subsection
21 (b)(2).

22 “(B) For the most recent calendar year for
23 which data is available, the 15 covered out-
24 patient drugs with the highest total spending
25 under such title.

1 “(C) Other information (not otherwise pro-
 2 hibited in law from being disclosed) that the
 3 Secretary determines would provide bene-
 4 ficiaries, clinicians, researchers, and the public
 5 with helpful information about covered out-
 6 patient drug spending and utilization (including
 7 trends of such spending and utilization).

8 “(e) DATA FILES.—The Secretary shall make avail-
 9 able the underlying data for each dashboard established
 10 under subsection (a) in a machine-readable format.”.

11 **SEC. 144. IMPROVING COORDINATION BETWEEN THE FOOD**
 12 **AND DRUG ADMINISTRATION AND THE CEN-**
 13 **TERS FOR MEDICARE & MEDICAID SERVICES.**

14 (a) IN GENERAL.—

15 (1) PUBLIC MEETING.—

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

1 scribed in subsection (c) on the market in the
2 United States.

3 (B) ATTENDEES.—The Secretary shall in-
4 vite the following to the public meeting:

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

12 (ii) Stakeholders with expertise in the
13 research and development of novel medical
14 products, including manufacturers of such
15 products.

16 (iii) Representatives of commercial
17 health insurance payers.

18 (iv) Stakeholders with expertise in the
19 administration and use of novel medical
20 products, including physicians.

21 (v) Stakeholders representing patients
22 and with expertise in the utilization of pa-
23 tient experience data in medical product
24 development.

1 (C) TOPICS.—The public meeting agenda
2 shall include—

3 (i) an overview of the types of prod-
4 ucts and product categories in the drug
5 and medical device development pipeline
6 and the volume of products which may
7 meet the description of a novel medical
8 product under subsection (c);

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

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

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

the Social Security Act pursuant to section 1862(a)(1)(A) of such Act (42 U.S.C. 1395y(a)(1)(A));

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

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

(D) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing under this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code.

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

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

Coverage: Coverage with Evidence Development” to address any opportunities to improve the availability and coordination of information as described in clauses (iv) through (vi) of paragraph (1)(C).

(B) FINAL GUIDANCE.—Not later than 12 months after issuing draft guidance under subparagraph (A), the Secretary shall finalize the updated guidance to address any such opportunities.

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

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

(2) Recommendations to—

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

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

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

17 (D) identify potential mechanisms to incor-
18 porate novel payment designs similar to those
19 in development in commercial insurance plans
20 and State plans under title XIX of such Act
21 (42 U.S.C. 1396 et seq.) into the Medicare pro-
22 gram.

23 (c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For
24 purposes of this section, a novel medical product described
25 in this subsection is a drug, including a biological product

1 (including gene and cell therapy), or medical device, that
 2 has been designated as a breakthrough therapy under sec-
 3 tion 506(a) of the Federal Food, Drug, and Cosmetic Act
 4 (21 U.S.C. 356(a)), a breakthrough device under section
 5 515B of such Act (21 U.S.C. 360e–3), or a regenerative
 6 advanced therapy under section 506(g) of such Act (21
 7 U.S.C. 356(g)).

8 **SEC. 145. PATIENT CONSULTATION IN MEDICARE NA-**
 9 **TIONAL AND LOCAL COVERAGE DETERMINA-**
 10 **TIONS IN ORDER TO MITIGATE BARRIERS TO**
 11 **INCLUSION OF SUCH PERSPECTIVES.**

12 Section 1862(l) of the Social Security Act (42 U.S.C.
 13 1395y(l)) is amended by adding at the end the following
 14 new paragraph:

15 “(7) PATIENT CONSULTATION IN NATIONAL
 16 AND LOCAL COVERAGE DETERMINATIONS.—With re-
 17 spect to national coverage determinations, the Sec-
 18 retary, and with respect to local coverage determina-
 19 tions, the Medicare administrative contractor, may
 20 consult with patients and organizations representing
 21 patients, including patients with disabilities, in mak-
 22 ing national and local coverage determinations.”.

1 **SEC. 146. GAO STUDY ON INCREASES TO MEDICARE AND**
2 **MEDICAID SPENDING DUE TO COPAYMENT**
3 **COUPONS AND OTHER PATIENT ASSISTANCE**
4 **PROGRAMS.**

5 (a) STUDY.—The Comptroller General of the United
6 States shall conduct a study on the impact of copayment
7 coupons and other patient assistance programs on pre-
8 scription drug pricing and expenditures within the Medi-
9 care and Medicaid programs. The study shall assess the
10 following:

11 (1) The extent to which copayment coupons and
12 other patient assistance programs contribute to in-
13 flated prescription drug prices under such programs.

14 (2) The impact copayment coupons and other
15 patient assistance programs have in the Medicare
16 Part D program established under part D of title
17 XVIII of the Social Security Act (42 U.S.C. 1395w–
18 101 et seq.) on utilization of higher-cost brand drugs
19 and lower utilization of generic drugs in that pro-
20 gram.

21 (3) The extent to which manufacturers report
22 or obtain tax benefits, including deductions of busi-
23 ness expenses and charitable contributions, for any
24 of the following:

25 (A) Offering copayment coupons or other
26 patient assistance programs.

1 (B) Sponsoring manufacturer patient as-
 2 sistance programs.

3 (C) Paying for sponsorships at outreach
 4 and advocacy events organized by patient as-
 5 sistance programs.

6 (4) The efficacy of oversight conducted to en-
 7 sure that independent charity patient assistance pro-
 8 grams adhere to guidance from the Office of the In-
 9 spector General of the Department of Health and
 10 Human Services on avoiding waste, fraud, and
 11 abuse.

12 (b) DEFINITIONS.—In this section:

13 (1) INDEPENDENT CHARITY PATIENT ASSIST-
 14 ANCE PROGRAM.—The term “independent charity
 15 patient assistance program” means any organization
 16 described in section 501(c)(3) of the Internal Rev-
 17 enue Code of 1986 and exempt from taxation under
 18 section 501(a) of such Code and which is not a pri-
 19 vate foundation (as defined in section 509(a) of such
 20 Code) that offers patient assistance.

21 (2) MANUFACTURER.—The term “manufac-
 22 turer” has the meaning given that term in section
 23 1927(k)(5) of the Social Security Act (42 U.S.C.
 24 1396r–8(k)(5)).

1 (3) MANUFACTURER PATIENT ASSISTANCE PRO-
 2 GRAM.—The term “manufacturer patient assistance
 3 program” means an organization, including a private
 4 foundation (as so defined), that is sponsored by, or
 5 receives funding from, a manufacturer and that of-
 6 fers patient assistance. Such term does not include
 7 an independent charity patient assistance program.

8 (4) PATIENT ASSISTANCE.—The term “patient
 9 assistance” means assistance provided to offset the
 10 cost of drugs for individuals. Such term includes free
 11 products, coupons, rebates, copay or discount cards,
 12 and other means of providing assistance to individ-
 13 uals related to drug costs, as determined by the Sec-
 14 retary of Health and Human Services.

