

**Calendar No. 225**116TH CONGRESS  
1ST SESSION**S. 2543****[Report No. 116-120]**

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

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**IN THE SENATE OF THE UNITED STATES**

SEPTEMBER 25, 2019

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

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**A BILL**

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

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

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

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

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

Sec. 1. Short title; table of contents.

**TITLE I—MEDICARE**

**Subtitle A—Part B**

- Sec. 101. Improving manufacturers’ reporting of average sales prices to set accurate payment rates.
- Sec. 102. Inclusion of value of coupons in determination of average sales price for drugs and biologicals under Medicare part B.
- Sec. 103. Payment for biosimilar biological products during initial period.
- Sec. 104. Temporary increase in Medicare part B payment for biosimilar biological products.
- Sec. 105. Improvements to Medicare site-of-service transparency.
- Sec. 106. Medicare part B rebate by manufacturers for drugs or biologicals with prices increasing faster than inflation.
- Sec. 107. Requiring manufacturers of certain single-dose container or single-use package drugs payable under part B of the Medicare program to provide refunds with respect to discarded amounts of such drugs.
- Sec. 108. Clarification of Medicare average sales price payment methodology.
- Sec. 109. Establishment of maximum add-on payment for drugs and biologicals.
- Sec. 110. Treatment of drug administration services furnished by certain excepted off-campus outpatient departments of a provider.
- Sec. 111. GAO study and report on average sales price.
- Sec. 112. Authority to use alternative payment for drugs and biologicals to prevent potential drug shortages.

**Subtitle B—Part D**

- Sec. 121. Medicare part D modernization redesign.
- Sec. 122. Providing the Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission with access to certain drug payment information, including certain rebate information.
- Sec. 123. Public disclosure of drug discounts and other pharmacy benefit manager (PBM) provisions.
- Sec. 124. Public disclosure of direct and indirect remuneration review and audit results.
- Sec. 125. Increasing the use of real-time benefit tools to lower beneficiary costs.
- Sec. 126. Improvements to provision of parts A and B claims data to prescription drug plans.
- Sec. 127. Permanently authorize a successful pilot on retroactive Medicare part D coverage for low-income beneficiaries.

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

#### Subtitle C—Miscellaneous

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

#### TITLE II—MEDICAID

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

**TITLE I—MEDICARE****Subtitle A—Part B**

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

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

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

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

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

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

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

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

3 “(i) Section 1927(b)(3)(A)(iii).

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

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

19 (b) CONFORMING AMENDMENTS.—

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

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

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

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

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

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

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

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

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

7 (1) in paragraph (3)—

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

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

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

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

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

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

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

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

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



1 “(L) DRUG COUPON PROGRAM.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 (1) in paragraph (1)—

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

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

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

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

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

21 (C) in subparagraph (A)—

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

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

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

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

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

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

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

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

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

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

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

4               “(1) REQUIREMENTS.—

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

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

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

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

1 “(B) MANUFACTURER REBATE.—

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

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

21 “(C) REQUEST FOR RECONSIDERATION.—

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



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

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

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

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

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

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

21 “(3) REBATE AMOUNT.—

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

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

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

7 “(ii) the amount (if any) by which—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14           “(6) ENFORCEMENT.—

15           “(A) CIVIL MONEY PENALTY.—

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

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

4                   “(II) 25 percent of such amount.

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

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

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

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

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

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

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

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

16 “(B) the determination of—

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

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

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



1 **SEC. 107. REQUIRING MANUFACTURERS OF CERTAIN SIN-**  
 2 **GLE-DOSE CONTAINER OR SINGLE-USE PACK-**  
 3 **AGE DRUGS PAYABLE UNDER PART B OF THE**  
 4 **MEDICARE PROGRAM TO PROVIDE REFUNDS**  
 5 **WITH RESPECT TO DISCARDED AMOUNTS OF**  
 6 **SUCH DRUGS.**

7 Section 1847A of the Social Security Act (42 U.S.C.  
 8 1395–3a), as amended by section 106, is amended by add-  
 9 ing at the end the following new subsection:

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

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

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

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

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

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

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

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

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

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

12 “(3) REFUND AMOUNT.—

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

21 “(i) the product of—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9           “(6) ENFORCEMENT.—

10           “(A) AUDITS.—

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

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

1 “(B) CIVIL MONEY PENALTY.—

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

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

14 “(II) 25 percent of such amount.

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

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



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

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

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

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

19 **PRICE PAYMENT METHODOLOGY.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12                   (1) in subsection (b)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 “(i) for each of 2021 through 2028,  
2 \$1,000; and

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

15 (a) STUDY.—

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

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

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

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

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

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

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

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

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

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

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

3                       (i) formulary placement;

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

6                       (iii) other purposes.

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

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

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

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

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

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

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

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

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

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

1 “(B) DRUG OR BIOLOGICAL DESCRIBED.—

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

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

16 “(ii) that—

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

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

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

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

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

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

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

4 (c) HHS REPORT AND RECOMMENDATIONS.—

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

10 (A) an analysis of—

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

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

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

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



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

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

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

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

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

## 19                                   **Subtitle B—Part D**

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

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

24                   (1) in paragraph (2)—

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

8 (B) in subparagraph (C)—

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

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

16 (C) in subparagraph (D)—

17 (i) in clause (i)—

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

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

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

5           (2) in paragraph (3)(A)—

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

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

12          (3) in paragraph (4)—

13          (A) in subparagraph (A)—

14           (i) in clause (i)—

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

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

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

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

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

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

9 (ii) in clause (ii)—

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

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

19 (B) in subparagraph (B)—

20 (i) in clause (i)—

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

23 (II) in subclause (VI)—

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

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

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

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

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

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

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

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

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

4 (1) in paragraph (1)—

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

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

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

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

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

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

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

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

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

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

19           “(i) for 2022, 60 percent;

20           “(ii) for 2023, 40 percent; and

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

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

25           “(i) for 2022, 80 percent;

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

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

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

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

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

22 “(b) TERMS OF AGREEMENT.—

23 “(1) IN GENERAL.—

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



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

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

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

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

1           “(4) LENGTH OF AGREEMENT.—

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

8           “(B) TERMINATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15           “(2) MONITORING COMPLIANCE.—

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

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

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

7           “(d) ADMINISTRATION.—

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

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

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

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

1 individuals or entities the Secretary determines  
2 appropriate;

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

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

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

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

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

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

12          “(e) ENFORCEMENT.—

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

16                 “(2) CIVIL MONEY PENALTY.—

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

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



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

5 “(ii) 25 percent of such amount.

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

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

19 “(g) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

13 “(4) DISCOUNTED PRICE.—

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

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

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

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

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

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

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

1 plan' has the meaning given such term in section  
2 1860D-22(a)(2).”.

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

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

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

12 “(h) SUNSET OF PROGRAM.—

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

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

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

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

3 (A) in subsection (b)(2)(C)(iii)—

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

7 “(I) the reinsurance”; and

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

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

15 (B) in subsection (c)(1)(C)—

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

19 “(i) the reinsurance”;

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

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

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

4           (d) DETERMINATION OF ALLOWABLE REINSURANCE  
5 COSTS.—Section 1860D–15(b) of the Social Security Act  
6 (42 U.S.C. 1395w–115(b)) is amended—

7           (1) in paragraph (2)—

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

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

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

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

24           (2) in paragraph (3)—

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

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

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

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

22 (f) CONFORMING AMENDMENTS.—

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



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

5 (B) in subsection (c)(1)(C)—

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

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

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

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

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

24 (A) in paragraph (1)—

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

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

7 (iii) in subparagraph (D)(iii), by strik-  
8 ing “1860D–2(b)(4)(A)(i)(I)” and insert-  
9 ing “1860D–2(b)(4)(A)(i)(I)(aa)”; and  
10 (B) in paragraph (2)—

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

15 (ii) in subparagraph (E)—

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

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

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

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

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

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

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

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

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

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

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

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

22           (7) Section 1860D–43(a)(1) of the Social Secu-  
23 rity Act (42 U.S.C. 1395w–153(a)(1)) is amended to  
24 read as follows:

25           “(1) participate in—

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

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

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

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

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

19           (1) in paragraph (2)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23                   (a) PUBLIC DISCLOSURE OF DRUG DISCOUNTS.—

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 “(ix) CIVIL MONETARY PENALTIES.—

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

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

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

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

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

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

5           “(B) TO PHARMACIES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

21                   (2) in paragraph (2)(C)—

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

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



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

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

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

14 “(I) A pharmacy.

15 “(II) A manufacturer.

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

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

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

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

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

4           “(1) DIR REVIEW RESULTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 natives included in the formulary of  
2 such plan.

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

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

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

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

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

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

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

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

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



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

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

8 (a) DATA USE.—

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

17 (A) in subparagraph (B)—

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

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

24 “(i) IN GENERAL.—A PDP sponsor.”;

25 and

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

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

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

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

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

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

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

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

23 “(ii) MANNER OF PROVISION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3                   “(4) PROGRAM ADMINISTRATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 “(a) REQUIREMENTS.—

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

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

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



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

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

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

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

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

22 “(2) MANUFACTURER REBATE.—

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

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

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

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

1           “(4) DEFINITIONS.—In this section:

2                   “(A) REBATE PERIOD.—

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

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

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

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

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

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

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

18          “(b) REBATE AMOUNT.—

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

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

4           “(B) the amount (if any) by which—

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

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

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

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

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

24                 “(ii) the ratio of—

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

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

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

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

18                  “(ii) the ratio of—

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

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

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

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

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

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

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

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

25           “(ii) the ratio of—

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

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

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

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

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



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

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

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

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

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

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

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

9 “(B) the ratio of—

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

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

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

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

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

3 “(B) the ratio of—

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

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

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

13 “(e) ADMINISTRATION.—

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

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

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

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

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

1 different than the calculation described in such  
2 paragraph.

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

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

12 “(A) the determination of—

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

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

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

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

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

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

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

3           “(f) CIVIL MONEY PENALTY.—

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

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

14                   “(B) 25 percent of such amount.

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

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

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

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

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

3 “(h) REBATE AGREEMENT.—

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

7 “(2) TERMS OF AGREEMENT.—

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

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

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

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

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

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

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

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



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

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

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

17 “(i) FUNDING.—

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

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

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

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

7           (b) CONFORMING AMENDMENTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 (a) STUDY.—

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

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



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

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

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

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

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

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

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

## 4 **Subtitle C—Miscellaneous**

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

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

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

11 “(a) IN GENERAL.—

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

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

23 “(b) APPLICABLE DRUG DESCRIBED.—

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

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

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

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

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

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

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

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

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

6           “(B) HIGH SPENDING WITH INCREASE.—

7           The drug—

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

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

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

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

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

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

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

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

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

22 “(2) SPECIAL RULES.—

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

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

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

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

24 “(c) JUSTIFICATION DESCRIBED.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

14                  “(d) TIMING.—

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

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

1           “(3) POSTING ON INTERNET WEBSITE.—

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

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

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

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

4 “(f) PENALTIES.—

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

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

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

1 under this subsection are in addition to other pen-  
2 alties as may be prescribed by law.

3 “(g) DEFINITIONS.—In this section:

4 “(1) DRUG.—The term ‘drug’ means a drug, as  
5 defined in section 201(g) of the Federal Food, Drug,  
6 and Cosmetic Act, that is intended for human use  
7 and subject to section 503(b)(1) of such Act, includ-  
8 ing a product licensed under section 351 of the Pub-  
9 lic health Service Act.

10 “(2) MANUFACTURER.—The term ‘manufac-  
11 turer’ has the meaning given that term in section  
12 1847A(c)(6)(A).

13 “(3) WHOLESALE ACQUISITION COST.—The  
14 term ‘wholesale acquisition cost’ has the meaning  
15 given that term in section 1847A(c)(6)(B).”.

16 **SEC. 142. STRENGTHENING AND EXPANDING PHARMACY**  
17 **BENEFIT MANAGERS TRANSPARENCY RE-**  
18 **QUIREMENTS.**

19 Section 1150A of the Social Security Act (42 U.S.C.  
20 1320b–23), as amended by section 123, is amended—

21 (1) in subsection (a)—

22 (A) in paragraph (1), by striking “or” at  
23 then end;

24 (B) in paragraph (2), by striking the  
25 comma at the end and inserting “; or”; and

1 (C) by inserting after paragraph (2) the  
2 following new paragraph:

3 “(3) a State plan under title XIX, including a  
4 managed care entity (as defined in section  
5 1932(a)(1)(B)),”;

6 (2) in subsection (b)—

7 (A) in paragraph (2)—

8 (i) by striking “(excluding bona fide”  
9 and all that follows through “patient edu-  
10 cation programs))”; and

11 (ii) by striking “aggregate amount of”  
12 and inserting “aggregate amount and per-  
13 centage of”;

14 (B) in paragraph (3), by striking “aggre-  
15 gate amount of” and inserting “aggregate  
16 amount and percentage (defined as a share of  
17 gross drug costs) of”; and

18 (C) by adding at the end the following new  
19 paragraph:

20 “(4) The aggregate amount of bona fide service  
21 fees (which include distribution service fees, inven-  
22 tory management fees, product stocking allowances,  
23 and fees associated with administrative services  
24 agreements and patient care programs (such as

1 medication compliance programs and patient edu-  
2 cation programs)) the PBM received from—

3 “(A) PDP sponsors;

4 “(B) qualified health benefit plans;

5 “(C) managed care entities (as defined in  
6 section 1932(a)(1)(b)); and

7 “(D) drug manufacturers.”;

8 (3) in subsection (c), by adding at the end the  
9 following new paragraphs:

10 “(5) To States to carry out their administration  
11 and oversight of the State plan under title XIX.

12 “(6) To the Federal Trade Commission to carry  
13 out section 5(a) of the Federal Trade Commission  
14 Act (15 U.S.C. 45a) and any other relevant con-  
15 sumer protection or antitrust authorities enforced by  
16 such Commission, including reviewing proposed  
17 mergers in the prescription drug sector.

