

117TH CONGRESS  
1ST SESSION

# H. R. 5260

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 HOUSE OF REPRESENTATIVES

SEPTEMBER 14, 2021

Mr. PETERS (for himself, Mr. SCHRADER, Miss RICE of New York, Mrs. MURPHY of Florida, and Mr. CORREA) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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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 “Reduced Costs and Continued Cures Act”.

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—ESTABLISHMENT OF PART B PAYMENT RULES FOR  
NEGOTIATION-ELIGIBLE DRUGS AND BIOLOGICALS**

Sec. 101. Establishment of part B payment rules for negotiation-eligible drugs  
and biologicals.

**TITLE II—MEDICARE**

**Subtitle A—Part B**

Sec. 201. Inclusion of value of coupons in determination of average sales price  
for drugs and biologicals under Medicare part B.

Sec. 202. Payment for biosimilar biological products during initial period.

Sec. 203. Temporary increase in Medicare part B payment for biosimilar bio-  
logical products.

Sec. 204. Medicare part B rebate by manufacturers.

Sec. 205. Establishment of maximum add-on payment for drugs and  
biologicals.

Sec. 206. GAO study and report on average sales price.

Sec. 207. Authority to use alternative payment for drugs and biologicals to pre-  
vent potential drug shortages.

Sec. 208. Change in definition of strength for the purposes of determining  
interchangeability of biological and biosimilar products.

**Subtitle B—Part D**

Sec. 209. Medicare part D modernization redesign.

Sec. 210. Public disclosure of drug discounts and other pharmacy benefit man-  
ager (PBM) provisions.

Sec. 211. Public disclosure of direct and indirect remuneration review and audit  
results.

Sec. 212. Improvements to provision of parts A and B claims data to prescrip-  
tion drug plans.

Sec. 213. Medicare part D rebate by manufacturers.

Sec. 214. Prohibiting branding on part D benefit cards.

Sec. 215. Requiring prescription drug plans and MA–PD plans to report poten-  
tial fraud, waste, and abuse to the Secretary of HHS.

Sec. 216. Establishment of pharmacy quality measures under Medicare part D.

Sec. 217. Addition of new measures based on access to biosimilar biological  
products to the 5-star rating system under Medicare Advan-  
tage.

Sec. 218. HHS study and report on the influence of pharmaceutical manufac-  
turer third-party reimbursement hubs on health care providers  
who prescribe their drugs and biologicals.

- Sec. 219. Establishing a monthly cap on beneficiary incurred costs for insulin products and supplies under a prescription drug plan or MA-PD plan.
- Sec. 220. Monthly out-of-pocket cost sharing maximum for enrollees who incur a significant portion of costs towards annual out-of-pocket threshold.

#### Subtitle C—Miscellaneous

- Sec. 221. Drug manufacturer price transparency.
- Sec. 222. Strengthening and expanding pharmacy benefit managers transparency requirements.
- Sec. 223. Prescription drug pricing dashboards.
- Sec. 224. Improving coordination between the Food and Drug Administration and the Centers for Medicare & Medicaid Services.
- Sec. 225. Patient consultation in Medicare national and local coverage determinations in order to mitigate barriers to inclusion of such perspectives.
- Sec. 226. GAO study on increases to Medicare and Medicaid spending due to copayment coupons and other patient assistance programs.
- Sec. 227. MedPAC report on shifting coverage of certain Medicare part B drugs to Medicare part D.
- Sec. 228. Taking steps to fulfill treaty obligations to Tribal communities.

#### TITLE III—MEDICAID

- Sec. 301. Medicaid pharmacy and therapeutics committee improvements.
- Sec. 302. Improving reporting requirements and developing standards for the use of drug use review boards in State Medicaid programs.
- Sec. 303. GAO report on conflicts of interest in State Medicaid program drug use review boards and pharmacy and therapeutics (P&T) committees.
- Sec. 304. Ensuring the accuracy of manufacturer price and drug product information under the Medicaid drug rebate program.
- Sec. 305. T-MSIS drug data analytics reports.
- Sec. 306. Risk-sharing value-based payment agreements for covered outpatient drugs under Medicaid.
- Sec. 307. Modification of maximum rebate amount under Medicaid drug rebate program.

#### TITLE IV—ADDRESSING INTERMEDIARIES AND DRUG COMPETITION

- Sec. 401. Health plan oversight of pharmacy benefit manager services.
- Sec. 402. Study of pharmaceutical supply chain intermediaries and merger activity.
- Sec. 403. Requirement that direct-to-consumer advertisements for prescription drugs and biological products include truthful and non-misleading pricing information.
- Sec. 404. Change conditions of first generic exclusivity to spur access and competition.
- Sec. 405. Ending the practice preventing market competition known as “Pay-for-Delay”.
- Sec. 406. Empowering the FTC to prevent “product hopping”.
- Sec. 407. Promoting competition by limiting patent thickets.

#### TITLE V—BENEFICIARY COST SHARING FAIRNESS

Sec. 501. Repealing of rule by the Department of Health and Human Services.  
 Sec. 502. Defining cost under prescription drug plans under part D of Medicare.

1 **TITLE I—ESTABLISHMENT OF**  
 2 **PART B PAYMENT RULES FOR**  
 3 **NEGOTIATION-ELIGIBLE**  
 4 **DRUGS AND BIOLOGICALS**

5 **SEC. 101. ESTABLISHMENT OF PART B PAYMENT RULES**  
 6 **FOR NEGOTIATION-ELIGIBLE DRUGS AND**  
 7 **BIOLOGICALS.**

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

10 (1) in paragraph (1)—

11 (A) in the matter preceding subparagraph  
 12 (A), by striking “Subject to paragraph (7)” and  
 13 inserting “Subject to paragraphs (7) and (9)”;

14 (B) in subparagraph (B), by striking at  
 15 the end “or”;

16 (C) in subparagraph (C), by striking the  
 17 period at the end and inserting “; or”; and

18 (D) by adding at the end the following new  
 19 subparagraph:

20 “(D) in the case of a negotiation-eligible  
 21 drug or biological, the maximum allowable cost  
 22 determined under paragraph (9).”; and

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

1           “(9) RULES FOR NEGOTIATION-ELIGIBLE  
2       DRUGS AND BIOLOGICALS.—

3           “(A) NOTIFICATION OF MANUFACTURERS  
4       OF NEGOTIATION-ELIGIBLE DRUGS AND  
5       BIOLOGICALS.—

6           “(i) IN GENERAL.—Not later than  
7       180 days after the date of the enactment  
8       of this paragraph, the Secretary shall no-  
9       tify each manufacturer of each negotiation-  
10      eligible drug or biological that is subject to  
11      negotiation for payment under this part.

12          “(ii) NEGOTIATION-ELIGIBLE DRUG  
13      OR BIOLOGICAL.—In this paragraph, the  
14      term ‘negotiation-eligible drug or biologi-  
15      cal’ means a single source drug or biologi-  
16      cal (as defined in subparagraph (C)) for  
17      which each of the following have expired:

18           “(I) The period of regulatory  
19      data protections or exclusivity granted  
20      for such drug or biological (including  
21      for new chemical entities, biologics,  
22      orphan drugs, pediatric formulations,  
23      and clinical trials).

24           “(II) Subject to the succeeding  
25      sentence, the period of any patents

1 issued for such drug or biological up  
2 to 1 year after the approval of such  
3 drug or biological. In the case of small  
4 molecule product that is a such a  
5 drug or biological, the period of any  
6 patents listed in the publication, Ap-  
7 proved Drug Products With Thera-  
8 peutic Equivalence Evaluations (re-  
9 ferred to as the ‘Orange Book’).

10 “(B) NEGOTIATION.—

11 “(i) IN GENERAL.—The Secretary and  
12 the manufacturer of a negotiation-eligible  
13 drug or biological shall during the negotia-  
14 tion period negotiate a maximum allowable  
15 cost for such drug or biological. In the case  
16 that the Secretary and the manufacturer  
17 do not determine a maximum allowable  
18 cost for such drug or biological, the Sec-  
19 retary shall determine the maximum allow-  
20 able cost for such drug or biological at an  
21 amount that is at least 65 percent and not  
22 more than 75 percent of the average sales  
23 price of such drug or biological.

24 “(ii) MAXIMUM ALLOWABLE COST.—

25 In this subparagraph, the term ‘maximum

allowable cost’ means the amount agreed to by the Secretary and the manufacturer of a negotiation-eligible drug or biological for a unit of such drug or biological that is not less than 65 percent and not more than 75 percent of the lowest average sales price of such drug or biological for the preceding 1-year period.

“(C) SINGLE SOURCE DRUG OR BIOLOGICAL.—For purposes of this paragraph, the term ‘single source drug or biological’ means—

“(i) a drug or drug product that—

“(I) is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and is marketed pursuant to such approval; and

“(II) is not the listed drug for any drug that is approved under section 505(j) and is marketed pursuant to such approval; or

“(ii) a biological product that—

“(I) is licensed under section 351(a) of the Public Health Service Act, including any product deemed to be licensed under such section pursu-

ant to section 7002(e)(4) of the Bio-  
logics Price Competition and Innova-  
tion Act and is marketed pursuant to  
section 351 of the Public Health Serv-  
ice Act; and

“(II) is not the reference product  
for any biological product that is li-  
censed and is marketed pursuant to  
such section of such Act.”.

## **TITLE II—MEDICARE**

### **Subtitle A—Part B**

#### **SEC. 201. INCLUSION OF VALUE OF COUPONS IN DETER- MINATION OF AVERAGE SALES PRICE FOR DRUGS AND BIOLOGICALS UNDER MEDICARE PART B.**

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

(1) in paragraph (3)—

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

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



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

3 “(B) COUPONS PROVIDED TO REDUCE  
4 COST-SHARING.—For calendar quarters begin-  
5 ning on or after July 1, 2024, in calculating the  
6 manufacturer’s average sales price under this  
7 subsection, such price shall include the value  
8 (as defined in paragraph (6)(J)) of any coupons  
9 provided under a drug coupon program of a  
10 manufacturer (as those terms are defined in  
11 subparagraphs (K) and (L), respectively, of  
12 paragraph (6)).”; and

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

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

19 “(i) the amount of any reduction or  
20 elimination of cost-sharing or other out-of-  
21 pocket costs described in such subpara-  
22 graph to a patient as a result of the use  
23 of such coupon; and

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

1           “(K) COUPON.—The term ‘coupon’ means  
2           any financial support that is provided to a pa-  
3           tient, either directly to the patient or indirectly  
4           to the patient through a physician, prescriber,  
5           pharmacy, or other provider, under a drug cou-  
6           pon program of a manufacturer (as defined in  
7           subparagraph (L)) that is used to reduce or  
8           eliminate cost-sharing or other out-of-pocket  
9           costs of the patient, including costs related to  
10          a deductible, coinsurance, or copayment, with  
11          respect to a drug or biological, including a bio-  
12          similar biological product, of the manufacturer.

13          “(L) DRUG COUPON PROGRAM.—

14                 “(i) IN GENERAL.—Subject to clause  
15                 (ii), the term ‘drug coupon program’  
16                 means, with respect to a manufacturer, a  
17                 program through which the manufacturer  
18                 provides coupons to patients as described  
19                 in subparagraph (K).

20                 “(ii) EXCLUSIONS.—Such term does  
21                 not include—

22                         “(I) a patient assistance program  
23                         operated by a manufacturer that pro-  
24                         vides free or discounted drugs or  
25                         biologicals, including biosimilar bio-

1                   logical products, (through in-kind do-  
 2                   nations) to patients of low income; or  
 3                   “(II) a contribution by a manu-  
 4                   facturer to a nonprofit or Foundation  
 5                   that provides free or discounted drugs  
 6                   or biologicals, including biosimilar bio-  
 7                   logical products, (through in-kind do-  
 8                   nations) to patients of low income.”.

9   **SEC. 202. PAYMENT FOR BIOSIMILAR BIOLOGICAL PROD-**  
 10                   **UCTS DURING INITIAL PERIOD.**

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

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

17               (2) by redesignating subparagraphs (A) and  
 18               (B) as clauses (i) and (ii) and moving such clauses  
 19               2 ems to the right;

20               (3) by striking “UNAVAILABLE.—In the case”  
 21               and inserting “UNAVAILABLE.—

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

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

1                   “(B) LIMITATION ON PAYMENT AMOUNT  
 2                   FOR BIOSIMILAR BIOLOGICAL PRODUCTS DUR-  
 3                   ING INITIAL PERIOD.—In the case of a bio-  
 4                   similar biological product furnished on or after  
 5                   July 1, 2023, in lieu of applying subparagraph  
 6                   (A) during the initial period described in such  
 7                   subparagraph with respect to the biosimilar bio-  
 8                   logical product, the amount payable under this  
 9                   section for the biosimilar biological product is  
 10                  the lesser of the following:

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

14                   “(ii) The amount determined under  
 15                   subsection (b)(1)(B) for the reference bio-  
 16                   logical product.”.

17 **SEC. 203. TEMPORARY INCREASE IN MEDICARE PART B**  
 18 **PAYMENT FOR BIOSIMILAR BIOLOGICAL**  
 19 **PRODUCTS.**

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

22                   (1) by redesignating subparagraphs (A) and  
 23                   (B) as clauses (i) and (ii), respectively, and indent-  
 24                   ing appropriately;

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

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

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

7           “(B) TEMPORARY PAYMENT INCREASE FOR  
8       BIOSIMILAR BIOLOGICAL PRODUCTS.—

9           “(i) IN GENERAL.—Beginning Janu-  
10       ary 1, 2023, in the case of a biosimilar bio-  
11       logical product described in paragraph  
12       (1)(C) that is furnished during the applica-  
13       ble 5-year period for such product, the  
14       amount specified in this paragraph for  
15       such product is an amount equal to the  
16       lesser of the following:

17           “(I) The amount specified in sub-  
18       paragraph (A) for such product if  
19       clause (ii) of such subparagraph was  
20       applied by substituting ‘8 percent’ for  
21       ‘6 percent’.

22           “(II) The amount determined  
23       under subsection (b)(1)(B) for the  
24       reference biological product.

1 “(ii) APPLICABLE 5-YEAR PERIOD.—

2 For purposes of clause (i), the applicable  
3 5-year period for a biosimilar biological  
4 product is—

5 “(I) in the case of such a product  
6 for which payment was made under  
7 this paragraph as of December 31,  
8 2012, the 5-year period beginning on  
9 January 1, 2023; and

10 “(II) in the case of such a prod-  
11 uct that is not described in subclause  
12 (I), the 5-year period beginning on the  
13 first day of the first calendar quarter  
14 in which payment was made for such  
15 product under this paragraph.”.

16 **SEC. 204. MEDICARE PART B REBATE BY MANUFACTURERS.**

17 (a) IN GENERAL.—Section 1834 of the Social Secu-  
18 rity Act (42 U.S.C. 1395m) is amended by adding at the  
19 end the following new subsection:

20 “(x) REBATE BY MANUFACTURERS FOR SINGLE  
21 SOURCE DRUGS WITH PRICES INCREASING FASTER  
22 THAN INFLATION.—

23 “(1) REQUIREMENTS.—

24 “(A) SECRETARIAL PROVISION OF INFOR-  
25 MATION.—Not later than 6 months after the

1 end of each calendar quarter beginning on or  
2 after July 1, 2024, the Secretary shall, for each  
3 part B rebatable drug, report to each manufac-  
4 turer of such part B rebatable drug the fol-  
5 lowing for such calendar quarter:

6 “(i) Information on the total number  
7 of units of the billing and payment code  
8 described in subparagraph (A)(i) of para-  
9 graph (3) with respect to such drug and  
10 calendar quarter.

11 “(ii) Information on the amount (if  
12 any) of the excess average sales price in-  
13 crease described in subparagraph (A)(ii) of  
14 such paragraph for such drug and calendar  
15 quarter.

16 “(iii) The rebate amount specified  
17 under such paragraph for such part B  
18 rebatable drug and calendar quarter.

19 “(B) MANUFACTURER REQUIREMENT.—  
20 For each calendar quarter beginning on or after  
21 July 1, 2024, the manufacturer of a part B  
22 rebatable drug shall, for such drug, not later  
23 than 30 days after the date of receipt from the  
24 Secretary of the information described in sub-  
25 paragraph (A) for such calendar quarter, pro-

vide to the Secretary a rebate that is equal to the amount specified in paragraph (3) for such drug for such calendar quarter.

“(2) PART B REBATABLE DRUG DEFINED.—

“(A) IN GENERAL.—In this subsection, the term ‘part B rebatable drug’ means a single source drug or biological (as defined in subparagraph (D) of section 1847A(c)(6)), including a biosimilar biological product (as defined in subparagraph (H) of such section), paid for under this part, except such term shall not include such a drug or biological—

“(i) if the average total allowed charges for a year per individual that uses such a drug or biological, as determined by the Secretary, are less than, subject to subparagraph (B), \$100; or

“(ii) that is a vaccine described in subparagraph (A) or (B) of section 1861(s)(10).

“(B) INCREASE.—The dollar amount applied under subparagraph (A)(i)—

“(i) for 2025, shall be the dollar amount specified under such subparagraph for 2024, increased by the percentage in-



crease in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year; and

“(ii) for a subsequent year, shall be the dollar amount specified in this clause (or clause (i)) for the previous year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year.

Any dollar amount specified under this subparagraph that is not a multiple of \$10 shall be rounded to the nearest multiple of \$10.

“(3) REBATE AMOUNT.—

“(A) IN GENERAL.—For purposes of paragraph (1), the amount specified in this paragraph for a part B rebatable drug assigned to a billing and payment code for a calendar quarter is, subject to paragraph (4), the amount equal to the product of—

“(i) subject to subparagraphs (B) and (G), the total number of units of the billing and payment code for such part B

1 rebatable drug furnished under this part  
2 during the calendar quarter; and

3 “(ii) the amount (if any) by which—

4 “(I) the payment amount under  
5 subparagraph (B) or (C) of section  
6 1847A(b)(1), as applicable, for such  
7 part B rebatable drug during the cal-  
8 endar quarter; exceeds

9 “(II) the inflation-adjusted pay-  
10 ment amount determined under sub-  
11 paragraph (C) for such part B  
12 rebatable drug during the calendar  
13 quarter.

14 “(B) EXCLUDED UNITS.—For purposes of  
15 subparagraph (A)(i), the total number of units  
16 of the billing and payment code for each part  
17 B rebatable drug furnished during a calendar  
18 quarter shall not include—

19 “(i) units packaged into the payment  
20 for a procedure or service under section  
21 1833(t) or under section 1833(i) (instead  
22 of separately payable under such respective  
23 section);

1 “(ii) units included under the single  
2 payment system for renal dialysis services  
3 under section 1881(b)(14); or

4 “(iii) units of a part B rebatable drug  
5 of a manufacturer furnished to an indi-  
6 vidual, if such manufacturer, with respect  
7 to the furnishing of such units of such  
8 drug, provides for discounts under section  
9 340B of the Public Health Service Act or  
10 for rebates under section 1927.

11 “(C) DETERMINATION OF INFLATION-AD-  
12 JUSTED PAYMENT AMOUNT.—The inflation-ad-  
13 justed payment amount determined under this  
14 subparagraph for a part B rebatable drug for  
15 a calendar quarter is—

16 “(i) the payment amount for the bill-  
17 ing and payment code for such drug in the  
18 payment amount benchmark quarter (as  
19 defined in subparagraph (D)); increased by

20 “(ii) the percentage by which the re-  
21 bate period CPI–U (as defined in subpara-  
22 graph (F)) for the calendar quarter ex-  
23 ceeds the benchmark period CPI–U (as de-  
24 fined in subparagraph (E)).

1           “(D) PROSPECTIVE PAYMENT AMOUNT  
2 BENCHMARK QUARTER.—The term ‘prospective  
3 payment amount benchmark quarter’ means the  
4 calendar quarter beginning January 1, 2016.

5           “(E) BENCHMARK PERIOD CPI-U.—The  
6 term ‘benchmark period CPI-U’ means the con-  
7 sumer price index for all urban consumers  
8 (United States city average) for July 2015.

9           “(F) REBATE PERIOD CPI-U.—The term  
10 ‘rebate period CPI-U’ means, with respect to a  
11 calendar quarter described in subparagraph  
12 (C), the greater of the benchmark period CPI-  
13 U and the consumer price index for all urban  
14 consumers (United States city average) for the  
15 first month of the calendar quarter that is two  
16 calendar quarters prior to such described cal-  
17 endar quarter.

18           “(G) COUNTING UNITS.—

19           “(i) CUT-OFF PERIOD TO COUNT  
20 UNITS.—For purposes of subparagraph  
21 (A)(i), subject to clause (ii), to count the  
22 total number of billing units for a part B  
23 rebatable drug for a quarter, the Secretary  
24 may use a cut-off period in order to ex-  
25 clude from such total number of billing

1 units for such quarter claims for services  
2 furnished during such quarter that were  
3 not processed at an appropriate time prior  
4 to the end of the cut-off period.

5 “(ii) COUNTING UNITS FOR CLAIMS  
6 PROCESSED AFTER CUT-OFF PERIOD.—If  
7 the Secretary uses a cut-off period pursu-  
8 ant to clause (i), in the case of units of a  
9 part B rebatable drug furnished during a  
10 quarter but pursuant to application of such  
11 cut-off period excluded for purposes of sub-  
12 paragraph (A)(i) from the total number of  
13 billing units for the drug for such quarter,  
14 the Secretary shall count such units of  
15 such drug so furnished in the total number  
16 of billing units for such drug for a subse-  
17 quent quarter, as the Secretary determines  
18 appropriate.

19 “(4) SPECIAL TREATMENT OF CERTAIN DRUGS  
20 AND EXEMPTION.—

21 “(A) SUBSEQUENTLY APPROVED DRUGS.—  
22 Subject to subparagraph (B), in the case of a  
23 part B rebatable drug first approved or licensed  
24 by the Food and Drug Administration after  
25 July 1, 2015, clause (i) of paragraph (3)(C)

1 shall be applied as if the term ‘payment amount  
2 benchmark quarter’ were defined under para-  
3 graph (3)(D) as the third full calendar quarter  
4 after the day on which the drug was first mar-  
5 keted and clause (ii) of paragraph (3)(C) shall  
6 be applied as if the term ‘benchmark period  
7 CPI–U’ were defined under paragraph (3)(E)  
8 as if the reference to ‘July 2015’ under such  
9 paragraph were a reference to ‘the first month  
10 of the first full calendar quarter after the day  
11 on which the drug was first marketed’.

12 “(B) TIMELINE FOR PROVISION OF RE-  
13 BATES FOR SUBSEQUENTLY APPROVED  
14 DRUGS.—In the case of a part B rebatable drug  
15 first approved or licensed by the Food and  
16 Drug Administration after July 1, 2015, para-  
17 graph (1)(B) shall be applied as if the reference  
18 to ‘July 1, 2024’ under such paragraph were a  
19 reference to the later of the 6th full calendar  
20 quarter after the day on which the drug was  
21 first marketed or July 1, 2024.

22 “(C) EXEMPTION FOR SHORTAGES.—The  
23 Secretary may reduce or waive the rebate  
24 amount under paragraph (1)(B) with respect to  
25 a part B rebatable drug that is described as

1 currently in shortage on the shortage list in ef-  
2 fect under section 506E of the Federal Food,  
3 Drug, and Cosmetic Act or in the case of other  
4 exigent circumstances, as determined by the  
5 Secretary.

6 “(D) SELECTED DRUGS.—In the case of a  
7 part B rebatable drug that is a selected drug  
8 (as defined in section 1192(c)) for a price appli-  
9 cability period (as defined in section  
10 1191(b)(2))—

11 “(i) for calendar quarters during such  
12 period for which a maximum fair price (as  
13 defined in section 1191(c)(2)) for such  
14 drug has been determined and is applied  
15 under part E of title XI, the rebate  
16 amount under paragraph (1)(B) shall be  
17 waived; and

18 “(ii) in the case such drug is deter-  
19 mined (pursuant to such section 1192(c))  
20 to no longer be a selected drug, for each  
21 applicable year beginning after the price  
22 applicability period with respect to such  
23 drug, clause (i) of paragraph (3)(C) shall  
24 be applied as if the term ‘payment amount  
25 benchmark quarter’ were defined under

1 paragraph (3)(D) as the calendar quarter  
2 beginning January 1 of the last year be-  
3 ginning during such price applicability pe-  
4 riod with respect to such selected drug and  
5 clause (ii) of paragraph (3)(C) shall be ap-  
6 plied as if the term ‘benchmark period  
7 CPI–U’ were defined under paragraph  
8 (3)(E) as if the reference to ‘July 2015’  
9 under such paragraph were a reference to  
10 the July of the year preceding such last  
11 year.

12 “(5) APPLICATION TO BENEFICIARY COINSUR-  
13 ANCE.—In the case of a part B rebatable drug, if  
14 the payment amount for a quarter exceeds the infla-  
15 tion adjusted payment for such quarter—

16 “(A) in computing the amount of any coin-  
17 surance applicable under this title to an indi-  
18 vidual with respect to such drug, the computa-  
19 tion of such coinsurance shall be based on the  
20 inflation-adjusted payment amount determined  
21 under paragraph (3)(C) for such part B  
22 rebatable drug; and

23 “(B) the amount of such coinsurance is  
24 equal to 20 percent of such inflation-adjusted  
25 payment amount so determined.



1           “(6) REBATE DEPOSITS.—Amounts paid as re-  
2       bates under paragraph (1)(B) shall be deposited into  
3       the Federal Supplementary Medical Insurance Trust  
4       Fund established under section 1841.

5           “(7) CIVIL MONEY PENALTY.—If a manufac-  
6       turer of a part B rebatable drug has failed to com-  
7       ply with the requirements under paragraph (1)(B)  
8       for such drug for a calendar quarter, the manufac-  
9       turer shall be subject to, in accordance with a proc-  
10      ess established by the Secretary pursuant to regula-  
11      tions, a civil money penalty in an amount equal to  
12      at least 125 percent of the amount specified in para-  
13      graph (3) for such drug for such calendar quarter.  
14      The provisions of section 1128A (other than sub-  
15      sections (a) (with respect to amounts of penalties or  
16      additional assessments) and (b)) shall apply to a  
17      civil money penalty under this paragraph in the  
18      same manner as such provisions apply to a penalty  
19      or proceeding under section 1128A(a).

20           “(8) STUDY AND REPORT.—

21           “(A) STUDY.—The Secretary shall conduct  
22           a study of the feasibility of and operational  
23           issues involved with the following:

1 “(i) Including multiple source drugs  
2 (as defined in section 1847A(c)(6)(C)) in  
3 the rebate system under this subsection.

4 “(ii) Including drugs and biologicals  
5 paid for under MA plans under part C in  
6 the rebate system under this subsection.

7 “(iii) Including drugs excluded under  
8 paragraph (2)(A) and units of the billing  
9 and payment code of the drugs excluded  
10 under paragraph (3)(B) in the rebate sys-  
11 tem under this subsection.

12 “(B) REPORT.—Not later than 3 years  
13 after the date of the enactment of this sub-  
14 section, the Secretary shall submit to Congress  
15 a report on the study conducted under subpara-  
16 graph (A).