15 (c) REPORT.—Not later than 24 months after the
 16 date of the enactment of this Act, the Comptroller General
 17 of the United States shall submit to Congress a report
 18 describing the findings of the study required under sub-
 19 section (a).

20 **SEC. 147. MEDPAC REPORT ON SHIFTING COVERAGE OF**
 21 **CERTAIN MEDICARE PART B DRUGS TO MEDI-**
 22 **CARE PART D.**

23 (a) STUDY.—The Medicare Payment Advisory Com-
 24 mission (in this section referred to as the “Commission”)
 25 shall conduct a study on shifting coverage of certain drugs

1 and biologicals for which payment is currently made under
 2 part B of title XVIII of the Social Security Act (42 U.S.C.
 3 1395j et seq.) to part D of such title (42 U.S.C. 1395w–
 4 21 et seq.). Such study shall include an analysis of—

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

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

15 (b) REPORT.—

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

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

23 (A) formulary design under such part D;

24 (B) the ability of the benefit structure
 25 under such part D to control total spending on

1 drugs and biologicals for which payment is cur-
 2 rently made under such part B;

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

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

11 **SEC. 148. TAKING STEPS TO FULFILL TREATY OBLIGATIONS**
 12 **TO TRIBAL COMMUNITIES.**

13 (a) GAO STUDY.—The Comptroller General shall
 14 conduct a study regarding access to, and the cost of, pre-
 15 scription drugs among Indians. The study shall include—

16 (1) a review of what Indian health programs
 17 pay for prescription drugs on reservations, in urban
 18 centers, and in Tribal communities relative to other
 19 consumers;

20 (2) recommendations to align the value of pre-
 21 scription drug discounts available under the Med-
 22 icaid drug rebate program established under section
 23 1927 of the Social Security Act (42 U.S.C. 1396r-
 24 8) with prescription drug discounts available to
 25 Tribal communities through the purchased/referred

1 care program of the Indian Health Service for physi-
2 cian administered drugs; and

3 (3) an examination of how Tribal communities
4 and urban Indian organizations utilize the Medicare
5 part D program established under title XVIII of the
6 Social Security Act (42 U.S.C. 1395w–101 et seq.)
7 and recommendations to improve enrollment among
8 Indians in that program.

9 (b) REPORT.—Not later than 18 months after the
10 date of the enactment of this Act, the Comptroller General
11 shall submit to Congress a report containing the results
12 of the study conducted under subsection (a), together with
13 recommendations for such legislation and administrative
14 action as the Comptroller General determines appropriate.

15 (c) DEFINITIONS.—In this section:

16 (1) COMPTROLLER GENERAL.—The term
17 “Comptroller General” means the Comptroller Gen-
18 eral of the United States.

19 (2) INDIAN; INDIAN HEALTH PROGRAM; INDIAN
20 TRIBE.—The terms “Indian”, “Indian health pro-
21 gram”, and “Indian tribe” have the meanings given
22 those terms in section 4 of the Indian Health Care
23 Improvement Act (25 U.S.C. 1603).

1 **TITLE II—MEDICAID DRUG**
2 **PRICING REFORMS**

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

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

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

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

17 “(I) is publicly accessible;

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

24 “(III) contains clear processes, such
25 as recusal from voting or discussion, for

1 those members who report a conflict of in-
2 terest, along with appropriate processes to
3 address any instance where a member fails
4 to report a conflict of interest.

5 “(iii) The membership of the pharmacy
6 and therapeutics committee—

7 “(I) is made publicly available;

8 “(II) is composed of members who are
9 independent and free of any conflict, in-
10 cluding with respect to manufacturers,
11 medicaid managed care entities, and phar-
12 macy benefit managers; and

13 “(III) includes at least 1 actively
14 practicing physician and at least 1 actively
15 practicing pharmacist, each of whom has
16 expertise in the care of 1 or more Med-
17 icaid-specific populations such as elderly or
18 disabled individuals, children with complex
19 medical needs, or low-income individuals
20 with chronic illnesses.

21 “(iv) At the option of the State, the
22 State’s drug use review board established under
23 subsection (g)(3) may serve as the pharmacy
24 and therapeutics committee provided the State

ensures that such board meets the requirements of clauses (ii) and (iii).

“(v) The State reviews and has final approval of the formulary established by the pharmacy and therapeutics committee.

“(vi) If the Secretary determines it appropriate or necessary based on the findings and recommendations of the Comptroller General of the United States in the report submitted to Congress under section 203 of the Prescription Drug Pricing Reduction Act of 2020, the Secretary shall issue guidance that States must follow for establishing conflict of interest policies for the pharmacy and therapeutics committee in accordance with the requirements of clause (ii), including appropriate standards and requirements for identifying, addressing, and reporting on conflicts of interest.”.

(b) APPLICATION TO MEDICAID MANAGED CARE ORGANIZATIONS.—

(1) IN GENERAL.—Clause (xiii) of section 1903(m)(2)(A) of the Social Security Act (42 U.S.C. 1396b(m)(2)(A)) is amended—

(A) by striking “and (III)” and inserting “(III)”;

(B) by striking the period at the end and inserting “, and (IV) any formulary used by the entity for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the entity is developed and reviewed by a pharmacy and therapeutics committee that meets the requirements of clauses (ii) and (iii) of section 1927(d)(4)(A).”; and

(C) by moving the left margin 2 ems to the left.

(2) APPLICATION TO PIHPS AND PAHPS.—Section 1903(m) of the Social Security Act (42 U.S.C. 1396b(m)) is amended by adding at the end the following new paragraph:

“(10) No payment shall be made under this title to a State with respect to expenditures incurred by the State for payment for services provided by an other specified entity (as defined in paragraph (9)(D)(iii)) unless such services are provided in accordance with a contract between the State and the entity which satisfies the requirements of paragraph (2)(A)(xiii).”.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 1 year 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 publicly available;

2 “(II) be composed of members
3 who are independent and free of any
4 conflict, including with respect to
5 manufacturers, medicaid managed
6 care entities, and pharmacy benefit
7 managers;

8 “(III) be made up of at least $\frac{1}{3}$
9 but no more than 51 percent members
10 who are licensed and actively prac-
11 ticing physicians and at least $\frac{1}{3}$ mem-
12 bers who are licensed and actively
13 practicing pharmacists; and

14 “(IV) include at least 1 actively
15 practicing physician and at least 1 ac-
16 tively practicing pharmacist, each of
17 whom has expertise in the care of 1 or
18 more Medicaid-specific populations
19 such as elderly or disabled individuals,
20 children with complex medical needs,
21 or low-income individuals with chronic
22 illnesses.