18 “(7) To assist the Department of Justice to  
19 carry out its antitrust authorities, including review-  
20 ing proposed mergers in the prescription drug sec-  
21 tor.”; and

22 (4) by adding at the end the following new sub-  
23 section:

24 “(f) ANNUAL OIG EVALUATION AND REPORT.—

1           “(1) ANALYSIS.—The Inspector General of the  
2 Department of Health and Human Services shall  
3 conduct an annual evaluation of the information pro-  
4 vided to the Secretary under this section. Such eval-  
5 uation shall include an analysis of—

6                   “(A) PBM rebates;

7                   “(B) administrative fees;

8                   “(C) the difference between what plans pay  
9 PBMs and what PBMs pay pharmacies;

10                  “(D) generic dispensing rates; and

11                  “(E) other areas determined appropriate  
12 by the Inspector General.

13           “(2) REPORT.—Not later than July 1, 2020,  
14 and annually thereafter, the Inspector General of the  
15 Department of Health and Human Services shall  
16 submit to Congress a report containing the results  
17 of the evaluation conducted under paragraph (1), to-  
18 gether with recommendations for such legislation  
19 and administrative action as the Inspector General  
20 determines appropriate. Such report shall not dis-  
21 close the identity of a specific PBM, plan, or price  
22 charged for a drug.”.

23 **SEC. 143. PRESCRIPTION DRUG PRICING DASHBOARDS.**

24           Part A of title XI of the Social Security Act is  
25 amended by adding at the end the following new section:

1 **“SEC. 1150C. PRESCRIPTION DRUG PRICING DASHBOARDS.**

2       “(a) IN GENERAL.—Beginning not later than Janu-  
3 ary 1, 2020, the Secretary shall establish, and annually  
4 update, internet website-based dashboards, through which  
5 beneficiaries, clinicians, researchers, and the public can re-  
6 view information on spending for, and utilization of, pre-  
7 scription drugs and biologicals (and related supplies and  
8 mechanisms of delivery) covered under each of parts B  
9 and D of title XVIII and under a State program under  
10 title XIX, including information on trends of such spend-  
11 ing and utilization over time.

12       “(b) MEDICARE PART B DRUG AND BIOLOGICAL  
13 DASHBOARD.—

14               “(1) IN GENERAL.—The dashboard established  
15 under subsection (a) for part B of title XVIII shall  
16 provide the information described in paragraph (2).

17               “(2) INFORMATION DESCRIBED.—The informa-  
18 tion described in this paragraph is the following in-  
19 formation with respect to drug or biologicals covered  
20 under such part B:

21                       “(A) The brand name and, if applicable,  
22 the generic names of the drug or biological.

23                       “(B) Consumer-friendly information on the  
24 uses and clinical indications of the drug or bio-  
25 logical.



1           “(C) The manufacturer or labeler of the  
2 drug or biological.

3           “(D) To the extent feasible, the following  
4 information:

5                   “(i) Average total spending per dos-  
6 age unit of the drug or biological in the  
7 most recent 2 calendar years for which  
8 data is available.

9                   “(ii) The percentage change in aver-  
10 age spending on the drug or biological per  
11 dosage unit between the most recent cal-  
12 endar year for which data is available  
13 and—

14                           “(I) the preceding calendar year;  
15 and

16                           “(II) the preceding 5 and 10 cal-  
17 endar years.

18                   “(iii) The annual growth rate in aver-  
19 age spending per dosage unit of the drug  
20 or biological in the most recent 5 or 10  
21 calendar years for which data is available.

22                   “(iv) Total spending for the drug or  
23 biological for the most recent calendar year  
24 for which data is available.

1           “(v) The number of beneficiaries re-  
2           ceiving the drug or biological in the most  
3           recent calendar year for which data is  
4           available.

5           “(vi) Average spending on the drug  
6           per beneficiary for the most recent cal-  
7           endar year for which data is available.

8           “(E) The average sales price of the drug  
9           or biological (as determined under section  
10          1847A) for the most recent quarter.

11          “(F) Consumer-friendly information about  
12          the coinsurance amount for the drug or biologi-  
13          cal for beneficiaries for the most recent quarter.  
14          Such information shall not include coinsurance  
15          amounts for qualified medicare beneficiaries (as  
16          defined in section 1905(p)(1)).

17          “(G) For the most recent calendar year for  
18          which data is available—

19                 “(i) the 15 drugs and biologicals with  
20                 the highest total spending under such part;  
21                 and

22                 “(ii) any drug or biological for which  
23                 the average annual per beneficiary spend-  
24                 ing exceeds the gross spending for covered  
25                 part D drugs at which the annual out-of-

1 pocket threshold under section 1860D–  
2 2(b)(4)(B) would be met for the year.

3 “(H) Other information (not otherwise  
4 prohibited in law from being disclosed) that the  
5 Secretary determines would provide bene-  
6 ficiaries, clinicians, researchers, and the public  
7 with helpful information about drug and bio-  
8 logical spending and utilization (including  
9 trends of such spending and utilization).

10 “(c) MEDICARE COVERED PART D DRUG DASH-  
11 BOARD.—

12 “(1) IN GENERAL.—The dashboard established  
13 under subsection (a) for part D of title XVIII shall  
14 provide the information described in paragraph (2).

15 “(2) INFORMATION DESCRIBED.—The informa-  
16 tion described in this paragraph is the following in-  
17 formation with respect to covered part D drugs  
18 under such part D:

19 “(A) The information described in sub-  
20 paragraphs (A) through (D) of subsection  
21 (b)(2).

22 “(B) Information on average annual bene-  
23 ficiary out-of-pocket costs below and above the  
24 annual out-of-pocket threshold under section  
25 1860D–2(b)(4)(B) for the current plan year.

1           Such information shall not include out-of-pocket  
2           costs for subsidy eligible individuals under sec-  
3           tion 1860D–14.

4           “(C) Information on how to access re-  
5           sources as described in sections 1860D–1(e)  
6           and 1851(d).

7           “(D) For the most recent calendar year for  
8           which data is available—

9                   “(i) the 15 covered part D drugs with  
10                   the highest total spending under such part;  
11                   and

12                   “(ii) any covered part D drug for  
13                   which the average annual per beneficiary  
14                   spending exceeds the gross spending for  
15                   covered part D drugs at which the annual  
16                   out-of-pocket threshold under section  
17                   1860D–2(b)(4)(B) would be met for the  
18                   year.

19           “(E) Other information (not otherwise pro-  
20           hibited in law from being disclosed) that the  
21           Secretary determines would provide bene-  
22           ficiaries, clinicians, researchers, and the public  
23           with helpful information about covered part D  
24           drug spending and utilization (including trends  
25           of such spending and utilization).

1       “(d) MEDICAID COVERED OUTPATIENT DRUG DASH-  
2 BOARD.—

3           “(1) IN GENERAL.—The dashboard established  
4       under subsection (a) for title XIX shall provide the  
5       information described in paragraph (2).

6           “(2) INFORMATION DESCRIBED.—The informa-  
7       tion described in this paragraph is the following in-  
8       formation with respect to covered outpatient drugs  
9       under such title:

10           “(A) The information described in sub-  
11       paragraphs (A) through (D) of subsection  
12       (b)(2).

13           “(B) For the most recent calendar year for  
14       which data is available, the 15 covered out-  
15       patient drugs with the highest total spending  
16       under such title.

17           “(C) Other information (not otherwise pro-  
18       hibited in law from being disclosed) that the  
19       Secretary determines would provide bene-  
20       ficiaries, clinicians, researchers, and the public  
21       with helpful information about covered out-  
22       patient drug spending and utilization (including  
23       trends of such spending and utilization).

1       “(e) DATA FILES.—The Secretary shall make avail-  
2 able the underlying data for each dashboard established  
3 under subsection (a) in a machine-readable format.”.

4 **SEC. 144. IMPROVING COORDINATION BETWEEN THE FOOD**  
5 **AND DRUG ADMINISTRATION AND THE CEN-**  
6 **TERS FOR MEDICARE & MEDICAID SERVICES.**

7       (a) IN GENERAL.—

8           (1) PUBLIC MEETING.—

9               (A) IN GENERAL.—Not later than 12  
10 months after the date of the enactment of this  
11 Act, the Secretary of Health and Human Serv-  
12 ices (referred to in this section as the “Sec-  
13 retary”) shall convene a public meeting for the  
14 purposes of discussing and providing input on  
15 improvements to coordination between the Food  
16 and Drug Administration and the Centers for  
17 Medicare & Medicaid Services in preparing for  
18 the availability of novel medical products de-  
19 scribed in subsection (c) on the market in the  
20 United States.

21               (B) ATTENDEES.—The public meeting  
22 shall include—

23                   (i) representatives of relevant Federal  
24 agencies, including representatives from  
25 each of the medical product centers within

1 the Food and Drug Administration and  
2 representatives from the coding, coverage,  
3 and payment offices within the Centers for  
4 Medicare & Medicaid Services;

5 (ii) stakeholders with expertise in the  
6 research and development of novel medical  
7 products, including manufacturers of such  
8 products;

9 (iii) representatives of commercial  
10 health insurance payers;

11 (iv) stakeholders with expertise in the  
12 administration and use of novel medical  
13 products, including physicians; and

14 (v) stakeholders representing patients  
15 and with expertise in the utilization of pa-  
16 tient experience data in medical product  
17 development.

18 (C) TOPICS.—The public meeting shall in-  
19 clude a discussion of—

20 (i) the status of the drug and medical  
21 device development pipeline related to the  
22 availability of novel medical products;

23 (ii) the anticipated expertise necessary  
24 to review the safety and effectiveness of  
25 such products at the Food and Drug Ad-

1           ministration and current gaps in such ex-  
2           pertise, if any;

3           (iii) the expertise necessary to make  
4           coding, coverage, and payment decisions  
5           with respect to such products within the  
6           Centers for Medicare & Medicaid Services,  
7           and current gaps in such expertise, if any;

8           (iv) trends in the differences in the  
9           data necessary to determine the safety and  
10          effectiveness of a novel medical product  
11          and the data necessary to determine  
12          whether a novel medical product meets the  
13          reasonable and necessary requirements for  
14          coverage and payment under title XVIII of  
15          the Social Security Act pursuant to section  
16          1862(a)(1)(A) of such Act (42 U.S.C.  
17          1395y(a)(1)(A));

18          (v) the availability of information for  
19          sponsors of such novel medical products to  
20          meet each of those requirements; and

21          (vi) the coordination of information  
22          related to significant clinical improvement  
23          over existing therapies for patients between  
24          the Food and Drug Administration and the



1                   Centers for Medicare & Medicaid Services  
2                   with respect to novel medical products.

3                   (D) TRADE SECRETS AND CONFIDENTIAL  
4                   INFORMATION.—No information discussed as a  
5                   part of the public meeting under this paragraph  
6                   shall be construed as authorizing the Secretary  
7                   to disclose any information that is a trade se-  
8                   cret or confidential information subject to sec-  
9                   tion 552(b)(4) of title 5, United States Code.

10                  (2) IMPROVING TRANSPARENCY OF CRITERIA  
11                  FOR MEDICARE COVERAGE.—

12                   (A) DRAFT GUIDANCE.—Not later than 18  
13                   months after the public meeting under para-  
14                   graph (1), the Secretary shall update the final  
15                   guidance titled “National Coverage Determina-  
16                   tions with Data Collection as a Condition of  
17                   Coverage: Coverage with Evidence Develop-  
18                   ment” to address any opportunities to improve  
19                   the availability and coordination of information  
20                   as described in clauses (iv) through (vi) of para-  
21                   graph (1)(C).

22                   (B) FINAL GUIDANCE.—Not later than 12  
23                   months after issuing draft guidance under sub-  
24                   paragraph (A), the Secretary shall finalize the

1 updated guidance to address any such opportu-  
2 nities.

3 (b) REPORT ON CODING, COVERAGE, AND PAYMENT  
4 PROCESSES UNDER MEDICARE FOR NOVEL MEDICAL  
5 PRODUCTS.—Not later than 12 months after the date of  
6 the enactment of this Act, the Secretary shall publish a  
7 report on the Internet website of the Department of  
8 Health and Human Services regarding processes under  
9 the Medicare program under title XVIII of the Social Se-  
10 curity Act (42 U.S.C. 1395 et seq.) with respect to the  
11 coding, coverage, and payment of novel medical products  
12 described in subsection (c). Such report shall include the  
13 following:

14 (1) A description of challenges in the coding,  
15 coverage, and payment processes under the Medicare  
16 program for novel medical products.

17 (2) Recommendations to—

18 (A) incorporate patient experience data  
19 (such as the impact of a disease or condition on  
20 the lives of patients and patient treatment pref-  
21 erences) into the coverage and payment proc-  
22 esses within the Centers for Medicare & Med-  
23 icaid Services;

24 (B) decrease the length of time to make  
25 national and local coverage determinations

1 under the Medicare program (as those terms  
2 are defined in subparagraph (A) and (B), re-  
3 spectively, of section 1862(l)(6) of the Social  
4 Security Act (42 U.S.C. 1395y(l)(6));

5 (C) streamline the coverage process under  
6 the Medicare program and incorporate input  
7 from relevant stakeholders into such coverage  
8 determinations; and

9 (D) identify potential mechanisms to incor-  
10 porate novel payment designs similar to those  
11 in development in commercial insurance plans  
12 and State plans under title XIX of such Act  
13 (42 U.S.C. 1396 et seq.) into the Medicare pro-  
14 gram.

15 (c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For  
16 purposes of this section, a novel medical product described  
17 in this subsection is a medical product, including a drug,  
18 biological (including gene and cell therapy), or medical de-  
19 vice, that has been designated as a breakthrough therapy  
20 under section 506(a) of the Federal Food, Drug, and Cos-  
21 metic Act (21 U.S.C. 356(a)), a breakthrough device  
22 under section 515B of such Act (21 U.S.C. 360e–3), or  
23 a regenerative advanced therapy under section 506(g) of  
24 such Act (21 U.S.C. 356(g)).