17 “(9) APPLICATION TO MULTIPLE SOURCE  
18 DRUGS.—The Secretary may, based on the report  
19 submitted under paragraph (8) and pursuant to  
20 rulemaking, apply the provisions of this subsection  
21 to multiple source drugs (as defined in section  
22 1847A(c)(6)(C)), including, for purposes of deter-  
23 mining the rebate amount under paragraph (3), by  
24 calculating manufacturer-specific average sales

1 prices for the benchmark period and the rebate pe-  
 2 riod.”.

3 (b) AMOUNTS PAYABLE; COST-SHARING.—Section  
 4 1833 of the Social Security Act (42 U.S.C. 1395l) is  
 5 amended—

6 (1) in subsection (a)—

7 (A) in paragraph (1)—

8 (i) in subparagraph (S), by striking  
 9 “with respect to” and inserting “subject to  
 10 subparagraph (DD), with respect to”;

11 (ii) by striking “and (CC)” and in-  
 12 serting “(CC)”; and

13 (iii) by inserting before the semicolon  
 14 at the end the following: “, and (DD) with  
 15 respect to a part B rebatable drug (as de-  
 16 fined in paragraph (2) of section 1834(x))  
 17 for which the payment amount for a cal-  
 18 endar quarter under paragraph  
 19 (3)(A)(ii)(I) of such section for such quar-  
 20 ter exceeds the inflation-adjusted payment  
 21 under paragraph (3)(A)(ii)(II) of such sec-  
 22 tion for such quarter, the amounts paid  
 23 shall be the difference between (i) the pay-  
 24 ment amount under paragraph  
 25 (3)(A)(ii)(I) of such section for such drug,

1                   and (ii) 20 percent of the inflation-ad-  
2                   justed payment amount under paragraph  
3                   (3)(A)(ii)(II) of such section for such  
4                   drug”; and

5                   (B) by adding at the end of the flush left  
6                   matter following paragraph (9) the following:

7                   “For purposes of applying paragraph (1)(DD), sub-  
8                   sections (i)(9) and (t)(8)(F), and section 1834(x)(5), the  
9                   Secretary shall make such estimates and use such data  
10                  as the Secretary determines appropriate, and notwith-  
11                  standing any other provision of law, may do so by program  
12                  instruction or otherwise.”;

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

15                  “(9) In the case of a part B rebatable drug (as  
16                  defined in paragraph (2) of section 1834(x)) for  
17                  which payment under this subsection is not pack-  
18                  aged into a payment for a covered OPD service (as  
19                  defined in subsection (t)(1)(B)) (or group of serv-  
20                  ices) furnished on or after July 1, 2024, under the  
21                  system under this subsection, in lieu of calculation  
22                  of coinsurance and the amount of payment otherwise  
23                  applicable under this subsection, the provisions of  
24                  section 1834(x)(5), paragraph (1)(DD) of subsection  
25                  (a), and the flush left matter following paragraph

(9) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1834(x)(5) and subsection (a) apply under such section and subsection.”; and

(3) in subsection (t)(8), by adding at the end the following new subparagraph:

“(F) PART B REBATABLE DRUGS.—In the case of a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) for which payment under this part is not packaged into a payment for a service furnished on or after July 1, 2024, under the system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1834(x)(5), paragraph (1)(DD) of subsection (a), and the flush left matter following paragraph (9) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1834(x)(5) and subsection (a) apply under such section and subsection.”.

(c) CONFORMING AMENDMENTS.—

1           (1) TO PART B ASP CALCULATION.—Section  
 2       1847A(c)(3) of the Social Security Act (42 U.S.C.  
 3       1395w–3a(c)(3)) is amended by inserting “or section  
 4       1834(x)” after “section 1927”.

5           (2) EXCLUDING PART B DRUG INFLATION RE-  
 6       BATE FROM BEST PRICE.—Section  
 7       1927(c)(1)(C)(ii)(I) of the Social Security Act (42  
 8       U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is amended by in-  
 9       serting “or section 1834(x)” after “this section”.

10          (3) COORDINATION WITH MEDICAID REBATE IN-  
 11       FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)  
 12       of the Social Security Act (42 U.S.C. 1396r–  
 13       8(b)(3)(D)(i)) is amended by striking “or to carry  
 14       out section 1847B” and inserting “to carry out sec-  
 15       tion 1847B or section 1834(x)”.

16   **SEC. 205. ESTABLISHMENT OF MAXIMUM ADD-ON PAYMENT**  
 17                           **FOR DRUGS AND BIOLOGICALS.**

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

20               (1) in subsection (b)—

21                       (A) in paragraph (1), in the matter pre-  
 22                       ceding subparagraph (A), by striking “para-  
 23                       graph (7)” and inserting “paragraphs (7) and  
 24                       (9)”; and

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

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

4 “(A) IN GENERAL.—In determining the  
5 payment amount under the provisions of sub-  
6 paragraph (A), (B), or (C) of paragraph (1) of  
7 this subsection, subsection (c)(4)(A)(ii), or sub-  
8 section (d)(3)(C) for a drug or biological fur-  
9 nished on or after January 1, 2024, if the ap-  
10 plicable add-on payment (as defined in subpara-  
11 graph (B)) for each drug or biological on a  
12 claim for a date of service exceeds the max-  
13 imum add-on payment amount specified under  
14 subparagraph (C) for the drug or biological,  
15 then the payment amount otherwise determined  
16 for the drug or biological under those provi-  
17 sions, as applicable, shall be reduced by the  
18 amount of such excess.

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

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

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

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

11 “(ii) In the case of a single source  
12 drug or biological, an amount equal to the  
13 difference between—

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

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

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

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



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

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

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

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

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

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

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

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

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

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

10 “(i) for each of 2024 through 2031,  
 11 \$1,000; and

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

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

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

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

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

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

10 “(I) APPLICATION OF MAXIMUM ADD-ON  
11 PAYMENT FOR SEPARATELY PAYABLE DRUGS  
12 AND BIOLOGICALS.—In establishing the amount  
13 of payment under subparagraph (A) for a speci-  
14 fied covered outpatient drug that is furnished  
15 as part of a covered OPD service (or group of  
16 services) on or after January 1, 2024, if such  
17 payment is determined based on the average  
18 price for the year established under section  
19 1847A pursuant to clause (iii)(II) of such sub-  
20 paragraph, the provisions of subsection (b)(9)  
21 of section 1847A shall apply to the amount of  
22 payment so established in the same manner as  
23 such provisions apply to the amount of payment  
24 under section 1847A.”.

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

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

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

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

9       “(vi) If there is a separate payment under the system  
 10   described in clause (i) for a drug or biological furnished  
 11   on or after January 1, 2024, the provisions of subsection  
 12   (t)(14)(I) shall apply to the establishment of the amount  
 13   of payment for the drug or biological under such system  
 14   in the same manner in which such provisions apply to the  
 15   establishment of the amount of payment under subsection  
 16   (t)(14)(A).”.

17   **SEC. 206. GAO STUDY AND REPORT ON AVERAGE SALES**  
 18                   **PRICE.**

19       (a) STUDY.—

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

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

4                   (A) for which reimbursement under such  
5           part B is based on the average sales price of  
6           the drug or biological; and

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

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

14                  (A) The extent to which each applicable  
15          drug is paid for—

16                          (i) under such part B for Medicare  
17          beneficiaries; or

18                          (ii) by private payers in the commer-  
19          cial market.

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

1           (C) The extent to which drug manufactur-  
2           ers provide rebates, discounts, or other price  
3           concessions to private payers in the commercial  
4           market for applicable drugs, which the manu-  
5           facturer includes in its average sales price cal-  
6           culation, for—

7                       (i) formulary placement;

8                       (ii) utilization management consider-  
9           ations; or

10                      (iii) other purposes.

11           (D) Barriers to drug manufacturers pro-  
12           viding such price concessions for applicable  
13           drugs.

14           (E) Other areas determined appropriate by  
15           the Comptroller General.

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

1 **SEC. 207. AUTHORITY TO USE ALTERNATIVE PAYMENT FOR**  
2 **DRUGS AND BIOLOGICALS TO PREVENT PO-**  
3 **TENTIAL DRUG SHORTAGES.**

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

6 (1) by striking “PAYMENT IN RESPONSE TO  
7 PUBLIC HEALTH EMERGENCY.—In the case” and  
8 inserting “PAYMENTS.—

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

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

13 “(2) PREVENTING POTENTIAL DRUG SHORT-  
14 AGES.—

15 “(A) IN GENERAL.—In the case of a drug  
16 or biological that the Secretary determines is  
17 described in subparagraph (B) for one or more  
18 quarters beginning on or after January 1,  
19 2024, the Secretary may use wholesale acquisi-  
20 tion cost (or other reasonable measure of a  
21 drug or biological price) instead of the manu-  
22 facturer’s average sales price for such quarters  
23 and for subsequent quarters until the end of  
24 the quarter in which such drug or biological is  
25 removed from the drug shortage list under sec-  
26 tion 506E of the Federal Food, Drug, and Cos-

1           metic Act, or in the case of a drug or biological  
2           described in subparagraph (B)(ii), the date on  
3           which the Secretary determines that the total  
4           manufacturing capacity or the total number of  
5           manufacturers of such drug or biological is suf-  
6           ficient to mitigate a potential shortage of the  
7           drug or biological.

8           “(B) DRUG OR BIOLOGICAL DESCRIBED.—  
9           For purposes of subparagraph (A), a drug or  
10          biological described in this subparagraph is a  
11          drug or biological—

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

23                 “(ii) that—

24                         “(I) is described in section  
25                         506C(a) of such Act;



1                   “(II) was listed on the drug  
2 shortage list maintained by the Food  
3 and Drug Administration pursuant to  
4 section 506E of such Act within the  
5 preceding 5 years; and

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

16                   “(C) PROVISION OF ADDITIONAL INFORMA-  
17 TION.—For each quarter in which the amount  
18 of payment for a drug or biological described in  
19 subparagraph (B) pursuant to subparagraph  
20 (A) exceeds the amount of payment for the  
21 drug or biological otherwise applicable under  
22 this section, each manufacturer of such drug or  
23 biological shall provide to the Secretary infor-  
24 mation related to the potential cause or causes

1           of the shortage and the expected duration of  
2           the shortage with respect to such drug.”.

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

12           (c) HHS REPORT AND RECOMMENDATIONS.—

13           (1) IN GENERAL.—Not later than July 1, 2024,  
14 the Secretary shall submit to Congress a report on  
15 shortages of drugs within the Medicare program  
16 under title XVIII of the Social Security Act (42  
17 U.S.C. 1395 et seq.). The report shall include—

18           (A) an analysis of—

19                   (i) the effect of drug shortages on  
20 Medicare beneficiary access, quality, safe-  
21 ty, and out-of-pocket costs;

22                   (ii) the effect of drug shortages on  
23 health providers, including hospitals and  
24 physicians, across the Medicare program;

(iii) the current role of the Centers for Medicare & Medicaid Services (CMS) in addressing drug shortages, including CMS's working relationship and communication with other Federal agencies and stakeholders;

(iv) the role of all actors in the drug supply chain (including drug manufacturers, distributors, wholesalers, secondary wholesalers, group purchasing organizations, hospitals, and physicians) on drug shortages within the Medicare program; and

(v) payment structures and incentives under parts A, B, C, and D of the Medicare program and their effect, if any, on drug shortages; and

(B) relevant findings and recommendations to Congress.

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

(3) CONSULTATION.—The Secretary shall consult with the drug shortage task force authorized under section 506D(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356d(a)(1)(A))

1 in preparing the report under this subsection, as ap-  
 2 propriate.

3 **SEC. 208. CHANGE IN DEFINITION OF STRENGTH FOR THE**  
 4 **PURPOSES OF DETERMINING INTERCHANGE-**  
 5 **ABILITY OF BIOLOGICAL AND BIOSIMILAR**  
 6 **PRODUCTS.**

7 (a) Section 351(i) of the Public Health Service Act  
 8 is amended by inserting the following after paragraph (4):

9 “(5) The term ‘strength’, in reference to a bio-  
 10 logical product intended for administration by injec-  
 11 tion, means the total content of drug substance in  
 12 the dosage form without regard to the concentration  
 13 of drug substance or total volume of the biological  
 14 product.”.

15 (b) Section 351(k)(7)(C)(ii)(I) of the Public Health  
 16 Service Act is amended by inserting “concentration,” after  
 17 “delivery device,”.

18 **Subtitle B—Part D**

19 **SEC. 209. MEDICARE PART D MODERNIZATION REDESIGN.**

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

23 (1) in paragraph (2)—

24 (A) in subparagraph (A), in the matter  
 25 preceding clause (i), by inserting “for a year

1 preceding 2024 and for costs above the annual  
2 deductible specified in paragraph (1) and up to  
3 the annual out-of-pocket threshold specified in  
4 paragraph (4)(B) for 2024 and each subsequent  
5 year” after “paragraph (3)”;

6 (B) in subparagraph (C)—

7 (i) in clause (i), in the matter pre-  
8 ceding subclause (I), by inserting “for a  
9 year preceding 2024,” after “paragraph  
10 (4),”; and

11 (ii) in clause (ii)(III), by striking  
12 “and each subsequent year” and inserting  
13 “, 2021, 2022, and 2023”; and

14 (C) in subparagraph (D)—

15 (i) in clause (i)—

16 (I) in the matter preceding sub-  
17 clause (I), by inserting “for a year  
18 preceding 2024,” after “paragraph  
19 (4),”; and

20 (II) in subclause (I)(bb), by  
21 striking “a year after 2018” and in-  
22 serting “each of years 2018 through  
23 2023”; and

1 (ii) in clause (ii)(V), by striking  
2 “2019 and each subsequent year” and in-  
3 serting “each of years through 2023”;

4 (2) in paragraph (3)(A)—

5 (A) in the matter preceding clause (i), by  
6 inserting “for a year preceding 2024,” after  
7 “and (4),”; and

8 (B) in clause (ii), by striking “for a subse-  
9 quent year” and inserting “for each of years  
10 2007 through 2023”; and

11 (3) in paragraph (4)—

12 (A) in subparagraph (A)—

13 (i) in clause (i)—

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

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

22 “(I) for a year preceding 2024,  
23 the greater of—”;

24 (III) by striking the period at the  
25 end of item (bb), as redesignated by

1 subclause (I), and inserting “; and”;  
 2 and  
 3 (IV) by adding at the end the fol-  
 4 lowing:  
 5 “(II) for and each succeeding  
 6 year, \$0.”; and  
 7 (ii) in clause (ii)—  
 8 (I) by striking “clause (i)(I)” and  
 9 inserting “clause (i)(I)(aa)”; and  
 10 (II) by adding at the end the fol-  
 11 lowing new sentence: “The Secretary  
 12 shall continue to calculate the dollar  
 13 amounts specified in clause (i)(I)(aa),  
 14 including with the adjustment under  
 15 this clause, after 2023 for purposes of  
 16 section 1860D–14(a)(1)(D)(iii).”;  
 17 (B) in subparagraph (B)—  
 18 (i) in clause (i)—  
 19 (I) in subclause (V), by striking  
 20 “or” at the end;  
 21 (II) in subclause (VI)—  
 22 (aa) by striking “for a sub-  
 23 sequent year” and inserting “for  
 24 2021, 2022, and 2023”; and

1 (bb) by striking the period  
2 at the end and inserting a semi-  
3 colon; and

4 (III) by adding at the end the  
5 following new subclauses:

6 “(VII) for 2024, is equal to—

7 “(aa) \$3,100 for bene-  
8 ficiaries determined to have in-  
9 come that is over 400 percent of  
10 the Federal poverty line applica-  
11 ble to a family of the size in-  
12 volved;

13 “(bb) \$1,800 for bene-  
14 ficiaries determined to have in-  
15 come that is between 300 to 400  
16 percent of the Federal poverty  
17 line applicable to a family of the  
18 size involved; or

19 “(cc) \$1,200 for bene-  
20 ficiaries determined to have in-  
21 come that is below 300 percent of  
22 the Federal poverty line applica-  
23 ble to a family of the size in-  
24 volved; or



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

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

9 (C) in subparagraph (C)(i), by striking  
 10 “and for amounts” and inserting “and for a  
 11 year preceding 2024 for amounts”; and

12 (D) in subparagraph (E), by striking “In  
 13 applying” and inserting “For each of 2011  
 14 through 2023, in applying”.

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

18 (1) in paragraph (1)—

19 (A) by striking “equal to 80 percent” and  
 20 inserting “equal to—

21 “(A) for a year preceding 2024, 80 per-  
 22 cent”;

23 (B) in subparagraph (A), as added by  
 24 paragraph (1), by striking the period at the end  
 25 and inserting “; and”; and

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

3 “(B) for 2024 and each subsequent year,  
4 the sum of—

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

16 “(ii) an amount equal to the applica-  
17 ble percentage specified in paragraph  
18 (5)(B) of allowable reinsurance costs at-  
19 tributable to that portion of gross prescrip-  
20 tion drug costs as specified in paragraph  
21 (3) incurred in the coverage year after  
22 such individual has incurred costs that ex-  
23 ceed the annual out-of-pocket threshold  
24 specified in section 1860D–2(b)(4)(B) with

1                   respect to covered part D drugs that are  
2                   not applicable drugs (as so defined).”; and

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

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

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

10                   “(i) for 2024, 60 percent;

11                   “(ii) for 2025, 40 percent; and

12                   “(iii) for 2026 and each subsequent  
13                   year, 20 percent; and

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

16                   “(i) for 2024, 80 percent;

17                   “(ii) for 2025, 60 percent; and

18                   “(iii) for 2026 and each subsequent  
19                   year, 40 percent.”.

20                   (c) MANUFACTURER DISCOUNT PROGRAM DURING  
21                   INITIAL AND CATASTROPHIC PHASES OF COVERAGE.—

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

1 **“SEC. 1860D-14B. MANUFACTURER DISCOUNT PROGRAM.**

2       “(a) ESTABLISHMENT.—The Secretary shall estab-  
3 lish a manufacturer discount program (in this section re-  
4 ferred to as the ‘program’). Under the program, the Sec-  
5 retary shall enter into agreements described in subsection  
6 (b) with manufacturers and provide for the performance  
7 of the duties described in subsection (c). The Secretary  
8 shall establish a model agreement for use under the pro-  
9 gram by not later than January 1, 2023, in consultation  
10 with manufacturers, and allow for comment on such model  
11 agreement.

12       “(b) TERMS OF AGREEMENT.—

13               “(1) IN GENERAL.—

14                       “(A) AGREEMENT.—An agreement under  
15 this section shall require the manufacturer to  
16 provide applicable beneficiaries access to dis-  
17 counted prices for applicable drugs of the man-  
18 ufacturer that are dispensed on or after Janu-  
19 ary 1, 2024.

20                       “(B) PROVISION OF DISCOUNTED PRICES  
21 AT THE POINT-OF-SALE.—The discounted prices  
22 described in subparagraph (A) shall be provided  
23 to the applicable beneficiary at the pharmacy or  
24 by the mail order service at the point-of-sale of  
25 an applicable drug.

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

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

16          “(4) LENGTH OF AGREEMENT.—

17                 “(A) IN GENERAL.—An agreement under  
18                 this section shall be effective for an initial pe-  
19                 riod of not less than 12 months and shall be  
20                 automatically renewed for a period of not less  
21                 than 1 year unless terminated under subpara-  
22                 graph (B).

23                 “(B) TERMINATION.—

24                         “(i) BY THE SECRETARY.—The Sec-  
25                         retary may provide for termination of an

1 agreement under this section for a knowing  
2 and willful violation of the requirements of  
3 the agreement or other good cause shown.  
4 Such termination shall not be effective ear-  
5 lier than 30 days after the date of notice  
6 to the manufacturer of such termination.  
7 The Secretary shall provide, upon request,  
8 a manufacturer with a hearing concerning  
9 such a termination, and such hearing shall  
10 take place prior to the effective date of the  
11 termination with sufficient time for such  
12 effective date to be repealed if the Sec-  
13 retary determines appropriate.

14 “(ii) BY A MANUFACTURER.—A man-  
15 ufacturer may terminate an agreement  
16 under this section for any reason. Any  
17 such termination shall be effective, with re-  
18 spect to a plan year—

19 “(I) if the termination occurs be-  
20 fore January 30 of a plan year, as of  
21 the day after the end of the plan year;  
22 and

23 “(II) if the termination occurs on  
24 or after January 30 of a plan year, as

1 of the day after the end of the suc-  
2 ceeding plan year.

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

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

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

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

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

23 “(A) the determination of the amount of  
24 the discounted price of an applicable drug of a  
25 manufacturer;

1           “(B) the establishment of procedures  
2           under which discounted prices are provided to  
3           applicable beneficiaries at pharmacies or by  
4           mail order service at the point-of-sale of an ap-  
5           plicable drug;

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

13                   “(i) the negotiated price of the appli-  
14                   cable drug; and

15                   “(ii) the discounted price of the appli-  
16                   cable drug;

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



1 “(E) providing a reasonable dispute resolu-  
 2 tion mechanism to resolve disagreements be-  
 3 tween manufacturers, applicable beneficiaries,  
 4 and the third party with a contract under sub-  
 5 section (d)(3).

6 “(2) MONITORING COMPLIANCE.—

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

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

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

22 “(d) ADMINISTRATION.—

23 “(1) IN GENERAL.—Subject to paragraph (2),  
 24 the Secretary shall provide for the implementation of

1       this section, including the performance of the duties  
2       described in subsection (c).

3               “(2) LIMITATION.—In providing for the imple-  
4       mentation of this section, the Secretary shall not re-  
5       ceive or distribute any funds of a manufacturer  
6       under the program.

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

14               “(A) receive and transmit information be-  
15      tween the Secretary, manufacturers, and other  
16      individuals or entities the Secretary determines  
17      appropriate;

18               “(B) receive, distribute, or facilitate the  
19      distribution of funds of manufacturers to ap-  
20      propriate individuals or entities in order to  
21      meet the obligations of manufacturers under  
22      agreements under this section;

23               “(C) provide adequate and timely informa-  
24      tion to manufacturers, consistent with the  
25      agreement with the manufacturer under this

1 section, as necessary for the manufacturer to  
2 fulfill its obligations under this section; and

3 “(D) permit manufacturers to conduct  
4 periodic audits, directly or through contracts, of  
5 the data and information used by the third  
6 party to determine discounts for applicable  
7 drugs of the manufacturer under the program.

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

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

17 “(6) FUNDING.—For purposes of carrying out  
18 this section, the Secretary shall provide for the  
19 transfer, from the Federal Supplementary Medical  
20 Insurance Trust Fund under section 1841 to the  
21 Centers for Medicare & Medicaid Services Program  
22 Management Account, of \$4,000,000 for each of fis-  
23 cal years 2021 through 2024, to remain available  
24 until expended.

25 “(e) ENFORCEMENT.—

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

4           “(2) CIVIL MONEY PENALTY.—

5                   “(A) IN GENERAL.—The Secretary shall  
6           impose a civil money penalty on a manufacturer  
7           that fails to provide applicable beneficiaries dis-  
8           counts for applicable drugs of the manufacturer  
9           in accordance with such agreement for each  
10          such failure in an amount the Secretary deter-  
11          mines is commensurate with the sum of—

12                   “(i) the amount that the manufac-  
13          turer would have paid with respect to such  
14          discounts under the agreement, which will  
15          then be used to pay the discounts which  
16          the manufacturer had failed to provide;  
17          and

18                   “(ii) 25 percent of such amount.

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

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

8       “(g) DEFINITIONS.—In this section:

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

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

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

16                       “(C) has incurred costs for covered part D  
17 drugs in the year that are above the annual de-  
18 ductible specified in section 1860D–2(b)(1) for  
19 such year.

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

23                       “(A) approved under a new drug applica-  
24 tion under section 505(c) of the Federal Food,  
25 Drug, and Cosmetic Act or, in the case of a bio-

1 logic product, licensed under section 351 of the  
2 Public Health Service Act (including a product  
3 licensed under subsection (k) of such section  
4 351); and

5 “(B)(i) if the PDP sponsor of the prescrip-  
6 tion drug plan or the MA organization offering  
7 the MA–PD plan uses a formulary, which is on  
8 the formulary of the prescription drug plan or  
9 MA–PD plan that the applicable beneficiary is  
10 enrolled in;

11 “(ii) if the PDP sponsor of the prescrip-  
12 tion drug plan or the MA organization offering  
13 the MA–PD plan does not use a formulary, for  
14 which benefits are available under the prescrip-  
15 tion drug plan or MA–PD plan that the appli-  
16 cable beneficiary is enrolled in; or

17 “(iii) is provided through an exception or  
18 appeal.

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

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

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

1 “(4) DISCOUNTED PRICE.—

2 “(A) IN GENERAL.—Except as provided in  
3 subparagraph (B), the term ‘discounted price’  
4 means 90 percent of the negotiated price of the  
5 applicable drug of a manufacturer.

6 “(B) PHASE-IN FOR CERTAIN DRUGS DIS-  
7 PENSED FOR SUBSIDY ELIGIBLE INDIVID-  
8 UALS.—

9 “(i) IN GENERAL.—In the case of an  
10 applicable drug of a specified manufacturer  
11 (as defined in clause (ii)) that is dispensed  
12 for an applicable beneficiary who is a sub-  
13 sidy eligible individual (as defined in sec-  
14 tion 1860D–14(a)(3), the term ‘discounted  
15 price’ means the specified LIS percent (as  
16 defined in clause (iii)) of the negotiated  
17 price of the applicable drug of the manu-  
18 facturer.

19 “(ii) SPECIFIED MANUFACTURER.—In  
20 this subparagraph, the term ‘specified  
21 manufacturer’ means a manufacturer of an  
22 applicable drug for which, in the calendar  
23 year 2 years prior to the current plan year  
24 (referred to in this clause as the ‘applicable  
25 period’), the total reimbursement under

1           this title during the applicable period rep-  
 2           resented less than 1 percent of the total re-  
 3           imbursement under this title for all pre-  
 4           scription drugs during such period.

5           “(iii) SPECIFIED LIS PERCENT.—In  
 6           this subparagraph, the term ‘specified LIS  
 7           percent’ means—

8                     “(I) for 2024, 98 percent;

9                     “(II) for 2025, 97 percent;

10                    “(III) for 2026, 96 percent;

11                    “(IV) for 2027, 95 percent;

12                    “(V) for 2028, 94 percent;

13                    “(VI) for 2029, 93 percent;

14                    “(VII) for 2030, 92 percent;

15                    “(VIII) for 2031, 91 percent;

16                    and

17                    “(IX) for 2032 and each subse-  
 18                    quent year, 90 percent.

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

23           “(5) MANUFACTURER.—The term ‘manufac-  
 24           turer’ means any entity which is engaged in the pro-  
 25           duction, preparation, propagation, compounding,



1 conversion, or processing of prescription drug prod-  
2 ucts, either directly or indirectly by extraction from  
3 substances of natural origin, or independently by  
4 means of chemical synthesis, or by a combination of  
5 extraction and chemical synthesis. Such term does  
6 not include a wholesale distributor of drugs or a re-  
7 tail pharmacy licensed under State law.