23 “(iii) CONFLICT OF INTEREST POL-
24 ICY.—The State shall establish and imple-

1 ment a conflict of interest policy for the
2 DUR Board that—

3 “(I) is publicly accessible;

4 “(II) requires all board members
5 to complete, on at least an annual
6 basis, a disclosure of relationships, as-
7 sociations, and financial dealings that
8 may affect their independence of
9 judgement in board matters; and

10 “(III) contains clear processes,
11 such as recusal from voting or discus-
12 sion, for those members who report a
13 conflict of interest, along with appro-
14 priate processes to address any in-
15 stance where a member fails to report
16 a conflict of interest.”; and

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

19 “(E) DUR BOARD MEMBERSHIP RE-
20 PORTS.—

21 “(i) DUR BOARD REPORTS.—Each
22 State shall require the DUR Board to pre-
23 pare and submit to the State an annual re-
24 port on the DUR Board membership. Each
25 such report shall include any conflicts of

1 interest with respect to members of the
2 DUR Board that the DUR Board recorded
3 or was aware of during the period that is
4 the subject of the report, and the process
5 applied to address such conflicts of inter-
6 est, in addition to any other information
7 required by the State.

8 “(ii) INCLUSION OF DUR BOARD MEM-
9 BERSHIP INFORMATION IN STATE RE-
10 PORTS.—Each annual State report to the
11 Secretary required under subparagraph
12 (D) shall include—

13 “(I) the number of individuals
14 serving on the State’s DUR Board;

15 “(II) the names and professions
16 of the individuals serving on such
17 DUR Board;

18 “(III) any conflicts of interest or
19 recusals with respect to members of
20 such DUR Board reported by the
21 DUR Board or that the State was
22 aware of during the period that is the
23 subject of the report; and

24 “(IV) whether the State has
25 elected for such DUR Board to serve

1 as the committee responsible for de-
 2 veloping a State formulary under sub-
 3 section (d)(4)(A).”.

4 (b) MANAGED CARE REQUIREMENTS.—Section
 5 1932(i) of the Social Security Act (42 U.S.C. 1396u–2(i))
 6 is amended—

7 (1) by inserting “and each contract under a
 8 State plan with an other specified entity (as defined
 9 in section 1903(m)(9)(D)(iii))” after “under section
 10 1903(m)”;

11 (2) by striking “section 483.3(s)(4)” and in-
 12 serting “section 438.3(s)(4)”;

13 (3) by striking “483.3(s)(5)” and inserting
 14 “438.3(s)(5)”;

15 (4) by adding at the end the following: “Such
 16 a managed care entity or other specified entity shall
 17 not be considered to be in compliance with the re-
 18 quirement of such section 438.3(s)(5) that the entity
 19 provide a detailed description of its drug utilization
 20 review activities unless the entity includes a descrip-
 21 tion of the prospective drug review activities de-
 22 scribed in paragraph (2)(A) of section 1927(g) and
 23 the activities listed in paragraph (3)(C) of section
 24 1927(g), makes the underlying drug utilization re-
 25 view data available to the State and the Secretary,

1 and provides such other information as deemed ap-
2 propriate 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 18 months
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 (including other specified entities
6 (as defined in section 1903(m)(9)(D)(iii) of the
7 Social Security Act (42 U.S.C.
8 1396b(m)(9)(D)(iii)) and collectively referred to
9 in this section as “Medicaid MCOs”); and

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

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

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

21 (4) An analysis of whether and how States or
22 P&T Committees establish participation and inde-
23 pendence requirements for DUR Boards and P&T
24 Committees, including with respect to entities with
25 connections with drug manufacturers, State Med-

1 icaid programs, managed care organizations, and
2 other entities or individuals in the pharmaceutical
3 industry.

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

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

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

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

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

1 legislative and administrative actions as the Comp-
 2 troller General determines appropriate.

3 **SEC. 204. ENSURING THE ACCURACY OF MANUFACTURER**
 4 **PRICE AND DRUG PRODUCT INFORMATION**
 5 **UNDER THE MEDICAID DRUG REBATE PRO-**
 6 **GRAM.**

7 (a) AUDIT OF MANUFACTURER PRICE AND DRUG
 8 PRODUCT INFORMATION.—

9 (1) IN GENERAL.—Subparagraph (B) of section
 10 1927(b)(3) of the Social Security Act (42 U.S.C.
 11 1396r–8(b)(3)) is amended to read as follows:

12 “(B) AUDITS AND SURVEYS OF MANUFAC-
 13 Turer PRICE AND DRUG PRODUCT INFORMA-
 14 TION.—

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

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

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

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

11 “(iv) REPORTS.—

12 “(I) REPORT TO CONGRESS.—

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

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

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

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

24 “(aa) error rates in the
25 price, drug product, and other

1 relevant information supplied by
2 manufacturers under subpara-
3 graph (A);

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

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

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

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

21 “(ff) the findings of such
22 audits, including which manufac-
23 turers, if any, were penalized
24 under this subparagraph; and

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

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

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

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

21 (b) INCREASED PENALTIES FOR NONCOMPLIANCE
 22 WITH REPORTING REQUIREMENTS.—

23 (1) INCREASED PENALTY FOR FAILURE TO PRO-
 24 VIDE TIMELY INFORMATION.—Section
 25 1927(b)(3)(C)(i) of the Social Security Act (42

1 U.S.C. 1396r–8(b)(3)(C)(i)) is amended by striking
2 “increased by \$10,000 for each day in which such
3 information has not been provided and such amount
4 shall be paid to the Treasury” and inserting “, for
5 each covered outpatient drug with respect to which
6 such information is not provided, \$50,000 for the
7 first day that such information is not provided on a
8 timely basis and \$19,000 for each subsequent day
9 that such information is not provided”.

10 (2) INCREASED PENALTY FOR KNOWINGLY RE-
11 PORTING FALSE INFORMATION.—Section
12 1927(b)(3)(C)(ii) of the Social Security Act (42
13 U.S.C. 1396r–8(b)(3)(C)(ii)) is amended by striking
14 “\$100,000” and inserting “\$500,000”.

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

19 (c) RULE OF CONSTRUCTION.—Nothing in this sec-
20 tion or the amendments made by this section shall be con-
21 strued to affect the application of the Federal Civil Pen-
22 alties Inflation Adjustment Act of 1990 (28 U.S.C. 2461
23 note) to any civil penalty amount under section 1927 of
24 the Social Security Act (42 U.S.C. 1396r–8).

1 **SEC. 205. APPLYING MEDICAID DRUG REBATE REQUIRE-**
 2 **MENT TO DRUGS PROVIDED AS PART OF OUT-**
 3 **PATIENT HOSPITAL SERVICES.**

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

7 “(3) LIMITING DEFINITION.—

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

16 “(i) Inpatient hospital services.

17 “(ii) Hospice services.

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

22 “(iv) Physicians’ services.

23 “(v) Outpatient hospital services.

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

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

3 “(viii) Renal dialysis.