1 **SEC. 145. PATIENT CONSULTATION IN MEDICARE NA-**  
2 **TIONAL AND LOCAL COVERAGE DETERMINA-**  
3 **TIONS IN ORDER TO MITIGATE BARRIERS TO**  
4 **INCLUSION OF SUCH PERSPECTIVES.**

5 Section 1862(l) of the Social Security Act (42 U.S.C.  
6 1395y(l)) is amended by adding at the end the following  
7 new paragraph:

8 “(7) PATIENT CONSULTATION IN NATIONAL  
9 AND LOCAL COVERAGE DETERMINATIONS.—The Sec-  
10 retary may consult with patients and organizations  
11 representing patients in making national and local  
12 coverage determinations.”.

13 **SEC. 146. GAO STUDY ON INCREASES TO MEDICARE AND**  
14 **MEDICAID SPENDING DUE TO COPAYMENT**  
15 **COUPONS AND OTHER PATIENT ASSISTANCE**  
16 **PROGRAMS.**

17 (a) STUDY.—The Comptroller General of the United  
18 States shall conduct a study on the impact of copayment  
19 coupons and other patient assistance programs on pre-  
20 scription drug pricing and expenditures within the Medi-  
21 care and Medicaid programs. The study shall assess the  
22 following:

23 (1) The extent to which copayment coupons and  
24 other patient assistance programs contribute to in-  
25 flated prescription drug prices under such programs.

1           (2) The impact copayment coupons and other  
2 patient assistance programs have in the Medicare  
3 Part D program established under part D of title  
4 XVIII of the Social Security Act (42 U.S.C. 1395w–  
5 101 et seq.) on utilization of higher-cost brand drugs  
6 and lower utilization of generic drugs in that pro-  
7 gram.

8           (3) The extent to which manufacturers report  
9 or obtain tax benefits, including deductions of busi-  
10 ness expenses and charitable contributions, for any  
11 of the following:

12                   (A) Offering copayment coupons or other  
13 patient assistance programs.

14                   (B) Sponsoring manufacturer patient as-  
15 sistance programs.

16                   (C) Paying for sponsorships at outreach  
17 and advocacy events organized by patient as-  
18 sistance programs.

19           (4) The efficacy of oversight conducted to en-  
20 sure that independent charity patient assistance pro-  
21 grams adhere to guidance from the Office of the In-  
22 spector General of the Department of Health and  
23 Human Services on avoiding waste, fraud, and  
24 abuse.

25           (b) DEFINITIONS.—In this section:

1           (1) INDEPENDENT CHARITY PATIENT ASSIST-  
2           ANCE PROGRAM.—The term “independent charity  
3           patient assistance program” means any organization  
4           described in section 501(c)(3) of the Internal Rev-  
5           enue Code of 1986 and exempt from taxation under  
6           section 501(a) of such Code and which is not a pri-  
7           vate foundation (as defined in section 509(a) of such  
8           Code) that offers patient assistance.

9           (2) MANUFACTURER.—The term “manufac-  
10          turer” has the meaning given that term in section  
11          1927(k)(5) of the Social Security Act (42 U.S.C.  
12          1396r–8(k)(5)).

13          (3) MANUFACTURER PATIENT ASSISTANCE PRO-  
14          GRAM.—The term “manufacturer patient assistance  
15          program” means an organization, including a private  
16          foundation (as so defined), that is sponsored by, or  
17          receives funding from, a manufacturer and that of-  
18          fers patient assistance. Such term does not include  
19          an independent charity patient assistance program.

20          (4) PATIENT ASSISTANCE.—The term “patient  
21          assistance” means assistance provided to offset the  
22          cost of drugs for individuals. Such term includes free  
23          products, coupons, rebates, copay or discount cards,  
24          and other means of providing assistance to individ-

1 uals related to drug costs, as determined by the Sec-  
2 retary of Health and Human Services.

3 (c) REPORT.—Not later than 24 months after the  
4 date of the enactment of this Act, the Comptroller General  
5 of the United States shall submit to Congress a report  
6 describing the findings of the study required under sub-  
7 section (a).

8 **SEC. 147. MEDPAC REPORT ON SHIFTING COVERAGE OF**  
9 **CERTAIN MEDICARE PART B DRUGS TO MEDI-**  
10 **CARE PART D.**

11 (a) STUDY.—The Medicare Payment Advisory Com-  
12 mission (in this section referred to as the “Commission”)  
13 shall conduct a study on shifting coverage of certain drugs  
14 and biologicals for which payment is currently made under  
15 part B of title XVIII of the Social Security Act (42 U.S.C.  
16 1395j et seq.) to part D of such title (42 U.S.C. 1395w-  
17 21 et seq.). Such study shall include an analysis of—

18 (1) differences in program structures and pay-  
19 ment methods for drugs and biologicals covered  
20 under such parts B and D, including effects of such  
21 a shift on program spending, beneficiary cost-shar-  
22 ing liability, and utilization management techniques  
23 for such drugs and biologicals; and

24 (2) the feasibility and policy implications of  
25 shifting coverage of drugs and biologicals for which

1 payment is currently made under such part B to  
2 such part D.

3 (b) REPORT.—

4 (1) IN GENERAL.—Not later than June 30,  
5 2021, the Commission shall submit to Congress a re-  
6 port containing the results of the study conducted  
7 under subsection (a).

8 (2) CONTENTS.—The report under paragraph  
9 (1) shall include information, and recommendations  
10 as the Commission deems appropriate, regarding—

11 (A) formulary design under such part D;

12 (B) the ability of the benefit structure  
13 under such part D to control total spending on  
14 drugs and biologicals for which payment is cur-  
15 rently made under such part B;

16 (C) changes to the bid process under such  
17 part D, if any, that may be necessary to inte-  
18 grate coverage of such drugs and biologicals  
19 into such part D; and

20 (D) any other changes to the program that  
21 Congress should consider in determining wheth-  
22 er to shift coverage of such drugs and  
23 biologicals from such part B to such part D.



1 **SEC. 148. TAKING STEPS TO FULFILL TREATY OBLIGATIONS**  
2 **TO TRIBAL COMMUNITIES.**

3 (a) GAO STUDY.—The Comptroller General shall  
4 conduct a study regarding access to, and the cost of, pre-  
5 scription drugs among Indians. The study shall include—

6 (1) a review of what Indian health programs  
7 pay for prescription drugs on reservations and in  
8 urban centers relative to other consumers;

9 (2) recommendations to align the value of pre-  
10 scription drug discounts available under the Med-  
11 icaid drug rebate program established under section  
12 1927 of the Social Security Act (42 U.S.C. 1396r-  
13 8) with prescription drug discounts available to  
14 Tribal communities through the purchased/referred  
15 care program of the Indian Health Service for physi-  
16 cian administered drugs; and

17 (3) an examination of how Tribal communities  
18 and urban Indian organizations utilize the Medicare  
19 part D program established under title XVIII of the  
20 Social Security Act (42 U.S.C. 1395w-101 et seq.)  
21 and recommendations to improve enrollment among  
22 Indians in that program.

23 (b) REPORT.—Not later than 18 months after the  
24 date of the enactment of this Act, the Comptroller General  
25 shall submit to Congress a report containing the results  
26 of the study conducted under subsection (a), together with

1 recommendations for such legislation and administrative  
2 action as the Comptroller General determines appropriate.

3 (c) DEFINITIONS.—In this section:

4 (1) COMPTROLLER GENERAL.—The term  
5 “Comptroller General” means the Comptroller Gen-  
6 eral of the United States.

7 (2) INDIAN; INDIAN HEALTH PROGRAM; INDIAN  
8 TRIBE.—The terms “Indian”, “Indian health pro-  
9 gram”, and “Indian tribe” have the meanings given  
10 those terms in section 4 of the Indian Health Care  
11 Improvement Act (25 U.S.C. 1603).

## 12 **TITLE II—MEDICAID**

### 13 **SEC. 201. MEDICAID PHARMACY AND THERAPEUTICS COM- 14 MITTEE IMPROVEMENTS.**

15 (a) IN GENERAL.—Subparagraph (A) of section  
16 1927(d)(4) of the Social Security Act (42 U.S.C. 1396r-  
17 8(d)(4)) is amended to read as follows:

18 “(A)(i) The formulary is developed and re-  
19 viewed by a pharmacy and therapeutics com-  
20 mittee consisting of physicians, pharmacists,  
21 and other appropriate individuals appointed by  
22 the Governor of the State.

23 “(ii) Subject to clause (vi), the State estab-  
24 lishes and implements a conflict of interest pol-

1           icy for the pharmacy and therapeutics com-  
2           mittee that—

3                   “(I) is publicly accessible;

4                   “(II) requires all committee members  
5           to complete, on at least an annual basis, a  
6           disclosure of relationships, associations,  
7           and financial dealings that may affect their  
8           independence of judgement in committee  
9           matters; and

10                   “(III) contains clear processes, such  
11           as recusal from voting or discussion, for  
12           those members who report a conflict of in-  
13           terest, along with appropriate processes to  
14           address any instance where a member fails  
15           to report a conflict of interest.

16                   “(iii) The membership of the pharmacy  
17           and therapeutics committee—

18                   “(I) includes at least 1 actively prac-  
19           ticing physician and at least 1 actively  
20           practicing pharmacist, each of whom—

21                   “(aa) is independent and free of  
22           conflict with respect to manufacturers  
23           and Medicaid participating plans or  
24           subcontractors, including pharmacy  
25           benefit managers; and

1                   “(bb) has expertise in the care of  
2                   1 or more Medicaid-specific popu-  
3                   lations such as elderly or disabled in-  
4                   dividuals, children with complex med-  
5                   ical needs, or low-income individuals  
6                   with chronic illnesses and

7                   “(II) is made publicly available.

8                   “(iv) At the option of the State, the  
9                   State’s drug use review board established under  
10                  subsection (g)(3) may serve as the pharmacy  
11                  and therapeutics committee provided the State  
12                  ensures that such board meets the requirements  
13                  of clauses (ii) and (iii).

14                  “(v) The State reviews and has final ap-  
15                  proval of the formulary established by the phar-  
16                  macy and therapeutics committee.

17                  “(vi) If the Secretary determines it appro-  
18                  priate or necessary based on the findings and  
19                  recommendations of the Comptroller General of  
20                  the United States in the report submitted to  
21                  Congress under section 203 of the Prescription  
22                  Drug Pricing Reduction Act of 2019, the Sec-  
23                  retary shall issue guidance that States must fol-  
24                  low for establishing conflict of interest policies  
25                  for the pharmacy and therapeutics committee in

1           accordance with the requirements of clause (ii),  
2           including appropriate standards and require-  
3           ments for identifying, addressing, and reporting  
4           on conflicts of interest.”.

5           (b) APPLICATION TO MEDICAID MANAGED CARE OR-  
6           GANIZATIONS.—Clause (xiii) of section 1903(m)(2)(A) of  
7           the Social Security Act (42 U.S.C. 1396b(m)(2)(A)) is  
8           amended—

9           (1) by striking “and (III)” and inserting  
10          “(III)”;

11          (2) by striking the period at the end and insert-  
12          ing “, and (IV) any formulary used by the entity for  
13          covered outpatient drugs dispensed to individuals eli-  
14          gible for medical assistance who are enrolled with  
15          the entity is developed and reviewed by a pharmacy  
16          and therapeutics committee that meets the require-  
17          ments of clauses (ii) and (iii) of section  
18          1927(d)(4)(A).”; and

19          (3) by moving the left margin 2 ems to the left.

20          (c) EFFECTIVE DATE.—The amendments made by  
21          this section shall take effect on the date that is 1 year  
22          after the date of enactment of this Act.

1 **SEC. 202. IMPROVING REPORTING REQUIREMENTS AND DE-**  
2 **VELOPING STANDARDS FOR THE USE OF**  
3 **DRUG USE REVIEW BOARDS IN STATE MED-**  
4 **ICAID PROGRAMS.**

5 (a) IN GENERAL.—Section 1927(g)(3) of the Social  
6 Security Act (42 U.S.C. 1396r–8(g)(3)) is amended—

7 (1) by amending subparagraph (B) to read as  
8 follows:

9 “(B) MEMBERSHIP.—

10 “(i) IN GENERAL.—The membership  
11 of the DUR Board shall include health  
12 care professionals who have recognized  
13 knowledge and expertise in one or more of  
14 the following:

15 “(I) The clinically appropriate  
16 prescribing of covered outpatient  
17 drugs.

18 “(II) The clinically appropriate  
19 dispensing and monitoring of covered  
20 outpatient drugs.

21 “(III) Drug use review, evalua-  
22 tion, and intervention.

23 “(IV) Medical quality assurance.

24 “(ii) MEMBERSHIP REQUIREMENTS.—  
25 The membership of the DUR Board  
26 shall—

1           “(I) be made up of at least  $\frac{1}{3}$   
2 but no more than 51 percent members  
3 who are licensed and actively prac-  
4 ticing physicians and at least  $\frac{1}{3}$  mem-  
5 bers who are licensed and actively  
6 practicing pharmacists; and

7           “(II) include at least 1 licensed  
8 and actively practicing physician and  
9 at least 1 licensed and actively prac-  
10 ticing pharmacist, each of whom—

11           “(aa) is independent and  
12 free of any conflict, including  
13 with respect to manufacturers,  
14 medicaid managed care entities,  
15 or pharmacy benefit managers;  
16 and

17           “(bb) has expertise in the  
18 care of 1 or more categories of  
19 individuals who are likely to be  
20 eligible for benefits under this  
21 title, including elderly or disabled  
22 individuals, children with complex  
23 medical needs, or low-income in-  
24 dividuals with chronic illnesses;  
25 and

1 “(III) be made publicly available.