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

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

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

21 (A) in subsection (a), in the first sentence,  
22 by striking “The Secretary” and inserting  
23 “Subject to subsection (h), the Secretary”; and

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

1 “(h) SUNSET OF PROGRAM.—

2 “(1) IN GENERAL.—The program shall not  
3 apply to applicable drugs dispensed on or after Jan-  
4 uary 1, 2024, and, subject to paragraph (2), agree-  
5 ments under this section shall be terminated as of  
6 such date.

7 “(2) CONTINUED APPLICATION FOR APPLICA-  
8 BLE DRUGS DISPENSED PRIOR TO SUNSET.—The  
9 provisions of this section (including all responsibil-  
10 ities and duties) shall continue to apply after Janu-  
11 ary 1, 2024, with respect to applicable drugs dis-  
12 pensed prior to such date.”.

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

17 (A) in subsection (b)(2)(C)(iii)—

18 (i) by striking “assumptions regarding  
19 the reinsurance” and inserting “an actu-  
20 arial valuation of—

21 “(I) the reinsurance”; and

22 (ii) by adding at the end the fol-  
23 lowing:

24 “(II) for 2024 and each subse-  
25 quent year, the manufacturer dis-

1 counts provided under section 1860D–  
 2 14B subtracted from the actuarial  
 3 value to produce such bid; and”; and  
 4 (B) in subsection (c)(1)(C)—

5 (i) by striking “an actuarial valuation  
 6 of the reinsurance” and inserting “an ac-  
 7 tuarial valuation of—

8 “(i) the reinsurance”;

9 (ii) in clause (i), as added by clause  
 10 (i) of this subparagraph, by adding “and”  
 11 at the end; and

12 (iii) by adding at the end the fol-  
 13 lowing:

14 “(ii) for 2024 and each subsequent  
 15 year, the manufacturer discounts provided  
 16 under section 1860D–14B;”.

17 (4) CLARIFICATION REGARDING EXCLUSION OF  
 18 MANUFACTURER DISCOUNTS FROM TROOP.—Section  
 19 1860D–2(b)(4) of the Social Security Act (42  
 20 U.S.C. 1395w–102(b)(4)) is amended—

21 (A) in subparagraph (C), by inserting “and  
 22 subject to subparagraph (F)” after “subpara-  
 23 graph (E)”; and

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

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

6           (d) DETERMINATION OF ALLOWABLE REINSURANCE  
 7           COSTS.—Section 1860D–15(b) of the Social Security Act  
 8           (42 U.S.C. 1395w–115(b)) is amended—

9           (1) in paragraph (2)—

10           (A) by striking “COSTS.—For purposes”  
 11           and inserting: “COSTS.—

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

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

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

1 (2) in paragraph (3)—

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

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

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

14 “(3) UPDATING RISK ADJUSTMENT METH-  
15 ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA-  
16 TION REDESIGN.—The Secretary shall update the  
17 risk adjustment methodologies used to adjust bid  
18 amounts pursuant to this subsection as appropriate  
19 to take into account changes in benefits under this  
20 part pursuant to the amendments made by section  
21 2 of the Seniors Prescription Drug Relief Act.”.

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

25 (1) in subsection (a)—

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

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

5 (C) by adding at the end the following new  
6 paragraphs:

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

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

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

17 (2) by striking subsection (b) and inserting the  
18 following:

19 “(b) EFFECTIVE DATE.—Paragraphs (1) through (3)  
20 of subsection (a) shall apply to covered part D drugs dis-  
21 pensed under this part on or after January 1, 2011, and  
22 before January 1, 2024, and paragraphs (4) through (6)  
23 of such subsection shall apply to covered part D drugs  
24 dispensed on or after January 1, 2024.”; and

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

3           “(2) the Secretary determines that in the period  
4           beginning on January 1, 2011, and ending on De-  
5           cember 31, 2011 (with respect to paragraphs (1)  
6           through (3) of subsection (a)), or the period begin-  
7           ning on January 1, 2024, and ending December 31,  
8           2024 (with respect to paragraphs (4) through (6) of  
9           such subsection), there were extenuating cir-  
10          cumstances.”.

11          (g) CONFORMING AMENDMENTS.—

12           (1) Section 1860D–2 of the Social Security Act  
13          (42 U.S.C. 1395w–102) is amended—

14           (A) in subsection (a)(2)(A)(i)(I), by strik-  
15           ing “, or an increase in the initial” and insert-  
16           ing “or for a year preceding 2024 an increase  
17           in the initial”;

18           (B) in subsection (c)(1)(C)—

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

22           (ii) by inserting “for a year preceding  
23           2024 or the annual out-of-pocket threshold  
24           specified in subsection (b)(4)(B) for the  
25           year for 2024 and each subsequent year”

1 after “subsection (b)(3) for the year” each  
 2 place it appears; and

3 (C) in subsection (d)(1)(A), by striking “or  
 4 an initial” and inserting “or for a year pre-  
 5 ceding 2024 an initial”.

6 (2) Section 1860D–4(a)(4)(B)(i) of the Social  
 7 Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is  
 8 amended by striking “the initial” and inserting “for  
 9 a year preceding 2024, the initial”.

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

12 (A) in paragraph (1)—

13 (i) in subparagraph (C), by striking  
 14 “The continuation” and inserting “For a  
 15 year preceding 2024, the continuation”;

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

19 (iii) in subparagraph (E), by striking  
 20 “The elimination” and inserting “For a  
 21 year preceding 2024, the elimination”; and

22 (B) in paragraph (2)—

23 (i) in subparagraph (C), by striking  
 24 “The continuation” and inserting “For a



1 year preceding 2024, the continuation”;  
 2 and

3 (ii) in subparagraph (E)—

4 (I) by inserting “for a year pre-  
 5 ceding 2024,” after “subsection (c)”;  
 6 and

7 (II) by striking “1860D-  
 8 2(b)(4)(A)(i)(I)” and inserting  
 9 “1860D-2(b)(4)(A)(i)(I)(aa)”.

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

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

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

19 “(i) for years prior to 2024, any dis-  
 20 count”;

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

24 (C) by adding at the end the following new  
 25 clause:

1 “(ii) for 2024 and each subsequent  
 2 year, any discount provided pursuant to  
 3 section 1860D–14B.”.

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

6 (A) by inserting “for a year before 2024”  
 7 after “1860D–2(b)(3)”; and

8 (B) by inserting “for such year” before the  
 9 period.

10 (h) EFFECTIVE DATE.—The amendments made by  
 11 this section shall apply to plan year 2024 and subsequent  
 12 plan years.

13 **SEC. 210. PUBLIC DISCLOSURE OF DRUG DISCOUNTS AND**  
 14 **OTHER PHARMACY BENEFIT MANAGER (PBM)**  
 15 **PROVISIONS.**

16 (a) PUBLIC DISCLOSURE OF DRUG DISCOUNTS.—

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

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

22 (B) by adding at the end the following new  
 23 subsection:

24 “(e) PUBLIC AVAILABILITY OF CERTAIN INFORMA-  
 25 TION.—

1           “(1) IN GENERAL.—Subject to paragraphs (2)  
2           and (3), in order to allow patients and employers to  
3           compare PBMs’ ability to negotiate rebates, dis-  
4           counts, and price concessions and the amount of  
5           such rebates, discounts, and price concessions that  
6           are passed through to plan sponsors, not later than  
7           July 1, 2025, the Secretary shall make available on  
8           the Internet website of the Department of Health  
9           and Human Services the information provided to the  
10          Secretary and described in paragraphs (2) and (3)  
11          of subsection (b) with respect to each PBM.

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

16          “(3) CONFIDENTIALITY.—The Secretary shall  
17          ensure that such information is displayed in a man-  
18          ner that prevents the disclosure of information on  
19          rebates, discounts, and price concessions with re-  
20          spect to an individual drug or an individual PDP  
21          sponsor, MA organization, or qualified health bene-  
22          fits plan.”.

23          (2) EFFECTIVE DATE.—The amendment made  
24          by paragraph (1)(A) shall take effect on January 1,  
25          2025.

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

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

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

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

10 “(B) AUDITS OF PHARMACY BENEFIT  
11 MANAGERS BY PDP SPONSORS AND MA ORGANI-  
12 ZATIONS.—

13 “(i) IN GENERAL.—Beginning Janu-  
14 ary 1, 2025, in order to ensure that—

15 “(I) contracting terms between a  
16 PDP sponsor offering a prescription  
17 drug plan or an MA organization of-  
18 fering an MA–PD plan and its con-  
19 tracted or owned pharmacy benefit  
20 manager are met; and

21 “(II) the PDP sponsor and MA  
22 organization can account for the cost  
23 of each covered part D drug net of all  
24 direct and indirect remuneration,

1 the PDP sponsor or MA organization shall  
2 conduct financial audits.

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

5 “(I) be conducted by an inde-  
6 pendent third party; and

7 “(II) account and reconcile flows  
8 of funds that determine the net cost  
9 of covered part D drugs, including di-  
10 rect and indirect remuneration from  
11 drug manufacturers and pharmacies  
12 or provided to pharmacies.

13 “(iii) REBATE AGREEMENTS.—A PDP  
14 sponsor and an MA organization shall re-  
15 quire pharmacy benefit managers to make  
16 rebate contracts with drug manufacturers  
17 made on their behalf available under audits  
18 described in clause (i).

19 “(iv) CONFIDENTIALITY AGREE-  
20 MENTS.—Audits described in clause (i)  
21 shall be subject to confidentiality agree-  
22 ments to prevent, except as required under  
23 clause (vii), the redisclosure of data trans-  
24 mitted under the audit.

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

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

14          “(vii) SUBMISSION OF AUDIT REPORTS  
15          TO THE SECRETARY.—

16               “(I) IN GENERAL.—A PDP spon-  
17               sor and an MA organization shall sub-  
18               mit to the Secretary the final report  
19               on any audit conducted under clause  
20               (i) within 30 days of the PDP sponsor  
21               or MA organization receiving the re-  
22               port from the independent third party  
23               conducting the audit.

24               “(II) REVIEW.—The Secretary  
25               shall review final reports submitted

1 under clause (i) to determine the ex-  
2 tent to which the goals specified in  
3 subclauses (I) and (II) of subpara-  
4 graph (B)(i) are met.

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

13 “(viii) NOTICE OF NONCOMPLI-  
14 ANCE.—A PDP sponsor and an MA orga-  
15 nization shall notify the Secretary if any  
16 pharmacy benefit manager is not com-  
17 plying with requests for access to informa-  
18 tion required under an audit under clause  
19 (i).

20 “(ix) CIVIL MONETARY PENALTIES.—

21 “(I) IN GENERAL.—Subject to  
22 subclause (II), if the Secretary deter-  
23 mines that a PDP sponsor or an MA  
24 organization has failed to conduct an  
25 audit under clause (i), the Secretary

1                   may impose a civil monetary penalty  
 2                   of not more than \$10,000 for each  
 3                   day of such noncompliance.

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

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

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

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

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

23                               “(B) TO PHARMACIES.—

24                                       “(i) IN GENERAL.—For plan year  
 25                  2025 and subsequent plan years, a PDP



1 sponsor offering a prescription drug plan  
2 and an MA organization offering an MA-  
3 PD plan shall report any pharmacy price  
4 concession or incentive payment that oc-  
5 curs with respect to a pharmacy after pay-  
6 ment for covered part D drugs at the  
7 point-of-sale, including by an intermediary  
8 organization with which a PDP sponsor or  
9 MA organization has contracted, to the  
10 pharmacy.

11 “(ii) TIMING.—The reporting of price  
12 concessions and incentive payments to a  
13 pharmacy under clause (i) shall be made  
14 on a periodic basis (but in no case less fre-  
15 quently than annually).

16 “(iii) CLAIM LEVEL.—The reporting  
17 of price concessions and incentive pay-  
18 ments to a pharmacy under clause (i) shall  
19 be at the claim level or approximated at  
20 the claim level if the price concession or in-  
21 centive payment was applied at a level  
22 other than at the claim level.”.

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

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

5                   “(iii) DISCLOSURE OF CONFLICTS OF  
6                   INTEREST.—With respect to plan year  
7                   2025 and subsequent plan years, a PDP  
8                   sponsor of a prescription drug plan and an  
9                   MA organization offering an MA–PD plan  
10                  shall, as part of its bid submission under  
11                  section 1860D–11(b), provide the Sec-  
12                  retary with a completed statement of fi-  
13                  nancial conflicts of interest, including with  
14                  manufacturers, from each member of any  
15                  pharmacy and therapeutic committee used  
16                  by the sponsor or organization pursuant to  
17                  this paragraph.”.

18           (2) INCLUSION IN BID.—Section 1860D–  
19       11(b)(2) of the Social Security Act (42 U.S.C.  
20       1395w–111(b)(2)) is amended—

21                   (A) by redesignating subparagraph (F) as  
22                   subparagraph (G); and

23                   (B) by inserting after subparagraph (E)  
24       the following new subparagraph:

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

4                   (e) INFORMATION ON DIRECT AND INDIRECT REMU-  
5                   NERATION REQUIRED TO BE INCLUDED IN BID.—Section  
6                   1860D–11(b) of the Social Security Act (42 U.S.C.  
7                   1395w–111(b)) is amended—

8                   (1) in paragraph (1), by adding at the end the  
9                   following new sentence: “With respect to actual  
10                  amounts of direct and indirect remuneration sub-  
11                  mitted pursuant to clause (v) of paragraph (2), such  
12                  amounts shall be consistent with data reported to  
13                  the Secretary in a prior year.”; and

14                  (2) in paragraph (2)(C)—

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

17                         (B) in clause (iv), by striking the period at  
18                         the end and inserting the following: “, and, with  
19                         respect to plan year 2025 and subsequent plan  
20                         years, actual and projected administrative ex-  
21                         penses assumed in the bid, categorized by the  
22                         type of such expense, including actual and pro-  
23                         jected price concessions retained by a pharmacy  
24                         benefit manager; and”; and

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

3 “(v) with respect to plan year 2025  
 4 and subsequent plan years, actual and pro-  
 5 jected direct and indirect remuneration,  
 6 categorized as received from each of the  
 7 following:

8 “(I) A pharmacy.

9 “(II) A manufacturer.

10 “(III) A pharmacy benefit man-  
 11 ager.

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

14 **SEC. 211. PUBLIC DISCLOSURE OF DIRECT AND INDIRECT**  
 15 **REMUNERATION REVIEW AND AUDIT RE-**  
 16 **SULTS.**

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

20 “(e) PUBLIC DISCLOSURE OF DIRECT AND INDIRECT  
 21 REMUNERATION REVIEW AND FINANCIAL AUDIT RE-  
 22 SULTS.—

23 “(1) DIR REVIEW RESULTS.—

24 “(A) IN GENERAL.—Except as provided in  
 25 subparagraph (B), in 2023 and each subse-

1           quent year, the Secretary shall make available  
2           to the public on the Internet website of the  
3           Centers for Medicare & Medicaid Services infor-  
4           mation on discrepancies related to summary  
5           and detailed DIR reports submitted by PDP  
6           sponsors pursuant to section 1860D–15 across  
7           all prescription drug plans based on the most  
8           recent data available. Information made avail-  
9           able under this subparagraph shall include the  
10          following:

11                   “(i) The number of potential errors  
12                   identified by the Secretary for PDP spon-  
13                   sors to review.

14                   “(ii) The extent to which PDP spon-  
15                   sors resubmitted DIR reports to make  
16                   changes for previous contract years.

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

20                   “(B) EXCLUSION OF CERTAIN SUBMIS-  
21                   SIONS IN CALCULATION.—The Secretary shall  
22                   exclude any information in DIR reports sub-  
23                   mitted with respect to PACE programs under  
24                   section 1894 (pursuant to section 1860D–21(f))  
25                   and qualified retiree prescription drug plans (as

1 defined in section 1860D–22(a)(2)) from the  
2 information that is made available to the public  
3 under subparagraph (A).

4 “(2) FINANCIAL AUDIT RESULTS.—In 2023 and  
5 each subsequent year, the Secretary shall make  
6 available to the public on the Internet website of the  
7 Centers for Medicare & Medicaid Services the results  
8 of DIR audits required under section 1860D–  
9 12(b)(3)(C). Information made available under this  
10 paragraph shall include the following:

11 “(A) With respect to the year, the number  
12 of PDP sponsors that received each of the fol-  
13 lowing:

14 “(i) A notice of observations or find-  
15 ings that required the sponsor to make  
16 DIR report corrections.

17 “(ii) An unqualified audit opinion that  
18 renders the audit closed.

19 “(iii) A qualified audit opinion that  
20 requires the sponsor to submit a corrective  
21 action plan to the Secretary.

22 “(iv) An adverse opinion, with a de-  
23 scription of the types of actions that the  
24 Secretary takes when issuing an adverse  
25 opinion.

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

2 “(i) The number of PDP sponsors  
3 that reopened a previously closed reconcili-  
4 ation as a result of an audit, including as  
5 a result of DIR changes.

6 “(ii) The extent to which the Sec-  
7 retary recouped an overpayment or made  
8 an underpayment as a result of a reopen-  
9 ing of a previously closed reconciliation.

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

15 **SEC. 212. IMPROVEMENTS TO PROVISION OF PARTS A AND**  
16 **B CLAIMS DATA TO PRESCRIPTION DRUG**  
17 **PLANS.**

18 (a) DATA USE.—

19 (1) IN GENERAL.—Paragraph (6) of section  
20 1860D–4(c) of the Social Security Act (42 U.S.C.  
21 1395w–104(c)), as added by section 50354 of divi-  
22 sion E of the Bipartisan Budget Act of 2018 (Public  
23 Law 115–123), relating to providing prescription  
24 drug plans with parts A and B claims data to pro-

1       mote the appropriate use of medications and im-  
 2       prove health outcomes, is amended—

3               (A) in subparagraph (B)—

4                   (i) by redesignating clauses (i), (ii),  
 5                   and (iii) as subclauses (I), (II), and (III),  
 6                   respectively, and moving such subclauses 2  
 7                   ems to the right;

8                   (ii) by striking “PURPOSES.—A PDP  
 9                   sponsor” and inserting “PURPOSES.—

10                   “(i) IN GENERAL.—A PDP sponsor.”;  
 11                   and

12                   (iii) by adding at the end the fol-  
 13                   lowing new clause:

14                   “(ii) CLARIFICATION.—The limitation  
 15                   on data use under subparagraph (C)(i)  
 16                   shall not apply to the extent that the PDP  
 17                   sponsor is using the data provided to carry  
 18                   out any of the purposes described in clause  
 19                   (i).”; and

20               (B) in subparagraph (C)(i), by striking  
 21               “To inform” and inserting “Subject to subpara-  
 22               graph (B)(ii), to inform”.

23               (2) EFFECTIVE DATE.—The amendments made  
 24       by this subsection shall apply to plan years begin-  
 25       ning on or after January 1, 2025.



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

3 (1) by striking “DESCRIBED.—The data de-  
4 scribed in this clause” and inserting “DESCRIBED.—  
5 “(i) IN GENERAL.—The data de-  
6 scribed in this subparagraph”; and

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

9 “(ii) MANNER OF PROVISION.—  
10 “(I) IN GENERAL.—Such data  
11 may be provided pursuant to this  
12 paragraph in the same manner as  
13 data under the Part D Enhanced  
14 Medication Therapy Management  
15 model tested under section 1115A,  
16 through Application Programming  
17 Interface, or in another manner as de-  
18 termined by the Secretary.

19 “(II) IMPLEMENTATION.—Not-  
20 withstanding any other provision of  
21 law, the Secretary may implement this  
22 clause by program instruction or oth-  
23 erwise.”.

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

1 **SEC. 213. MEDICARE PART D REBATE BY MANUFACTURERS.**

2 (a) IN GENERAL.—Part D of title XVIII of the Social  
3 Security Act is amended by inserting after section 1860D–  
4 14A (42 U.S.C. 1395w–114a) the following new section:

5 **“SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN**  
6 **DRUGS WITH PRICES INCREASING FASTER**  
7 **THAN INFLATION.**

8 “(a) IN GENERAL.—

9 “(1) IN GENERAL.—Subject to the provisions of  
10 this section, in order for coverage to be available  
11 under this part for a part D rebatable drug (as de-  
12 fined in subsection (h)(1)) of a manufacturer (as de-  
13 fined in section 1927(k)(5)) dispensed during an ap-  
14 plicable year, the manufacturer must have entered  
15 into and have in effect an agreement described in  
16 subsection (b).

17 “(2) AUTHORIZING COVERAGE FOR DRUGS NOT  
18 COVERED UNDER AGREEMENTS.—Paragraph (1)  
19 shall not apply to the dispensing of a covered part  
20 D drug if—

21 “(A) the Secretary has made a determina-  
22 tion that the availability of the drug is essential  
23 to the health of beneficiaries under this part; or

24 “(B) the Secretary determines that in the  
25 period beginning on January 1, 2025, and end-

1           ing on December 31, 2025, there were extenu-  
2           ating circumstances.

3           “(3) APPLICABLE YEAR.—For purposes of this  
4           section the term ‘applicable year’ means a year be-  
5           ginning with 2025.

6           “(b) AGREEMENTS.—

7           “(1) TERMS OF AGREEMENT.—An agreement  
8           described in this subsection, with respect to a manu-  
9           facturer of a part D rebatable drug, is an agreement  
10          under which the following shall apply:

11           “(A) SECRETARIAL PROVISION OF INFOR-  
12          MATION.—Not later than 9 months after the  
13          end of each applicable year with respect to  
14          which the agreement is in effect, the Secretary,  
15          for each part D rebatable drug of the manufac-  
16          turer, shall report to the manufacturer the fol-  
17          lowing for such year:

18           “(i) Information on the total number  
19          of units (as defined in subsection (h)(2))  
20          for each dosage form and strength with re-  
21          spect to such part D rebatable drug and  
22          year.

23           “(ii) Information on the amount (if  
24          any) of the excess average manufacturer  
25          price increase described in subsection

1 (c)(1)(B) for each dosage form and  
2 strength with respect to such drug and  
3 year.

4 “(iii) The rebate amount specified  
5 under subsection (c) for each dosage form  
6 and strength with respect to such drug and  
7 year.

8 “(B) MANUFACTURER REQUIREMENTS.—  
9 For each applicable year with respect to which  
10 the agreement is in effect, the manufacturer of  
11 the part D rebatable drug, for each dosage  
12 form and strength with respect to such drug,  
13 not later than 30 days after the date of receipt  
14 from the Secretary of the information described  
15 in subparagraph (A) for such year, shall pro-  
16 vide to the Secretary a rebate that is equal to  
17 the amount specified in subsection (c) for such  
18 dosage form and strength with respect to such  
19 drug for such year.

20 “(2) LENGTH OF AGREEMENT.—

21 “(A) IN GENERAL.—An agreement under  
22 this section, with respect to a part D rebatable  
23 drug, shall be effective for an initial period of  
24 not less than one year and shall be automati-  
25 cally renewed for a period of not less than one

1 year unless terminated under subparagraph  
2 (B).

3 “(B) TERMINATION.—

4 “(i) BY SECRETARY.—The Secretary  
5 may provide for termination of an agree-  
6 ment under this section for violation of the  
7 requirements of the agreement or other  
8 good cause shown. Such termination shall  
9 not be effective earlier than 30 days after  
10 the date of notice of such termination. The  
11 Secretary shall provide, upon request, a  
12 manufacturer with a hearing concerning  
13 such a termination, but such hearing shall  
14 not delay the effective date of the termi-  
15 nation.

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

21 “(I) if the termination occurs be-  
22 fore January 30 of the plan year, as  
23 of the day after the end of the plan  
24 year; and

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

5                   “(C) EFFECTIVENESS OF TERMINATION.—  
6                   Any termination under this paragraph shall not  
7                   affect rebates due under the agreement under  
8                   this section before the effective date of its ter-  
9                   mination.

10                  “(D) DELAY BEFORE REENTRY.—In the  
11                  case of any agreement under this section with  
12                  a manufacturer that is terminated in a plan  
13                  year, the Secretary may not enter into another  
14                  such agreement with the manufacturer (or a  
15                  successor manufacturer) before the subsequent  
16                  plan year, unless the Secretary finds good cause  
17                  for an earlier reinstatement of such an agree-  
18                  ment.

19                  “(c) REBATE AMOUNT.—

20                  “(1) IN GENERAL.—For purposes of this sec-  
21                  tion, the amount specified in this subsection for a  
22                  dosage form and strength with respect to a part D  
23                  rebtable drug and applicable year is, subject to sub-  
24                  paragraphs (B) and (C) of paragraph (5), the  
25                  amount equal to the product of—

1 “(A) the total number of units of such dos-  
 2 age form and strength with respect to such part  
 3 D rebatable drug and year; and

4 “(B) the amount (if any) by which—

5 “(i) the annual manufacturer price  
 6 (as determined in paragraph (2)) paid for  
 7 such dosage form and strength with re-  
 8 spect to such part D rebatable drug for the  
 9 year; exceeds

10 “(ii) the inflation-adjusted payment  
 11 amount determined under paragraph (3)  
 12 for such dosage form and strength with re-  
 13 spect to such part D rebatable drug for the  
 14 year.

15 “(2) DETERMINATION OF ANNUAL MANUFAC-  
 16 Turer PRICE.—The annual manufacturer price de-  
 17 termined under this paragraph for a dosage form  
 18 and strength, with respect to a part D rebatable  
 19 drug and an applicable year, is the sum of the prod-  
 20 ucts of—

21 “(A) the average manufacturer price (as  
 22 defined in subsection (h)(6)) of such dosage  
 23 form and strength, as calculated for a unit of  
 24 such drug, with respect to each of the calendar  
 25 quarters of such year; and

1 “(B) the ratio of—

2 “(i) the total number of units of such  
3 dosage form and strength dispensed during  
4 each such calendar quarter of such year; to

5 “(ii) the total number of units of such  
6 dosage form and strength dispensed during  
7 such year.

8 “(3) DETERMINATION OF INFLATION-ADJUSTED  
9 PAYMENT AMOUNT.—The inflation-adjusted payment  
10 amount determined under this paragraph for a dos-  
11 age form and strength with respect to a part D  
12 rebatable drug for an applicable year, subject to sub-  
13 paragraphs (A) and (D) of paragraph (5), is—

14 “(A) the benchmark year manufacturer  
15 price determined under paragraph (4) for such  
16 dosage form and strength with respect to such  
17 drug and an applicable year; increased by

18 “(B) the percentage by which the applica-  
19 ble year CPI-U (as defined in subsection  
20 (h)(5)) for the applicable year exceeds the  
21 benchmark period CPI-U (as defined in sub-  
22 section (h)(4)).

23 “(4) DETERMINATION OF BENCHMARK YEAR  
24 MANUFACTURER PRICE.—The benchmark year man-  
25 ufacturer price determined under this paragraph for



1 a dosage form and strength, with respect to a part  
 2 D rebatable drug and an applicable year, is the sum  
 3 of the products of—

4 “(A) the average manufacturer price (as  
 5 defined in subsection (h)(6)) of such dosage  
 6 form and strength, as calculated for a unit of  
 7 such drug, with respect to each of the calendar  
 8 quarters of the payment amount benchmark  
 9 year (as defined in subsection (h)(3)); and

10 “(B) the ratio of—

11 “(i) the total number of units of such  
 12 dosage form and strength dispensed during  
 13 each such calendar quarter of such pay-  
 14 ment amount benchmark year; to

15 “(ii) the total number of units of such  
 16 dosage form and strength dispensed during  
 17 such payment amount benchmark year.