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

11 “(C) STATE OPTION.—At the option of a
12 State, such term may include any drug, biologi-
13 cal product, or insulin provided on an out-
14 patient basis as part of, or as incident to and
15 in the same setting as, described in clause (iv)
16 or (v) of subparagraph (A) (such as a drug, bi-
17 ological product, or insulin being provided as
18 part of a bundled payment).

19 “(D) NO EFFECT ON BEST PRICE.—Any
20 drug, biological product, or insulin excluded
21 from the definition of such term as a result of
22 this paragraph shall be treated as a covered
23 outpatient drug for purposes of determining the
24 best price (as defined in subsection (c)(1)(C))
25 for such drug, biological product, or insulin.”.

1 (b) EFFECTIVE DATE; IMPLEMENTATION GUID-
2 ANCE.—

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

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

16 **SEC. 206. IMPROVING TRANSPARENCY AND PREVENTING**
17 **THE USE OF ABUSIVE SPREAD PRICING AND**
18 **RELATED PRACTICES IN MEDICAID.**

19 (a) PASS-THROUGH PRICING REQUIRED.—

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

23 “(6) PASS-THROUGH PRICING REQUIRED.—A
24 contract between the State and a pharmacy benefit
25 manager (referred to in this paragraph as a ‘PBM’),

1 or a contract between the State and a managed care
2 entity or other specified entity (as such terms are
3 defined in section 1903(m)(9)(D)) that includes pro-
4 visions making the entity responsible for coverage of
5 covered outpatient drugs dispensed to individuals en-
6 rolled with the entity, shall require that payment for
7 such drugs (excluding, at the option of the State,
8 any drug that is subject to an agreement under sec-
9 tion 340B of the Public Health Service Act) and re-
10 lated administrative services (as applicable), includ-
11 ing payments made by a PBM on behalf of the State
12 or entity, is based on a pass-through pricing model
13 under which—

14 “(A) any payment made by the entity or
15 the PBM (as applicable) for such a drug—

16 “(i) is limited to—

17 “(I) ingredient cost; and

18 “(II) a professional dispensing
19 fee that is not less than the profes-
20 sional dispensing fee that the State
21 plan or waiver would pay if the plan
22 or waiver was making the payment di-
23 rectly;

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

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

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

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

1 such as direct and indirect remuneration fees,
2 and any and all other remuneration; and

3 “(D) any form of spread pricing whereby
4 any amount charged or claimed by the entity or
5 the PBM (as applicable) is in excess of the
6 amount paid to the pharmacies on behalf of the
7 entity, including any post-sale or post-invoice
8 fees, discounts, effective rate contract adjust-
9 ments, or related adjustments such as direct
10 and indirect remuneration fees or assessments
11 (after allowing for a reasonable administrative
12 fee as described in subparagraph (B)) is not al-
13 lowable for purposes of claiming Federal match-
14 ing 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)), as amended by section
18 201(b)(1), is amended—

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

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

1 rangement between the entity and the phar-
 2 macy benefit manager, shall comply with the re-
 3 quirements of section 1927(e)(6)”.
 4

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-
 ly basis of retail survey prices of the na-

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

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

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

1 aged care entity or other specified entity (as
2 such terms are defined in section
3 1903(m)(9)(D)), shall respond to surveys of re-
4 tail prices conducted under this subsection.

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

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

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

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

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

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

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

3 “(H) PENALTIES.—

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

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

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

graph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

“(I) REPORT ON SPECIALTY DRUGS AND PHARMACIES.—

“(i) IN GENERAL.—Not later than 18 months after the effective date of this subparagraph, the Secretary shall submit a report to Congress examining specialty drug coverage and reimbursement under this title.

“(ii) CONTENT OF REPORT.—Such report shall include a description of how State Medicaid programs define specialty drugs, how much State Medicaid programs pay for specialty drugs, how States and managed care plans determine payment for specialty drugs, the settings in which specialty drugs are dispensed (such as retail community pharmacies or specialty pharmacies), whether acquisition costs for specialty drugs are captured in the national average drug acquisition cost survey, and recommendations as to whether specialty pharmacies should be included in the sur-

vey of retail prices to ensure national average drug acquisition costs capture drugs sold at specialty pharmacies and how such specialty pharmacies should be defined.”;

(C) in paragraph (2)—

(i) in subparagraph (A), by inserting “, including payments rates under Medicaid managed care plans,” after “under this title”; and

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

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

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

(c) MANUFACTURER REPORTING OF WHOLESALE ACQUISITION COST.—Section 1927(b)(3) of such Act (42 U.S.C. 1396r–8(b)(3)) is amended—

(1) in subparagraph (A)(i)—

(A) in subclause (I), by striking “and” 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 patterns related to prescriptions filled by pro-
 21 viders and reimbursed under the Medicaid 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 available forms or mod-
14 els of reimbursement used under the plan
15 or waiver;

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

18 (iii) by episodes of care for—

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

1 (II) procedural groupings; and

2 (III) rare disease diagnosis codes

3 (except where the inclusion of such in-

4 formation would jeopardize the pri-

5 vacy of an individual, as determined

6 by the Secretary);

7 (iv) by patient demographic character-

8 istics, including race (to the extent that

9 the Secretary determines that there is suf-

10 ficient data available with respect to such

11 characteristic in a majority of States and

12 that inclusion of such characteristic would

13 not jeopardize the privacy of the indi-

14 vidual), gender, and age;

15 (v) by patient high-utilizer or risk sta-

16 tus; and

17 (vi) by high and low resource settings

18 by facility and place of service categories,

19 as determined by the Secretary.

20 (B) In the case of medical assistance for

21 covered outpatient drugs (as so defined) pro-

22 vided under a State Medicaid plan or waiver of

23 such plan in a managed care setting, an anal-

24 ysis of the differences in managed care pre-

25 scribing patterns when a covered outpatient

1 drug is prescribed in a managed care setting as
2 compared to when the drug is prescribed in a
3 fee-for-service setting.

4 (2) ADDITIONAL CONTENT.—To the extent
5 available, a report required under subsection (a) for
6 a calendar year may include State-specific informa-
7 tion about prescription utilization management tools
8 under State Medicaid plans or waivers of such plans,
9 including—

10 (A) a description of prescription utilization
11 management tools under State programs to pro-
12 vide long-term services and supports under a
13 State Medicaid plan or a waiver of such plan;

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

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

1 (D) a comparison of the prescription utili-
2 zation management tools applicable to each en-
3 rollment category under a State Medicaid plan
4 or waiver; and

5 (E) a comparison of the prescription utili-
6 zation management tools applicable under the
7 State Medicaid plan or waiver by patient high-
8 utilizer or risk status.

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

12 (A) analyses of national, State, and local
13 patterns of Medicaid population-based pre-
14 scribing behaviors (including an analysis of the
15 impact of non-filled prescriptions on identifying
16 such patterns); and

17 (B) recommendations for administrative or
18 legislative action to improve the effectiveness of,
19 and reduce costs for, covered outpatient drugs
20 under Medicaid while ensuring timely bene-
21 ficiary access to medically necessary covered
22 outpatient drugs.