2 “(iii) CONFLICT OF INTEREST POL-  
3 ICY.—The State shall establish and imple-  
4 ment a conflict of interest policy for the  
5 DUR Board that—

6 “(I) is publicly accessible;

7 “(II) requires all board members  
8 to complete, on at least an annual  
9 basis, a disclosure of relationships, as-  
10 sociations, and financial dealings that  
11 may affect their independence of  
12 judgement in board matters; and

13 “(III) contains clear processes,  
14 such as recusal from voting or discus-  
15 sion, for those members who report a  
16 conflict of interest, along with appro-  
17 priate processes to address any in-  
18 stance where a member fails to report  
19 a conflict of interest.”; and

20 (2) by adding at the end the following new sub-  
21 paragraph:

22 “(E) DUR BOARD MEMBERSHIP RE-  
23 PORTS.—

24 “(i) DUR BOARD REPORTS.—Each  
25 State shall require the DUR Board to pre-



1           pare and submit to the State an annual re-  
2           port on the DUR Board membership. Each  
3           such report shall include any conflicts of  
4           interest with respect to members of the  
5           DUR Board that the DUR Board recorded  
6           or was aware of during the period that is  
7           the subject of the report, and the process  
8           applied to address such conflicts of inter-  
9           est, in addition to any other information  
10          required by the State.

11           “(ii) INCLUSION OF DUR BOARD MEM-  
12          BERSHIP INFORMATION IN STATE RE-  
13          PORTS.—Each annual State report to the  
14          Secretary required under subparagraph  
15          (D) shall include—

16                   “(I) the number of individuals  
17                   serving on the State’s DUR Board;

18                   “(II) the names and professions  
19                   of the individuals serving on such  
20                   DUR Board;

21                   “(III) any conflicts of interest or  
22                   recusals with respect to members of  
23                   such DUR Board reported by the  
24                   DUR Board or that the State was

1 aware of during the period that is the  
2 subject of the report; and

3 “(IV) whether the State has  
4 elected for such DUR Board to serve  
5 as the committee responsible for de-  
6 veloping a State formulary under sub-  
7 section (d)(4)(A).”.

8 (b) MANAGED CARE REQUIREMENTS.—Section  
9 1932(i) of the Social Security Act (42 U.S.C. 1396u–2(i))  
10 is amended—

11 (1) by striking “section 483.3(s)(4)” and in-  
12 serting “section 438.3(s)(4)”;

13 (2) by striking “483.3(s)(5)” and inserting  
14 “438.3(s)(5)”; and

15 (3) by adding at the end the following: “Such  
16 a managed care entity shall not be considered to be  
17 in compliance with the requirement of such section  
18 438.3(s)(5) that the entity provide a detailed de-  
19 scription of its drug utilization review activities un-  
20 less the entity includes a description of the prospec-  
21 tive drug review activities described in paragraph  
22 (2)(A) of section 1927(g) and the activities listed in  
23 paragraph (3)(C) of section 1927(g), makes the un-  
24 derlying drug utilization review data available to the

1 State and the Secretary, and provides such other in-  
2 formation as deemed appropriate by the Secretary.”.

3 (c) DEVELOPMENT OF NATIONAL STANDARDS FOR  
4 MEDICAID DRUG USE REVIEW.—The Secretary of Health  
5 and Human Services may promulgate regulations or guid-  
6 ance establishing national standards for Medicaid drug  
7 use review programs under section 1927(g) of the Social  
8 Security Act (42 U.S.C. 1396r–8) and drug utilization re-  
9 view activities and requirements under section 1932(i) of  
10 such Act (42 U.S.C. 1396u–2(i)), for the purpose of align-  
11 ing review criteria for prospective and retrospective drug  
12 use review across all State Medicaid programs.

13 (d) CMS GUIDANCE.—Not later than 18 months  
14 after the date of enactment of this Act, the Secretary of  
15 Health and Human Services shall issue guidance—

16 (1) outlining steps that States must take to  
17 come into compliance with statutory and regulatory  
18 requirements for prospective and retrospective drug  
19 use review under section 1927(g) of the Social Secu-  
20 rity Act (42 U.S.C. 1396r–8(g)) and drug utilization  
21 review activities and requirements under section  
22 1932(i) of such Act (42 U.S.C. 1396u–2(i)) (includ-  
23 ing with respect to requirements that were in effect  
24 before the date of enactment of this Act); and

1           (2) describing the actions that the Secretary  
2           will take to enforce such requirements.

3           (e) EFFECTIVE DATE.—The amendments made by  
4 this section shall take effect on the date that is 1 year  
5 after the date of enactment of this Act.

6 **SEC. 203. GAO REPORT ON CONFLICTS OF INTEREST IN**  
7                   **STATE MEDICAID PROGRAM DRUG USE RE-**  
8                   **VIEW BOARDS AND PHARMACY AND THERA-**  
9                   **PEUTICS (P&T) COMMITTEES.**

10          (a) INVESTIGATION.—The Comptroller General of the  
11 United States shall conduct an investigation of potential  
12 or existing conflicts of interest among members of State  
13 Medicaid program State drug use review boards (in this  
14 section referred to as “DUR Boards”) and pharmacy and  
15 therapeutics committees (in this section referred to as  
16 “P&T Committees”).

17          (b) REPORT.—Not later than 24 months after the  
18 date of enactment of this Act, the Comptroller General  
19 shall submit to Congress a report on the investigation con-  
20 ducted under subsection (a) that includes the following:

21               (1) A description outlining how DUR Boards  
22               and P&T Committees operate in States, including  
23               details with respect to—

24                       (A) the structure and operation of DUR  
25               Boards and statewide P&T Committees;

1 (B) States that operate separate P&T  
2 Committees for their fee-for-service Medicaid  
3 program and their Medicaid managed care or-  
4 ganizations or other Medicaid managed care ar-  
5 rangements (collectively referred to in this sec-  
6 tion as “Medicaid MCOs”); and

7 (C) States that allow Medicaid MCOs to  
8 have their own P&T Committees and the extent  
9 to which pharmacy benefit managers administer  
10 or participate in such P&T Committees.

11 (2) A description outlining the differences be-  
12 tween DUR Boards established in accordance with  
13 section 1927(g)(3) of the Social Security Act (42  
14 U.S.C. 1396r(g)(3)) and P&T Committees.

15 (3) A description outlining the tools P&T Com-  
16 mittees may use to determine Medicaid drug cov-  
17 erage and utilization management policies.

18 (4) An analysis of whether and how States or  
19 P&T Committees establish participation and inde-  
20 pendence requirements for DUR Boards and P&T  
21 Committees, including with respect to entities with  
22 connections with drug manufacturers, State Med-  
23 icaid programs, managed care organizations, and  
24 other entities or individuals in the pharmaceutical  
25 industry.

1           (5) A description outlining how States, DUR  
2 Boards, or P&T Committees define conflicts of inter-  
3 est.

4           (6) A description of how DUR Boards and P&T  
5 Committees address conflicts of interest, including  
6 who is responsible for implementing such policies.

7           (7) A description of the tools, if any, States use  
8 to ensure that there are no conflicts of interest on  
9 DUR Boards and P&T Committees.

10          (8) An analysis of the effectiveness of tools  
11 States use to ensure that there are no conflicts of  
12 interest on DUR Boards and P&T Committees and,  
13 if applicable, recommendations as to how such tools  
14 could be improved.

15          (9) A review of strategies States may use to  
16 guard against conflicts of interest on DUR Boards  
17 and P&T Committees and to ensure compliance with  
18 the requirements of titles XI and XIX of the Social  
19 Security Act (42 U.S.C. 1301 et seq., 1396 et seq.)  
20 and access to effective, clinically appropriate, and  
21 medically necessary drug treatments for Medicaid  
22 beneficiaries, including recommendations for such  
23 legislative and administrative actions as the Comp-  
24 troller General determines appropriate.

1 **SEC. 204. ENSURING THE ACCURACY OF MANUFACTURER**  
2 **PRICE AND DRUG PRODUCT INFORMATION**  
3 **UNDER THE MEDICAID DRUG REBATE PRO-**  
4 **GRAM.**

5 (a) **AUDIT OF MANUFACTURER PRICE AND DRUG**  
6 **PRODUCT INFORMATION.—**

7 (1) **IN GENERAL.—**Subparagraph (B) of section  
8 1927(b)(3) of the Social Security Act (42 U.S.C.  
9 1396r–8(b)(3)) is amended to read as follows:

10 “(B) **AUDITS AND SURVEYS OF MANUFAC-**  
11 **TURER PRICE AND DRUG PRODUCT INFORMA-**  
12 **TION.—**

13 “(i) **AUDITS.—**The Secretary shall  
14 conduct ongoing audits of the price and  
15 drug product information reported by man-  
16 ufacturers under subparagraph (A) for the  
17 most recently ended rebate period to en-  
18 sure the accuracy and timeliness of such  
19 information. In conducting such audits, the  
20 Secretary may employ evaluations, surveys,  
21 statistical sampling, predictive analytics  
22 and other relevant tools and methods .

23 “(ii) **VERIFICATIONS SURVEYS OF AV-**  
24 **ERAGE MANUFACTURER PRICE AND MANU-**  
25 **FACTURER’S AVERAGE SALES PRICE.—**In  
26 addition to the audits required under

1 clause (i), the Secretary may survey whole-  
2 salers and manufacturers (including manu-  
3 facturers that directly distribute their cov-  
4 ered outpatient drugs (in this subpara-  
5 graph referred to as ‘direct sellers’)), when  
6 necessary, to verify manufacturer prices  
7 and manufacturer’s average sales prices  
8 (including wholesale acquisition cost) to  
9 make payment reported under subpara-  
10 graph (A).

11 “(iii) PENALTIES.—In addition to  
12 other penalties as may be prescribed by  
13 law, including under subparagraph (C) of  
14 this paragraph, the Secretary may impose  
15 a civil monetary penalty in an amount not  
16 to exceed \$185,000 on an annual basis on  
17 a wholesaler, manufacturer, or direct sell-  
18 er, if the wholesaler, manufacturer, or di-  
19 rect seller of a covered outpatient drug re-  
20 fuses a request for information about  
21 charges or prices by the Secretary in con-  
22 nection with an audit or survey under this  
23 subparagraph or knowingly provides false  
24 information. The provisions of section  
25 1128A (other than subsections (a) (with



1 respect to amounts of penalties or addi-  
2 tional assessments) and (b)) shall apply to  
3 a civil money penalty under this clause in  
4 the same manner as such provisions apply  
5 to a penalty or proceeding under section  
6 1128A(a).

7 “(iv) REPORTS.—

8 “(I) REPORT TO CONGRESS.—

9 The Secretary shall, not later than 18  
10 months after date of enactment of  
11 this subparagraph, submit a report to  
12 the Committee on Energy and Com-  
13 merce of the House of Representatives  
14 and the Committee on Finance of the  
15 Senate regarding additional regulatory  
16 or statutory changes that may be re-  
17 quired in order to ensure accurate and  
18 timely reporting and oversight of  
19 manufacturer price and drug product  
20 information, including whether  
21 changes should be made to reasonable  
22 assumption requirements to ensure  
23 such assumptions are reasonable and  
24 accurate or whether another method-  
25 ology for ensuring accurate and timely

1 reporting of price and drug product  
2 information should be considered to  
3 ensure the integrity of the drug rebate  
4 program under this section.

5 “(II) ANNUAL REPORTS.—The  
6 Secretary shall, on at least an annual  
7 basis, submit a report to the Com-  
8 mittee on Energy and Commerce of  
9 the House of Representatives and the  
10 Committee on Finance of the Senate  
11 summarizing the results of the audits  
12 and surveys conducted under this sub-  
13 paragraph during the period that is  
14 the subject of the report.

15 “(III) CONTENT.—Each report  
16 submitted under subclause (II) shall,  
17 with respect to the period that is the  
18 subject of the report, include sum-  
19 maries of—

20 “(aa) error rates in the  
21 price, drug product, and other  
22 relevant information supplied by  
23 manufacturers under subpara-  
24 graph (A);

1           “(bb) the timeliness with  
2           which manufacturers, whole-  
3           salers, and direct sellers provide  
4           information required under sub-  
5           paragraph (A) or under clause (i)  
6           or (ii) of this subparagraph;

7           “(cc) the number of manu-  
8           facturers, wholesalers, and direct  
9           sellers and drug products audited  
10          under this subparagraph;

11          “(dd) the types of price and  
12          drug product information re-  
13          viewed under the audits con-  
14          ducted under this subparagraph;

15          “(ee) the tools and meth-  
16          odologies employed in such au-  
17          dits;

18          “(ff) the findings of such  
19          audits, including which manufac-  
20          turers, if any, were penalized  
21          under this subparagraph; and

22          “(gg) such other relevant in-  
23          formation as the Secretary shall  
24          deem appropriate.

1                   “(IV) PROTECTION OF INFORMA-  
2                   TION.—In preparing a report required  
3                   under subclause (II), the Secretary  
4                   shall redact such proprietary informa-  
5                   tion as the Secretary determines ap-  
6                   propriate to prevent disclosure of, and  
7                   to safeguard, such information.

8                   “(v) APPROPRIATIONS.—Out of any  
9                   funds in the Treasury not otherwise appro-  
10                  priated, there is appropriated to the Sec-  
11                  retary \$2,000,000 for fiscal year 2020 and  
12                  each fiscal year thereafter to carry out this  
13                  subparagraph.”.

14                  (2) EFFECTIVE DATE.—The amendments made  
15                  by this subsection shall take effect on the first day  
16                  of the first fiscal quarter that begins after the date  
17                  of enactment of this Act.