18 “(5) SPECIAL TREATMENT OF CERTAIN DRUGS  
 19 AND EXEMPTION.—

20 “(A) SUBSEQUENTLY APPROVED DRUGS.—

21 In the case of a part D rebatable drug first ap-  
 22 proved or licensed by the Food and Drug Ad-  
 23 ministration after January 1, 2016, subpara-  
 24 graphs (A) and (B) of paragraph (4) shall be  
 25 applied as if the term ‘payment amount bench-

mark year’ were defined under subsection (h)(3) as the first calendar year beginning after the day on which the drug was first marketed by any manufacturer and subparagraph (B) of paragraph (3) shall be applied as if the term ‘benchmark period CPI-U’ were defined under subsection (h)(4) as if the reference to ‘January 2016’ under such subsection were a reference to ‘January of the first year beginning after the date on which the drug was first marketed by any manufacturer’.

“(B) EXEMPTION FOR SHORTAGES.—The Secretary may reduce or waive the rebate under paragraph (1) with respect to a part D rebatable drug that is described as currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act or in the case of other exigent circumstances, as determined by the Secretary.

“(C) TREATMENT OF NEW FORMULATIONS.—

“(i) IN GENERAL.—In the case of a part D rebatable drug that is a line extension of a part D rebatable drug that is an oral solid dosage form, the Secretary shall

1 establish a formula for determining the  
2 amount specified in this subsection with  
3 respect to such part D rebatable drug and  
4 an applicable year with consideration of  
5 the original part D rebatable drug.

6 “(ii) LINE EXTENSION DEFINED.—In  
7 this subparagraph, the term ‘line exten-  
8 sion’ means, with respect to a part D  
9 rebatable drug, a new formulation of the  
10 drug (as determined by the Secretary),  
11 such as an extended release formulation,  
12 but does not include an abuse-deterrent  
13 formulation of the drug (as determined by  
14 the Secretary), regardless of whether such  
15 abuse-deterrent formulation is an extended  
16 release formulation.

17 “(D) SELECTED DRUGS.—In the case of a  
18 part D rebatable drug that is a selected drug  
19 (as defined in section 1192(c)) for a price appli-  
20 cability period (as defined in section  
21 1191(b)(2))—

22 “(i) for plan years during such period  
23 for which a maximum fair price (as defined  
24 in section 1191(c)(2)) for such drug has  
25 been determined and is applied under part

1 E of title XI, the rebate under subsection  
2 (b)(1)(B) shall be waived; and

3 “(ii) in the case such drug is deter-  
4 mined (pursuant to such section 1192(c))  
5 to no longer be a selected drug, for each  
6 applicable year beginning after the price  
7 applicability period with respect to such  
8 drug, subparagraphs (A) and (B) of para-  
9 graph (4) shall be applied as if the term  
10 ‘payment amount benchmark year’ were  
11 defined under subsection (h)(3) as the last  
12 year beginning during such price applica-  
13 bility period with respect to such selected  
14 drug and subparagraph (B) of paragraph  
15 (3) shall be applied as if the term ‘bench-  
16 mark period CPI–U’ were defined under  
17 subsection (h)(4) as if the reference to  
18 ‘January 2016’ under such subsection were  
19 a reference to January of the last year be-  
20 ginning during such price applicability pe-  
21 riod with respect to such drug.

22 “(d) REBATE DEPOSITS.—Amounts paid as rebates  
23 under subsection (c) shall be deposited into the Medicare  
24 Prescription Drug Account in the Federal Supplementary

1 Medical Insurance Trust Fund established under section  
2 1841.

3 “(e) INFORMATION.—For purposes of carrying out  
4 this section, the Secretary shall use information submitted  
5 by manufacturers under section 1927(b)(3).

6 “(f) CIVIL MONEY PENALTY.—In the case of a man-  
7 ufacturer of a part D rebatable drug with an agreement  
8 in effect under this section who has failed to comply with  
9 the terms of the agreement under subsection (b)(1)(B)  
10 with respect to such drug for an applicable year, the Sec-  
11 retary may impose a civil money penalty on such manufac-  
12 turer in an amount equal to 125 percent of the amount  
13 specified in subsection (c) for such drug for such year.  
14 The provisions of section 1128A (other than subsections  
15 (a) (with respect to amounts of penalties or additional as-  
16 sessments) and (b)) shall apply to a civil money penalty  
17 under this subsection in the same manner as such provi-  
18 sions apply to a penalty or proceeding under section  
19 1128A(a).

20 “(g) JUDICIAL REVIEW.—There shall be no judicial  
21 review of the following:

22 “(1) The determination of units under this sec-  
23 tion.

24 “(2) The determination of whether a drug is a  
25 part D rebatable drug under this section.

1           “(3) The calculation of the rebate amount  
2           under this section.

3           “(h) DEFINITIONS.—In this section:

4           “(1) PART D REBATABLE DRUG DEFINED.—

5           “(A) IN GENERAL.—The term ‘part D  
6           rebtable drug’ means a drug or biological that  
7           would (without application of this section) be a  
8           covered part D drug, except such term shall,  
9           with respect to an applicable year, not include  
10          such a drug or biological if the average annual  
11          total cost under this part for such year per in-  
12          dividual who uses such a drug or biological, as  
13          determined by the Secretary, is less than, sub-  
14          ject to subparagraph (B), \$100, as determined  
15          by the Secretary using the most recent data  
16          available or, if data is not available, as esti-  
17          mated by the Secretary.

18          “(B) INCREASE.—The dollar amount ap-  
19          plied under subparagraph (A)—

20                 “(i) for 2026, shall be the dollar  
21                 amount specified under such subparagraph  
22                 for 2025, increased by the percentage in-  
23                 crease in the consumer price index for all  
24                 urban consumers (United States city aver-

1 age) for the 12-month period beginning  
2 with January of 2025; and

3 “(ii) for a subsequent year, shall be  
4 the dollar amount specified in this sub-  
5 paragraph for the previous year, increased  
6 by the percentage increase in the consumer  
7 price index for all urban consumers  
8 (United States city average) for the 12-  
9 month period beginning with January of  
10 the previous year.

11 Any dollar amount specified under this sub-  
12 paragraph that is not a multiple of \$10 shall be  
13 rounded to the nearest multiple of \$10.

14 “(2) UNIT DEFINED.—The term ‘unit’ means,  
15 with respect to a part D rebatable drug, the lowest  
16 identifiable quantity (such as a capsule or tablet,  
17 milligram of molecules, or grams) of the part D  
18 rebatable drug that is dispensed to individuals under  
19 this part.

20 “(3) PAYMENT AMOUNT BENCHMARK YEAR.—  
21 The term ‘payment amount benchmark year’ means  
22 the year beginning January 1, 2016.

23 “(4) BENCHMARK PERIOD CPI-U.—The term  
24 ‘benchmark period CPI-U’ means the consumer

price index for all urban consumers (United States city average) for January 2016.

“(5) APPLICABLE YEAR CPI-U.—The term ‘applicable year CPI-U’ means, with respect to an applicable year, the consumer price index for all urban consumers (United States city average) for January of such year.

“(6) AVERAGE MANUFACTURER PRICE.—The term ‘average manufacturer price’ has the meaning, with respect to a part D rebatable drug of a manufacturer, given such term in section 1927(k)(1), with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927.”.

(b) CONFORMING AMENDMENTS.—

(1) TO PART B ASP CALCULATION.—Section 1847A(c)(3) of the Social Security Act (42 U.S.C. 1395w–3a(c)(3)), as amended by section 201(c)(1), is further amended by striking “section 1927 or section 1834(x)” and inserting “section 1927, section 1834(x), or section 1860D–14B”.

(2) EXCLUDING PART D DRUG INFLATION REBATE FROM BEST PRICE.—Section 1927(c)(1)(C)(ii)(I) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)), as amended by section 201(c)(2), is further amended by striking “or



1 section 1834(x)” and inserting “, section 1834(x), or  
2 section 1860D–14B”.

3 (3) COORDINATION WITH MEDICAID REBATE IN-  
4 FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)  
5 of the Social Security Act (42 U.S.C. 1396r–  
6 8(b)(3)(D)(i)), as amended by section 201(c)(3), is  
7 further amended by striking “or section 1834(x)”  
8 and inserting “, section 1834(x), or section 1860D–  
9 14B”.

10 **SEC. 214. PROHIBITING BRANDING ON PART D BENEFIT**  
11 **CARDS.**

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

17 (b) EFFECTIVE DATE.—The amendment made by  
18 subsection (a) shall apply to plan years beginning on or  
19 after January 1, 2025.

20 **SEC. 215. REQUIRING PRESCRIPTION DRUG PLANS AND**  
21 **MA-PD PLANS TO REPORT POTENTIAL**  
22 **FRAUD, WASTE, AND ABUSE TO THE SEC-**  
23 **RETARY OF HHS.**

24 Section 1860D–4 of the Social Security Act (42  
25 U.S.C. 1395w–104), as amended by section 225, is

1 amended by adding at the end the following new sub-  
2 section:

3 “(p) REPORTING POTENTIAL FRAUD, WASTE, AND  
4 ABUSE.—Beginning January 1, 2024, the PDP sponsor  
5 of a prescription drug plan shall report to the Secretary,  
6 as specified by the Secretary—

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

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

14 **SEC. 216. ESTABLISHMENT OF PHARMACY QUALITY MEAS-**  
15 **URES UNDER MEDICARE PART D.**

16 Section 1860D–4(c) of the Social Security Act (42  
17 U.S.C. 1395w–104(c)), as amended by section 226, is  
18 amended by adding at the end the following new para-  
19 graph:

20 “(8) APPLICATION OF PHARMACY QUALITY  
21 MEASURES.—

22 “(A) IN GENERAL.—A PDP sponsor that  
23 implements incentive payments to a pharmacy  
24 or price concessions paid by a pharmacy based  
25 on quality measures shall use measures estab-

1           lished or approved by the Secretary under sub-  
2           paragraph (B) with respect to payment for cov-  
3           ered part D drugs dispensed by such pharmacy.

4           “(B) STANDARD PHARMACY QUALITY  
5           MEASURES.—The Secretary shall establish or  
6           approve standard quality measures from a con-  
7           sensus and evidence-based organization for pay-  
8           ments described in subparagraph (A). Such  
9           measures shall focus on patient health outcomes  
10          and be based on proven criteria measuring  
11          pharmacy performance.

12          “(C) EFFECTIVE DATE.—The requirement  
13          under subparagraph (A) shall take effect for  
14          plan years beginning on or after January 1,  
15          2026, or such earlier date specified by the Sec-  
16          retary if the Secretary determines there are suf-  
17          ficient measures established or approved under  
18          subparagraph (B) to meet the requirement  
19          under subparagraph (A).”.

1 **SEC. 217. ADDITION OF NEW MEASURES BASED ON ACCESS**  
2 **TO BIOSIMILAR BIOLOGICAL PRODUCTS TO**  
3 **THE 5-STAR RATING SYSTEM UNDER MEDI-**  
4 **CARE ADVANTAGE.**

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

8 “(E) ADDITION OF NEW MEASURES BASED  
9 ON ACCESS TO BIOSIMILAR BIOLOGICAL PROD-  
10 UCTS.—

11 “(i) IN GENERAL.—For 2028 and  
12 subsequent years, the Secretary shall add a  
13 new set of measures to the 5-star rating  
14 system based on access to biosimilar bio-  
15 logical products covered under part B and,  
16 in the case of MA–PD plans, such prod-  
17 ucts that are covered part D drugs. Such  
18 measures shall assess the impact a plan’s  
19 benefit structure may have on enrollees’  
20 utilization of or ability to access biosimilar  
21 biological products, including in compari-  
22 son to the reference biological product, and  
23 shall include measures, as applicable, with  
24 respect to the following:

25 “(I) COVERAGE.—Assessing  
26 whether a biosimilar biological prod-

1 uct is on the plan formulary in lieu of  
2 or in addition to the reference biological  
3 cal product.

4 “(II) PREFERENCING.—Assess-  
5 ing tier placement or cost-sharing for  
6 a biosimilar biological product relative  
7 to the reference biological product.

8 “(III) UTILIZATION MANAGE-  
9 MENT TOOLS.—Assessing whether and  
10 how utilization management tools are  
11 used with respect to a biosimilar bio-  
12 logical product relative to the ref-  
13 erence biological product.

14 “(IV) UTILIZATION.—Assessing  
15 the percentage of enrollees prescribed  
16 the biosimilar biological product and  
17 the percentage of enrollees prescribed  
18 the reference biological product when  
19 the reference biological product is also  
20 on the plan formulary.

21 “(ii) DEFINITIONS.—In this subpara-  
22 graph, the terms ‘biosimilar biological  
23 product’ and ‘reference biological product’  
24 have the meaning given those terms in sec-  
25 tion 1847A(c)(6).

1 “(iii) PROTECTING PATIENT INTER-  
2 ESTS.—In developing such measures, the  
3 Secretary shall ensure that each measure  
4 developed to address coverage,  
5 preferencing, or utilization management is  
6 constructed such that patients retain ac-  
7 cess to appropriate therapeutic options  
8 without undue administrative burden.”.

9 (b) CLARIFICATION REGARDING APPLICATION TO  
10 PRESCRIPTION DRUG PLANS.—To the extent the Sec-  
11 retary of Health and Human Services applies the 5-star  
12 rating system under section 1853(o)(4) of the Social Secu-  
13 rity Act (42 U.S.C. 1395w–23(o)(4)), or a similar system,  
14 to prescription drug plans under part D of title XVIII of  
15 such Act, the provisions of subparagraph (E) of such sec-  
16 tion, as added by subsection (a) of this section, shall apply  
17 under the system with respect to such plans in the same  
18 manner as such provisions apply to the 5-star rating sys-  
19 tem under such section 1853(o)(4).

20 **SEC. 218. HHS STUDY AND REPORT ON THE INFLUENCE OF**  
21 **PHARMACEUTICAL MANUFACTURER THIRD-**  
22 **PARTY REIMBURSEMENT HUBS ON HEALTH**  
23 **CARE PROVIDERS WHO PRESCRIBE THEIR**  
24 **DRUGS AND BIOLOGICALS.**

25 (a) STUDY.—

1           (1) IN GENERAL.—The Secretary of Health and  
2       Human Services (in this section referred to as the  
3       “Secretary”) shall conduct a study on the influence  
4       of pharmaceutical manufacturer distribution models  
5       that provide third-party reimbursement hub services  
6       on health care providers who prescribe the manufac-  
7       turer’s drugs and biologicals, including for Medicare  
8       part D beneficiaries.

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

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

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

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

24           (iii) whether hub services could im-  
25      properly incentivize health care providers

1 to deem a drug or biological as medically  
 2 necessary under section 423.578 of title  
 3 42, Code of Federal Regulations.

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

6 (b) REPORT.—Not later than January 1, 2024, the  
 7 Secretary shall submit to Congress a report on the study  
 8 conducted under subsection (a), together with rec-  
 9 ommendations for such legislation and administrative ac-  
 10 tion as the Secretary determines appropriate.

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

14 **SEC. 219. ESTABLISHING A MONTHLY CAP ON BENEFICIARY**  
 15 **INCURRED COSTS FOR INSULIN PRODUCTS**  
 16 **AND SUPPLIES UNDER A PRESCRIPTION**  
 17 **DRUG PLAN OR MA-PD PLAN.**

18 (a) IN GENERAL.—Section 1860D–2 of the Social  
 19 Security Act (42 U.S.C. 1395w–102), as amended by sec-  
 20 tions 121 and 133, is further amended—

21 (1) in subsection (b)(2)—

22 (A) in subparagraph (A), by striking “and  
 23 (E)” and inserting “(E), and (F)”;

24 (B) in subparagraph (B), by striking “and  
 25 (D)” and inserting “(D), and (F)”; and



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

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

5 “(i) IN GENERAL.—The coverage pro-  
6 vides benefits, for costs above the annual  
7 deductible specified in paragraph (1) and  
8 up to the annual out-of-pocket threshold  
9 described in paragraph (4)(B) and with re-  
10 spect to a month (beginning with January  
11 of 2022), with cost sharing that is equal to  
12 \$0 for a specified covered part D drug (as  
13 defined in clause (iii)) furnished to an indi-  
14 vidual who has incurred costs during such  
15 month with respect to specified covered  
16 part D drugs equal to—

17 “(I) for months occurring in  
18 2022, \$50; or

19 “(II) for months occurring in a  
20 subsequent year, the amount applica-  
21 ble under this clause for months oc-  
22 ccurring in the year preceding such  
23 subsequent year, increased by the an-  
24 nual percentage increase specified in  
25 paragraph (6) for such subsequent

1 year and rounded to the nearest dol-  
2 lar.

3 “(ii) APPLICATION.—The provisions  
4 of clauses (i) through (iii) of paragraph  
5 (4)(C) shall apply with respect to the de-  
6 termination of the incurred costs for speci-  
7 fied covered part D drugs for purposes of  
8 clause (i) in the same manner as such pro-  
9 visions apply with respect to the deter-  
10 mination of incurred costs for covered part  
11 D drugs for purposes of paragraph (4)(A).

12 “(iii) SPECIFIED COVERED PART D  
13 DRUG.—For purposes of this subpara-  
14 graph, the term ‘specified covered part D  
15 drug’ means a covered part D drug that  
16 is—

17 “(I) insulin; or

18 “(II) a medical supply associated  
19 with the injection of insulin (as de-  
20 fined in regulations of the Secretary  
21 promulgated pursuant to subsection  
22 (e)(1)(B)).”; and

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

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

5 (b) CONFORMING AMENDMENTS.—

6 (1) IN GENERAL.—Section 1860D–14(a)(1)(D)  
 7 of the Social Security Act (42 U.S.C. 1395w–  
 8 114(a)(1)(D)), as amended by section 121, is fur-  
 9 ther amended—

10 (A) in clause (ii), by striking “section  
 11 1860D–2(b)(2)” and inserting “section 1860D–  
 12 2(b)(2)(A)”; and

13 (B) in clause (iii), by striking “section  
 14 1860D–2(b)(2)” and inserting “section 1860D–  
 15 2(b)(2)(A)”.

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

19 **SEC. 220. MONTHLY OUT-OF-POCKET COST SHARING MAX-**  
 20 **IMUM FOR ENROLLEES WHO INCUR A SIG-**  
 21 **NIFICANT PORTION OF COSTS TOWARDS AN-**  
 22 **NUAL OUT-OF-POCKET THRESHOLD.**

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

1 (1) in paragraph (2)—

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

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

6 “(E) MONTHLY OUT-OF-POCKET COST  
7 SHARING MAXIMUM FOR ENROLLEES WHO  
8 INCUR A SIGNIFICANT PORTION OF COSTS TO-  
9 WARDS ANNUAL OUT-OF-POCKET THRESH-  
10 OLD.—

11 “(i) ESTABLISHMENT OF PROCESS.—

12 “(I) IN GENERAL.—For plan  
13 years beginning on or after January  
14 1, 2024, the Secretary shall, through  
15 notice and comment rulemaking, es-  
16 tablish a process under which each  
17 PDP sponsor offering a prescription  
18 drug plan and each MA organization  
19 offering an MA–PD plan shall each  
20 plan year automatically enroll applica-  
21 ble enrollees in the option to have  
22 their monthly out-of-pocket cost-shar-  
23 ing under the plan capped and paid in  
24 monthly installments in accordance  
25 with this subparagraph (referred to in

1 this subparagraph as the ‘monthly  
2 out-of-pocket cost sharing maximum  
3 option’).

4 “(II) OPT OUT.—The process es-  
5 tablished under this clause shall per-  
6 mit an applicable enrollee, prior to the  
7 beginning of the plan year or at any  
8 point during the plan year, to opt out  
9 of enrollment in the monthly out-of-  
10 pocket cost sharing maximum option  
11 and pay any out-of-pocket cost-shar-  
12 ing otherwise applicable for any cov-  
13 ered part D drug in full at the time  
14 of the dispensing of such drug (or at  
15 the time of such opt out in the case  
16 of costs incurred during such enroll-  
17 ment that have not yet been billed to  
18 the enrollee).

19 “(ii) DEFINITIONS.—

20 “(I) APPLICABLE ENROLLEE.—  
21 In this subparagraph, the term ‘appli-  
22 cable enrollee’ means any enrollee in a  
23 prescription drug plan or an MA–PD  
24 plan, including an enrollee who is a  
25 subsidy eligible individual (as defined

1 in paragraph (3) of section 1860D–  
2 14(a)), who incurs or is likely to incur  
3 a significant percentage of costs for  
4 covered part D drugs.

5 “(II) SIGNIFICANT PERCENT-  
6 AGE.—For purposes of subclause (I),  
7 the Secretary shall, in the rulemaking  
8 under clause (i), define the term ‘sig-  
9 nificant percentage’ with respect to a  
10 percentage of the annual out-of-pocket  
11 threshold specified in paragraph  
12 (4)(B) but in no case shall the ‘sig-  
13 nificant percentage’ be less than 50  
14 percent or more than 100 percent of  
15 the annual out-of-pocket threshold.

16 “(iii) DETERMINATION OF MONTHLY  
17 OUT-OF-POCKET COST SHARING MAX-  
18 IMUM.—For each month in a plan year in  
19 which an applicable enrollee is enrolled in  
20 the monthly out-of-pocket cost sharing  
21 maximum option, the PDP sponsor or MA  
22 organization shall determine a monthly  
23 out-of-pocket cost sharing maximum (as  
24 defined in clause (v)) for such enrollee.

1                   “(iv) BENEFICIARY MONTHLY PAY-  
2                   MENTS.—With respect to an applicable en-  
3                   rollee who is enrolled in the monthly out-  
4                   of-pocket cost sharing maximum option,  
5                   for each month described in clause (iii),  
6                   the PDP sponsor or MA organization shall  
7                   bill such enrollee an amount (not to exceed  
8                   the monthly out-of-pocket cost sharing  
9                   maximum) for the out-of-pocket costs of  
10                  such enrollee in such month.

11                  “(v) MONTHLY OUT-OF-POCKET COST  
12                  SHARING MAXIMUM DEFINED.—In this  
13                  subparagraph, the term ‘monthly out-of-  
14                  pocket cost sharing maximum’ means, with  
15                  respect to an enrollee—

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

19                                 “(aa) the annual out-of-  
20                                 pocket threshold specified in  
21                                 paragraph (4)(B) minus the in-  
22                                 curred costs of the enrollee as de-  
23                                 scribed in paragraph (4)(C); di-  
24                                 vided by

1 “(bb) the number of months  
2 remaining in the plan year; and

3 “(II) for a subsequent month, an  
4 amount determined by calculating—

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

12 “(bb) the number of months  
13 remaining in the plan year.

14 “(vi) ADDITIONAL REQUIREMENTS.—  
15 The following requirements shall apply  
16 with respect to the monthly out-of-pocket  
17 cost sharing maximum option under this  
18 subparagraph:

19 “(I) SECRETARIAL RESPONSIBIL-  
20 ITIES.—The Secretary shall provide  
21 information to part D eligible individ-  
22 uals on the monthly out-of-pocket cost  
23 sharing maximum option through edu-  
24 cational materials, including through



1 the notices provided under section  
2 1804(a).

3 “(II) PDP SPONSOR AND MA OR-  
4 GANIZATION RESPONSIBILITIES.—  
5 Each PDP sponsor offering a pre-  
6 scription drug plan or MA organiza-  
7 tion offering an MA–PD plan—

8 “(aa) shall not limit the ap-  
9 plication of the monthly out-of-  
10 pocket cost sharing maximum op-  
11 tion to certain covered part D  
12 drugs;

13 “(bb) shall, prior to the plan  
14 year, notify prospective enrollees  
15 of such option, including the  
16 availability of the opt out under  
17 clause (i)(II);

18 “(cc) shall include informa-  
19 tion on such option in enrollee  
20 educational materials, including  
21 the availability of the opt out  
22 under clause (i)(II);

23 “(dd) shall have in place a  
24 mechanism to notify a pharmacy  
25 during the plan year when an en-

1 enrollee incurs out-of-pocket costs  
2 with respect to covered part D  
3 drugs that make it likely the en-  
4 rollee is an applicable enrollee;

5 “(ee) shall provide that a  
6 pharmacy, after receiving a noti-  
7 fication described in item (dd)  
8 with respect to an enrollee, in-  
9 forms the enrollee of such notifi-  
10 cation;

11 “(ff) shall ensure that the  
12 application of this subparagraph  
13 has no effect on the amount paid  
14 to pharmacies (or the timing of  
15 such payments) with respect to  
16 covered part D drugs dispensed  
17 to the enrollee; and

18 “(gg) shall have in place a  
19 financial reconciliation process to  
20 correct inaccuracies in payments  
21 made by an enrollee under this  
22 subparagraph with respect to  
23 covered part D drugs during the  
24 plan year.

1                   “(III) FAILURE TO PAY AMOUNT  
2                   BILLED UNDER MONTHLY OUT-OF-  
3                   POCKET COST SHARING MAXIMUM OP-  
4                   TION.—If an applicable enrollee fails  
5                   to pay the amount billed for a month  
6                   as required under this subparagraph,  
7                   the applicable enrollee’s enrollment in  
8                   the monthly out-of-pocket cost sharing  
9                   maximum option shall be terminated  
10                  and the enrollee shall pay the cost-  
11                  sharing otherwise applicable for any  
12                  covered part D drugs subsequently  
13                  dispensed to the enrollee up to the an-  
14                  nual out-of-pocket threshold specified  
15                  in paragraph (4)(B).

16                  “(IV) CLARIFICATION REGARD-  
17                  ING PAST DUE AMOUNTS.—Nothing in  
18                  this subparagraph shall be construed  
19                  as prohibiting a PDP sponsor or an  
20                  MA organization from billing an en-  
21                  rollee for an amount owed under this  
22                  subparagraph.

23                  “(V) TREATMENT OF UNSET-  
24                  TLED BALANCES.—Any unsettled bal-  
25                  ances with respect to amounts owed

1 under this subparagraph shall be  
 2 treated as plan losses and the Sec-  
 3 retary shall not be liable for any such  
 4 balances outside of those assumed as  
 5 losses estimated in plan bids.”; and

6 (2) in paragraph (4)—

7 (A) in subparagraph (C), by striking “and  
 8 subject to subparagraph (F)” and inserting  
 9 “and subject to subparagraphs (F) and (G)”;  
 10 and

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

13 “(G) INCLUSION OF COSTS PAID UNDER  
 14 MONTHLY OUT-OF-POCKET COST SHARING MAX-  
 15 IMUM OPTION.—In applying subparagraph (A),  
 16 with respect to an applicable enrollee who is en-  
 17 rolled in the monthly out-of-pocket cost sharing  
 18 maximum option described in clause (i)(I) of  
 19 paragraph (2)(E), costs shall be treated as in-  
 20 curred if such costs are paid by a PDP sponsor  
 21 or an MA organization under the process pro-  
 22 vided under such paragraph.”.