23 (c) USE OF T-MSIS DATA.—Each report required
24 under subsection (a) shall, to the extent practicable—

1 (1) be prepared using data and definitions from
 2 the Transformed Medicaid Statistical Information
 3 System (“T-MSIS”) data set (or a successor data
 4 set) that is not more than 24 months old on the date
 5 that the report is published; and

6 (2) as appropriate, include a description with
 7 respect to each State of the quality and complete-
 8 ness of the data, as well as any necessary caveats
 9 describing the limitations of the data reported to the
 10 Secretary by the State that are sufficient to commu-
 11 nicate the appropriate uses for the information.

12 (d) PREPARATION OF REPORT.—Each report re-
 13 quired under subsection (a) shall be prepared by the Ad-
 14 ministrators for the Centers for Medicare & Medicaid Serv-
 15 ices.

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

19 **SEC. 208. RISK-SHARING VALUE-BASED PAYMENT AGREE-**
 20 **MENTS FOR COVERED OUTPATIENT DRUGS**
 21 **UNDER MEDICAID.**

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

1 “(l) STATE OPTION TO PAY FOR COVERED OUT-
2 PATIENT DRUGS THROUGH RISK-SHARING VALUE-BASED
3 AGREEMENTS.—

4 “(1) IN GENERAL.—Beginning January 1,
5 2022, a State shall have the option to pay (whether
6 on a fee-for-service or managed care basis) for cov-
7 ered outpatient drugs that are potentially curative
8 treatments intended for one-time use that are ad-
9 ministered to individuals under this title by entering
10 into a risk-sharing value-based payment agreement
11 with the manufacturer of the drug in accordance
12 with the requirements of this subsection.

13 “(2) SECRETARIAL APPROVAL.—

14 “(A) IN GENERAL.—A State shall submit a
15 request to the Secretary to enter into a risk-
16 sharing value-based payment agreement, and
17 the Secretary shall not approve a proposed risk-
18 sharing value-based payment agreement be-
19 tween a State and a manufacturer for payment
20 for a covered outpatient drug of the manufac-
21 turer unless the following requirements are met:

22 “(i) MANUFACTURER HAS IN EFFECT
23 A REBATE AGREEMENT AND IS IN COMPLI-
24 ANCE WITH ALL APPLICABLE REQUIRE-
25 MENTS.—The manufacturer has a rebate

1 agreement in effect as required under sub-
 2 sections (a) and (b) of this section and is
 3 in compliance with all applicable require-
 4 ments under this title.

5 “(ii) NO EXPECTED INCREASE TO
 6 PROJECTED NET FEDERAL SPENDING.—

7 “(I) IN GENERAL.—The Chief
 8 Actuary certifies that the projected
 9 payments for each covered outpatient
 10 drug under a proposed risk-sharing
 11 value-based payment agreement is not
 12 expected to result in greater estimated
 13 Federal spending under this title than
 14 the net Federal spending that would
 15 result in the absence of such agree-
 16 ment.

17 “(II) NET FEDERAL SPENDING
 18 DEFINED.—For purposes of this sub-
 19 section, the term ‘net Federal spend-
 20 ing’ means the amount of Federal
 21 payments the Chief Actuary estimates
 22 would be made under this title for ad-
 23 ministering a covered outpatient drug
 24 to an individual eligible for medical
 25 assistance under a State plan or a

1 waiver of such plan, reduced by the
2 amount of all rebates the Chief Actu-
3 ary estimates would be paid with re-
4 spect to the administering of such
5 drug, including all rebates under this
6 title and any supplemental or other
7 additional rebates, in the absence of
8 such an agreement.

9 “(III) INFORMATION.—The Chief
10 Actuary shall make the certifications
11 required under this clause based on
12 the most recently available and reli-
13 able drug pricing and product infor-
14 mation. The State and manufacturer
15 shall provide the Secretary and the
16 Chief Actuary with all necessary infor-
17 mation required to make the estimates
18 needed for such certifications.

19 “(iii) LAUNCH AND LIST PRICE JUS-
20 TIFICATIONS.—The manufacturer submits
21 all relevant information and supporting
22 documentation necessary for pricing deci-
23 sions as deemed appropriate by the Sec-
24 retary, which shall be truthful and non-
25 misleading, including manufacturer infor-

1 mation and supporting documentation for
2 launch price or list price increases, and
3 any applicable justification required under
4 section 1128L.

5 “(iv) CONFIDENTIALITY OF INFORMA-
6 TION; PENALTIES.—The provisions of sub-
7 paragraphs (C) and (D) of subsection
8 (b)(3) shall apply to a manufacturer that
9 fails to submit the information and docu-
10 mentation required under clauses (ii) and
11 (iii) on a timely basis, or that knowingly
12 provides false or misleading information, in
13 the same manner as such provisions apply
14 to a manufacturer with a rebate agreement
15 under this section.

16 “(B) CONSIDERATION OF STATE REQUEST
17 FOR APPROVAL.—

18 “(i) IN GENERAL.—The Secretary
19 shall treat a State request for approval of
20 a risk-sharing value-based payment agree-
21 ment in the same manner that the Sec-
22 retary treats a State plan amendment, and
23 subpart B of part 430 of title 42, Code of
24 Federal Regulations, including, subject to
25 clause (ii), the timing requirements of sec-

1 tion 430.16 of such title (as in effect on
2 the date of enactment of this subsection),
3 shall apply to a request for approval of a
4 risk-sharing value-based payment agree-
5 ment in the same manner as such subpart
6 applies to a State plan amendment.

7 “(ii) TIMING.—The Secretary shall
8 consult with the Commissioner of Food
9 and Drugs as required under subpara-
10 graph (C) and make a determination on
11 whether to approve a request from a State
12 for approval of a proposed risk-sharing
13 value-based payment agreement (or request
14 additional information necessary to allow
15 the Secretary to make a determination
16 with respect to such request for approval)
17 within the time period, to the extent prac-
18 ticable, specified in section 430.16 of title
19 42, Code of Federal Regulations (as in ef-
20 fect on the date of enactment of this sub-
21 section), but in no case shall the Secretary
22 take more than 180 days after the receipt
23 of such request for approval or response to
24 such request for additional information to

1 make such a determination (or request ad-
2 ditional information).

3 “(C) CONSULTATION WITH THE COMMIS-
4 SIONER OF FOOD AND DRUGS.—In considering
5 whether to approve a risk-sharing value-based
6 payment agreement, the Secretary, to the ex-
7 tent necessary, shall consult with the Commis-
8 sioner of Food and Drugs to determine whether
9 the relevant clinical parameters specified in
10 such agreement are appropriate.