18                  (b) INCREASED PENALTIES FOR NONCOMPLIANCE  
19 WITH REPORTING REQUIREMENTS.—

20                  (1) INCREASED PENALTY FOR LATE REPORTING  
21                  OF INFORMATION.—Section 1927(b)(3)(C)(i) of the  
22                  Social Security Act (42 U.S.C. 1396r–8(b)(3)(C)(i))  
23                  is amended by striking “increased by \$10,000 for  
24                  each day in which such information has not been  
25                  provided and such amount shall be paid to the

1 Treasury” and inserting “, for each covered out-  
2 patient drug with respect to which such information  
3 is not provided, \$50,000 for the first day that such  
4 information is not provided on a timely basis and  
5 \$19,000 for each subsequent day that such informa-  
6 tion is not provided”.

7 (2) INCREASED PENALTY FOR KNOWINGLY RE-  
8 PORTING FALSE INFORMATION.—Section  
9 1927(b)(3)(C)(ii) of the Social Security Act (42  
10 U.S.C. 1396r–8(b)(3)(C)(ii)) is amended by striking  
11 “\$100,000” and inserting “\$500,000”.

12 (3) EFFECTIVE DATE.—The amendments made  
13 by this subsection shall take effect on the first day  
14 of the first fiscal quarter that begins after the date  
15 of enactment of this Act.

16 **SEC. 205. EXCLUDING AUTHORIZED GENERIC DRUGS FROM**  
17 **CALCULATION OF AVERAGE MANUFACTURER**  
18 **PRICE UNDER THE MEDICAID DRUG REBATE**  
19 **PROGRAM.**

20 (a) IN GENERAL.—Subparagraph (C) of section  
21 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r–  
22 8(k)(1)) is amended—

23 (1) in the subparagraph heading, by striking  
24 “INCLUSION” and inserting “EXCLUSION”;

1           (2) by striking “a new drug application” and  
 2           inserting “the manufacturer’s new drug applica-  
 3           tion”; and

4           (3) by striking “inclusive” and inserting “exclu-  
 5           sive”.

6           (b) **EXCLUDING MANUFACTURERS FROM DEFINI-**  
 7 **TION OF WHOLESALER.**—Section 1927(k)(11) of the So-  
 8 cial Security Act (42 U.S.C. 1396r–8(k)(11)) is amend-  
 9 ed—

10           (1) by striking “manufacturers,”;

11           (2) by striking “manufacturer’s and”; and

12           (3) by adding at the end the following: “Such  
 13           term does not include a manufacturer engaged in  
 14           wholesale distribution or a manufacturer’s ware-  
 15           houses.”.

16           (c) **EFFECTIVE DATE.**—The amendments made by  
 17 this section shall take effect on the first day of the first  
 18 fiscal quarter that begins after the date of enactment of  
 19 this Act.

20 **SEC. 206. IMPROVING TRANSPARENCY AND PREVENTING**  
 21 **THE USE OF ABUSIVE SPREAD PRICING AND**  
 22 **RELATED PRACTICES IN MEDICAID.**

23           (a) **PASS-THROUGH PRICING REQUIRED.**—

1           (1) IN GENERAL.—Section 1927(e) of the So-  
 2           cial Security Act (42 U.S.C. 1396r–8(e)) is amended  
 3           by adding at the end the following:

4           “(6) PASS-THROUGH PRICING REQUIRED.—A  
 5           contract between the State and a pharmacy benefit  
 6           manager (referred to in this paragraph as a ‘PBM’),  
 7           or a contract between the State and a managed care  
 8           entity or other specified entity (as such terms are  
 9           defined in section 1903(m)(9)(D)) that includes pro-  
 10          visions making the entity responsible for coverage of  
 11          covered outpatient drugs dispensed to individuals en-  
 12          rolled with the entity, shall require that payment for  
 13          such drugs and related administrative services (as  
 14          applicable), including payments made by a PBM on  
 15          behalf of the State or entity, is based on a pass-  
 16          through pricing model under which—

17                   “(A) any payment made by the entity or  
 18                   the PBM (as applicable) for such a drug—

19                           “(i) is limited to—

20                                   “(I) ingredient cost; and

21                                   “(II) a professional dispensing  
 22                                   fee that is not less than the profes-  
 23                                   sional dispensing fee that the State  
 24                                   plan or waiver would pay if the plan

1 or waiver was making the payment di-  
2 rectly;

3 “(ii) is passed through in its entirety  
4 by the entity or PBM to the pharmacy  
5 that dispenses the drug; and

6 “(iii) is made in a manner that is con-  
7 sistent with section 1902(a)(30)(A) and  
8 sections 447.512, 447.514, and 447.518 of  
9 title 42, Code of Federal Regulations (or  
10 any successor regulation) as if such re-  
11 quirements applied directly to the entity or  
12 the PBM;

13 “(B) payment to the entity or the PBM  
14 (as applicable) for administrative services per-  
15 formed by the entity or PBM is limited to a  
16 reasonable administrative fee that covers the  
17 reasonable cost of providing such services;

18 “(C) the entity or the PBM (as applicable)  
19 shall make available to the State, and the Sec-  
20 retary upon request, all costs and payments re-  
21 lated to covered outpatient drugs and accom-  
22 panying administrative services incurred, re-  
23 ceived, or made by the entity or the PBM, in-  
24 cluding ingredient costs, professional dispensing  
25 fees, administrative fees, post-sale and post-in-



1 voice fees, discounts, or related adjustments  
2 such as direct and indirect remuneration fees,  
3 and any and all other remuneration; and

4 “(D) any form of spread pricing whereby  
5 any amount charged or claimed by the entity or  
6 the PBM (as applicable) is in excess of the  
7 amount paid to the pharmacies on behalf of the  
8 entity, including any post-sale or post-invoice  
9 fees, discounts, or related adjustments such as  
10 direct and indirect remuneration fees or assess-  
11 ments (after allowing for a reasonable adminis-  
12 trative fee as described in subparagraph (B)) is  
13 not allowable for purposes of claiming Federal  
14 matching payments under this title.”.

15 (2) CONFORMING AMENDMENT.—Section  
16 1903(m)(2)(A)(xiii) of such Act (42 U.S.C.  
17 1396b(m)(2)(A)(xiii)) is amended—

18 (A) by striking “and (III)” and inserting  
19 “(III)”;

20 (B) by inserting before the period at the  
21 end the following: “, and (IV) pharmacy benefit  
22 management services provided by the entity, or  
23 provided by a pharmacy benefit manager on be-  
24 half of the entity under a contract or other ar-  
25 rangement between the entity and the phar-

1 macy benefit manager, shall comply with the re-  
2 quirements of section 1927(e)(6)”; and

3 (C) by moving the left margin 2 ems to the  
4 left.

5 (3) EFFECTIVE DATE.—The amendments made  
6 by this subsection apply to contracts between States  
7 and managed care entities, other specified entities,  
8 or pharmacy benefits managers that are entered into  
9 or renewed on or after the date that is 18 months  
10 after the date of enactment of this Act.

11 (b) SURVEY OF RETAIL PRICES.—

12 (1) IN GENERAL.—Section 1927(f) of the Social  
13 Security Act (42 U.S.C. 1396r–8(f)) is amended—

14 (A) by striking “and” after the semicolon  
15 at the end of paragraph (1)(A)(i) and all that  
16 precedes it through “(1)” and inserting the fol-  
17 lowing:

18 “(1) SURVEY OF RETAIL PRICES.—The Sec-  
19 retary shall conduct a survey of retail community  
20 drug prices, to include at least the national average  
21 drug acquisition cost, as follows:

22 “(A) USE OF VENDOR.—The Secretary  
23 may contract services for—

24 “(i) with respect to retail community  
25 pharmacies, the determination on a month-

1 ly basis of retail survey prices of the na-  
2 tional average drug acquisition cost for  
3 covered outpatient drugs for such phar-  
4 macies, net of all discounts and rebates (to  
5 the extent any information with respect to  
6 such discounts and rebates is available),  
7 the average reimbursement received for  
8 such drugs by such pharmacies from all  
9 sources of payment, including third par-  
10 ties, and, to the extent available, the usual  
11 and customary charges to consumers for  
12 such drugs; and”;

13 (B) by adding at the end of paragraph (1)  
14 the following:

15 “(F) SURVEY REPORTING.—In order to  
16 meet the requirement of section 1902(a)(54), a  
17 State shall require that any retail community  
18 pharmacy in the State that receives any pay-  
19 ment, administrative fee, discount, or rebate re-  
20 lated to the dispensing of covered outpatient  
21 drugs to individuals receiving benefits under  
22 this title, regardless of whether such payment,  
23 fee, discount, or rebate is received from the  
24 State or a managed care entity directly or from  
25 a pharmacy benefit manager or another entity

1 that has a contract with the State or a man-  
2 aged care entity, shall respond to surveys of re-  
3 tail prices conducted under this subsection.

4 “(G) SURVEY INFORMATION.—Information  
5 on retail community prices obtained under this  
6 paragraph shall be made publicly available and  
7 shall include at least the following:

8 “(i) The monthly response rate of the  
9 survey including a list of pharmacies not in  
10 compliance with subparagraph (F).

11 “(ii) The sampling frame and number  
12 of pharmacies sampled monthly.

13 “(iii) Characteristics of reporting  
14 pharmacies, including type (such as inde-  
15 pendent or chain), geographic or regional  
16 location, and dispensing volume.

17 “(iv) Reporting of a separate national  
18 average drug acquisition cost for each drug  
19 for independent retail pharmacies and  
20 chain operated pharmacies.

21 “(v) Information on price concessions  
22 including on and off invoice discounts, re-  
23 bates, and other price concessions.

24 “(vi) Information on average profes-  
25 sional dispensing fees paid.

1 “(H) PENALTIES.—

2 “(i) FAILURE TO PROVIDE TIMELY IN-  
3 FORMATION.—A retail community phar-  
4 macy that fails to respond to a survey con-  
5 ducted under this subsection on a timely  
6 basis may be subject to a civil monetary  
7 penalty in the amount of \$10,000 for each  
8 day in which such information has not  
9 been provided.

10 “(ii) FALSE INFORMATION.—A retail  
11 community pharmacy that knowingly pro-  
12 vides false information in response to a  
13 survey conducted under this subsection  
14 may be subject to a civil money penalty in  
15 an amount not to exceed \$100,000 for  
16 each item of false information.

17 “(iii) OTHER PENALTIES.—Any civil  
18 money penalties imposed under this sub-  
19 paragraph shall be in addition to other  
20 penalties as may be prescribed by law. The  
21 provisions of section 1128A (other than  
22 subsections (a) and (b)) shall apply to a  
23 civil money penalty under this subpara-  
24 graph in the same manner as such provi-

1           sions apply to a penalty or proceeding  
2           under section 1128A(a).

3           “(I) REPORT ON SPECIALTY PHAR-  
4           MACIES.—

5                   “(i) IN GENERAL.—Not later than 1  
6           year after the effective date of this sub-  
7           paragraph, the Secretary shall submit a re-  
8           port to Congress examining specialty drug  
9           coverage and reimbursement under this  
10          title.

11                   “(ii) CONTENT OF REPORT.—Such re-  
12          port shall include a description of how  
13          State Medicaid programs define specialty  
14          drugs, how much State Medicaid programs  
15          pay for specialty drugs, how States and  
16          managed care plans determine payment for  
17          specialty drugs, the settings in which spe-  
18          cialty drugs are dispensed (such as retail  
19          community pharmacies or specialty phar-  
20          macies), whether acquisition costs for spe-  
21          cialty drugs are captured in the national  
22          average drug acquisition cost survey, and  
23          recommendations as to whether specialty  
24          pharmacies should be included in the sur-  
25          vey of retail prices to ensure national aver-

1           age drug acquisition costs capture drugs  
2           sold at specialty pharmacies and how such  
3           specialty pharmacies should be defined.”;

4           (C) in paragraph (2)—

5                 (i) in subparagraph (A), by inserting  
6                 “, including payments rates under Med-  
7                 icaid managed care plans,” after “under  
8                 this title”; and

9                 (ii) in subparagraph (B), by inserting  
10                “and the basis for such dispensing fees”  
11                before the semicolon; and

12           (D) in paragraph (4), by inserting “, and  
13           \$5,000,000 for fiscal year 2020 and each fiscal  
14           year thereafter,” after “2010”.

15           (2) EFFECTIVE DATE.—The amendments made  
16           by this subsection take effect on the 1st day of the  
17           1st quarter that begins on or after the date that is  
18           18 months after the date of enactment of this Act.

19           (c) MANUFACTURER REPORTING OF WHOLESALE  
20           ACQUISITION COST.—Section 1927(b)(3) of such Act (42  
21           U.S.C. 1396r–8(b)(3)) is amended—

22                 (1) in subparagraph (A)(i)—

23                 (A) in subclause (I), by striking “and”  
24                 after the semicolon;

1 (B) in subclause (II), by adding “and”  
2 after the semicolon;

3 (C) by moving the left margins of sub-  
4 clause (I) and (II) 2 ems to the right; and

5 (D) by adding at the end the following:

6 “(III) in the case of rebate peri-  
7 ods that begin on or after the date of  
8 enactment of this subclause, on the  
9 wholesale acquisition cost (as defined  
10 in section 1847A(c)(6)(B)) for cov-  
11 ered outpatient drugs for the rebate  
12 period under the agreement (including  
13 for all such drugs that are sold under  
14 a new drug application approved  
15 under section 505(c) of the Federal  
16 Food, Drug, and Cosmetic Act);”;

17 (2) in subparagraph (D)—

18 (A) in the matter preceding clause (i), by  
19 inserting “and clause (vii) of this subpara-  
20 graph” after “1847A”;

21 (B) in clause (v), by striking “and” after  
22 the comma;

23 (C) in clause (vi), by striking the period  
24 and inserting “, and”; and



1 (D) by inserting after clause (vi) the fol-  
 2 lowing:

3 “(vii) to the Secretary to disclose  
 4 (through a website accessible to the public)  
 5 the most recently reported wholesale acqui-  
 6 sition cost (as defined in section  
 7 1847A(c)(6)(B)) for each covered out-  
 8 patient drug (including for all such drugs  
 9 that are sold under a new drug application  
 10 approved under section 505(c) of the Fed-  
 11 eral Food, Drug, and Cosmetic Act), as re-  
 12 ported under subparagraph (A)(i)(III).”.