23 (b) APPLICATION TO ALTERNATIVE PRESCRIPTION  
 24 DRUG COVERAGE.—Section 1860D–2(c) of the Social Se-

1 curity Act (42 U.S.C. 1395w–102(c)) is amended by add-  
 2 ing at the end the following new paragraph:

3 “(4) SAME MONTHLY OUT-OF-POCKET COST  
 4 SHARING MAXIMUM.—For plan years beginning on  
 5 or after January 1, 2024, the monthly out-of-pocket  
 6 cost sharing maximum for applicable enrollees under  
 7 the process provided under subsection (b)(2)(E)  
 8 shall apply to such coverage.”.

## 9 **Subtitle C—Miscellaneous**

### 10 **SEC. 221. DRUG MANUFACTURER PRICE TRANSPARENCY.**

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

#### 14 **“SEC. 1128L. DRUG MANUFACTURER PRICE TRANS-** 15 **PARENCY.**

16 “(a) IN GENERAL.—

17 “(1) DETERMINATIONS.—Beginning July 1,  
 18 2025, the Secretary shall make determinations as to  
 19 whether a drug is an applicable drug as described in  
 20 subsection (b).

21 “(2) REQUIRED JUSTIFICATION.—If the Sec-  
 22 retary determines under paragraph (1) that an ap-  
 23 plicable drug is described in subsection (b), the man-  
 24 ufacturer of the applicable drug shall submit to the  
 25 Secretary the justification described in subsection (c)

1 in accordance with the timing described in sub-  
2 section (d).

3 “(b) APPLICABLE DRUG DESCRIBED.—

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

7 “(A) LARGE INCREASE.—The drug (per  
8 dose)—

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

11 “(ii) had an increase in the wholesale  
12 acquisition cost, with respect to determina-  
13 tions made—

14 “(I) during 2023, of at least 100  
15 percent since the date of the enact-  
16 ment of this section;

17 “(II) during 2024, of at least  
18 100 percent in the preceding 12  
19 months or of at least 150 percent in  
20 the preceding 24 months;

21 “(III) during 2025, of at least  
22 100 percent in the preceding 12  
23 months or of at least 200 percent in  
24 the preceding 36 months;

1 “(IV) during 2026, of at least  
2 100 percent in the preceding 12  
3 months or of at least 250 percent in  
4 the preceding 48 months; or

5 “(V) on or after January 1,  
6 2027, of at least 100 percent in the  
7 preceding 12 months or of at least  
8 300 percent in the preceding 60  
9 months.

10 “(B) HIGH SPENDING WITH INCREASE.—

11 The drug—

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

17 “(ii) per dose, had an increase in the  
18 wholesale acquisition cost, with respect to  
19 determinations made—

20 “(I) during 2023, of at least 15  
21 percent since the date of the enact-  
22 ment of this section;

23 “(II) during 2024, of at least 15  
24 percent in the preceding 12 months or

1 of at least 20 percent in the preceding  
2 24 months;

3 “(III) during 2025, of at least 15  
4 percent in the preceding 12 months or  
5 of at least 30 percent in the preceding  
6 36 months;

7 “(IV) during 2026, of at least 15  
8 percent in the preceding 12 months or  
9 of at least 40 percent in the preceding  
10 48 months; or

11 “(V) on or after January 1,  
12 2027, of at least 15 percent in the  
13 preceding 12 months or of at least 50  
14 percent in the preceding 60 months.

15 “(C) HIGH LAUNCH PRICE FOR NEW  
16 DRUGS.—In the case of a drug that is marketed  
17 for the first time on or after January 1, 2023,  
18 and for which the manufacturer has established  
19 the first wholesale acquisition cost on or after  
20 such date, such wholesale acquisition cost for a  
21 year’s supply or a course of treatment for such  
22 drug exceeds the gross spending for covered  
23 part D drugs at which the annual out-of-pocket  
24 threshold under section 1860D–2(b)(4)(B)  
25 would be met for the year.



1 “(2) SPECIAL RULES.—

2 “(A) AUTHORITY OF SECRETARY TO SUB-  
3 STITUTE PERCENTAGES WITHIN A DE MINIMIS  
4 RANGE.—For purposes of applying paragraph  
5 (1), the Secretary may substitute for each per-  
6 centage described in subparagraph (A) or (B)  
7 of such paragraph (other than the percentile de-  
8 scribed subparagraph (B)(i) of such paragraph)  
9 a percentage within a de minimis range speci-  
10 fied by the Secretary below the percentage so  
11 described.

12 “(B) DRUGS WITH HIGH LAUNCH PRICES  
13 ANNUALLY REPORT UNTIL A THERAPEUTIC  
14 EQUIVALENT IS AVAILABLE.—In the case of a  
15 drug that the Secretary determines is an appli-  
16 cable drug described in subparagraph (C) of  
17 paragraph (1), such drug shall remain de-  
18 scribed in such subparagraph (C) (and the  
19 manufacturer of such drug shall annually re-  
20 port the justification under subsection (c)(2))  
21 until the Secretary determines that there is a  
22 therapeutic equivalent (as defined in section  
23 314.3 of title 21, Code of Federal Regulations,  
24 or any successor regulation) for such drug.

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

4           “(c) JUSTIFICATION DESCRIBED.—

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

15                 “(A) The individual factors that have con-  
16                 tributed to the increase in the wholesale acqui-  
17                 sition cost.

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

20                 “(C) Total expenditures of the manufac-  
21                 turer on—

22                         “(i) materials and manufacturing for  
23                         such drug;

24                         “(ii) acquiring patents and licensing  
25                         for each drug of the manufacturer; and

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

3 “(D) The percentage of total expenditures  
4 of the manufacturer on research and develop-  
5 ment for such drug that was derived from Fed-  
6 eral funds.

7 “(E) The total expenditures of the manu-  
8 facturer on research and development for such  
9 drug.

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

13 “(G) The total expenditures of the manu-  
14 facturer that are associated with marketing and  
15 advertising for the applicable drug.

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

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

21 “(ii) metrics used to determine execu-  
22 tive compensation; and

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

1 “(I) drug research and develop-  
2 ment; or

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

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

16 “(d) TIMING.—

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

23 “(2) SUBMISSION OF JUSTIFICATION.—Not  
24 later than 180 days after the date on which a manu-  
25 facturer receives a notification under paragraph (1),

1 the manufacturer shall submit to the Secretary the  
2 justification required under subsection (a).

3 “(3) POSTING ON INTERNET WEBSITE.—

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

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

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

1 section (d)(1) with respect to the applicable drug of the  
2 manufacturer, reduces the wholesale acquisition cost of a  
3 drug so that it no longer is described in such subpara-  
4 graph (A) or (B) for at least a 4-month period, as deter-  
5 mined by the Secretary.

6 “(f) PENALTIES.—

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

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

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

provisions apply to a penalty or proceeding under section 1128A(a). Civil monetary penalties imposed under this subsection are in addition to other penalties as may be prescribed by law.

“(g) DEFINITIONS.—In this section:

“(1) DRUG.—The term ‘drug’ means a drug, as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act, that is intended for human use and subject to section 503(b)(1) of such Act, including a product licensed under section 351 of the Public Health Service Act.

“(2) MANUFACTURER.—The term ‘manufacturer’ has the meaning given that term in section 1847A(c)(6)(A).

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

**SEC. 222. STRENGTHENING AND EXPANDING PHARMACY  
BENEFIT MANAGERS TRANSPARENCY RE-  
QUIREMENTS.**

Section 1150A of the Social Security Act (42 U.S.C. 1320b–23), as amended by section 223, is amended—

(1) in subsection (a)—

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

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

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

5 “(3) a State plan under title XIX, including a  
6 managed care entity (as defined in section  
7 1932(a)(1)(B)),”;

8 (2) in subsection (b)—

9 (A) in paragraph (2)—

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

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

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

20 (C) by adding at the end the following new  
21 paragraph:

22 “(4) The aggregate amount of bona fide service  
23 fees (which include distribution service fees, inven-  
24 tory management fees, product stocking allowances,  
25 and fees associated with administrative services



1 agreements and patient care programs (such as  
2 medication compliance programs and patient edu-  
3 cation programs)) the PBM received from—

4 “(A) PDP sponsors;

5 “(B) qualified health benefit plans;

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

8 “(D) drug manufacturers.”;

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

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

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

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

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

25 “(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, 2023,  
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. 223. 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, 2023, 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(c)  
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. 224. 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

Centers for Medicare & Medicaid Services  
with respect to novel medical products.

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

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

(A) DRAFT GUIDANCE.—Not later than 18  
months after the public meeting under para-  
graph (1), the Secretary shall update the final  
guidance titled “National Coverage Determina-  
tions with Data Collection as a Condition of  
Coverage: Coverage with Evidence Develop-  
ment” to address any opportunities to improve  
the availability and coordination of information  
as described in clauses (iv) through (vi) of para-  
graph (1)(C).

(B) FINAL GUIDANCE.—Not later than 12  
months after issuing draft guidance under sub-  
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. 225. 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. 226. 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. 227. 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 2024, 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. 228. 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 III—MEDICAID**

### 13 **SEC. 301. 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 303 of the Reduced  
22 Costs and Continued Cures Act, the Secretary  
23 shall issue guidance that States must follow for  
24 establishing conflict of interest policies for the  
25 pharmacy and therapeutics committee in ac-

1 cordance 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. 302. 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;

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)”;

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. 303. 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. 304. 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 2023 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. 305. T-MSIS DRUG DATA ANALYTICS REPORTS.**

17 (a) IN GENERAL.—Not later than May 1 of each cal-  
 18 endar year beginning with calendar year 2024, the Sec-  
 19 retary of Health and Human Services (in this section re-  
 20 ferred to as the “Secretary”) shall publish on the Internet  
 21 website of the Centers for Medicare & Medicaid Services  
 22 that is accessible to the public a report of the most re-  
 23 cently available data on provider prescribing patterns  
 24 under the Medicaid program.

25 (b) CONTENT OF REPORT.—



1           (1) REQUIRED CONTENT.—Each report re-  
2       quired under subsection (a) for a calendar year shall  
3       include the following information with respect to  
4       each State (and, to the extent available, with respect  
5       to Puerto Rico, the United States Virgin Islands,  
6       Guam, the Northern Mariana Islands, and American  
7       Samoa):

8           (A) A comparison of covered outpatient  
9       drug (as defined in section 1927(k)(2) of the  
10      Social Security Act (42 U.S.C. 1396r–8(k)(2)))  
11      prescribing patterns under the State Medicaid  
12      plan or waiver of such plan (including drugs  
13      prescribed on a fee-for-service basis and drugs  
14      prescribed under managed care arrangements  
15      under such plan or waiver)—

16           (i) across all forms or models of reim-  
17      bursement used under the plan or waiver;

18           (ii) within specialties and subspecial-  
19      ties, as defined by the Secretary;

20           (iii) by episodes of care for—

21           (I) each chronic disease category,  
22      as defined by the Secretary, that is  
23      represented in the 10 conditions that  
24      accounted for the greatest share of  
25      total spending under the plan or waiv-

1                   er during the year that is the subject  
2                   of the report;

3                   (II) procedural groupings; and

4                   (III) rare disease diagnosis codes;

5                   (iv) by patient demographic character-  
6                   istics, including race (to the extent that  
7                   the Secretary determines that there is suf-  
8                   ficient data available with respect to such  
9                   characteristic in a majority of States), gen-  
10                  der, and age;

11                  (v) by patient high-utilizer or risk sta-  
12                  tus; and

13                  (vi) by high and low resource settings  
14                  by facility and place of service categories,  
15                  as determined by the Secretary.

16                  (B) In the case of medical assistance for  
17                  covered outpatient drugs (as so defined) pro-  
18                  vided under a State Medicaid plan or waiver of  
19                  such plan in a managed care setting, an anal-  
20                  ysis of the differences in managed care pre-  
21                  scribing patterns when a covered outpatient  
22                  drug is prescribed in a managed care setting as  
23                  compared to when the drug is prescribed in a  
24                  fee-for-service setting.

1           (2) ADDITIONAL CONTENT.—A report required  
2       under subsection (a) for a calendar year may include  
3       State-specific information about prescription utiliza-  
4       tion management tools under State Medicaid plans  
5       or waivers of such plans, including—

6           (A) a description of prescription utilization  
7       management tools under State programs to pro-  
8       vide long-term services and supports under a  
9       State Medicaid plan or a waiver of such plan;

10          (B) a comparison of prescription utilization  
11       management tools applicable to populations cov-  
12       ered under a State Medicaid plan waiver under  
13       section 1115 of the Social Security Act (42  
14       U.S.C. 1315) and the models applicable to pop-  
15       ulations that are not covered under the waiver;

16          (C) a comparison of the prescription utili-  
17       zation management tools employed by different  
18       Medicaid managed care organizations, phar-  
19       macy benefit managers, and related entities  
20       within the State;

21          (D) a comparison of the prescription utili-  
22       zation management tools applicable to each en-  
23       rollment category under a State Medicaid plan  
24       or waiver; and

1           (E) a comparison of the prescription utili-  
2           zation management tools applicable under the  
3           State Medicaid plan or waiver by patient high-  
4           utilizer or risk status.

5           (3) ADDITIONAL ANALYSIS.—To the extent  
6           practicable, the Secretary shall include in each re-  
7           port published under subsection (a)—

8                 (A) analyses of national, State, and local  
9                 patterns of Medicaid population-based pre-  
10                scribing behaviors; and

11               (B) recommendations for administrative or  
12               legislative action to improve the effectiveness of,  
13               and reduce costs for, covered outpatient drugs  
14               under Medicaid while ensuring timely bene-  
15               ficiary access to medically necessary covered  
16               outpatient drugs.

17           (c) USE OF T-MSIS DATA.—Each report required  
18           under subsection (a) shall—

19               (1) be prepared using data and definitions from  
20               the Transformed Medicaid Statistical Information  
21               System (“T-MSIS”) data set (or a successor data  
22               set) that is not more than 24 months old on the date  
23               that the report is published; and

24               (2) as appropriate, include a description with  
25               respect to each State of the quality and complete-

1       ness of the data, as well as any necessary caveats  
 2       describing the limitations of the data reported to the  
 3       Secretary by the State that are sufficient to commu-  
 4       nicate the appropriate uses for the information.

5       (d) PREPARATION OF REPORT.—Each report re-  
 6       quired under subsection (a) shall be prepared by the Ad-  
 7       ministrators for the Centers for Medicare & Medicaid Serv-  
 8       ices.

9       (e) APPROPRIATION.—For fiscal year 2023 and each  
 10      fiscal year thereafter, there is appropriated to the Sec-  
 11      retary \$2,000,000 to carry out this section.

12   **SEC. 306. RISK-SHARING VALUE-BASED PAYMENT AGREE-**  
 13                   **MENTS FOR COVERED OUTPATIENT DRUGS**  
 14                   **UNDER MEDICAID.**

15      (a) IN GENERAL.—Section 1927 of the Social Secu-  
 16      rity Act (42 U.S.C. 1396r–8) is amended by adding at  
 17      the end the following new subsection:

18      “(l) STATE OPTION TO PAY FOR COVERED OUT-  
 19      PATIENT DRUGS THROUGH RISK-SHARING VALUE-BASED  
 20      AGREEMENTS.—

21           “(1) IN GENERAL.—Beginning January 1,  
 22      2025, a State shall have the option to pay (whether  
 23      on a fee-for-service or managed care basis) for cov-  
 24      ered outpatient drugs that are potentially curative  
 25      treatments intended for one-time use that are ad-

1 ministered to individuals under this title by entering  
 2 into a risk-sharing value-based payment agreement  
 3 with the manufacturer of the drug in accordance  
 4 with the requirements of this subsection.

5 “(2) SECRETARIAL APPROVAL.—

6 “(A) IN GENERAL.—A State shall submit a  
 7 request to the Secretary to enter into a risk-  
 8 sharing value based payment agreement, and  
 9 the Secretary shall not approve a proposed risk-  
 10 sharing value-based payment agreement be-  
 11 tween a State and a manufacturer for payment  
 12 for a covered outpatient drug of the manufac-  
 13 turer unless the following requirements are met:

14 “(i) MANUFACTURER IS PARTY TO RE-  
 15 BATE AGREEMENT AND IN COMPLIANCE  
 16 WITH REQUIREMENTS.—The manufacturer  
 17 has a rebate agreement in effect as re-  
 18 quired under subsections (a) and (b) of  
 19 this section and is in compliance with all  
 20 applicable requirements under this title.

21 “(ii) NO INCREASE TO PROJECTED  
 22 NET FEDERAL SPENDING.—

23 “(I) IN GENERAL.—The Chief  
 24 Actuary certifies that the projected  
 25 payments for each covered outpatient

1 drug under such proposed agreement  
2 would not result in greater estimated  
3 Federal spending under this title than  
4 the net Federal spending that would  
5 result in the absence of the agree-  
6 ment.

7 “(II) NET FEDERAL SPENDING  
8 DEFINED.—For purposes of this sub-  
9 section, the term ‘net Federal spend-  
10 ing’ means the amount of Federal  
11 payments the Chief Actuary estimates  
12 would be made under this title for ad-  
13 ministering a covered outpatient drug  
14 to an individual eligible for medical  
15 assistance under a State plan or a  
16 waiver of such plan, reduced by the  
17 amount of all rebates the Chief Actu-  
18 ary estimates would be paid with re-  
19 spect to the administering of such  
20 drug, including all rebates under this  
21 title and any supplemental or other  
22 additional rebates, in the absence of  
23 such an agreement.

24 “(III) INFORMATION.—The Chief  
25 Actuary shall make the certifications

1 required under this clause based on  
2 the most recently available and reli-  
3 able drug pricing and product infor-  
4 mation. The State and manufacturer  
5 shall provide the Secretary and the  
6 Chief Actuary with all necessary infor-  
7 mation required to make the estimates  
8 needed for such certifications.

9 “(iii) LAUNCH AND LIST PRICE JUS-  
10 TIFICATIONS.—The manufacturer submits  
11 all relevant information and supporting  
12 documentation necessary for pricing deci-  
13 sions as deemed appropriate by the Sec-  
14 retary, which shall be truthful and non-  
15 misleading, including manufacturer infor-  
16 mation and supporting documentation for  
17 launch price or list price increases, and  
18 any applicable justification required under  
19 section 1128L.

20 “(iv) CONFIDENTIALITY OF INFORMA-  
21 TION; PENALTIES.—The provisions of sub-  
22 paragraphs (C) and (D) of subsection  
23 (b)(3) shall apply to a manufacturer that  
24 fails to submit the information and docu-  
25 mentation required under clauses (ii) and



1 (iii) on a timely basis, or that knowingly  
2 provides false or misleading information, in  
3 the same manner as such provisions apply  
4 to a manufacturer with a rebate agreement  
5 under this section.

6 “(B) CONSIDERATION OF STATE REQUEST  
7 FOR APPROVAL.—

8 “(i) IN GENERAL.—The Secretary  
9 shall treat a State request for approval of  
10 a risk-sharing value-based payment agree-  
11 ment in the same manner that the Sec-  
12 retary treats a State plan amendment, and  
13 subpart B of part 430 of title 42, Code of  
14 Federal Regulations, including, subject to  
15 clause (ii), the timing requirements of sec-  
16 tion 430.16 of such title (as in effect on  
17 the date of enactment of this subsection),  
18 shall apply to a request for approval of a  
19 risk-sharing value-based payment agree-  
20 ment in the same manner as such subpart  
21 applies to a State plan amendment.

22 “(ii) TIMING.—The Secretary shall  
23 consult with the Commissioner of Food  
24 and Drugs as required under subpara-  
25 graph (C) and make a determination on

1           whether to approve a request from a State  
2           for approval of a proposed risk-sharing  
3           value-based payment agreement (or request  
4           additional information necessary to allow  
5           the Secretary to make a determination  
6           with respect to such request for approval)  
7           within the time period, to the extent prac-  
8           ticable, specified in section 430.16 of title  
9           42, Code of Federal Regulations (as in ef-  
10          fect on the date of enactment of this sub-  
11          section), but in no case shall the Secretary  
12          take more than 180 days after the receipt  
13          of such request for approval or response to  
14          such request for additional information to  
15          make such a determination (or request ad-  
16          ditional information).

17           “(C) CONSULTATION WITH THE COMMIS-  
18          SIONER OF FOOD AND DRUGS.—In considering  
19          whether to approve a risk-sharing value-based  
20          payment agreement, the Secretary, to the ex-  
21          tent necessary, shall consult with the Commis-  
22          sioner of Food and Drugs to determine whether  
23          the relevant clinical parameters specified in  
24          such agreement are appropriate.

1           “(3) INSTALLMENT-BASED PAYMENT STRUC-  
2       TURE.—

3           “(A) IN GENERAL.—A risk-sharing value-  
4       based payment agreement shall provide for a  
5       payment structure under which, for every in-  
6       stallment year of the agreement (subject to sub-  
7       paragraph (B)), the State shall pay the total in-  
8       stallment year amount in equal installments to  
9       be paid at regular intervals over a period of  
10      time that shall be specified in the agreement.

11          “(B) REQUIREMENTS FOR INSTALLMENT  
12      PAYMENTS.—

13           “(i) TIMING OF FIRST PAYMENT.—  
14      The State shall make the first of the in-  
15      stallment payments described in subpara-  
16      graph (A) for an installment year not later  
17      than 30 days after the end of such year.

18           “(ii) LENGTH OF INSTALLMENT PE-  
19      RIOD.—The period of time over which the  
20      State shall make the installment payments  
21      described in subparagraph (A) for an in-  
22      stallment year shall not be longer than 5  
23      years.

24           “(iii) NONPAYMENT OR REDUCED  
25      PAYMENT OF INSTALLMENTS FOLLOWING

1           A FAILURE TO MEET CLINICAL PARAM-  
2           ETER.—If, prior to the payment date (as  
3           specified in the agreement) of any install-  
4           ment payment described in subparagraph  
5           (A) or any other alternative date or time  
6           frame (as otherwise specified in the agree-  
7           ment), the covered outpatient drug which  
8           is subject to the agreement fails to meet a  
9           relevant clinical parameter of the agree-  
10          ment, the agreement shall provide that—

11                   “(I) the installment payment  
12                   shall not be made; or

13                   “(II) the installment payment  
14                   shall be reduced by a percentage spec-  
15                   ified in the agreement that is based  
16                   on the outcome achieved by the drug  
17                   relative to the relevant clinical param-  
18                   eter.

19          “(4) NOTICE OF INTENT.—

20                   “(A) IN GENERAL.—Subject to subpara-  
21                   graph (B), a manufacturer of a covered out-  
22                   patient drug shall not be eligible to enter into  
23                   a risk-sharing value-based payment agreement  
24                   under this subsection with respect to such drug  
25                   unless the manufacturer notifies the Secretary

1           that the manufacturer is interested in entering  
2           into such an agreement with respect to such  
3           drug. The decision to submit and timing of a  
4           request to enter into a proposed risk-sharing  
5           value-based payment agreement shall remain  
6           solely within the discretion of the State and  
7           shall only be effective upon Secretarial approval  
8           as required under this subsection.

9           “(B) TREATMENT OF SUBSEQUENTLY AP-  
10          PROVED DRUGS.—

11           “(i) IN GENERAL.—In the case of a  
12          manufacturer of a covered outpatient drug  
13          approved under section 505 of the Federal  
14          Food, Drug, and Cosmetic Act or licensed  
15          under section 351 of the Public Health  
16          Service Act after the date of enactment of  
17          this subsection, not more than 90 days  
18          after meeting with the Food and Drug Ad-  
19          ministration following phase II clinical  
20          trials for such drug (or, in the case of a  
21          drug described in clause (ii), not later than  
22          March 31, 2025), the manufacturer must  
23          notify the Secretary of the manufacturer’s  
24          intent to enter into a risk-sharing value-  
25          based payment agreement under this sub-

1 section with respect to such drug. If no  
2 such meeting has occurred, the Secretary  
3 may use discretion as to whether a poten-  
4 tially curative treatment intended for one-  
5 time use may qualify for a risk-sharing  
6 value-based payment agreement under this  
7 section. A manufacturer notification of in-  
8 terest shall not have any influence on a de-  
9 cision for approval by the Food and Drug  
10 Administration.

11 “(ii) APPLICATION TO CERTAIN SUB-  
12 SEQUENTLY APPROVED DRUGS.—A drug  
13 described in this clause is a covered out-  
14 patient drug of a manufacturer—

15 “(I) that is approved under sec-  
16 tion 505 of the Federal Food, Drug,  
17 and Cosmetic Act or licensed under  
18 section 351 of the Public Health Serv-  
19 ice Act after the date of enactment of  
20 this subsection; and

21 “(II) with respect to which, as of  
22 January 1, 2025, more than 90 days  
23 have passed after the manufacturer’s  
24 meeting with the Food and Drug Ad-

1           ministration following phase II clinical  
2           trials for such drug.

3           “(iii) PARALLEL APPROVAL.—The  
4           Secretary, in coordination with the Admin-  
5           istrator of the Centers for Medicare &  
6           Medicaid Services and the Commissioner of  
7           Food and Drugs, shall, to the extent prac-  
8           ticable, approve a State’s request to enter  
9           into a proposed risk-sharing value-based  
10          payment agreement that otherwise meets  
11          the requirements of this subsection at the  
12          time that such a drug is approved by the  
13          Food and Drug Administration to help  
14          provide that no State that wishes to enter  
15          into such an agreement is required to pay  
16          for the drug in full at one time if the State  
17          is seeking to pay over a period of time as  
18          outlined in the proposed agreement.

19          “(iv) RULE OF CONSTRUCTION.—  
20          Nothing in this paragraph shall be applied  
21          or construed to modify or affect the time-  
22          frames or factors involved in the Sec-  
23          retary’s determination of whether to ap-  
24          prove or license a drug under section 505  
25          of the Federal Food, Drug, and Cosmetic

1 Act or section 351 of the Public Health  
2 Service Act.

3 “(5) SPECIAL PAYMENT RULES.—

4 “(A) IN GENERAL.—Except as otherwise  
5 provided in this paragraph, with respect to an  
6 individual who is administered a unit of a cov-  
7 ered outpatient drug that is purchased under a  
8 State plan by a State Medicaid agency under a  
9 risk-sharing value-based payment agreement in  
10 an installment year, the State shall remain lia-  
11 ble to the manufacturer of such drug for pay-  
12 ment for such unit without regard to whether  
13 the individual remains enrolled in the State  
14 plan under this title (or a waiver of such plan)  
15 for each installment year for which the State is  
16 to make installment payments for covered out-  
17 patient drugs purchased under the agreement  
18 in such year.

19 “(B) DEATH.—In the case of an individual  
20 described in subparagraph (A) who dies during  
21 the period described in such subparagraph, the  
22 State plan shall not be liable for any remaining  
23 payment for the unit of the covered outpatient  
24 drug administered to the individual which is



1           owed under the agreement described in such  
2           subparagraph.

3           “(C) WITHDRAWAL OF APPROVAL.—In the  
4           case of a covered outpatient drug that is the  
5           subject of a risk-sharing value-based agreement  
6           between a State and a manufacturer under this  
7           subsection, including a drug approved in ac-  
8           cordance with section 506(c) of the Federal  
9           Food, Drug, and Cosmetic Act, and such drug  
10          is the subject of an application that has been  
11          withdrawn by the Secretary, the State plan  
12          shall not be liable for any remaining payment  
13          that is owed under the agreement.