11 “(3) INSTALLMENT-BASED PAYMENT STRUC-
12 TURE.—

13 “(A) IN GENERAL.—A risk-sharing value-
14 based payment agreement shall provide for a
15 payment structure under which, for every in-
16 stallment year of the agreement (subject to sub-
17 paragraph (B)), the State shall pay the total in-
18 stallment year amount in equal installments to
19 be paid at regular intervals over a period of
20 time that shall be specified in the agreement.

21 “(B) REQUIREMENTS FOR INSTALLMENT
22 PAYMENTS.—

23 “(i) TIMING OF FIRST PAYMENT.—
24 The State shall make the first of the in-
25 stallment payments described in subpara-

1 graph (A) for an installment year not later
2 than 30 days after the end of such year.

3 “(ii) LENGTH OF INSTALLMENT PE-
4 RIOD.—The period of time over which the
5 State shall make the installment payments
6 described in subparagraph (A) for an in-
7 stallment year shall not be longer than 5
8 years.

9 “(iii) NONPAYMENT OR REDUCED
10 PAYMENT OF INSTALLMENTS FOLLOWING
11 A FAILURE TO MEET CLINICAL PARAM-
12 ETER.—If, prior to the payment date (as
13 specified in the agreement) of any install-
14 ment payment described in subparagraph
15 (A) or any other alternative date or time
16 frame (as otherwise specified in the agree-
17 ment), the covered outpatient drug which
18 is subject to the agreement fails to meet a
19 relevant clinical parameter of the agree-
20 ment, the agreement shall provide that—

21 “(I) the installment payment
22 shall not be made; or

23 “(II) the installment payment
24 shall be reduced by a percentage spec-
25 ified in the agreement that is based

1 on the outcome achieved by the drug
2 relative to the relevant clinical param-
3 eter.

4 “(4) NOTICE OF INTENT.—

5 “(A) IN GENERAL.—Subject to subpara-
6 graph (B), a manufacturer of a covered out-
7 patient drug shall not be eligible to enter into
8 a risk-sharing value-based payment agreement
9 under this subsection with respect to such drug
10 unless the manufacturer notifies the Secretary
11 that the manufacturer is interested in entering
12 into such an agreement with respect to such
13 drug. The decision to submit and timing of a
14 request to enter into a proposed risk-sharing
15 value-based payment agreement shall remain
16 solely within the discretion of the State and
17 shall only be effective upon Secretarial approval
18 as required under this subsection.

19 “(B) TREATMENT OF SUBSEQUENTLY AP-
20 PROVED DRUGS.—

21 “(i) IN GENERAL.—In the case of a
22 manufacturer of a covered outpatient drug
23 designated under section 526 of the Fed-
24 eral Food, Drug, and Cosmetics Act, and
25 approved under section 505 of such Act or

1 licensed under subsection (a) or (k) of sec-
2 tion 351 of the Public Health Service Act
3 after the date of enactment of this sub-
4 section, not more than 90 days after meet-
5 ing with the Food and Drug Administra-
6 tion following phase II clinical trials for
7 such drug (or, in the case of a drug de-
8 scribed in clause (ii), not later than March
9 31, 2022), the manufacturer must notify
10 the Secretary of the manufacturer's intent
11 to enter into a risk-sharing value-based
12 payment agreement under this subsection
13 with respect to such drug. If no such meet-
14 ing has occurred, the Secretary may use
15 discretion as to whether a potentially cura-
16 tive treatment intended for one-time use
17 may qualify for a risk-sharing value-based
18 payment agreement under this section. A
19 manufacturer notification of interest shall
20 not have any influence on a decision for
21 drug approval by the Food and Drug Ad-
22 ministration.

23 “(ii) APPLICATION TO CERTAIN SUB-
24 SEQUENTLY APPROVED DRUGS.—A drug

described in this clause is a covered outpatient drug of a manufacturer—

“(I) that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act after the date of enactment of this subsection; and

“(II) with respect to which, as of January 1, 2022, more than 90 days have passed after the manufacturer’s meeting with the Food and Drug Administration following phase II clinical trials for such drug.

“(iii) PARALLEL APPROVAL.—The Secretary, in coordination with the Administrator of the Centers for Medicare & Medicaid Services and the Commissioner of Food and Drugs, shall, to the extent practicable, approve a State’s request to enter into a proposed risk-sharing value-based payment agreement that otherwise meets the requirements of this subsection at the time that such a drug is approved by the Food and Drug Administration to help

1 provide that no State that wishes to enter
2 into such an agreement is required to pay
3 for the drug in full at one time if the State
4 is seeking to pay over a period of time as
5 outlined in the proposed agreement.

6 “(iv) RULE OF CONSTRUCTION.—
7 Nothing in this paragraph shall be applied
8 or construed to modify or affect the time-
9 frames or factors involved in the Sec-
10 retary’s determination of whether to ap-
11 prove or license a drug under section 505
12 of the Federal Food, Drug, and Cosmetic
13 Act or section 351 of the Public Health
14 Service Act.

15 “(5) SPECIAL PAYMENT RULES.—

16 “(A) IN GENERAL.—Except as otherwise
17 provided in this paragraph, with respect to an
18 individual who is administered a unit of a cov-
19 ered outpatient drug that is reimbursed under
20 a State plan by a State Medicaid agency under
21 a risk-sharing value-based payment agreement
22 in an installment year, the State shall remain
23 liable to the manufacturer of such drug for pay-
24 ment for such unit without regard to whether
25 the individual remains enrolled in the State

1 plan under this title (or a waiver of such plan)
2 for each installment year for which the State is
3 to make installment payments for covered out-
4 patient drugs purchased under the agreement
5 in such year.

6 “(B) DEATH.—In the case of an individual
7 described in subparagraph (A) who dies during
8 the period described in such subparagraph, the
9 State plan shall not be liable for any remaining
10 payment for the unit of the covered outpatient
11 drug administered to the individual which is
12 owed under the agreement described in such
13 subparagraph.

14 “(C) WITHDRAWAL OF APPROVAL.—In the
15 case of a covered outpatient drug that is the
16 subject of a risk-sharing value-based payment
17 agreement between a State and a manufacturer
18 under this subsection, including a drug ap-
19 proved in accordance with section 506(c) of the
20 Federal Food, Drug, and Cosmetic Act, and
21 such drug is the subject of an application that
22 has been withdrawn by the Secretary, the State
23 plan shall not be liable for any remaining pay-
24 ment that is owed under the agreement.

1 “(D) ALTERNATIVE ARRANGEMENT UNDER
2 AGREEMENT.—Subject to approval by the Sec-
3 retary, the terms of a proposed risk-sharing
4 value-based payment agreement submitted for
5 approval by a State may provide that subpara-
6 graph (A) shall not apply.

7 “(E) GUIDANCE.—Not later than January
8 1, 2022, the Secretary shall issue guidance to
9 States establishing a process for States to no-
10 tify the Secretary when an individual who is ad-
11 ministered a unit of a covered outpatient drug
12 that is purchased by a State plan under a risk-
13 sharing value-based payment agreement ceases
14 to be enrolled under the State plan under this
15 title (or a waiver of such plan) or dies before
16 the end of the installment period applicable to
17 such unit under the agreement.