13 **SEC. 207. T-MSIS DRUG DATA ANALYTICS REPORTS.**

14 (a) IN GENERAL.—Not later than May 1 of each cal-  
 15 endar year beginning with calendar year 2021, the Sec-  
 16 retary of Health and Human Services (in this section re-  
 17 ferred to as the “Secretary”) shall publish on a website  
 18 of the Centers for Medicare & Medicaid Services that is  
 19 accessible to the public a report of the most recently avail-  
 20 able data on provider prescribing patterns under the Med-  
 21 icaid program.

22 (b) CONTENT OF REPORT.—

23 (1) REQUIRED CONTENT.—Each report re-  
 24 quired under subsection (a) for a calendar year shall  
 25 include the following information with respect to

1 each State (and, to the extent available, with respect  
2 to Puerto Rico, the United States Virgin Islands,  
3 Guam, the Northern Mariana Islands, and American  
4 Samoa):

5 (A) A comparison of covered outpatient  
6 drug (as defined in section 1927(k)(2) of the  
7 Social Security Act (42 U.S.C. 1396r–8(k)(2)))  
8 prescribing patterns under the State Medicaid  
9 plan or waiver of such plan (including drugs  
10 prescribed on a fee-for-service basis and drugs  
11 prescribed under managed care arrangements  
12 under such plan or waiver)—

13 (i) across all forms or models of reim-  
14 bursement used under the plan or waiver;

15 (ii) within specialties and subspecial-  
16 ties, as defined by the Secretary;

17 (iii) by episodes of care for—

18 (I) each chronic disease category,  
19 as defined by the Secretary, that is  
20 represented in the 10 conditions that  
21 accounted for the greatest share of  
22 total spending under the plan or waiv-  
23 er during the year that is the subject  
24 of the report;

25 (II) procedural groupings; and

- 1 (III) rare disease diagnosis codes;
- 2 (iv) by patient demographic character-
- 3 istics, including race (to the extent that
- 4 the Secretary determines that there is suf-
- 5 ficient data available with respect to such
- 6 characteristic in a majority of States), gen-
- 7 der, and age;
- 8 (v) by patient high-utilizer or risk sta-
- 9 tus; and
- 10 (vi) by high and low resource settings
- 11 by facility and place of service categories,
- 12 as determined by the Secretary.

13 (B) In the case of medical assistance for

14 covered outpatient drugs (as so defined) pro-

15 vided under a State Medicaid plan or waiver of

16 such plan in a managed care setting, an anal-

17 ysis of the differences in managed care pre-

18 scribing patterns when a covered outpatient

19 drug is prescribed in a managed care setting as

20 compared to when the drug is prescribed in a

21 fee-for-service setting.

22 (2) ADDITIONAL CONTENT.—A report required

23 under subsection (a) for a calendar year may include

24 State-specific information about prescription utiliza-

1       tion management tools under State Medicaid plans  
2       or waivers of such plans, including—

3               (A) a description of prescription utilization  
4               management tools under State programs to pro-  
5               vide long-term services and supports under a  
6               State Medicaid plan or a waiver of such plan;

7               (B) a comparison of prescription utilization  
8               management tools applicable to populations cov-  
9               ered under a State Medicaid plan waiver under  
10              section 1115 of the Social Security Act (42  
11              U.S.C. 1315) and the models applicable to pop-  
12              ulations that are not covered under the waiver;

13              (C) a comparison of the prescription utili-  
14              zation management tools employed by different  
15              Medicaid managed care organizations, phar-  
16              macy benefit managers, and related entities  
17              within the State;

18              (D) a comparison of the prescription utili-  
19              zation management tools applicable to each en-  
20              rollment category under a State Medicaid plan  
21              or waiver; and

22              (E) a comparison of the prescription utili-  
23              zation management tools applicable under the  
24              State Medicaid plan or waiver by patient high-  
25              utilizer or risk status.

1           (3) ADDITIONAL ANALYSIS.—To the extent  
2           practicable, the Secretary shall include in each re-  
3           port published under subsection (a)—

4                   (A) analyses of national, State, and local  
5                   patterns of Medicaid population-based pre-  
6                   scribing behaviors; and

7                   (B) recommendations for administrative or  
8                   legislative action to improve the effectiveness of,  
9                   and reduce costs for, covered outpatient drugs  
10                  under Medicaid while ensuring timely bene-  
11                  ficiary access to medically necessary covered  
12                  outpatient drugs.

13          (c) USE OF T-MSIS DATA.—Each report required  
14          under subsection (a) shall—

15                  (1) be prepared using data and definitions from  
16                  the Transformed Medicaid Statistical Information  
17                  System (“T-MSIS”) data set (or a successor data  
18                  set) that is not more than 24 months old on the date  
19                  that the report is published; and

20                  (2) as appropriate, include a description with  
21                  respect to each State of the quality and complete-  
22                  ness of the data, as well as any necessary caveats  
23                  describing the limitations of the data reported to the  
24                  Secretary by the State that are sufficient to commu-  
25                  nicate the appropriate uses for the information.

1 (d) PREPARATION OF REPORT.—Each report re-  
 2 quired under subsection (a) shall be prepared by the Ad-  
 3 ministrator for the Centers for Medicare & Medicaid Serv-  
 4 ices.

5 (e) APPROPRIATION.—For fiscal year 2020 and each  
 6 fiscal year thereafter, there is appropriated to the Sec-  
 7 retary \$2,000,000 to carry out this section.

8 **SEC. 208. RISK-SHARING VALUE-BASED PAYMENT AGREE-**  
 9 **MENTS FOR COVERED OUTPATIENT DRUGS**  
 10 **UNDER MEDICAID.**

11 (a) IN GENERAL.—Section 1927 of the Social Secu-  
 12 rity Act (42 U.S.C. 1396r–8) is amended by adding at  
 13 the end the following new subsection:

14 “(1) STATE OPTION TO PAY FOR COVERED OUT-  
 15 PATIENT DRUGS THROUGH RISK-SHARING VALUE-BASED  
 16 AGREEMENTS.—

17 “(1) IN GENERAL.—Beginning January 1,  
 18 2022, a State shall have the option to pay (whether  
 19 on a fee-for-service or managed care basis) for cov-  
 20 ered outpatient drugs that are potentially curative  
 21 treatments intended for one-time use that are ad-  
 22 ministered to individuals under this title by entering  
 23 into a risk-sharing value-based payment agreement  
 24 with the manufacturer of the drug in accordance  
 25 with the requirements of this subsection.

1           “(2) SECRETARIAL APPROVAL.—

2                   “(A) IN GENERAL.—A State shall submit a  
3 request to the Secretary to enter into a risk-  
4 sharing value based payment agreement, and  
5 the Secretary shall not approve a proposed risk-  
6 sharing value-based payment agreement be-  
7 tween a State and a manufacturer for payment  
8 for a covered outpatient drug of the manufac-  
9 turer unless the following requirements are met:

10                   “(i) MANUFACTURER IS PARTY TO RE-  
11 BATE AGREEMENT AND IN COMPLIANCE  
12 WITH REQUIREMENTS.—The manufacturer  
13 has a rebate agreement in effect as re-  
14 quired under subsection (a) and (b) of this  
15 section and is in compliance with all appli-  
16 cable requirements under this title.

17                   “(ii) NO INCREASE TO PROJECTED  
18 NET FEDERAL SPENDING.—

19                   “(I) IN GENERAL.—The Chief  
20 Actuary certifies that the projected  
21 payments for each covered outpatient  
22 drug under such proposed agreement  
23 would not result in greater estimated  
24 Federal spending under this title than  
25 the net Federal spending that would

1 result in the absence of the agree-  
2 ment.

3 “(II) NET FEDERAL SPENDING  
4 DEFINED.—For purposes of this sub-  
5 section, the term ‘net Federal spend-  
6 ing’ means the amount of Federal  
7 payments the Chief Actuary estimates  
8 would be made under this title for ad-  
9 ministering a covered outpatient drug  
10 to an individual eligible for medical  
11 assistance under a State plan or a  
12 waiver of such plan, reduced by the  
13 amount of all rebates the Chief Actu-  
14 ary estimates would be paid with re-  
15 spect to the administering of such  
16 drug, including all rebates under this  
17 title and any supplemental or other  
18 additional rebates, in the absence of  
19 such an agreement.

20 “(III) INFORMATION.—The Chief  
21 Actuary shall make the certifications  
22 required under this clause based on  
23 the most recently available and reli-  
24 able drug pricing and product infor-  
25 mation. The State and manufacturer



1 shall provide the Secretary and the  
2 Chief Actuary with all necessary infor-  
3 mation required to make the estimates  
4 needed for such certifications.

5 “(iii) LAUNCH AND LIST PRICE JUS-  
6 TIFICATIONS.—The manufacturer submits  
7 all relevant information and supporting  
8 documentation necessary for pricing deci-  
9 sions as deemed appropriate by the Sec-  
10 retary, which shall be truthful and non-  
11 misleading, including manufacturer infor-  
12 mation and supporting documentation for  
13 launch price or list price increases, and  
14 any applicable justification required under  
15 section 1128L.

16 “(iv) CONFIDENTIALITY OF INFORMA-  
17 TION; PENALTIES.—The provisions of sub-  
18 paragraphs (C) and (D) of subsection  
19 (b)(3) shall apply to a manufacturer that  
20 fails to submit the information and docu-  
21 mentation required under clauses (ii) and  
22 (iii) on a timely basis, or that knowingly  
23 provides false or misleading information, in  
24 the same manner as such provisions apply

1 to a manufacturer with a rebate agreement  
2 under this section.

3 “(B) CONSIDERATION OF STATE REQUEST  
4 FOR APPROVAL.—

5 “(i) IN GENERAL.—The Secretary  
6 shall treat a State request for approval of  
7 a risk-sharing value-based payment agree-  
8 ment in the same manner that the Sec-  
9 retary treats a State plan amendment, and  
10 subpart B of part 430 of title 42, Code of  
11 Federal Regulations, including, subject to  
12 clause (ii), the timing requirements of sec-  
13 tion 430.16 of such title (as in effect on  
14 the date of enactment of this subsection),  
15 shall apply to a request for approval of a  
16 risk-sharing value-based payment agree-  
17 ment in the same manner as such subpart  
18 applies to a State plan amendment.

19 “(ii) TIMING.—The Secretary shall  
20 consult with the Commissioner of Food  
21 and Drugs as required under subpara-  
22 graph (C) and make a determination on  
23 whether to approve a request from a State  
24 for approval of a proposed risk-sharing  
25 value-based payment agreement (or request

1 additional information necessary to allow  
2 the Secretary to make a determination  
3 with respect to such request for approval)  
4 within the time period, to the extent prac-  
5 ticable, specified in section 430.16 of title  
6 42, Code of Federal Regulations (as in ef-  
7 fect on the date of enactment of this sub-  
8 section), but in no case shall the Secretary  
9 take more than 180 days after the receipt  
10 of such request for approval or response to  
11 such request for additional information to  
12 make such a determination (or request ad-  
13 ditional information).

14 “(C) CONSULTATION WITH THE COMMIS-  
15 SIONER OF FOOD AND DRUGS.—In considering  
16 whether to approve a risk-sharing value-based  
17 payment agreement, the Secretary, to the ex-  
18 tent necessary, shall consult with the Commis-  
19 sioner of Food and Drugs to determine whether  
20 the relevant clinical parameters specified in  
21 such agreement are appropriate.

22 “(3) INSTALLMENT-BASED PAYMENT STRUC-  
23 TURE.—

24 “(A) IN GENERAL.—A risk-sharing value-  
25 based payment agreement shall provide for a

1 payment structure under which, for every in-  
2 stallment year of the agreement (subject to sub-  
3 paragraph (B)), the State shall pay the total in-  
4 stallment year amount in equal installments to  
5 be paid at regular intervals over a period of  
6 time that shall be specified in the agreement.

7 “(B) REQUIREMENTS FOR INSTALLMENT  
8 PAYMENTS.—

9 “(i) TIMING OF FIRST PAYMENT.—

10 The State shall make the first of the in-  
11 stallment payments described in subpara-  
12 graph (A) for an installment year not later  
13 than 30 days after the end of such year.

14 “(ii) LENGTH OF INSTALLMENT PE-  
15 RIOD.—The period of time over which the  
16 State shall make the installment payments  
17 described in subparagraph (A) for an in-  
18 stallment year shall not be longer than 5  
19 years.

20 “(iii) NONPAYMENT OR REDUCED  
21 PAYMENT OF INSTALLMENTS FOLLOWING  
22 A FAILURE TO MEET CLINICAL PARAM-  
23 ETER.—If, prior to the payment date (as  
24 specified in the agreement) of any install-  
25 ment payment described in subparagraph

1 (A) or any other alternative date or time  
2 frame (as otherwise specified in the agree-  
3 ment), the covered outpatient drug which  
4 is subject to the agreement fails to meet a  
5 relevant clinical parameter of the agree-  
6 ment, the agreement shall provide that—

7 “(I) the installment payment  
8 shall not be made; or

9 “(II) the installment payment  
10 shall be reduced by a percentage spec-  
11 ified in the agreement that is based  
12 on the outcome achieved by the drug  
13 relative to the relevant clinical param-  
14 eter.