14          “(D) ALTERNATIVE ARRANGEMENT UNDER  
15          AGREEMENT.—Subject to approval by the Sec-  
16          retary, the terms of a proposed risk-sharing  
17          value-based payment agreement submitted for  
18          approval by a State may provide that subpara-  
19          graph (A) shall not apply.

20          “(E) GUIDANCE.—Not later than January  
21          1, 2025, the Secretary shall issue guidance to  
22          States establishing a process for States to no-  
23          tify the Secretary when an individual who is ad-  
24          ministered a unit of a covered outpatient drug  
25          that is purchased by a State plan under a risk-

1           sharing value-based payment agreement ceases  
2           to be enrolled under the State plan under this  
3           title (or a waiver of such plan) or dies before  
4           the end of the installment period applicable to  
5           such unit under the agreement.

6           “(6) TREATMENT OF PAYMENTS UNDER RISK-  
7           SHARING VALUE-BASED AGREEMENTS FOR PUR-  
8           POSES OF AVERAGE MANUFACTURER PRICE; BEST  
9           PRICE.—The Secretary shall treat any payments  
10          made to the manufacturer of a covered outpatient  
11          drug under a risk-sharing value-based payment  
12          agreement under this subsection during a rebate pe-  
13          riod in the same manner that the Secretary treats  
14          payments made under a State supplemental rebate  
15          agreement under sections 447.504(c)(19) and  
16          447.505(c)(7) of title 42, Code of Federal Regula-  
17          tions (or any successor regulations) for purposes of  
18          determining average manufacturer price and best  
19          price under this section with respect to the covered  
20          outpatient drug and a rebate period and for pur-  
21          poses of offsets required under subsection (b)(1)(B).

22          “(7) ASSESSMENTS AND REPORT TO CON-  
23          GRESS.—

24                 “(A) ASSESSMENTS.—

1           “(i) IN GENERAL.—Not later than  
2           180 days after the end of each assessment  
3           period of any risk-sharing value-based pay-  
4           ment agreement for a State approved  
5           under this subsection, the Secretary shall  
6           conduct an evaluation of such agreement  
7           which shall include an evaluation by the  
8           Chief Actuary to determine whether pro-  
9           gram spending under the risk-sharing  
10          value-based payment agreement aligned  
11          with the projections for the agreement  
12          made under paragraph (2)(A)(ii), including  
13          an assessment of whether actual Federal  
14          spending under this title under the agree-  
15          ment was less or more than net Federal  
16          spending would have been in the absence  
17          of the agreement.

18          “(ii) ASSESSMENT PERIOD.—For pur-  
19          poses of clause (i)—

20                 “(I) the first assessment period  
21                 for a risk-sharing value-based pay-  
22                 ment agreement shall be the period of  
23                 time over which payments are sched-  
24                 uled to be made under the agreement  
25                 for the first 10 individuals who are

1 administered covered outpatient drugs  
2 under the agreement except that such  
3 period shall not exceed the 5-year pe-  
4 riod after the date on which the Sec-  
5 retary approves the agreement; and

6 “(II) each subsequent assessment  
7 period for a risk-sharing value-based  
8 payment agreement shall be the 5-  
9 year period following the end of the  
10 previous assessment period.

11 “(B) RESULTS OF ASSESSMENTS.—

12 “(i) TERMINATION OPTION.—If the  
13 Secretary determines as a result of the as-  
14 sessment by the Chief Actuary under sub-  
15 paragraph (A) that the actual Federal  
16 spending under this title for any covered  
17 outpatient drug that was the subject of the  
18 State’s risk-sharing value-based payment  
19 agreement was greater than the net Fed-  
20 eral spending that would have resulted in  
21 the absence of the agreement, the Sec-  
22 retary may terminate approval of such  
23 agreement and shall immediately conduct  
24 an assessment under this paragraph of any  
25 other ongoing risk-sharing value-based

1 payment agreement to which the same  
2 manufacturer is a party.

3 “(ii) REPAYMENT REQUIRED.—

4 “(I) IN GENERAL.—If the Sec-  
5 retary determines as a result of the  
6 assessment by the Chief Actuary  
7 under subparagraph (A) that the Fed-  
8 eral spending under the risk-sharing  
9 value-based agreement for a covered  
10 outpatient drug that was subject to  
11 such agreement was greater than the  
12 net Federal spending that would have  
13 resulted in the absence of the agree-  
14 ment, the manufacturer shall repay  
15 the difference to the State and Fed-  
16 eral governments in a timely manner  
17 as determined by the Secretary.

18 “(II) TERMINATION FOR FAIL-  
19 URE TO PAY.—The failure of a manu-  
20 facturer to make repayments required  
21 under subclause (I) in a timely man-  
22 ner shall result in immediate termi-  
23 nation of all risk-sharing value-based  
24 agreements to which the manufacturer  
25 is a party.

1                   “(III)        ADDITIONAL        PEN-  
2                   ALTIES.—In the case of a manufac-  
3                   turer that fails to make repayments  
4                   required under subclause (I), the Sec-  
5                   retary may treat such manufacturer  
6                   in the same manner as a manufac-  
7                   turer that fails to pay required re-  
8                   bates under this section, and the Sec-  
9                   retary may—

10                   “(aa) suspend or terminate  
11                   the manufacturer’s rebate agree-  
12                   ment under this section; and

13                   “(bb) pursue any other rem-  
14                   edy that would be available if the  
15                   manufacturer had failed to pay  
16                   required rebates under this sec-  
17                   tion.

18                   “(C) REPORT TO CONGRESS.—Not later  
19                   than 5 years after the first risk-sharing value-  
20                   based payment agreement is approved under  
21                   this subsection, the Secretary shall submit to  
22                   Congress and make available to the public a re-  
23                   port that includes—

24                   “(i) an assessment of the impact of  
25                   risk-sharing value-based payment agree-

1           ments on access for individuals who are eli-  
2           gible for benefits under a State plan or  
3           waiver under this title to medically nec-  
4           essary covered outpatient drugs and re-  
5           lated treatments;

6           “(ii) an analysis of the impact of such  
7           agreements on overall State and Federal  
8           spending under this title;

9           “(iii) an assessment of the impact of  
10          such agreements on drug prices, including  
11          launch price and price increases; and

12          “(iv) such recommendations to Con-  
13          gress as the Secretary deems appropriate.

14       “(8) GUIDANCE AND REGULATIONS.—

15           “(A) IN GENERAL.—Not later than Janu-  
16          ary 1, 2025, the Secretary shall issue guidance  
17          to States seeking to enter into risk-sharing  
18          value-based payment agreements under this  
19          subsection that includes a model template for  
20          such agreements. The Secretary may issue any  
21          additional guidance or promulgate regulations  
22          as necessary to implement and enforce the pro-  
23          visions of this subsection.

24          “(B) MODEL AGREEMENTS.—

1           “(i) IN GENERAL.—If a State ex-  
2           presses an interest in pursuing a risk-shar-  
3           ing value-based payment agreement under  
4           this subsection with a manufacturer for  
5           the purchase of a covered outpatient drug,  
6           the Secretary may share with such State  
7           any risk-sharing value-based agreement be-  
8           tween a State and the manufacturer for  
9           the purchase of such drug that has been  
10          approved under this subsection. While such  
11          shared agreement may serve as a template  
12          for a State that wishes to propose, the use  
13          of a previously approved agreement shall  
14          not affect the submission and approval  
15          process for approval of a proposed risk-  
16          sharing value-based payment agreement  
17          under this subsection, including the re-  
18          quirements under paragraph (2)(A).

19          “(ii) CONFIDENTIALITY.—In the case  
20          of a risk-sharing value-based payment  
21          agreement that is disclosed to a State by  
22          the Secretary under this subparagraph and  
23          that is only in effect with respect to a sin-  
24          gle State, the confidentiality of information



provisions described in subsection  
(b)(3)(D) shall apply to such information.

“(C) OIG CONSULTATION.—

“(i) IN GENERAL.—The Secretary shall consult with the Office of the Inspector General of the Department of Health and Human Services to determine whether there are potential program integrity concerns with agreement approvals or templates and address accordingly.

“(ii) OIG POLICY UPDATES AS NECESSARY.—The Inspector General of the Department of Health and Human Services shall review and update, as necessary, any policies or guidelines of the Office of the Inspector General of the Department of Human Services (including policies related to the enforcement of section 1128B) to accommodate the use of risk-sharing value-based payment agreements in accordance with this section.

“(9) RULES OF CONSTRUCTION.—

“(A) MODIFICATIONS.—Nothing in this subsection or any regulations promulgated under this subsection shall prohibit a State

1 from requesting a modification from the Sec-  
2 retary to the terms of a risk-sharing value-  
3 based payment agreement. A modification that  
4 is expected to result in any increase to pro-  
5 jected net State or Federal spending under the  
6 agreement shall be subject to recertification by  
7 the Chief Actuary as described in paragraph  
8 (2)(A)(ii) before the modification may be ap-  
9 proved.

10 “(B) REBATE AGREEMENTS.—Nothing in  
11 this subsection shall be construed as requiring  
12 a State to enter into a risk-sharing value-based  
13 payment agreement or as limiting or super-  
14 seding the ability of a State to enter into a sup-  
15 plemental rebate agreement for a covered out-  
16 patient drug.

17 “(C) FFP FOR PAYMENTS UNDER RISK-  
18 SHARING VALUE-BASED PAYMENT AGREE-  
19 MENTS.—Federal financial participation shall  
20 be available under this title for any payment  
21 made by a State to a manufacturer for a cov-  
22 ered outpatient drug under a risk-sharing  
23 value-based payment agreement in accordance  
24 with this subsection, except that no Federal fi-  
25 nancial participation shall be available for any

1 payment made by a State to a manufacturer  
2 under such an agreement on and after the ef-  
3 fective date of a disapproval of such agreement  
4 by the Secretary.

5 “(D) CONTINUED APPLICATION OF OTHER  
6 PROVISIONS.—Except as expressly provided in  
7 this subsection, nothing in this subsection or in  
8 any regulations promulgated under this sub-  
9 section shall affect the application of any other  
10 provision of this Act.

11 “(10) APPROPRIATIONS.—For fiscal year 2023  
12 and each fiscal year thereafter, there are appro-  
13 priated to the Secretary \$5,000,000 for the purpose  
14 of carrying out this subsection.

15 “(11) DEFINITIONS.—In this subsection:

16 “(A) CHIEF ACTUARY.—The term ‘Chief  
17 Actuary’ means the Chief Actuary of the Cen-  
18 ters for Medicare & Medicaid Services.

19 “(B) INSTALLMENT YEAR.—The term ‘in-  
20 stallment year’ means, with respect to a risk-  
21 sharing value-based payment agreement, a 12-  
22 month period during which a covered outpatient  
23 drug is administered under the agreement.

24 “(C) POTENTIALLY CURATIVE TREATMENT  
25 INTENDED FOR ONE-TIME USE.—The term ‘po-

1 tentially curative treatment intended for one-  
2 time use’ means a treatment that consists of  
3 the administration of a covered outpatient drug  
4 that—

5 “(i) is a form of gene therapy for a  
6 rare disease, as defined by the Commis-  
7 sioner of Food and Drugs, designated  
8 under section 526 of the Federal Food,  
9 Drug, and Cosmetics Act, and approved  
10 under section 505 of such Act or licensed  
11 under subsection (a) or (k) of section 351  
12 of the Public Health Service Act to treat  
13 a serious or life-threatening disease or con-  
14 dition;

15 “(ii) if administered in accordance  
16 with the labeling of such drug, is expected  
17 to result in either—

18 “(I) the cure of such disease or  
19 condition; or

20 “(II) a reduction in the symp-  
21 toms of such disease or condition to  
22 the extent that such disease or condi-  
23 tion is not expected to lead to early  
24 mortality; and

1 “(iii) is expected to achieve a result  
2 described in clause (ii), which may be  
3 achieved over an extended period of time,  
4 after not more than 3 administrations.

5 “(D) RELEVANT CLINICAL PARAMETER.—  
6 The term ‘relevant clinical parameter’ means,  
7 with respect to a covered outpatient drug that  
8 is the subject of a risk-sharing value-based pay-  
9 ment agreement—

10 “(i) a clinical endpoint specified in the  
11 drug’s labeling or supported by one or  
12 more of the compendia described in section  
13 1861(t)(2)(B)(ii)(I) that—

14 “(I) is able to be measured or  
15 evaluated on an annual basis for each  
16 year of the agreement on an inde-  
17 pendent basis by a provider or other  
18 entity; and

19 “(II) is required to be achieved  
20 (based on observed metrics in patient  
21 populations) under the terms of the  
22 agreement; or

23 “(ii) a surrogate endpoint (as defined  
24 in section 507(e)(9) of the Federal Food,  
25 Drug, and Cosmetic Act), including those

1 developed by patient-focused drug develop-  
2 ment tools, that—

3 “(I) is able to be measured or  
4 evaluated on an annual basis for each  
5 year of the agreement on an inde-  
6 pendent basis by a provider or other  
7 entity; and

8 “(II) has been qualified by the  
9 Food and Drug Administration.

10 “(E) RISK-SHARING VALUE-BASED PAY-  
11 MENT AGREEMENT.—The term ‘risk-sharing  
12 value-based payment agreement’ means an  
13 agreement between a State plan and a manu-  
14 facturer—

15 “(i) for the purchase of a covered out-  
16 patient drug of the manufacturer that is a  
17 potentially curative treatment intended for  
18 one-time use;

19 “(ii) under which payment for such  
20 drug shall be made pursuant to an install-  
21 ment-based payment structure that meets  
22 the requirements of paragraph (3);

23 “(iii) which conditions payment on the  
24 achievement of at least 2 relevant clinical

parameters (as defined in subparagraph  
(C));

“(iv) which provides that—

“(I) the State plan will directly  
reimburse the manufacturer for the  
drug; or

“(II) a third party will reimburse  
the manufacture in a manner ap-  
proved by the Secretary; and

“(v) is approved by the Secretary in  
accordance with paragraph (2).

“(F) TOTAL INSTALLMENT YEAR  
AMOUNT.—The term ‘total installment year  
amount’ means, with respect to a risk-sharing  
value-based payment agreement for the pur-  
chase of a covered outpatient drug and an in-  
stallment year, an amount equal to the product  
of—

“(i) the unit price of the drug charged  
under the agreement; and

“(ii) the number of units of such drug  
administered under the agreement during  
such installment year.”.

(b) CONFORMING AMENDMENTS.—

1           (1) Section 1903(i)(10)(A) of the Social Secu-  
2           rity Act (42 U.S.C. 1396b(i)(10)(A)) is amended by  
3           striking “or unless section 1927(a)(3) applies” and  
4           inserting “, section 1927(a)(3) applies with respect  
5           to such drugs, or such drugs are the subject of a  
6           risk-sharing value-based payment agreement under  
7           section 1927(l)”.

8           (2) Section 1927(b) of the Social Security Act  
9           (42 U.S.C. 1396r–8(b)) is amended—

10           (A) in paragraph (1)(A), by inserting “(ex-  
11           cept for drugs for which payment is made by a  
12           State under a risk-sharing value-based payment  
13           agreement under subsection (l))” after “under  
14           the State plan for such period”; and

15           (B) in paragraph (3)—

16           (i) in subparagraph (C)(i), by insert-  
17           ing “or subsection (l)(2)(A)” after “sub-  
18           paragraph (A)”; and

19           (ii) in subparagraph (D), in the mat-  
20           ter preceding clause (i), by inserting “,  
21           under subsection (l)(2)(A),” after “under  
22           this paragraph”.



1 **SEC. 307. MODIFICATION OF MAXIMUM REBATE AMOUNT**  
2 **UNDER MEDICAID DRUG REBATE PROGRAM.**

3 (a) IN GENERAL.—Subparagraph (D) of section  
4 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r–  
5 8(c)(2)) is amended to read as follows:

6 “(D) MAXIMUM REBATE AMOUNT.—

7 “(i) IN GENERAL.—Except as pro-  
8 vided in clause (ii), in no case shall the  
9 sum of the amounts applied under para-  
10 graph (1)(A)(ii) and this paragraph with  
11 respect to each dosage form and strength  
12 of a single source drug or an innovator  
13 multiple source drug for a rebate period  
14 exceed—

15 “(I) for rebate periods beginning  
16 after December 31, 2009, and before  
17 September 30, 2025, 100 percent of  
18 the average manufacturer price of the  
19 drug; and

20 “(II) for rebate periods beginning  
21 on or after October 1, 2025, 125 per-  
22 cent of the average manufacturer  
23 price of the drug.

24 “(ii) NO MAXIMUM AMOUNT FOR  
25 DRUGS IF AMP INCREASES OUTPACE IN-  
26 FLATION.—

1                   “(I) IN GENERAL.—If the aver-  
2                   age manufacturer price with respect  
3                   to each dosage form and strength of  
4                   a single source drug or an innovator  
5                   multiple source drug increases on or  
6                   after October 1, 2024, and such in-  
7                   creased average manufacturer price  
8                   exceeds the inflation-adjusted average  
9                   manufacturer price determined with  
10                  respect to such drug under subclause  
11                  (II) for the rebate period, clause (i)  
12                  shall not apply and there shall be no  
13                  limitation on the sum of the amounts  
14                  applied under paragraph (1)(A)(ii)  
15                  and this paragraph for the rebate pe-  
16                  riod with respect to each dosage form  
17                  and strength of the single source drug  
18                  or innovator multiple source drug.

19                  “(II) INFLATION-ADJUSTED AV-  
20                  ERAGE MANUFACTURER PRICE DE-  
21                  FINED.—In this clause, the term ‘in-  
22                  flation-adjusted average manufacturer  
23                  price’ means, with respect to a single  
24                  source drug or an innovator multiple  
25                  source drug and a rebate period, the

1 average manufacturer price for each  
2 dosage form and strength of the drug  
3 for the calendar quarter beginning  
4 July 1, 1990 (without regard to  
5 whether or not the drug has been sold  
6 or transferred to an entity, including  
7 a division or subsidiary of the manu-  
8 facturer, after the 1<sup>st</sup> day of such  
9 quarter), increased by the percentage  
10 by which the consumer price index for  
11 all urban consumers (United States  
12 city average) for the month before the  
13 month in which the rebate period be-  
14 gins exceeds such index for September  
15 1990.”.

16 (b) TREATMENT OF SUBSEQUENTLY APPROVED  
17 DRUGS.—Section 1927(c)(2)(B) of the Social Security Act  
18 (42 U.S.C. 1396r–8(c)(2)(B)) is amended by inserting  
19 “and clause (ii)(II) of subparagraph (D)” after “clause  
20 (ii)(II) of subparagraph (A)”.

21 (c) TECHNICAL AMENDMENTS.—Section  
22 1927(c)(3)(C)(ii)(IV) of the Social Security Act (42  
23 U.S.C. 1396r–9(c)(3)(C)(ii)(IV)) is amended—

24 (1) by striking “subparagraph (A)” and insert-  
25 ing “paragraph (3)(A)”; and

1 (2) by striking “this subparagraph” and insert-  
 2 ing “paragraph (3)(C)”.

3 **TITLE IV—ADDRESSING INTER-**  
 4 **MEDIARIES AND DRUG COM-**  
 5 **PETITION**

6 **SEC. 401. HEALTH PLAN OVERSIGHT OF PHARMACY BEN-**  
 7 **EFIT MANAGER SERVICES.**

8 Subpart II of part A of title XXVII of the Public  
 9 Health Service Act (42 U.S.C. 300gg–11 et seq.) is  
 10 amended by adding at the end the following:

11 **“SEC. 2729A. HEALTH PLAN OVERSIGHT OF PHARMACY**  
 12 **BENEFIT MANAGER SERVICES.**

13 “(a) IN GENERAL.—A group health plan or health  
 14 insurance issuer offering group or individual health insur-  
 15 ance coverage or an entity or subsidiary providing phar-  
 16 macy benefits management services shall not enter into  
 17 a contract with a drug manufacturer, distributor, whole-  
 18 saler, subcontractor, rebate aggregator, or any associated  
 19 third party that limits the disclosure of information to  
 20 plan sponsors in such a manner that prevents the plan  
 21 or coverage, or an entity or subsidiary providing pharmacy  
 22 benefits management services on behalf of a plan or cov-  
 23 erage from making the reports described in subsection (b).

24 “(b) REPORTS TO GROUP PLAN SPONSORS.—

1           “(1) IN GENERAL.—Beginning with the first  
2           plan year that begins after the date of enactment of  
3           this section, not less frequently than once every six  
4           months, a health insurance issuer offering group  
5           health insurance coverage or an entity providing  
6           pharmacy benefits management services on behalf of  
7           a group health plan shall submit to the self-funded  
8           group health plan and at the request of any other  
9           group health plan a report in accordance with this  
10          subsection and make such report available to the  
11          plan sponsor in a machine-readable format. Each  
12          such report shall include, with respect to the applica-  
13          ble group health plan or health insurance coverage—

14               “(A) information collected from drug man-  
15               ufacturers by such issuer or entity on the total  
16               amount of copayment assistance dollars paid, or  
17               copayment cards applied, that were funded by  
18               the drug manufacturer with respect to the en-  
19               rollees in such plan or coverage;

20               “(B) a list of each covered drug dispensed  
21               during the reporting period, including, with re-  
22               spect to each such drug during the reporting  
23               period—

24                       “(i) the brand name, chemical entity,  
25                       and National Drug Code;

1           “(ii) the number of enrollees for  
2           whom the drug was filled during the plan  
3           year, the total number of prescription fills  
4           for the drug (including original prescrip-  
5           tions and refills), and the total number of  
6           dosage units of the drug dispensed across  
7           the plan year, including whether the dis-  
8           pensing channel was by retail, mail order,  
9           or specialty pharmacy;

10           “(iii) the wholesale acquisition cost,  
11           listed as cost per days supply and cost per  
12           pill, or in the case of a drug in another  
13           form, per dose;

14           “(iv) the total out-of-pocket spending  
15           by enrollees on such drug, including en-  
16           rollee spending through copayments, coin-  
17           surance, and deductibles; and

18           “(v) for any drug for which gross  
19           spending of the group health plan or  
20           health insurance coverage exceeded  
21           \$10,000 during the reporting period—

22           “(I) a list of all other available  
23           drugs in the same therapeutic cat-  
24           egory or class, including brand name  
25           drugs and biological products and ge-

1                   neric drugs or biosimilar biological  
2                   products that are in the same thera-  
3                   peutic category or class; and

4                   “(II) the rationale for preferred  
5                   formulary placement of a particular  
6                   drug or drugs in that therapeutic cat-  
7                   egory or class;

8                   “(C) a list of each therapeutic category or  
9                   class of drugs that were dispensed under the  
10                  health plan or health insurance coverage during  
11                  the reporting period, and, with respect to each  
12                  such therapeutic category or class of drugs,  
13                  during the reporting period—

14                  “(i) total gross spending by the plan,  
15                  before manufacturer rebates, fees, or other  
16                  manufacturer remuneration;

17                  “(ii) the number of enrollees who  
18                  filled a prescription for a drug in that cat-  
19                  egory or class;

20                  “(iii) if applicable to that category or  
21                  class, a description of the formulary tiers  
22                  and utilization mechanisms (such as prior  
23                  authorization or step therapy) employed  
24                  for drugs in that category or class;

1 “(iv) the total out-of-pocket spending  
2 by enrollees, including enrollee spending  
3 through copayments, coinsurance, and  
4 deductibles; and

5 “(v) for each therapeutic category or  
6 class under which three or more drugs are  
7 marketed and available—

8 “(I) the amount received, or ex-  
9 pected to be received, from drug man-  
10 ufacturers in rebates, fees, alternative  
11 discounts, or other remuneration—

12 “(aa) to be paid by drug  
13 manufacturers for claims in-  
14 curred during the reporting pe-  
15 riod; or

16 “(bb) that is related to utili-  
17 zation of drugs, in such thera-  
18 peutic category or class;

19 “(II) the total net spending by  
20 the health plan or health insurance  
21 coverage on that category or class of  
22 drugs; and

23 “(III) the net price per dosage  
24 unit or course of treatment incurred  
25 by the health plan or health insurance



1 coverage and its enrollees, after man-  
2 ufacturer rebates, fees, and other re-  
3 munerations for drugs dispensed within  
4 such therapeutic category or class  
5 during the reporting period;

6 “(D) total gross spending on prescription  
7 drugs by the plan or coverage during the re-  
8 porting period, before rebates and other manu-  
9 facturer fees or remuneration;

10 “(E) total amount received, or expected to  
11 be received, by the health plan or health insur-  
12 ance coverage in drug manufacturer rebates,  
13 fees, alternative discounts, and all other remu-  
14 nation received from the manufacturer or any  
15 third party related to utilization of drug or  
16 drug spending under that health plan or health  
17 insurance coverage during the reporting period;

18 “(F) the total net spending on prescription  
19 drugs by the health plan or health insurance  
20 coverage during the reporting period; and

21 “(G) amounts paid directly or indirectly in  
22 rebates, fees, or any other type of remuneration  
23 to brokers, consultants, advisors, or any other  
24 individual or firm who referred the group health

1           plan’s or health insurance issuer’s business to  
2           the pharmacy benefit manager.

3           “(2) PRIVACY REQUIREMENTS.—Health insur-  
4           ance issuers offering group health insurance cov-  
5           erage and entities providing pharmacy benefits man-  
6           agement services on behalf of a group health plan  
7           shall provide information under paragraph (1) in a  
8           manner consistent with the privacy, security, and  
9           breach notification regulations promulgated under  
10          section 264(c) of the Health Insurance Portability  
11          and Accountability Act of 1996 (or successor regula-  
12          tions), and shall restrict the use and disclosure of  
13          such information according to such privacy regula-  
14          tions.

15          “(3) DISCLOSURE AND REDISCLOSURE.—

16                 “(A) LIMITATION TO BUSINESS ASSOCI-  
17                 ATES.—A group health plan receiving a report  
18                 under paragraph (1) may disclose such informa-  
19                 tion only to business associates of such plan as  
20                 defined in section 160.103 of title 45, Code of  
21                 Federal Regulations (or successor regulations).

22                 “(B) CLARIFICATION REGARDING PUBLIC  
23                 DISCLOSURE OF INFORMATION.—Nothing in  
24                 this section prevents a health insurance issuer  
25                 offering group health insurance coverage or an

1           entity providing pharmacy benefits management  
2           services on behalf of a group health plan from  
3           placing reasonable restrictions on the public dis-  
4           closure of the information contained in a report  
5           described in paragraph (1).

6           “(c) ENFORCEMENT.—

7                 “(1) IN GENERAL.—The Secretary, in consulta-  
8           tion with the Secretary of Labor and the Secretary  
9           of the Treasury, shall enforce this section.

10                “(2) FAILURE TO PROVIDE TIMELY INFORMA-  
11           TION.—A health insurance issuer or an entity pro-  
12           viding pharmacy benefit management services that  
13           violates subsection (a) or fails to provide information  
14           required under subsection (b) or a drug manufac-  
15           turer that fails to provide information under sub-  
16           section (b)(1)(A), in a timely manner shall be sub-  
17           ject to a civil monetary penalty in the amount of  
18           \$10,000 for each day during which such violation  
19           continues or such information is not disclosed or re-  
20           ported.