18 “(6) TREATMENT OF PAYMENTS UNDER RISK-
19 SHARING VALUE-BASED AGREEMENTS FOR PUR-
20 POSES OF AVERAGE MANUFACTURER PRICE; BEST
21 PRICE.—The Secretary shall treat any payments
22 made to the manufacturer of a covered outpatient
23 drug under a risk-sharing value-based payment
24 agreement under this subsection during a rebate pe-
25 riod in the same manner that the Secretary treats

1 payments made under a State supplemental rebate
2 agreement under sections 447.504(c)(19) and
3 447.505(c)(7) of title 42, Code of Federal Regula-
4 tions (or any successor regulations) for purposes of
5 determining average manufacturer price and best
6 price under this section with respect to the covered
7 outpatient drug and a rebate period and for pur-
8 poses of offsets required under subsection (b)(1)(B).

9 “(7) ASSESSMENTS AND REPORT TO CON-
10 GRESS.—

11 “(A) ASSESSMENTS.—

12 “(i) IN GENERAL.—Not later than
13 180 days after the end of each assessment
14 period of any risk-sharing value-based pay-
15 ment agreement for a State approved
16 under this subsection, the Secretary shall
17 conduct an evaluation of such agreement
18 which shall include an evaluation by the
19 Chief Actuary to determine whether pro-
20 gram spending under the risk-sharing
21 value-based payment agreement aligned
22 with the projections for the agreement
23 made under paragraph (2)(A)(ii), including
24 an assessment of whether actual Federal
25 spending under this title under the agree-

1 ment was less or more than net Federal
2 spending would have been in the absence
3 of the agreement.

4 “(ii) ASSESSMENT PERIOD.—For pur-
5 poses of clause (i)—

6 “(I) the first assessment period
7 for a risk-sharing value-based pay-
8 ment agreement shall be the period of
9 time over which payments are sched-
10 uled to be made under the agreement
11 for the first 10 individuals who are
12 administered covered outpatient drugs
13 under the agreement except that such
14 period shall not exceed the 5-year pe-
15 riod after the date on which the Sec-
16 retary approves the agreement; and

17 “(II) each subsequent assessment
18 period for a risk-sharing value-based
19 payment agreement shall be the 5-
20 year period following the end of the
21 previous assessment period.

22 “(B) RESULTS OF ASSESSMENTS.—

23 “(i) TERMINATION OPTION.—If the
24 Secretary determines as a result of the as-
25 sessment by the Chief Actuary under sub-

1 paragraph (A) that the actual Federal
2 spending under this title for any covered
3 outpatient drug that was the subject of the
4 State’s risk-sharing value-based payment
5 agreement was greater than the net Fed-
6 eral spending that would have resulted in
7 the absence of the agreement, the Sec-
8 retary may terminate approval of such
9 agreement and shall immediately conduct
10 an assessment under this paragraph of any
11 other ongoing risk-sharing value-based
12 payment agreement to which the same
13 manufacturer is a party.

14 “(ii) REPAYMENT REQUIRED.—

15 “(I) IN GENERAL.—If the Sec-
16 retary determines as a result of the
17 assessment by the Chief Actuary
18 under subparagraph (A) that the Fed-
19 eral spending under the risk-sharing
20 value-based agreement for a covered
21 outpatient drug that was subject to
22 such agreement was greater than the
23 net Federal spending that would have
24 resulted in the absence of the agree-
25 ment, the manufacturer shall repay

1 the difference to the State and Fed-
2 eral governments in a timely manner
3 as determined by the Secretary.

4 “(II) TERMINATION FOR FAIL-
5 URE TO PAY.—The failure of a manu-
6 facturer to make repayments required
7 under subclause (I) in a timely man-
8 ner shall result in immediate termi-
9 nation of all risk-sharing value-based
10 agreements to which the manufacturer
11 is a party.

12 “(III) ADDITIONAL PEN-
13 ALTIES.—In the case of a manufac-
14 turer that fails to make repayments
15 required under subclause (I), the Sec-
16 retary may treat such manufacturer
17 in the same manner as a manufac-
18 turer that fails to pay required re-
19 bates under this section, and the Sec-
20 retary may—

21 “(aa) suspend or terminate
22 the manufacturer’s rebate agree-
23 ment under this section; and

24 “(bb) pursue any other rem-
25 edy that would be available if the

1 manufacturer had failed to pay
2 required rebates under this sec-
3 tion.

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

10 “(i) an assessment of the impact of
11 risk-sharing value-based payment agree-
12 ments on access for individuals who are eli-
13 gible for benefits under a State plan or
14 waiver under this title to medically nec-
15 essary covered outpatient drugs and re-
16 lated treatments;

17 “(ii) an analysis of the impact of such
18 agreements on overall State and Federal
19 spending under this title;

20 “(iii) an assessment of the impact of
21 such agreements on drug prices, including
22 launch price and price increases; and

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

25 “(8) GUIDANCE AND REGULATIONS.—

1 “(A) IN GENERAL.—Not later than Janu-
2 ary 1, 2022, the Secretary shall issue guidance
3 to States seeking to enter into risk-sharing
4 value-based payment agreements under this
5 subsection that includes a model template for
6 such agreements. The Secretary may issue any
7 additional guidance or promulgate regulations
8 as necessary to implement and enforce the pro-
9 visions of this subsection.

10 “(B) MODEL AGREEMENTS.—

11 “(i) IN GENERAL.—If a State ex-
12 presses an interest in pursuing a risk-shar-
13 ing value-based payment agreement under
14 this subsection with a manufacturer for
15 the purchase of a covered outpatient drug,
16 the Secretary may share with such State
17 any risk-sharing value-based agreement be-
18 tween a State and the manufacturer for
19 the purchase of such drug that has been
20 approved under this subsection. While such
21 shared agreement may serve as a template
22 for a State that wishes to propose, the use
23 of a previously approved agreement shall
24 not affect the submission and approval
25 process for approval of a proposed risk-

1 sharing value-based payment agreement
2 under this subsection, including the re-
3 quirements under paragraph (2)(A).

4 “(ii) CONFIDENTIALITY.—In the case
5 of a risk-sharing value-based payment
6 agreement that is disclosed to a State by
7 the Secretary under this subparagraph and
8 that is only in effect with respect to a sin-
9 gle State, the confidentiality of information
10 provisions described in subsection
11 (b)(3)(D) shall apply to such information.

12 “(C) OIG CONSULTATION.—

13 “(i) IN GENERAL.—The Secretary
14 shall consult with the Office of the Inspec-
15 tor General of the Department of Health
16 and Human Services to determine whether
17 there are potential program integrity con-
18 cerns (including issues related to compli-
19 ance with sections 1128B and 1877) with
20 agreement approvals or templates and ad-
21 dress accordingly.