15 “(4) NOTICE OF INTENT.—

16 “(A) IN GENERAL.—Subject to subpara-  
17 graph (B), a manufacturer of a covered out-  
18 patient drug shall not be eligible to enter into  
19 a risk-sharing value-based payment agreement  
20 under this subsection with respect to such drug  
21 unless the manufacturer notifies the Secretary  
22 that the manufacturer is interested in entering  
23 into such an agreement with respect to such  
24 drug. The decision to submit and timing of a  
25 request to enter into a proposed risk-sharing

1 value-based payment agreement shall remain  
2 solely within the discretion of the State and  
3 shall only be effective upon Secretarial approval  
4 as required under this subsection.

5 “(B) TREATMENT OF SUBSEQUENTLY AP-  
6 PROVED DRUGS.—

7 “(i) IN GENERAL.—In the case of a  
8 manufacturer of a covered outpatient drug  
9 approved under section 505 of the Federal  
10 Food, Drug, and Cosmetic Act or licensed  
11 under section 351 of the Public Health  
12 Service Act after the date of enactment of  
13 this subsection, not more than 90 days  
14 after meeting with the Food and Drug Ad-  
15 ministration following phase II clinical  
16 trials for such drug (or, in the case of a  
17 drug described in clause (ii), not later than  
18 March 31, 2022), the manufacturer must  
19 notify the Secretary of the manufacturer’s  
20 intent to enter into a risk-sharing value-  
21 based payment agreement under this sub-  
22 section with respect to such drug. If no  
23 such meeting has occurred, the Secretary  
24 may use discretion as to whether a poten-  
25 tially curative treatment intended for one-

1 time use may qualify for a risk-sharing  
2 value-based payment agreement under this  
3 section. A manufacturer notification of in-  
4 terest shall not have any influence on a de-  
5 cision for approval by the Food and Drug  
6 Administration.

7 “(ii) APPLICATION TO CERTAIN SUB-  
8 SEQUENTLY APPROVED DRUGS.—A drug  
9 described in this clause is a covered out-  
10 patient drug of a manufacturer—

11 “(I) that is approved under sec-  
12 tion 505 of the Federal Food, Drug,  
13 and Cosmetic Act or licensed under  
14 section 351 of the Public Health Serv-  
15 ice Act after the date of enactment of  
16 this subsection; and

17 “(II) with respect to which, as of  
18 January 1, 2022, more than 90 days  
19 have passed after the manufacturer’s  
20 meeting with the Food and Drug Ad-  
21 ministration following phase II clinical  
22 trials for such drug.

23 “(iii) PARALLEL APPROVAL.—The  
24 Secretary, in coordination with the Admin-  
25 istrator of the Centers for Medicare &

1 Medicaid Services and the Commissioner of  
2 Food and Drugs, shall, to the extent prac-  
3 ticable, approve a State’s request to enter  
4 into a proposed risk-sharing value-based  
5 payment agreement that otherwise meets  
6 the requirements of this subsection at the  
7 time that such a drug is approved by the  
8 Food and Drug Administration to help  
9 provide that no State that wishes to enter  
10 into such an agreement is required to pay  
11 for the drug in full at one time if the State  
12 is seeking to pay over a period of time as  
13 outlined in the proposed agreement.

14 “(iv) RULE OF CONSTRUCTION.—  
15 Nothing in this paragraph shall be applied  
16 or construed to modify or affect the time-  
17 frames or factors involved in the Sec-  
18 retary’s determination of whether to ap-  
19 prove or license a drug under section 505  
20 of the Federal Food, Drug, and Cosmetic  
21 Act or section 351 of the Public Health  
22 Service Act.

23 “(5) SPECIAL PAYMENT RULES.—

24 “(A) IN GENERAL.—Except as otherwise  
25 provided in this paragraph, with respect to an



1 individual who is administered a unit of a cov-  
2 ered outpatient drug that is purchased under a  
3 State plan by a State Medicaid agency under a  
4 risk-sharing value-based payment agreement in  
5 an installment year, the State shall remain lia-  
6 ble to the manufacturer of such drug for pay-  
7 ment for such unit without regard to whether  
8 the individual remains enrolled in the State  
9 plan under this title (or a waiver of such plan)  
10 for each installment year for which the State is  
11 to make installment payments for covered out-  
12 patient drugs purchased under the agreement  
13 in such year.

14 “(B) DEATH.—In the case of an individual  
15 described in subparagraph (A) who dies during  
16 the period described in such subparagraph, the  
17 State plan shall not be liable for any remaining  
18 payment for the unit of the covered outpatient  
19 drug administered to the individual which is  
20 owed under the agreement described in such  
21 subparagraph.

22 “(C) WITHDRAWAL OF APPROVAL.—In the  
23 case of a covered outpatient drug that is the  
24 subject of a risk-sharing value-based agreement  
25 between a State and a manufacturer under this

1 subsection, including a drug approved in ac-  
2 cordance with section 506(c) of the Federal  
3 Food, Drug, and Cosmetic Act, and such drug  
4 is the subject of an application that has been  
5 withdrawn by the Secretary, the State plan  
6 shall not be liable for any remaining payment  
7 that is owed under the agreement.

8 “(D) ALTERNATIVE ARRANGEMENT UNDER  
9 AGREEMENT.—Subject to approval by the Sec-  
10 retary, the terms of a proposed risk-sharing  
11 value-based payment agreement submitted for  
12 approval by a State may provide that subpara-  
13 graph (A) shall not apply.

14 “(E) GUIDANCE.—Not later than January  
15 1, 2022, the Secretary shall issue guidance to  
16 States establishing a process for States to no-  
17 tify the Secretary when an individual who is ad-  
18 ministered a unit of a covered outpatient drug  
19 that is purchased by a State plan under a risk-  
20 sharing value-based payment agreement ceases  
21 to be enrolled under the State plan under this  
22 title (or a waiver of such plan) or dies before  
23 the end of the installment period applicable to  
24 such unit under the agreement.

1           “(6) TREATMENT OF PAYMENTS UNDER RISK-  
2           SHARING VALUE-BASED AGREEMENTS FOR PUR-  
3           POSES OF AVERAGE MANUFACTURER PRICE; BEST  
4           PRICE.—The Secretary shall treat any payments  
5           made to the manufacturer of a covered outpatient  
6           drug under a risk-sharing value-based payment  
7           agreement under this subsection during a rebate pe-  
8           riod in the same manner that the Secretary treats  
9           payments made under a State supplemental rebate  
10          agreement under sections 447.504(c)(19) and  
11          447.505(e)(7) of title 42, Code of Federal Regula-  
12          tions (or any successor regulations) for purposes of  
13          determining average manufacturer price and best  
14          price under this section with respect to the covered  
15          outpatient drug and a rebate period and for pur-  
16          poses of offsets required under subsection (b)(1)(B).

17          “(7) ASSESSMENTS AND REPORT TO CON-  
18          GRESS.—

19                 “(A) ASSESSMENTS.—

20                         “(i) IN GENERAL.—Not later than  
21                         180 days after the end of each assessment  
22                         period of any risk-sharing value-based pay-  
23                         ment agreement for a State approved  
24                         under this subsection, the Secretary shall  
25                         conduct an evaluation of such agreement

1 which shall include an evaluation by the  
2 Chief Actuary to determine whether pro-  
3 gram spending under the risk-sharing  
4 value-based payment agreement aligned  
5 with the projections for the agreement  
6 made under paragraph (2)(A)(ii), including  
7 an assessment of whether actual Federal  
8 spending under this title under the agree-  
9 ment was less or more than net Federal  
10 spending would have been in the absence  
11 of the agreement.

12 “(ii) ASSESSMENT PERIOD.—For pur-  
13 poses of clause (i)—

14 “(I) the first assessment period  
15 for a risk-sharing value-based pay-  
16 ment agreement shall be the period of  
17 time over which payments are sched-  
18 uled to be made under the agreement  
19 for the first 10 individuals who are  
20 administered covered outpatient drugs  
21 under the agreement except that such  
22 period shall not exceed the 5-year pe-  
23 riod after the date on which the Sec-  
24 retary approves the agreement; and

1           “(II) each subsequent assessment  
2           period for a risk-sharing value-based  
3           payment agreement shall be the 5-  
4           year period following the end of the  
5           previous assessment period.

6           “(B) RESULTS OF ASSESSMENTS.—

7           “(i) TERMINATION OPTION.—If the  
8           Secretary determines as a result of the as-  
9           sessment by the Chief Actuary under sub-  
10          paragraph (A) that the actual Federal  
11          spending under this title for any covered  
12          outpatient drug that was the subject of the  
13          State’s risk-sharing value-based payment  
14          agreement was greater than the net Fed-  
15          eral spending that would have resulted in  
16          the absence of the agreement, the Sec-  
17          retary may terminate approval of such  
18          agreement and shall immediately conduct  
19          an assessment under this paragraph of any  
20          other ongoing risk-sharing value-based  
21          payment agreement to which the same  
22          manufacturer is a party.

23          “(ii) REPAYMENT REQUIRED.—

24          “(I) IN GENERAL.—If the Sec-  
25          retary determines as a result of the

1 assessment by the Chief Actuary  
2 under subparagraph (A) that the Fed-  
3 eral spending under the risk-sharing  
4 value-based agreement for a covered  
5 outpatient drug that was subject to  
6 such agreement was greater than the  
7 net Federal spending that would have  
8 resulted in the absence of the agree-  
9 ment, the manufacturer shall repay  
10 the difference to the State and Fed-  
11 eral governments in a timely manner  
12 as determined by the Secretary.

13 “(II) TERMINATION FOR FAIL-  
14 URE TO PAY.—The failure of a manu-  
15 facturer to make repayments required  
16 under subclause (I) in a timely man-  
17 ner shall result in immediate termi-  
18 nation of all risk-sharing value-based  
19 agreements to which the manufacturer  
20 is a party.

21 “(III) ADDITIONAL PEN-  
22 ALTIES.—In the case of a manufac-  
23 turer that fails to make repayments  
24 required under subclause (I), the Sec-  
25 retary may treat such manufacturer

1 in the same manner as a manufac-  
2 turer that fails to pay required re-  
3 bates under this section, and the Sec-  
4 retary may—

5 “(aa) suspend or terminate  
6 the manufacturer’s rebate agree-  
7 ment under this section; and

8 “(bb) pursue any other rem-  
9 edy that would be available if the  
10 manufacturer had failed to pay  
11 required rebates under this sec-  
12 tion.

13 “(C) REPORT TO CONGRESS.—Not later  
14 than 5 years after the first risk-sharing value-  
15 based payment agreement is approved under  
16 this subsection, the Secretary shall submit to  
17 Congress and make available to the public a re-  
18 port that includes—

19 “(i) an assessment of the impact of  
20 risk-sharing value-based payment agree-  
21 ments on access for individuals who are eli-  
22 gible for benefits under a State plan or  
23 waiver under this title to medically nec-  
24 essary covered outpatient drugs and re-  
25 lated treatments;

1           “(ii) an analysis of the impact of such  
2           agreements on overall State and Federal  
3           spending under this title;

4           “(iii) an assessment of the impact of  
5           such agreements on drug prices, including  
6           launch price and price increases; and

7           “(iv) such recommendations to Con-  
8           gress as the Secretary deems appropriate.

9           “(8) GUIDANCE AND REGULATIONS.—

10           “(A) IN GENERAL.—Not later than Janu-  
11           ary 1, 2022, the Secretary shall issue guidance  
12           to States seeking to enter into risk-sharing  
13           value-based payment agreements under this  
14           subsection that includes a model template for  
15           such agreements. The Secretary may issue any  
16           additional guidance or promulgate regulations  
17           as necessary to implement and enforce the pro-  
18           visions of this subsection.

19           “(B) MODEL AGREEMENTS.—

20           “(i) IN GENERAL.—If a State ex-  
21           presses an interest in pursuing a risk-shar-  
22           ing value-based payment agreement under  
23           this subsection with a manufacturer for  
24           the purchase of a covered outpatient drug,  
25           the Secretary may share with such State



1 any risk-sharing value-based agreement be-  
2 tween a State and the manufacturer for  
3 the purchase of such drug that has been  
4 approved under this subsection. While such  
5 shared agreement may serve as a template  
6 for a State that wishes to propose, the use  
7 of a previously approved agreement shall  
8 not affect the submission and approval  
9 process for approval of a proposed risk-  
10 sharing value-based payment agreement  
11 under this subsection, including the re-  
12 quirements under paragraph (2)(A).

13 “(ii) CONFIDENTIALITY.—In the case  
14 of a risk-sharing value-based payment  
15 agreement that is disclosed to a State by  
16 the Secretary under this subparagraph and  
17 that is only in effect with respect to a sin-  
18 gle State, the confidentiality of information  
19 provisions described in subsection  
20 (b)(3)(D) shall apply to such information.

21 “(C) OIG CONSULTATION.—

22 “(i) IN GENERAL.—The Secretary  
23 shall consult with the Office of the Inspec-  
24 tor General of the Department of Health  
25 and Human Services to determine whether

1           there are potential program integrity con-  
2           cerns with agreement approvals or tem-  
3           plates and address accordingly.

4           “(ii) ~~OIG POLICY UPDATES AS NEC-~~  
5           ~~CESSARY.~~—The Inspector General of the  
6           Department of Health and Human Serv-  
7           ices shall review and update, as necessary,  
8           any policies or guidelines of the Office of  
9           the Inspector General of the Department  
10          of Human Services (including policies re-  
11          lated to the enforcement of section 1128B)  
12          to accommodate the use of risk-sharing  
13          value-based payment agreements in accord-  
14          ance with this section.

15          “(9) RULES OF CONSTRUCTION.—

16          “(A) MODIFICATIONS.—Nothing in this  
17          subsection or any regulations promulgated  
18          under this subsection shall prohibit a State  
19          from requesting a modification from the Sec-  
20          retary to the terms of a risk-sharing value-  
21          based payment agreement. A modification that  
22          is expected to result in any increase to pro-  
23          jected net State or Federal spending under the  
24          agreement shall be subject to recertification by  
25          the Chief Actuary as described in paragraph

1 (2)(A)(ii) before the modification may be ap-  
2 proved.