21                “(3) FALSE INFORMATION.—A health insurance  
22           issuer, entity providing pharmacy benefit manage-  
23           ment services, or drug manufacturer that knowingly  
24           provides false information under this section shall be  
25           subject to a civil money penalty in an amount not

1 to exceed \$100,000 for each item of false informa-  
2 tion. Such civil money penalty shall be in addition to  
3 other penalties as may be prescribed by law.

4 “(4) PROCEDURE.—The provisions of section  
5 1128A of the Social Security Act, other than sub-  
6 sections (a) and (b) and the first sentence of sub-  
7 section (c)(1) of such section shall apply to civil  
8 monetary penalties under this subsection in the  
9 same manner as such provisions apply to a penalty  
10 or proceeding under section 1128A of the Social Se-  
11 curity Act.

12 “(5) SAFE HARBOR.—The Secretary may waive  
13 penalties under paragraph (2), or extend the period  
14 of time for compliance with a requirement of this  
15 section, for an entity in violation of this section that  
16 has made a good-faith effort to comply with this sec-  
17 tion.

18 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-  
19 tion shall be construed to prohibit entities providing phar-  
20 macy benefits management services from retaining bona  
21 fide service fees, provided that such fees are transparent  
22 to group health plans and health insurance issuers and  
23 are not linked directly to the price or formulary placement  
24 or position of a drug.

25 “(e) DEFINITIONS.—In this section—

1 “(1) the term ‘similarly situated pharmacy’  
2 means, with respect to a particular pharmacy, an-  
3 other pharmacy that is approximately the same size  
4 (as measured by the number of prescription drugs  
5 dispensed), and that serves patients in the same geo-  
6 graphical area, whether through physical locations or  
7 mail order;

8 “(2) the term ‘wholesale acquisition cost’ has  
9 the meaning given such term in section  
10 1847A(c)(6)(B) of the Social Security Act; and

11 “(3) the term ‘bona fide service fees’ means  
12 fees paid by a manufacturer, customer, or client  
13 (other than a group health plan or health insurance  
14 issuer) of an entity providing pharmacy benefit man-  
15 agement services, to an entity providing pharmacy  
16 benefit management services, that represent fair  
17 market value for bona fide, itemized services actually  
18 performed on behalf of the manufacturer, customer,  
19 or client would otherwise perform or contract for in  
20 the absence of the service arrangement, without  
21 prior consent for any specific arrangements.”.

22 **SEC. 402. STUDY OF PHARMACEUTICAL SUPPLY CHAIN**  
23 **INTERMEDIARIES AND MERGER ACTIVITY.**

24 (a) INITIAL REPORT.—Not later than 1 year after  
25 the date of enactment of this Act, the Commission shall

1 submit to the appropriate committees of Congress a report  
2 that—

3 (1) addresses at minimum—

4 (A) whether pharmacy benefit managers—

5 (i) charge payers a higher price than  
6 the reimbursement rate at which the phar-  
7 macy benefit managers reimburse com-  
8 peting pharmacies;

9 (ii) steer patients for anticompetitive  
10 purposes to any pharmacies, including re-  
11 tail, mail-order, or any other type of phar-  
12 macy, in which the pharmacy benefit man-  
13 ager has an ownership interest;

14 (iii) audit or review proprietary data,  
15 including acquisition costs, patient infor-  
16 mation, or dispensing information, of com-  
17 peting pharmacies that can be used for  
18 anticompetitive purposes; or

19 (iv) use formulary designs to increase  
20 the market share of higher cost prescrip-  
21 tion drugs and depress the market share of  
22 lower cost prescription drugs (each net of  
23 rebates and discounts);

24 (B) how companies and payers assess the  
25 benefits, costs, and risks of contracting with

1 intermediaries, including pharmacy services ad-  
2 ministrative organizations, and whether more  
3 information about the roles of intermediaries  
4 should be available to consumers and payers;  
5 and

6 (C) whether there are any specific legal or  
7 regulatory obstacles the Commission currently  
8 faces in ensuring a competitive and transparent  
9 marketplace in the pharmaceutical supply  
10 chain, including the pharmacy benefit manager  
11 marketplace and pharmacy services administra-  
12 tive organizations; and

13 (2) provides—

14 (A) observations or conclusions drawn  
15 from the November 2017 roundtable entitled  
16 “Understanding Competition in Prescription  
17 Drug Markets: Entry and Supply Chain Dy-  
18 namics”, and any similar efforts;

19 (B) specific actions the Commission in-  
20 tends to take as a result of the November 2017  
21 roundtable, and any similar efforts, including a  
22 detailed description of relevant forthcoming ac-  
23 tions, additional research or roundtable discus-  
24 sions, consumer education efforts, or enforce-  
25 ment actions; and

1 (C) policy or legislative recommendations  
2 to—

3 (i) improve transparency and competi-  
4 tion in the pharmaceutical supply chain;

5 (ii) prevent and deter anticompetitive  
6 behavior in the pharmaceutical supply  
7 chain; and

8 (iii) best ensure that consumers ben-  
9 efit from any cost savings or efficiencies  
10 that may result from mergers and consoli-  
11 dations.

12 (b) INTERIM REPORT.—Not later than 180 days  
13 after the date of enactment of this Act, the Commission  
14 shall submit to the appropriate committees of Congress  
15 an interim report on the progress of the report required  
16 by subsection (a), along with preliminary findings and  
17 conclusions based on information collected to that date.

18 (c) DEFINITIONS.—In this section:

19 (1) APPROPRIATE COMMITTEES OF CON-  
20 GRESS.—The term “appropriate committees of Con-  
21 gress” means—

22 (A) the Committee on Energy and Com-  
23 merce of the House of Representatives;

24 (B) the Committee on the Judiciary of the  
25 Senate; and



1 (C) the Committee on the Judiciary of the  
2 House of Representatives.

3 (2) COMMISSION.—The term “Commission”  
4 means the Federal Trade Commission.

5 **SEC. 403. REQUIREMENT THAT DIRECT-TO-CONSUMER AD-**  
6 **VERTISEMENTS FOR PRESCRIPTION DRUGS**  
7 **AND BIOLOGICAL PRODUCTS INCLUDE**  
8 **TRUTHFUL AND NON-MISLEADING PRICING**  
9 **INFORMATION.**

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

12 **“SEC. 1150D. REQUIREMENT THAT DIRECT-TO-CONSUMER**  
13 **ADVERTISEMENTS FOR PRESCRIPTION**  
14 **DRUGS AND BIOLOGICAL PRODUCTS IN-**  
15 **CLUDE TRUTHFUL AND NON-MISLEADING**  
16 **PRICING INFORMATION.**

17 “(a) IN GENERAL.—The Secretary shall require that  
18 each direct-to-consumer advertisement for a prescription  
19 drug or biological product for which payment is available  
20 under title XVIII or XIX includes an appropriate disclo-  
21 sure of truthful and non-misleading pricing information  
22 with respect to the drug or product.

23 “(b) DETERMINATION BY CMS.—The Secretary, act-  
24 ing through the Administrator of the Centers for Medicare  
25 & Medicaid Services, shall determine the components of

1 the requirement under subsection (a), such as the forms  
2 of advertising, the manner of disclosure, the price point  
3 listing, and the price information for disclosure.”.

4 **SEC. 404. CHANGE CONDITIONS OF FIRST GENERIC EXCLU-**  
5 **SIVITY TO SPUR ACCESS AND COMPETITION.**

6 Clause (iv) of section 505(j)(5)(B) of the Federal  
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B))  
8 is amended—

9 (1) in subclause (I), after “180 days after the  
10 date of the first commercial marketing of the drug  
11 (including the commercial marketing of the listed  
12 drug) by any first applicant” by inserting “or by an  
13 applicant whose application is approved pursuant to  
14 subclause (III)”;

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

17 “(III) APPLICANT APPROVAL.—An applica-  
18 tion containing a certification described in para-  
19 graph (2)(A)(vii)(IV) that is for a drug for  
20 which a first applicant has submitted an appli-  
21 cation containing such a certification can be ap-  
22 proved notwithstanding the eligibility of a first  
23 applicant for the 180-day exclusivity period de-  
24 scribed in subclause (II)(aa) if each of the fol-  
25 lowing conditions is met:

1           “(aa) The approval of such an appli-  
 2           cation could be made effective, but for the  
 3           eligibility of a first applicant for 180-day  
 4           exclusivity under this clause.

5           “(bb) At least 30 months have passed  
 6           since the date of submission of an applica-  
 7           tion for the drug by at least one first ap-  
 8           plicant.

9           “(cc) Approval of an application for  
 10          the drug submitted by at least one first ap-  
 11          plicant is not precluded under clause (iii).

12          “(dd) No application for the drug  
 13          submitted by any first applicant is ap-  
 14          proved at the time the conditions under  
 15          items (aa), (bb), and (cc) are all met, re-  
 16          gardless of whether such an application is  
 17          subsequently approved.”.

18 **SEC. 405. ENDING THE PRACTICE PREVENTING MARKET**  
 19 **COMPETITION KNOWN AS “PAY-FOR-DELAY”.**

20          (a) CONGRESSIONAL FINDINGS AND DECLARATION  
 21 OF PURPOSES.—

22           (1) FINDINGS.—Congress finds the following:

23           (A) In 1984, the Drug Price Competition  
 24           and Patent Term Restoration Act (Public Law  
 25           98–417) (referred to in this Act as the “1984

1 Act”), was enacted with the intent of facili-  
2 tating the early entry of generic drugs while  
3 preserving incentives for innovation.

4 (B) Prescription drugs make up approxi-  
5 mately 10 percent of the national health care  
6 spending.

7 (C) Initially, the 1984 Act was successful  
8 in facilitating generic competition to the benefit  
9 of consumers and health care payers, although  
10 88 percent of all prescriptions dispensed in the  
11 United States are generic drugs, they account  
12 for only 28 percent of all expenditures.

13 (D) Generic drugs cost substantially less  
14 than brand name drugs, with discounts off the  
15 brand price averaging 80 to 85 percent.

16 (E) Federal dollars currently account for  
17 over 40 percent of the \$325,000,000,000 spent  
18 on retail prescription drugs, and this share is  
19 expected to rise to 47 percent by 2025.

20 (F)(i) In recent years, the intent of the  
21 1984 Act has been subverted by certain settle-  
22 ment agreements in which brand name compa-  
23 nies transfer value to their potential generic  
24 competitors to settle claims that the generic

1 company is infringing the branded company's  
2 patents.

3 (ii) These “reverse payment” settlement  
4 agreements—

5 (I) allow a branded company to share  
6 its monopoly profits with the generic com-  
7 pany as a way to protect the branded com-  
8 pany's monopoly; and

9 (II) have unduly delayed the mar-  
10 keting of low-cost generic drugs contrary  
11 to free competition, the interests of con-  
12 sumers, and the principles underlying anti-  
13 trust law.

14 (iii) Because of the price disparity between  
15 brand name and generic drugs, such agree-  
16 ments are more profitable for both the brand  
17 and generic manufacturers than competition  
18 and will become increasingly common unless  
19 prohibited.

20 (iv) These agreements result in consumers  
21 losing the benefits that the 1984 Act was in-  
22 tended to provide.

23 (G) In 2010, the Biologics Price Competi-  
24 tion and Innovation Act (Public Law 111–148)  
25 (referred to in this Act as the “BPCIA”), was

1 enacted with the intent of facilitating the early  
2 entry of biosimilar and interchangeable follow-  
3 on versions of branded biological products while  
4 preserving incentives for innovation.

5 (H) Biological drugs play an important  
6 role in treating many serious illnesses, from  
7 cancers to genetic disorders. They are also ex-  
8 pensive, representing more than 40 percent of  
9 all prescription drug spending.

10 (I) Competition from biosimilar and inter-  
11 changeable biological products promises to  
12 lower drug costs and increase patient access to  
13 biological medicines. But “reverse payment”  
14 settlement agreements also threaten to delay  
15 the entry of biosimilar and interchangeable bio-  
16 logical products, which would undermine the  
17 goals of BPCIA.

18 (2) PURPOSES.—The purposes of this Act  
19 are—

20 (A) to enhance competition in the pharma-  
21 ceutical market by stopping anticompetitive  
22 agreements between brand name and generic  
23 drug and biosimilar biological product manufac-  
24 turers that limit, delay, or otherwise prevent

1 competition from generic drugs and biosimilar  
2 biological products; and

3 (B) to support the purpose and intent of  
4 antitrust law by prohibiting anticompetitive  
5 practices in the pharmaceutical industry that  
6 harm consumers.

7 (b) UNLAWFUL COMPENSATION FOR DELAY.—

8 (1) IN GENERAL.—The Federal Trade Commis-  
9 sion Act (15 U.S.C. 44 et seq.) is amended by in-  
10 serting after section 26 (15 U.S.C. 57c–2) the fol-  
11 lowing:

12 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS**  
13 **AND BIOSIMILARS.**

14 “(a) IN GENERAL.—

15 “(1) ENFORCEMENT PROCEEDING.—The Com-  
16 mission may initiate a proceeding to enforce the pro-  
17 visions of this section against the parties to any  
18 agreement resolving or settling, on a final or interim  
19 basis, a patent claim, in connection with the sale of  
20 a drug product or biological product.

21 “(2) PRESUMPTION AND VIOLATION.—

22 “(A) IN GENERAL.—Subject to subpara-  
23 graph (B), in such a proceeding, an agreement  
24 shall be presumed to have anticompetitive ef-  
25 fects and shall be a violation of this section if—

1           “(i) an ANDA filer or a biosimilar bi-  
2           ological product application filer receives  
3           anything of value, including an exclusive li-  
4           cense; and

5           “(ii) the ANDA filer or biosimilar bio-  
6           logical product application filer agrees to  
7           limit or forgo research, development, man-  
8           ufacturing, marketing, or sales of the  
9           ANDA product or biosimilar biological  
10          product, as applicable, for any period of  
11          time.

12          “(B)   EXCEPTION.—Subparagraph   (A)  
13          shall not apply if the parties to such agreement  
14          demonstrate by clear and convincing evidence  
15          that—

16               “(i) the value described in subpara-  
17               graph (A)(i) is compensation solely for  
18               other goods or services that the ANDA  
19               filer or biosimilar biological product appli-  
20               cation filer has promised to provide; or

21               “(ii) the procompetitive benefits of the  
22               agreement outweigh the anticompetitive ef-  
23               fects of the agreement.



1       “(b) LIMITATIONS.—In determining whether the set-  
2 tling parties have met their burden under subsection  
3 (a)(2)(B), the fact finder shall not presume—

4               “(1) that entry would not have occurred until  
5 the expiration of the relevant patent or statutory ex-  
6 clusivity; or

7               “(2) that the agreement’s provision for entry of  
8 the ANDA product or biosimilar biological product  
9 prior to the expiration of the relevant patent or stat-  
10 utory exclusivity means that the agreement is pro-  
11 competitive.

12       “(c) EXCLUSIONS.—Nothing in this section shall pro-  
13 hibit a resolution or settlement of a patent infringement  
14 claim in which the consideration that the ANDA filer or  
15 biosimilar biological product application filer, respectively,  
16 receives as part of the resolution or settlement includes  
17 only one or more of the following:

18               “(1) The right to market and secure final ap-  
19 proval in the United States for the ANDA product  
20 or biosimilar biological product at a date, whether  
21 certain or contingent, prior to the expiration of—

22                       “(A) any patent that is the basis for the  
23 patent infringement claim; or

24                       “(B) any patent right or other statutory  
25 exclusivity that would prevent the marketing of

1           such ANDA product or biosimilar biological  
2           product.

3           “(2) A payment for reasonable litigation ex-  
4           penses not to exceed—

5                   “(A) for calendar year 2021, \$7,500,000;  
6           or

7                   “(B) for calendar year 2022 and each sub-  
8           sequent calendar year, the amount determined  
9           for the preceding calendar year adjusted to re-  
10          flect the percentage increase (if any) in the  
11          Producer Price Index for Legal Services pub-  
12          lished by the Bureau of Labor Statistics of the  
13          Department of Labor for the most recent cal-  
14          endar year.

15          “(3) A covenant not to sue on any claim that  
16          the ANDA product or biosimilar biological product  
17          infringes a United States patent.

18          “(d) ENFORCEMENT.—

19                  “(1) ENFORCEMENT.—A violation of this sec-  
20          tion shall be treated as an unfair method of competi-  
21          tion under section 5(a)(1).

22          “(2) JUDICIAL REVIEW.—

23                  “(A) IN GENERAL.—Any party that is sub-  
24          ject to a final order of the Commission, issued  
25          in an administrative adjudicative proceeding

1 under the authority of subsection (a)(1), may,  
2 within 30 days of the issuance of such order,  
3 petition for review of such order in—

4 “(i) the United States Court of Ap-  
5 peals for the District of Columbia Circuit;

6 “(ii) the United States Court of Ap-  
7 peals for the circuit in which the ultimate  
8 parent entity, as defined in section  
9 801.1(a)(3) of title 16, Code of Federal  
10 Regulations, or any successor thereto, of  
11 the NDA holder or biological product li-  
12 cense holder is incorporated as of the date  
13 that the NDA or biological product license  
14 application, as applicable, is filed with the  
15 Commissioner of Food and Drugs; or

16 “(iii) the United States Court of Ap-  
17 peals for the circuit in which the ultimate  
18 parent entity of the ANDA filer or bio-  
19 similar biological product application filer  
20 is incorporated as of the date that the  
21 ANDA or biosimilar biological product ap-  
22 plication is filed with the Commissioner of  
23 Food and Drugs.

24 “(B) TREATMENT OF FINDINGS.—In a  
25 proceeding for judicial review of a final order of

1           the Commission, the findings of the Commis-  
2           sion as to the facts, if supported by evidence,  
3           shall be conclusive.

4           “(e) ANTITRUST LAWS.—Nothing in this section  
5 shall modify, impair, limit, or supersede the applicability  
6 of the antitrust laws as defined in subsection (a) of the  
7 first section of the Clayton Act (15 U.S.C. 12(a)), and  
8 of section 5 of this Act to the extent that section 5 applies  
9 to unfair methods of competition. Nothing in this section  
10 shall modify, impair, limit, or supersede the right of an  
11 ANDA filer or biosimilar biological product application  
12 filer to assert claims or counterclaims against any person,  
13 under the antitrust laws or other laws relating to unfair  
14 competition.

15          “(f) PENALTIES.—

16               “(1) FORFEITURE.—Each party that violates or  
17 assists in the violation of this section shall forfeit  
18 and pay to the United States a civil penalty suffi-  
19 cient to deter violations of this section, but in no  
20 event greater than 3 times the value received by the  
21 party that is reasonably attributable to the violation  
22 of this section. If no such value has been received by  
23 the NDA holder, the biological product license hold-  
24 er, the ANDA filer, or the biosimilar biological prod-  
25 uct application filer, the penalty to the NDA holder,

1 the biological product license holder, the ANDA  
2 filer, or the biosimilar biological product application  
3 filer shall be sufficient to deter violations, but in no  
4 event shall be greater than 3 times the value given  
5 to an ANDA filer or biosimilar biological product  
6 application filer reasonably attributable to the viola-  
7 tion of this section. Such penalty shall accrue to the  
8 United States and may be recovered in a civil action  
9 brought by the Commission, in its own name by any  
10 of its attorneys designated by it for such purpose, in  
11 a district court of the United States against any  
12 party that violates this section. In such actions, the  
13 United States district courts are empowered to grant  
14 mandatory injunctions and such other and further  
15 equitable relief as they deem appropriate.

16 “(2) CEASE AND DESIST.—

17 “(A) IN GENERAL.—If the Commission has  
18 issued a cease and desist order with respect to  
19 a party in an administrative adjudicative pro-  
20 ceeding under the authority of subsection  
21 (a)(1), an action brought pursuant to para-  
22 graph (1) may be commenced against such  
23 party at any time before the expiration of 1  
24 year after such order becomes final pursuant to  
25 section 5(g).

1           “(B) EXCEPTION.—In an action under  
2           subparagraph (A), the findings of the Commis-  
3           sion as to the material facts in the administra-  
4           tive adjudicative proceeding with respect to the  
5           violation of this section by a party shall be con-  
6           clusive unless—

7                   “(i) the terms of such cease and de-  
8                   sist order expressly provide that the Com-  
9                   mission’s findings shall not be conclusive;  
10                  or

11                  “(ii) the order became final by reason  
12                  of section 5(g)(1), in which case such find-  
13                  ing shall be conclusive if supported by evi-  
14                  dence.

15           “(3) CIVIL PENALTY.—In determining the  
16           amount of the civil penalty described in this section,  
17           the court shall take into account—

18                   “(A) the nature, circumstances, extent,  
19                   and gravity of the violation;

20                   “(B) with respect to the violator, the de-  
21                   gree of culpability, any history of violations, the  
22                   ability to pay, any effect on the ability to con-  
23                   tinue doing business, profits earned by the  
24                   NDA holder, the biological product license hold-  
25                   er, the ANDA filer, or the biosimilar biological

1 product application filer, compensation received  
2 by the ANDA filer or biosimilar biological prod-  
3 uct application filer, and the amount of com-  
4 merce affected; and

5 “(C) other matters that justice requires.

6 “(4) REMEDIES IN ADDITION.—Remedies pro-  
7 vided in this subsection are in addition to, and not  
8 in lieu of, any other remedy provided by Federal  
9 law. Nothing in this paragraph shall be construed to  
10 affect any authority of the Commission under any  
11 other provision of law.

12 “(g) DEFINITIONS.—In this section:

13 “(1) AGREEMENT.—The term ‘agreement’  
14 means anything that would constitute an agreement  
15 under section 1 of the Sherman Act (15 U.S.C. 1)  
16 or section 5 of this Act.

17 “(2) AGREEMENT RESOLVING OR SETTLING A  
18 PATENT INFRINGEMENT CLAIM.—The term ‘agree-  
19 ment resolving or settling a patent infringement  
20 claim’ includes any agreement that is entered into  
21 within 30 days of the resolution or the settlement of  
22 the claim, or any other agreement that is contingent  
23 upon, provides a contingent condition for, or is oth-  
24 erwise related to the resolution or settlement of the  
25 claim.

1           “(3) ANDA.—The term ‘ANDA’ means an ab-  
2           breviated new drug application filed under section  
3           505(j) of the Federal Food, Drug, and Cosmetic Act  
4           (21 U.S.C. 355(j)) or a new drug application filed  
5           under section 505(b)(2) of the Federal Food, Drug,  
6           and Cosmetic Act (21 U.S.C. 355(b)(2)).

7           “(4) ANDA FILER.—The term ‘ANDA filer’  
8           means a party that owns or controls an ANDA filed  
9           with the Food and Drug Administration or has the  
10          exclusive rights under such ANDA to distribute the  
11          ANDA product.

12          “(5) ANDA PRODUCT.—The term ‘ANDA  
13          product’ means the product to be manufactured  
14          under the ANDA that is the subject of the patent  
15          infringement claim.

16          “(6) BIOLOGICAL PRODUCT.—The term ‘bio-  
17          logical product’ has the meaning given such term in  
18          section 351(i)(1) of the Public Health Service Act  
19          (42 U.S.C. 262(i)(1)).

20          “(7) BIOLOGICAL PRODUCT LICENSE APPLICA-  
21          TION.—The term ‘biological product license applica-  
22          tion’ means an application under section 351(a) of  
23          the Public Health Service Act (42 U.S.C. 262(a)).



1           “(8) BIOLOGICAL PRODUCT LICENSE HOLD-  
2           ER.—The term ‘biological product license holder’  
3           means—

4                   “(A) the holder of an approved biological  
5                   product license application for a biological prod-  
6                   uct;

7                   “(B) a person owning or controlling en-  
8                   forcement of any patents that claim the biologi-  
9                   cal product that is the subject of such approved  
10                  application; or

11                  “(C) the predecessors, subsidiaries, divi-  
12                  sions, groups, and affiliates controlled by, con-  
13                  trolling, or under common control with any of  
14                  the entities described in subparagraphs (A) and  
15                  (B) (such control to be presumed by direct or  
16                  indirect share ownership of 50 percent or great-  
17                  er), as well as the licensees, licensors, succes-  
18                  sors, and assigns of each of the entities.

19           “(9) BIOSIMILAR BIOLOGICAL PRODUCT.—The  
20           term ‘biosimilar biological product’ means the prod-  
21           uct to be manufactured under the biosimilar biologi-  
22           cal product application that is the subject of the pat-  
23           ent infringement claim.

24           “(10) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-  
25           CATION.—The term ‘biosimilar biological product ap-

1       plication’ means an application under section 351(k)  
2       of the Public Health Service Act (42 U.S.C. 262(k))  
3       for licensure of a biological product as biosimilar to,  
4       or interchangeable with, a reference product.

5               “(11) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-  
6       CATION FILER.—The term ‘biosimilar biological  
7       product application filer’ means a party that owns or  
8       controls a biosimilar biological product application  
9       filed with the Food and Drug Administration or has  
10      the exclusive rights under such application to dis-  
11      tribute the biosimilar biological product.

12              “(12) DRUG PRODUCT.—The term ‘drug prod-  
13      uct’ has the meaning given such term in section  
14      314.3(b) of title 21, Code of Federal Regulations (or  
15      any successor regulation).

16              “(13) MARKET.—The term ‘market’ means the  
17      promotion, offering for sale, selling, or distribution  
18      of a drug product.

19              “(14) NDA.—The term ‘NDA’ means a new  
20      drug application filed under section 505(b) of the  
21      Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
22      355(b)).

23              “(15) NDA HOLDER.—The term ‘NDA holder’  
24      means—

1           “(A) the holder of an approved NDA appli-  
2           cation for a drug product;

3           “(B) a person owning or controlling en-  
4           forcement of the patent listed in the Approved  
5           Drug Products With Therapeutic Equivalence  
6           Evaluations (commonly known as the ‘FDA Or-  
7           ange Book’) in connection with the NDA; or

8           “(C) the predecessors, subsidiaries, divi-  
9           sions, groups, and affiliates controlled by, con-  
10          trolling, or under common control with any of  
11          the entities described in subparagraphs (A) and  
12          (B) (such control to be presumed by direct or  
13          indirect share ownership of 50 percent or great-  
14          er), as well as the licensees, licensors, succes-  
15          sors, and assigns of each of the entities.

16          “(16) PARTY.—The term ‘party’ means any  
17          person, partnership, corporation, or other legal enti-  
18          ty.

19          “(17) PATENT INFRINGEMENT.—The term  
20          ‘patent infringement’ means infringement of any  
21          patent or of any filed patent application, including  
22          any extension, reissue, renewal, division, continu-  
23          ation, continuation in part, reexamination, patent  
24          term restoration, patents of addition, and extensions  
25          thereof.

1           “(18) PATENT INFRINGEMENT CLAIM.—The  
2           term ‘patent infringement claim’ means any allega-  
3           tion made to an ANDA filer or biosimilar biological  
4           product application filer, whether or not included in  
5           a complaint filed with a court of law, that its ANDA  
6           or ANDA product, or biosimilar biological product li-  
7           cense application or biosimilar biological product,  
8           may infringe any patent held by, or exclusively li-  
9           censed to, the NDA holder, biological product license  
10          holder, ANDA filer, or biosimilar biological product  
11          application filer of the drug product or biological  
12          product, as applicable.