22 “(ii) OIG POLICY UPDATES AS NEC-
23 ESSARY.—The Inspector General of the
24 Department of Health and Human Serv-
25 ices shall review and update, as necessary,

1 any policies or guidelines of the Office of
2 the Inspector General of the Department
3 of Human Services (including policies re-
4 lated to the enforcement of section 1128B)
5 to accommodate the use of risk-sharing
6 value-based payment agreements in accord-
7 ance with this section.

8 “(9) RULES OF CONSTRUCTION.—

9 “(A) MODIFICATIONS.—Nothing in this
10 subsection or any regulations promulgated
11 under this subsection shall prohibit a State
12 from requesting a modification from the Sec-
13 retary to the terms of a risk-sharing value-
14 based payment agreement. A modification that
15 is expected to result in any increase to pro-
16 jected net State or Federal spending under the
17 agreement shall be subject to recertification by
18 the Chief Actuary as described in paragraph
19 (2)(A)(ii) before the modification may be ap-
20 proved.

21 “(B) REBATE AGREEMENTS.—Nothing in
22 this subsection shall be construed as requiring
23 a State to enter into a risk-sharing value-based
24 payment agreement or as limiting or super-
25 seding the ability of a State to enter into a sup-

1 plemental rebate agreement for a covered out-
2 patient drug.

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

16 “(D) CONTINUED APPLICATION OF OTHER
17 PROVISIONS.—Except as expressly provided in
18 this subsection, nothing in this subsection or in
19 any regulations promulgated under this sub-
20 section shall affect the application of any other
21 provision of this Act.

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

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

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

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

10 “(C) POTENTIALLY CURATIVE TREATMENT
11 INTENDED FOR ONE-TIME USE.—The term ‘po-
12 tentially curative treatment intended for one-
13 time use’ means a treatment that consists of
14 the administration of a covered outpatient drug
15 that—

16 “(i) is a form of gene therapy for a
17 rare disease, as defined by the Commis-
18 sioner of Food and Drugs, designated
19 under section 526 of the Federal Food,
20 Drug, and Cosmetics Act, and approved
21 under section 505 of such Act or licensed
22 under subsection (a) or (k) of section 351
23 of the Public Health Service Act to treat
24 a serious or life-threatening disease or con-
25 dition;

1 “(ii) if administered in accordance
2 with the labeling of such drug, is expected
3 to result in either—

4 “(I) the cure of such disease or
5 condition; or

6 “(II) a reduction in the symp-
7 toms of such disease or condition to
8 the extent that such disease or condi-
9 tion is not expected to lead to early
10 mortality; and

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

15 “(D) RELEVANT CLINICAL PARAMETER.—

16 The term ‘relevant clinical parameter’ means,
17 with respect to a covered outpatient drug that
18 is the subject of a risk-sharing value-based pay-
19 ment agreement—

20 “(i) a clinical endpoint specified in the
21 drug’s labeling or supported by one or
22 more of the compendia described in section
23 1861(t)(2)(B)(ii)(I) that—

24 “(I) is able to be measured or
25 evaluated on an annual basis for each

1 year of the agreement on an inde-
2 pendent basis by a provider or other
3 entity; and

4 “(II) is required to be achieved
5 (based on observed metrics in patient
6 populations) under the terms of the
7 agreement; or

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

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

18 “(II) has been qualified by the
19 Food and Drug Administration.

20 “(E) RISK-SHARING VALUE-BASED PAY-
21 MENT AGREEMENT.—The term ‘risk-sharing
22 value-based payment agreement’ means an
23 agreement between a State plan and a manu-
24 facturer—

1 “(i) for the purchase of a covered out-
 2 patient drug of the manufacturer that is a
 3 potentially curative treatment intended for
 4 one-time use;

5 “(ii) under which payment for such
 6 drug shall be made pursuant to an install-
 7 ment-based payment structure that meets
 8 the requirements of paragraph (3);

9 “(iii) which conditions payment on the
 10 achievement of at least 2 relevant clinical
 11 parameters (as defined in subparagraph
 12 (C));

13 “(iv) which provides that—

14 “(I) the State plan will directly
 15 reimburse the manufacturer for the
 16 drug; or

17 “(II) a third party will reimburse
 18 the manufacture in a manner ap-
 19 proved by the Secretary;

20 “(v) is approved by the Secretary in
 21 accordance with paragraph (2).

22 “(F) TOTAL INSTALLMENT YEAR
 23 AMOUNT.—The term ‘total installment year
 24 amount’ means, with respect to a risk-sharing
 25 value-based payment agreement for the pur-

chase of a covered outpatient drug and an installment year, an amount equal to the product of—

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

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

(b) CONFORMING AMENDMENTS.—

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

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

(A) in paragraph (1)(A), by inserting “but excluding any drugs for which payment is made by a State under a risk-sharing value-based payment agreement under subsection (l))” after “for coverage of such drugs”; and

(B) in paragraph (3)—

(i) in subparagraph (C)(i), by inserting “or subsection (l)(2)(A)” after “subparagraph (A)”; and

(ii) in subparagraph (D), in the matter preceding clause (i), by inserting “, under subsection (l)(2)(A),” after “under this paragraph”.

**SEC. 209. MODIFICATION OF MAXIMUM REBATE AMOUNT
UNDER MEDICAID DRUG REBATE PROGRAM.**

(a) IN GENERAL.—Subparagraph (D) of section 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)) is amended to read as follows:

“(D) MAXIMUM REBATE AMOUNT.—

“(i) IN GENERAL.—Except as provided in clause (ii), in no case shall the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator multiple source drug for a rebate period exceed—

“(I) for rebate periods beginning after December 31, 2009, and before September 30, 2022, 100 percent of

1 the average manufacturer price of the
2 drug; and

3 “(II) for rebate periods beginning
4 on or after October 1, 2022, 125 per-
5 cent of the average manufacturer
6 price of the drug.

7 “(ii) NO MAXIMUM AMOUNT FOR
8 DRUGS IF AMP INCREASES OUTPACE IN-
9 FLATION.—

10 “(I) IN GENERAL.—If the aver-
11 age manufacturer price with respect
12 to each dosage form and strength of
13 a single source drug or an innovator
14 multiple source drug increases on or
15 after October 1, 2021, and such in-
16 creased average manufacturer price
17 exceeds the inflation-adjusted average
18 manufacturer price determined with
19 respect to such drug under subclause
20 (II) for the rebate period, clause (i)
21 shall not apply and there shall be no
22 limitation on the sum of the amounts
23 applied under paragraph (1)(A)(ii)
24 and this paragraph for the rebate pe-
25 riod, and any subsequent rebate pe-

1 riod until the average manufacturer
2 price of the drug is the same or less
3 than the inflation-adjusted average
4 manufacturer price determined with
5 respect to such drug under subclause
6 (II) for the rebate period, with respect
7 to each dosage form and strength of
8 the single source drug or innovator
9 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)”.

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