3 “(B) REBATE AGREEMENTS.—Nothing in  
4 this subsection shall be construed as requiring  
5 a State to enter into a risk-sharing value-based  
6 payment agreement or as limiting or super-  
7 seding the ability of a State to enter into a sup-  
8 plemental rebate agreement for a covered out-  
9 patient drug.

10 “(C) FFP FOR PAYMENTS UNDER RISK-  
11 SHARING VALUE-BASED PAYMENT AGREE-  
12 MENTS.—Federal financial participation shall  
13 be available under this title for any payment  
14 made by a State to a manufacturer for a cov-  
15 ered outpatient drug under a risk-sharing  
16 value-based payment agreement in accordance  
17 with this subsection, except that no Federal fi-  
18 nancial participation shall be available for any  
19 payment made by a State to a manufacturer  
20 under such an agreement on and after the ef-  
21 fective date of a disapproval of such agreement  
22 by the Secretary.

23 “(D) CONTINUED APPLICATION OF OTHER  
24 PROVISIONS.—Except as expressly provided in  
25 this subsection, nothing in this subsection or in

1 any regulations promulgated under this sub-  
2 section shall affect the application of any other  
3 provision of this Act.

4 “(10) APPROPRIATIONS.—For fiscal year 2020  
5 and each fiscal year thereafter, there are appro-  
6 priated to the Secretary \$5,000,000 for the purpose  
7 of carrying out this subsection.

8 “(11) DEFINITIONS.—In this subsection:

9 “(A) CHIEF ACTUARY.—The term ‘Chief  
10 Actuary’ means the Chief Actuary of the Cen-  
11 ters for Medicare & Medicaid Services.

12 “(B) INSTALLMENT YEAR.—The term ‘in-  
13 stallment year’ means, with respect to a risk-  
14 sharing value-based payment agreement, a 12-  
15 month period during which a covered outpatient  
16 drug is administered under the agreement.

17 “(C) POTENTIALLY CURATIVE TREATMENT  
18 INTENDED FOR ONE-TIME USE.—The term ‘po-  
19 tentially curative treatment intended for one-  
20 time use’ means a treatment that consists of  
21 the administration of a covered outpatient drug  
22 that—

23 “(i) is a form of gene therapy for a  
24 rare disease, as defined by the Commis-  
25 sioner of Food and Drugs, designated

1 under section 526 of the Federal Food,  
2 Drug, and Cosmetics Act, and approved  
3 under section 505 of such Act or licensed  
4 under subsection (a) or (k) of section 351  
5 of the Public Health Service Act to treat  
6 a serious or life-threatening disease or con-  
7 dition;

8 “(ii) if administered in accordance  
9 with the labeling of such drug, is expected  
10 to result in either—

11 “(I) the cure of such disease or  
12 condition; or

13 “(II) a reduction in the symp-  
14 toms of such disease or condition to  
15 the extent that such disease or condi-  
16 tion is not expected to lead to early  
17 mortality; and

18 “(iii) is expected to achieve a result  
19 described in clause (ii), which may be  
20 achieved over an extended period of time,  
21 after not more than 3 administrations.

22 “(D) RELEVANT CLINICAL PARAMETER.—

23 The term ‘relevant clinical parameter’ means,  
24 with respect to a covered outpatient drug that

1 is the subject of a risk-sharing value-based pay-  
2 ment agreement—

3 “(i) a clinical endpoint specified in the  
4 drug’s labeling or supported by one or  
5 more of the compendia described in section  
6 1861(t)(2)(B)(ii)(I) that—

7 “(I) is able to be measured or  
8 evaluated on an annual basis for each  
9 year of the agreement on an inde-  
10 pendent basis by a provider or other  
11 entity; and

12 “(II) is required to be achieved  
13 (based on observed metrics in patient  
14 populations) under the terms of the  
15 agreement; or

16 “(ii) a surrogate endpoint (as defined  
17 in section 507(e)(9) of the Federal Food,  
18 Drug, and Cosmetic Act), including those  
19 developed by patient-focused drug develop-  
20 ment tools, that—

21 “(I) is able to be measured or  
22 evaluated on an annual basis for each  
23 year of the agreement on an inde-  
24 pendent basis by a provider or other  
25 entity; and

1                   “(II) has been qualified by the  
2                   Food and Drug Administration.

3                   “(E) RISK-SHARING VALUE-BASED PAY-  
4                   MENT AGREEMENT.—The term ‘risk-sharing  
5                   value-based payment agreement’ means an  
6                   agreement between a State plan and a manu-  
7                   facturer—

8                   “(i) for the purchase of a covered out-  
9                   patient drug of the manufacturer that is a  
10                  potentially curative treatment intended for  
11                  one-time use;

12                  “(ii) under which payment for such  
13                  drug shall be made pursuant to an install-  
14                  ment-based payment structure that meets  
15                  the requirements of paragraph (3);

16                  “(iii) which conditions payment on the  
17                  achievement of at least 2 relevant clinical  
18                  parameters (as defined in subparagraph  
19                  (C));

20                  “(iv) which provides that—

21                         “(I) the State plan will directly  
22                         reimburse the manufacturer for the  
23                         drug; or

1                   “(II) a third party will reimburse  
2                   the manufacture in a manner ap-  
3                   proved by the Secretary;

4                   “(v) is approved by the Secretary in  
5                   accordance with paragraph (2).

6                   “(F)     TOTAL     INSTALLMENT     YEAR  
7                   AMOUNT.—The term ‘total installment year  
8                   amount’ means, with respect to a risk-sharing  
9                   value-based payment agreement for the pur-  
10                  chase of a covered outpatient drug and an in-  
11                  stallment year, an amount equal to the product  
12                  of—

13                  “(i) the unit price of the drug charged  
14                  under the agreement; and

15                  “(ii) the number of units of such drug  
16                  administered under the agreement during  
17                  such installment year.”.

18                  (b) CONFORMING AMENDMENTS.—

19                  (1) Section 1903(i)(10)(A) of the Social Secu-  
20                  rity Act (42 U.S.C. 1396b(i)(10)(A)) is amended by  
21                  striking “or unless section 1927(a)(3) applies” and  
22                  inserting “, section 1927(a)(3) applies with respect  
23                  to such drugs, or such drugs are the subject of a  
24                  risk-sharing value-based payment agreement under  
25                  section 1927(l)”.



1           (2) Section 1927(b) of the Social Security Act  
2           (42 U.S.C. 1396r–8(b)) is amended—

3                   (A) in paragraph (1)(A), by inserting “(ex-  
4                   cept for drugs for which payment is made by a  
5                   State under a risk-sharing value-based payment  
6                   agreement under subsection (l))” after “under  
7                   the State plan for such period”; and

8                   (B) in paragraph (3)—

9                           (i) in subparagraph (C)(i), by insert-  
10                           ing “or subsection (l)(2)(A)” after “sub-  
11                           paragraph (A)”; and

12                           (ii) in subparagraph (D), in the mat-  
13                           ter preceding clause (i), by inserting “,  
14                           under subsection (l)(2)(A),” after “under  
15                           this paragraph”.

16 **SEC. 209. MODIFICATION OF MAXIMUM REBATE AMOUNT**  
17 **UNDER MEDICAID DRUG REBATE PROGRAM.**

18           (a) IN GENERAL.—Subparagraph (D) of section  
19 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r–  
20 8(c)(2)) is amended to read as follows:

21                   “(D) MAXIMUM REBATE AMOUNT.—

22                           “(i) IN GENERAL.—Except as pro-  
23                           vided in clause (ii), in no case shall the  
24                           sum of the amounts applied under para-  
25                           graph (1)(A)(ii) and this paragraph with

1           respect to each dosage form and strength  
2           of a single source drug or an innovator  
3           multiple source drug for a rebate period  
4           exceed—

5                   “(I) for rebate periods beginning  
6                   after December 31, 2009, and before  
7                   September 30, 2022, 100 percent of  
8                   the average manufacturer price of the  
9                   drug; and

10                   “(II) for rebate periods beginning  
11                   on or after October 1, 2022, 125 per-  
12                   cent of the average manufacturer  
13                   price of the drug.

14                   “(ii) NO MAXIMUM AMOUNT FOR  
15                   DRUGS IF AMP INCREASES OUTPACE IN-  
16                   FLATION.—

17                   “(I) IN GENERAL.—If the aver-  
18                   age manufacturer price with respect  
19                   to each dosage form and strength of  
20                   a single source drug or an innovator  
21                   multiple source drug increases on or  
22                   after October 1, 2021, and such in-  
23                   creased average manufacturer price  
24                   exceeds the inflation-adjusted average  
25                   manufacturer price determined with

1 respect to such drug under subclause  
2 (II) for the rebate period, clause (i)  
3 shall not apply and there shall be no  
4 limitation on the sum of the amounts  
5 applied under paragraph (1)(A)(ii)  
6 and this paragraph for the rebate pe-  
7 riod with respect to each dosage form  
8 and strength of the single source drug  
9 or innovator multiple source drug.

10 “(II) INFLATION-ADJUSTED AV-  
11 ERAGE MANUFACTURER PRICE DE-  
12 FINED.—In this clause, the term ‘in-  
13 flation-adjusted average manufacturer  
14 price’ means, with respect to a single  
15 source drug or an innovator multiple  
16 source drug and a rebate period, the  
17 average manufacturer price for each  
18 dosage form and strength of the drug  
19 for the calendar quarter beginning  
20 July 1, 1990 (without regard to  
21 whether or not the drug has been sold  
22 or transferred to an entity, including  
23 a division or subsidiary of the manu-  
24 facturer, after the 1<sup>st</sup> day of such  
25 quarter), increased by the percentage

1 by which the consumer price index for  
 2 all urban consumers (United States  
 3 city average) for the month before the  
 4 month in which the rebate period be-  
 5 gins exceeds such index for September  
 6 1990.”.

7 (b) TREATMENT OF SUBSEQUENTLY APPROVED  
 8 DRUGS.—Section 1927(c)(2)(B) of the Social Security Act  
 9 (42 U.S.C. 1396r–8(c)(2)(B)) is amended by inserting  
 10 “and clause (ii)(II) of subparagraph (D)” after “clause  
 11 (ii)(II) of subparagraph (A)”.

12 (c) TECHNICAL AMENDMENTS.—Section  
 13 1927(c)(3)(C)(ii)(IV) of the Social Security Act (42  
 14 U.S.C. 1396r–9(c)(3)(C)(ii)(IV)) is amended—

15 (1) by striking “subparagraph (A)” and insert-  
 16 ing “paragraph (3)(A)”; and

17 (2) by striking “this subparagraph” and insert-  
 18 ing “paragraph (3)(C)”.

19 **SEC. 210. APPLYING MEDICAID DRUG REBATE REQUIRE-**  
 20 **MENT TO DRUGS PROVIDED AS PART OF OUT-**  
 21 **PATIENT HOSPITAL SERVICES.**

22 (a) IN GENERAL.—Section 1927(k)(3) of the Social  
 23 Security Act (42 U.S.C. 1396r–8(k)(3)) is amended to  
 24 read as follows:

25 “(3) LIMITING DEFINITION.—

1           “(A) IN GENERAL.—The term ‘covered  
2           outpatient drug’ does not include any drug, bio-  
3           logical product, or insulin provided as part of,  
4           or as incident to and in the same setting as,  
5           any of the following (and for which payment  
6           may be made under this title as part of pay-  
7           ment for the following and not as direct reim-  
8           bursement for the drug):

9                   “(i) Inpatient hospital services.

10                   “(ii) Hospice services.

11                   “(iii) Dental services, except that  
12           drugs for which the State plan authorizes  
13           direct reimbursement to the dispensing  
14           dentist are covered outpatient drugs.

15                   “(iv) Physicians’ services.

16                   “(v) Outpatient hospital services.

17                   “(vi) Nursing facility services and  
18           services provided by an intermediate care  
19           facility for the mentally retarded.

20                   “(vii) Other laboratory and x-ray serv-  
21           ices.

22                   “(viii) Renal dialysis.

23           “(B) OTHER EXCLUSIONS.—Such term  
24           also does not include any such drug or product  
25           for which a National Drug Code number is not

1 required by the Food and Drug Administration  
2 or a drug or biological used for a medical indi-  
3 cation which is not a medically accepted indica-  
4 tion.

5 “(C) STATE OPTION.—At the option of a  
6 State, such term may include any drug, biologi-  
7 cal product, or insulin provided on an out-  
8 patient basis as part of, or as incident to and  
9 in the same setting as, described in clause (iv)  
10 or (v) of subparagraph (A) (such as a drug, bi-  
11 ological product, or insulin being provided as  
12 part of a bundled payment).

13 “(D) NO EFFECT ON BEST PRICE.—Any  
14 drug, biological product, or insulin excluded  
15 from the definition of such term as a result of  
16 this paragraph shall be treated as a covered  
17 outpatient drug for purposes of determining the  
18 best price (as defined in subsection (c)(1)(C))  
19 for such drug, biological product, or insulin.”.

20 (b) EFFECTIVE DATE; IMPLEMENTATION GUID-  
21 ANCE.—

22 (1) IN GENERAL.—The amendment made by  
23 subsection (a) shall take effect on the date that is  
24 1 year after the date of enactment of this Act.

1           (2) IMPLEMENTATION AND GUIDANCE.—Not  
2 later than 1 year after the date of enactment of this  
3 Act, the Secretary of Health and Human Services  
4 shall issue guidance and relevant informational bul-  
5 letins for States, manufacturers (as defined in sec-  
6 tion 1927(k)(5) of the Social Security Act (42  
7 U.S.C. 1396r-8(k)(5)), and other relevant stake-  
8 holders, including health care providers, regarding  
9 implementation of the amendment made by sub-  
10 section (a).

Calendar No. 225

116<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session

**S. 2543**

[Report No. 116-120]

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**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.

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SEPTEMBER 25, 2019

Read twice and placed on the calendar