13          “(19) STATUTORY EXCLUSIVITY.—The term  
14          ‘statutory exclusivity’ means those prohibitions on  
15          the approval of drug applications under clauses (ii)  
16          through (iv) of section 505(c)(3)(E) (5- and 3-year  
17          data exclusivity), section 527 (orphan drug exclu-  
18          sivity), or section 505A (pediatric exclusivity) of the  
19          Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
20          355(c)(3)(E), 360cc, 355a), or on the licensing of  
21          biological product applications under section  
22          351(k)(7) (12-year exclusivity) or paragraph (2) or  
23          (3) of section 351(m) (pediatric exclusivity) of the  
24          Public Health Service Act (42 U.S.C. 262) or under  
25          section 527 of the Federal Food, Drug, and Cos-

1       metetic Act (21 U.S.C. 360cc) (orphan drug exclu-  
2       sivity).”.

3               (2) EFFECTIVE DATE.—Section 27 of the Fed-  
4       eral Trade Commission Act, as added by this sec-  
5       tion, shall apply to all agreements described in sec-  
6       tion 27(a)(1) of that Act entered into on or after the  
7       date of enactment of this Act.

8       (c) CERTIFICATION OF AGREEMENTS.—

9               (1) NOTICE OF ALL AGREEMENTS.—Section  
10       1111(7) of the Medicare Prescription Drug, Im-  
11       provement, and Modernization Act of 2003 (21  
12       U.S.C. 355 note) is amended by inserting “, or the  
13       owner of a patent for which a claim of infringement  
14       could reasonably be asserted against any person for  
15       making, using, offering to sell, selling, or importing  
16       into the United States a biological product that is  
17       the subject of a biosimilar biological product applica-  
18       tion” before the period at the end.

19               (2) CERTIFICATION OF AGREEMENTS.—Section  
20       1112 of the Medicare Prescription Drug, Improve-  
21       ment, and Modernization Act of 2003 (21 U.S.C.  
22       355 note) is amended by adding at the end the fol-  
23       lowing:

24       “(d) CERTIFICATION.—The Chief Executive Officer  
25       or the company official responsible for negotiating any

1 agreement under subsection (a) or (b) that is required to  
2 be filed under subsection (c), within 30 days after such  
3 filing, shall execute and file with the Assistant Attorney  
4 General and the Commission a certification as follows: ‘I  
5 declare that the following is true, correct, and complete  
6 to the best of my knowledge: The materials filed with the  
7 Federal Trade Commission and the Department of Justice  
8 under section 1112 of subtitle B of title XI of the Medi-  
9 care Prescription Drug, Improvement, and Modernization  
10 Act of 2003, with respect to the agreement referenced in  
11 this certification—

12           “(1) represent the complete, final, and exclu-  
13           sive agreement between the parties;

14           “(2) include any ancillary agreements that are  
15           contingent upon, provide a contingent condition for,  
16           or are otherwise related to, the referenced agree-  
17           ment; and

18           “(3) include written descriptions of any oral  
19           agreements, representations, commitments, or prom-  
20           ises between the parties that are responsive to sub-  
21           section (a) or (b) of such section 1112 and have not  
22           been reduced to writing.’”.

23           (d) NOTIFICATION OF AGREEMENTS.—Section 1112  
24 of the Medicare Prescription Drug, Improvement, and  
25 Modernization Act of 2003 (21 U.S.C. 355 note), as

1 amended by section 4(b), is further amended by adding  
2 at the end the following:

3 “(e) RULE OF CONSTRUCTION.—

4 “(1) IN GENERAL.—An agreement that is re-  
5 quired under subsection (a) or (b) shall include  
6 agreements resolving any outstanding disputes, in-  
7 cluding agreements resolving or settling a Patent  
8 Trial and Appeal Board proceeding.

9 “(2) DEFINITION.—For purposes of subpara-  
10 graph (A), the term ‘Patent Trial and Appeal Board  
11 proceeding’ means a proceeding conducted by the  
12 Patent Trial and Appeal Board of the United States  
13 Patent and Trademark Office, including an inter  
14 partes review instituted under chapter 31 of title 35,  
15 United States Code, a post-grant review instituted  
16 under chapter 32 of that title (including a pro-  
17 ceeding instituted pursuant to the transitional pro-  
18 gram for covered business method patents, as de-  
19 scribed in section 18 of the Leahy-Smith America  
20 Invents Act (35 U.S.C. 321 note)), and a derivation  
21 proceeding instituted under section 135 of that  
22 title.”.

23 (e) FORFEITURE OF 180-DAY EXCLUSIVITY PE-  
24 RIOD.—Section 505(j)(5)(D)(i)(V) of the Federal Food,  
25 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))

1 is amended by inserting “section 27 of the Federal Trade  
2 Commission Act or” after “that the agreement has vio-  
3 lated”.

4 (f) COMMISSION LITIGATION AUTHORITY.—Section  
5 16(a)(2) of the Federal Trade Commission Act (15 U.S.C.  
6 56(a)(2)) is amended—

7 (1) in subparagraph (D), by striking “or” after  
8 the semicolon;

9 (2) in subparagraph (E), by inserting “or”  
10 after the semicolon; and

11 (3) inserting after subparagraph (E) the fol-  
12 lowing:

13 “(F) under section 27,”.

14 (g) REPORT ON ADDITIONAL EXCLUSION.—

15 (1) IN GENERAL.—Not later than 1 year after  
16 the date of enactment of this Act, the Federal Trade  
17 Commission shall submit to the Committee on the  
18 Judiciary of the Senate and the Committee on the  
19 Judiciary of the House of Representatives a rec-  
20 ommendation, and the Commission’s basis for such  
21 recommendation, regarding a potential amendment  
22 to include in section 27(c) of the Federal Trade  
23 Commission Act (as added by section 3 of this Act)  
24 an additional exclusion for consideration granted by  
25 an NDA holder to a ANDA filer or by a biological



1 product license holder to a biosimilar biological prod-  
2 uct application filer as part of the resolution or set-  
3 tlement, a release, waiver, or limitation of a claim  
4 for damages or other monetary relief.

5 (2) DEFINITIONS.—In this section, the terms  
6 “ANDA filer”, “biological product license holder”,  
7 “biosimilar biological product application filer”, and  
8 “NDA holder” have the meanings given such terms  
9 in section 27(g) of the Federal Trade Commission  
10 Act (as added by section 3 of this Act).

11 (h) STATUTE OF LIMITATIONS.—The Federal Trade  
12 Commission shall commence any enforcement proceeding  
13 described in section 27 of the Federal Trade Commission  
14 Act, as added by section 3, except for an action described  
15 in section 27(f)(2) of the Federal Trade Commission Act,  
16 not later than 6 years after the date on which the parties  
17 to the agreement file the certification under section  
18 1112(d) of the Medicare Prescription Drug Improvement  
19 and Modernization Act of 2003 (21 U.S.C. 355 note).

20 (i) SEVERABILITY.—If any provision of this Act, an  
21 amendment made by this Act, or the application of such  
22 provision or amendment to any person or circumstance is  
23 held to be unconstitutional, the remainder of this Act, the  
24 amendments made by this Act, and the application of the

1 provisions of such Act or amendments to any person or  
2 circumstance shall not be affected.

3 **SEC. 406. EMPOWERING THE FTC TO PREVENT “PRODUCT**  
4 **HOPPING”.**

5 (a) IN GENERAL.—The Federal Trade Commission  
6 Act (15 U.S.C. 41 et seq.) is amended by inserting after  
7 section 26 (15 U.S.C. 57c–2) the following:

8 **“SEC. 27. PRODUCT HOPPING.**

9 “(a) DEFINITIONS.—In this section:

10 “(1) ABBREVIATED NEW DRUG APPLICATION.—

11 The term ‘abbreviated new drug application’ means  
12 an application under subsection (b)(2) or (j) of sec-  
13 tion 505 of the Federal Food, Drug, and Cosmetic  
14 Act (21 U.S.C. 355).

15 “(2) BIOSIMILAR BIOLOGICAL PRODUCT.—The  
16 term ‘biosimilar biological product’ means a biologi-  
17 cal product licensed under section 351(k) of the  
18 Public Health Service Act (42 U.S.C. 262(k)).

19 “(3) BIOSIMILAR BIOLOGICAL PRODUCT LI-  
20 CENSE APPLICATION.—The term ‘biosimilar biologi-  
21 cal product license application’ means an application  
22 submitted under section 351(k) of the Public Health  
23 Service Act (42 U.S.C. 262(k)).

24 “(4) FOLLOW-ON PRODUCT.—The term ‘follow-  
25 on product’—

1           “(A) means a drug approved through an  
2           application or supplement to an application sub-  
3           mitted under section 505(b) of the Federal  
4           Food, Drug, and Cosmetic Act (21 U.S.C.  
5           355(b)) or a biological product licensed through  
6           an application or supplement to an application  
7           submitted under section 351(a) of the Public  
8           Health Service Act (42 U.S.C. 262(a)) for a  
9           change, modification, or reformulation to the  
10          same manufacturer’s previously approved drug  
11          or biological product that treats the same med-  
12          ical condition; and

13          “(B) excludes such an application or sup-  
14          plement to an application for a change, modi-  
15          fication, or reformulation of a drug or biological  
16          product that is requested by the Secretary or  
17          necessary to comply with law, including sections  
18          505A and 505B of the Federal Food, Drug,  
19          and Cosmetic Act (21 U.S.C. 355a, 355c).

20          “(5) GENERIC DRUG.—The term ‘generic drug’  
21          means a drug approved under an application sub-  
22          mitted under subsection (b)(2) or (j) of section 505  
23          of the Federal Food, Drug, and Cosmetic Act (21  
24          U.S.C. 355).

1           “(6) LISTED DRUG.—The term ‘listed drug’  
2       means a drug listed under section 505(j)(7) of the  
3       Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
4       355(j)(7)).

5           “(7) MANUFACTURER.—The term ‘manufac-  
6       turer’ means the holder, licensee, or assignee of—

7               “(A) an approved application for a drug  
8               under section 505(c) of the Federal Food,  
9               Drug, and Cosmetic Act (21 U.S.C. 355(c)); or

10               “(B) a biological product license under sec-  
11               tion 351(a) of the Public Health Service Act  
12               (42 U.S.C. 262(a)).

13           “(8) REFERENCE PRODUCT.—The term ‘ref-  
14       erence product’ has the meaning given the term in  
15       section 351(i) of the Public Health Service Act (42  
16       U.S.C. 262(i)).

17           “(9) ULTIMATE PARENT ENTITY.—The term  
18       ‘ultimate parent entity’ has the meaning given the  
19       term in section 801.1 of title 16, Code of Federal  
20       Regulations, or any successor regulation.

21       “(b) PROHIBITION ON PRODUCT HOPPING.—

22               “(1) PRIMA FACIE.—Except as provided in  
23       paragraph (2), a manufacturer of a reference prod-  
24       uct or listed drug shall be considered to have en-  
25       gaged in an unfair method of competition in or af-

1       fecting commerce in violation of section 5(a) if the  
2       Commission demonstrates by a preponderance of the  
3       evidence in a proceeding initiated by the Commission  
4       under subsection (c)(1)(A), or in a suit brought  
5       under subparagraph (B) or (C) of subsection (c)(1),  
6       that, during the period beginning on the date on  
7       which the manufacturer of the reference product or  
8       listed drug first receives notice that an applicant has  
9       submitted to the Commissioner of Food and Drugs  
10      an abbreviated new drug application or biosimilar bi-  
11      ological product license application and ending on  
12      the date that is 180 days after the date on which  
13      that generic drug or biosimilar biological product is  
14      first marketed, the manufacturer engaged in either  
15      of the following actions:

16               “(A) The manufacturer engaged in a hard  
17               switch, which shall be established by dem-  
18               onstrating that the manufacturer engaged in ei-  
19               ther of the following actions:

20                       “(i) Upon the request of the manufac-  
21                       turer of the listed drug or reference prod-  
22                       uct, the Commissioner of Food and Drugs  
23                       withdrew the approval of the application  
24                       for the listed drug or reference product or  
25                       placed the listed drug or reference product

1 on the discontinued products list and the  
2 manufacturer marketed or sold a follow-on  
3 product.

4 “(ii) The manufacturer of the listed  
5 drug or reference product—

6 “(I)(aa) announced withdrawal  
7 of, discontinuance of the manufacture  
8 of, or intent to withdraw the applica-  
9 tion with respect to the drug or ref-  
10 erence product in a manner that im-  
11 pedes competition from a generic drug  
12 or a biosimilar biological product, as  
13 established by objective circumstances;  
14 or

15 “(bb) destroyed the inventory of  
16 the listed drug or reference product in  
17 a manner that impedes competition  
18 from a generic drug or a biosimilar bi-  
19 ological product, which may be estab-  
20 lished by objective circumstances; and

21 “(II) marketed or sold a follow-  
22 on product.

23 “(B) The manufacturer engaged in a soft  
24 switch, which shall be established by dem-

onstrating that the manufacturer engaged in  
both of the following actions:

“(i) The manufacturer took actions  
with respect to the listed drug or reference  
product other than those described in sub-  
paragraph (A) that unfairly disadvantage  
the listed drug or reference product rel-  
ative to the follow-on product described in  
clause (ii) in a manner that impedes com-  
petition from a generic drug or a bio-  
similar biological product that is highly  
similar to, and has no clinically meaningful  
difference with respect to safety, purity,  
and potency from, the reference product,  
which may be established by objective cir-  
cumstances.

“(ii) The manufacturer marketed or  
sold a follow-on product.

“(2) JUSTIFICATION.—

“(A) IN GENERAL.—Subject to paragraph  
(3), the actions described in paragraph (1) by  
a manufacturer of a listed drug or reference  
product shall not be considered to be an unfair  
method of competition in or affecting commerce  
if—

1 “(i) the manufacturer demonstrates to  
2 the Commission or a district court of the  
3 United States, as applicable, by a prepon-  
4 derance of the evidence in a proceeding ini-  
5 tiated by the Commission under subsection  
6 (c)(1)(A), or in a suit brought under sub-  
7 paragraph (B) or (C) of subsection (c)(1),  
8 that—

9 “(I) the manufacturer would  
10 have taken the actions regardless of  
11 whether a generic drug that ref-  
12 erences the listed drug or biosimilar  
13 biological product that references the  
14 reference product had already entered  
15 the market; and

16 “(II)(aa) with respect to a hard  
17 switch under paragraph (1)(A), the  
18 manufacturer took the action for rea-  
19 sons relating to the safety risk to pa-  
20 tients of the listed drug or reference  
21 product;

22 “(bb) with respect to an action  
23 described in item (aa) or (bb) of para-  
24 graph (1)(A)(ii)(I), there is a supply  
25 disruption that—



1                   “(AA) is outside of the con-  
2                   trol of the manufacturer;

3                   “(BB) prevents the produc-  
4                   tion or distribution of the appli-  
5                   cable listed drug or reference  
6                   product; and

7                   “(CC) cannot be remedied  
8                   by reasonable efforts; or

9                   “(cc) with respect to a soft  
10                  switch under paragraph (1)(B), the  
11                  manufacturer had legitimate pro-com-  
12                  petitive reasons, apart from the finan-  
13                  cial effects of reduced competition, to  
14                  take the action.

15                 “(B) RULE OF CONSTRUCTION.—Nothing  
16                 in subparagraph (A) may be construed to limit  
17                 the information that the Commission may oth-  
18                 erwise obtain in any proceeding or action insti-  
19                 tuted with respect to a violation of this section.

20                 “(3) RESPONSE.—With respect to a justifica-  
21                 tion offered by a manufacturer under paragraph (2),  
22                 the Commission may—

23                         “(A) rebut any evidence presented by a  
24                         manufacturer during that justification; or

1           “(B) establish by a preponderance of the  
2           evidence that, on balance, the pro-competitive  
3           benefits from the conduct described in subpara-  
4           graph (A) or (B) of paragraph (1), as applica-  
5           ble, do not outweigh any anticompetitive effects  
6           of the conduct, even in consideration of the jus-  
7           tification so offered.

8           “(c) ENFORCEMENT.—

9           “(1) IN GENERAL.—If the Commission has rea-  
10          son to believe that any manufacturer has violated, is  
11          violating, or is about to violate this section, the  
12          Commission may take any of the following actions:

13               “(A) Institute a proceeding—

14                   “(i) that, except as provided in para-  
15                   graph (2), complies with the requirements  
16                   under section 5(b); and

17                   “(ii) in which the Commission may  
18                   impose on the manufacturer any penalty  
19                   that the Commission may impose for a vio-  
20                   lation of section 5.

21               “(B) In the same manner and to the same  
22               extent as provided in section 13(b), bring suit  
23               in a district court of the United States to tem-  
24               porarily enjoin the action of the manufacturer.

1           “(C) Bring suit in a district court of the  
2           United States, in which the Commission may  
3           seek—

4                   “(i) to permanently enjoin the action  
5                   of the manufacturer;

6                   “(ii) any of the remedies described in  
7                   paragraph (3); and

8                   “(iii) any other equitable remedy, in-  
9                   cluding ancillary equitable relief.

10          “(2) JUDICIAL REVIEW.—

11               “(A) IN GENERAL.—Notwithstanding any  
12               provision of section 5, any manufacturer that is  
13               subject to a final order of the Commission that  
14               is issued in a proceeding instituted under para-  
15               graph (1)(A) may, not later than 30 days after  
16               the date on which the Commission issues the  
17               order, petition for review of the order in—

18                   “(i) the United States Court of Ap-  
19                   peals for the District of Columbia Circuit;  
20                   or

21                   “(ii) the court of appeals of the  
22                   United States for the circuit in which the  
23                   ultimate parent entity of the manufacturer  
24                   is incorporated.

1           “(B) TREATMENT OF FINDINGS.—In a re-  
2 view of an order issued by the Commission con-  
3 ducted by a court of appeals of the United  
4 States under subparagraph (A), the factual  
5 findings of the Commission shall be conclusive  
6 if those facts are supported by the evidence.

7           “(3) EQUITABLE REMEDIES.—

8           “(A) DISGORGEMENT.—

9           “(i) IN GENERAL.—In a suit brought  
10 under paragraph (1)(C), the Commission  
11 may seek, and the court may order,  
12 disgorgement of any unjust enrichment  
13 that a person obtained as a result of the  
14 violation that gives rise to the suit.

15           “(ii) CALCULATION.—Any disgor-  
16 gement that is ordered with respect to a  
17 person under clause (i) shall be offset by  
18 any amount of restitution ordered under  
19 subparagraph (B).

20           “(iii) LIMITATIONS PERIOD.—The  
21 Commission may seek disgorgement under  
22 this subparagraph not later than 5 years  
23 after the latest date on which the person  
24 from which the disgorgement is sought re-  
25 ceives any unjust enrichment from the ef-

fects of the violation that gives rise to the  
suit in which the Commission seeks the  
disgorgement.

“(B) RESTITUTION.—

“(i) IN GENERAL.—In a suit brought  
under paragraph (1)(C), the Commission  
may seek, and the court may order, res-  
titution with respect to the violation that  
gives rise to the suit.

“(ii) LIMITATIONS PERIOD.—The  
Commission may seek restitution under  
this subparagraph not later than 5 years  
after the latest date on which the person  
from which the restitution is sought re-  
ceives any unjust enrichment from the ef-  
fects of the violation that gives rise to the  
suit in which the Commission seeks the  
restitution.

“(4) RULES OF CONSTRUCTION.—Nothing in  
this subsection may be construed as—

“(A) requiring the Commission to bring a  
suit seeking a temporary injunction under pa-  
graph (1)(B) before bringing a suit seeking a  
permanent injunction under paragraph (1)(C);  
or

1                   “(B) affecting any other authority of the  
2                   Commission under this Act to seek relief or ob-  
3                   tain a remedy with respect to a violation of this  
4                   Act.”.

5           (b) APPLICABILITY.—Section 27 of the Federal  
6 Trade Commission Act, as added by subsection (a), shall  
7 apply with respect to any—

8                   (1) conduct that occurs on or after the date of  
9                   enactment of this Act; and

10                   (2) action or proceeding that is commenced on  
11                   or after the date of enactment of this Act.

12           (c) ANTITRUST LAWS.—Nothing in this section, or  
13 the amendments made by this section, shall modify, im-  
14 pair, limit, or supersede the applicability of the antitrust  
15 laws as defined in subsection (a) of the first section of  
16 the Clayton Act (15 U.S.C. 12(a)), and of section 5 of  
17 the Federal Trade Commission Act (15 U.S.C. 45) to the  
18 extent that it applies to unfair methods of competition.

19           (d) RULEMAKING.—The Federal Trade Commission  
20 may issue rules under section 553 of title 5, United States  
21 Code, to carry out section 27 of the Federal Trade Com-  
22 mission Act, as added by subsection (a), including by de-  
23 fining any terms used in such section 27 (other than terms  
24 that are defined in subsection (a) of such section 27).

1 **SEC. 407. PROMOTING COMPETITION BY LIMITING PATENT**  
2 **THICKETS.**

3 (a) IN GENERAL.—Section 271(e) of title 35, United  
4 States Code, is amended—

5 (1) in paragraph (2)(C), in the flush text fol-  
6 lowing clause (ii), by adding at the end the fol-  
7 lowing: “With respect to a submission described in  
8 clause (ii), the act of infringement shall extend to  
9 any patent that claims the biological product, a  
10 method of using the biological product, or a method  
11 or product used to manufacture the biological prod-  
12 uct.”; and

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

14 “(7)(A) Subject to subparagraphs (C), (D), and (E),  
15 if the sponsor of an approved application for a reference  
16 product, as defined in section 351(i) of the Public Health  
17 Service Act (42 U.S.C. 262(i)) (referred to in this para-  
18 graph as the ‘reference product sponsor’), brings an action  
19 for infringement under this section against an applicant  
20 for approval of a biological product under section 351(k)  
21 of such Act that references that reference product (re-  
22 ferred to in this paragraph as the ‘subsection (k) appli-  
23 cant’), the reference product sponsor may assert in the  
24 action a total of not more than 20 patents of the type  
25 described in subparagraph (B), not more than 10 of which

1 shall have issued after the date specified in section  
2 351(l)(7)(A) of such Act.

3 “(B) The patents described in this subparagraph are  
4 patents that satisfy each of the following requirements:

5 “(i) Patents that claim the biological product  
6 that is the subject of an application under section  
7 351(k) of the Public Health Service Act (42 U.S.C.  
8 262(k)) (or a use of that product) or a method or  
9 product used in the manufacture of such biological  
10 product.

11 “(ii) Patents that are included on the list of  
12 patents described in section 351(l)(3)(A) of the Pub-  
13 lic Health Service Act (42 U.S.C. 262(l)(3)(A)), in-  
14 cluding as provided under section 351(l)(7) of such  
15 Act.

16 “(iii) Patents that—

17 “(I) have an actual filing date of more  
18 than 4 years after the date on which the ref-  
19 erence product is approved; or

20 “(II) include a claim to a method in a  
21 manufacturing process that is not used by the  
22 reference product sponsor.

23 “(C) The court in which an action described in sub-  
24 paragraph (A) is brought may increase the number of pat-  
25 ents limited under that subparagraph—



1           “(i) if the request to increase that number is  
2       made without undue delay; and

3           “(ii)(I) if the interest of justice so requires; or  
4       “(II) for good cause shown, which—

5           “(aa) shall be established if the subsection  
6       (k) applicant fails to provide information re-  
7       quired under section 351(l)(2)(A) of the Public  
8       Health Service Act (42 U.S.C. 262(l)(2)(A))  
9       that would enable the reference product sponsor  
10      to form a reasonable belief with respect to  
11      whether a claim of infringement under this sec-  
12      tion could reasonably be asserted; and

13          “(bb) may be established—

14               “(AA) if there is a material change to  
15              the biological product (or process with re-  
16              spect to the biological product) of the sub-  
17              section (k) applicant that is the subject of  
18              the application;

19               “(BB) if, with respect to a patent on  
20              the supplemental list described in section  
21              351(l)(7)(A) of Public Health Service Act  
22              (42 U.S.C. 262(l)(7)(A)), the patent would  
23              have issued before the date specified in  
24              such section 351(l)(7)(A) but for the fail-  
25              ure of the Office to issue the patent or a

1 delay in the issuance of the patent, as de-  
2 scribed in paragraph (1) of section 154(b)  
3 and subject to the limitations under para-  
4 graph (2) of such section 154(b); or

5 “(CC) for another reason that shows  
6 good cause, as determined appropriate by  
7 the court.

8 “(D) In determining whether good cause has been  
9 shown for the purposes of subparagraph (C)(ii)(II), a  
10 court may consider whether the reference product sponsor  
11 has provided a reasonable description of the identity and  
12 relevance of any information beyond the subsection (k) ap-  
13 plication that the court believes is necessary to enable the  
14 court to form a belief with respect to whether a claim of  
15 infringement under this section could reasonably be as-  
16 serted.

17 “(E) The limitation imposed under subparagraph  
18 (A)—

19 “(i) shall apply only if the subsection (k) appli-  
20 cant completes all actions required under paragraphs  
21 (2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of  
22 section 351(l) of the Public Health Service Act (42  
23 U.S.C. 262(l)); and

24 “(ii) shall not apply with respect to any patent  
25 that claims, with respect to a biological product, a

1 method for using that product in therapy, diagnosis,  
2 or prophylaxis, such as an indication or method of  
3 treatment or other condition of use.”.

4 (b) APPLICABILITY.—The amendments made by sub-  
5 section (a) shall apply with respect to an application sub-  
6 mitted under section 351(k) of the Public Health Service  
7 Act (42 U.S.C. 262(k)) on or after the date of enactment  
8 of this Act.

## 9 **TITLE V—BENEFICIARY COST** 10 **SHARING FAIRNESS**

### 11 **SEC. 501. REPEALING OF RULE BY THE DEPARTMENT OF** 12 **HEALTH AND HUMAN SERVICES.**

13 The final rule of the Department of Health and  
14 Human Services titled “Fraud And Abuse; Removal of  
15 Safe Harbor Protection for Rebates Involving Prescription  
16 Pharmaceuticals And Creation of New Safe Harbor Pro-  
17 tection for Certain Point-of-Sale Reductions in Price on  
18 Prescription Pharmaceuticals and Certain Pharmacy Ben-  
19 efit Manager Service Fees; Additional Delayed Effective  
20 Date” published on November 30, 2020 (85 Fed. Reg.  
21 76666–76731), shall have no force or effect of law.

### 22 **SEC. 502. DEFINING COST UNDER PRESCRIPTION DRUG** 23 **PLANS UNDER PART D OF MEDICARE.**

24 Section 1860D–2(b)(2)(A) of the Social Security Act  
25 (42 U.S.C. 1395w–102(b)(2)(A)) is amended—

1           (1) in clause (i), by inserting “of the net costs  
2           to the plan, inclusive of all direct and indirect remuneration,  
3           including rebates paid by manufacturers to  
4           the plan sponsor, either directly or through a pharmacy  
5           benefit manager or other third party” before  
6           the semicolon; and

7           (2) in clause (ii), by inserting “net” before  
8           “costs”.

○