

117TH CONGRESS  
1ST SESSION

# H. R. 5237

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 10, 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 of 2021”.

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. Requiring manufacturers of certain single-dose container or single-use  
package drugs payable under part B of the Medicare program  
to provide refunds with respect to discarded amounts of such  
drugs.

Sec. 206. Establishment of maximum add-on payment for drugs and  
biologicals.

Sec. 207. Treatment of drug administration services furnished by certain ex-  
cepted off-campus outpatient departments of a provider.

Sec. 208. GAO study and report on average sales price.

Sec. 209. Authority to use alternative payment for drugs and biologicals to pre-  
vent potential drug shortages.

**Subtitle B—Part D**

Sec. 221. Medicare part D modernization redesign.

Sec. 222. Monthly out-of-pocket cost sharing maximum for enrollees who incur  
a significant portion of costs towards annual out-of-pocket  
threshold.

Sec. 223. Public disclosure of drug discounts and other pharmacy benefit man-  
ager (PBM) provisions.

Sec. 224. Public disclosure of direct and indirect remuneration review and audit  
results.

Sec. 225. Improvements to provision of parts A and B claims data to prescrip-  
tion drug plans.

Sec. 226. Medicare part D rebate by manufacturers.

Sec. 227. Prohibiting branding on part D benefit cards.

Sec. 228. Requiring prescription drug plans and MA–PD plans to report poten-  
tial fraud, waste, and abuse to the Secretary of HHS.

- Sec. 229. Establishment of pharmacy quality measures under Medicare part D.
- Sec. 230. Addition of new measures based on access to biosimilar biological products to the 5-star rating system under Medicare Advantage.
- Sec. 231. HHS study and report on the influence of pharmaceutical manufacturer third-party reimbursement hubs on health care providers who prescribe their drugs and biologicals.
- Sec. 232. Definition of strength for the purposes of determining interchangeability of biologic and biosimilar products.

#### Subtitle C—Miscellaneous

- Sec. 233. Drug manufacturer price transparency.
- Sec. 234. Strengthening and expanding pharmacy benefit managers transparency requirements.
- Sec. 235. Prescription drug pricing dashboards.
- Sec. 236. Improving coordination between the Food and Drug Administration and the Centers for Medicare & Medicaid Services.
- Sec. 237. Patient consultation in Medicare national and local coverage determinations in order to mitigate barriers to inclusion of such perspectives.
- Sec. 238. GAO study on increases to Medicare and Medicaid spending due to copayment coupons and other patient assistance programs.
- Sec. 239. MedPAC report on shifting coverage of certain Medicare part B drugs to Medicare part D.
- Sec. 240. Taking steps to fulfill treaty obligations to Tribal communities.
- Sec. 241. Establishing a monthly cap on beneficiary incurred costs for insulin products and supplies under a prescription drug plan or MA-PD plan.

#### 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.
- Sec. 308. Applying Medicaid drug rebate requirement to drugs provided as part of outpatient hospital services.

#### 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

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

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

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

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

10 “(A) NOTIFICATION OF MANUFACTURERS  
11 OF NEGOTIATION-ELIGIBLE DRUGS AND  
12 BIOLOGICALS.—

13 “(i) IN GENERAL.—Not later than  
14 180 days after the date of the enactment  
15 of this paragraph, the Secretary shall no-  
16 tify each manufacturer of each negotiation-  
17 eligible drug or biological that is subject to  
18 negotiation for payment under this part.

19 “(ii) NEGOTIATION-ELIGIBLE DRUG  
20 OR BIOLOGICAL.—In this paragraph, the  
21 term ‘negotiation-eligible drug or biologi-  
22 cal’ means a single source drug or biologi-  
23 cal for which each of the following have ex-  
24 pired:

1                   “(I) The period of regulatory  
2                   data protections or exclusivity granted  
3                   for such drug or biological (including  
4                   for new chemical entities, biologics,  
5                   orphan drugs, pediatric formulations,  
6                   and clinical trials).

7                   “(II) Subject to the succeeding  
8                   sentence, the period of any patents  
9                   issued for such drug or biological up  
10                  to 1 year after the approval of such  
11                  drug or biological. In the case of small  
12                  molecule product that is a such a  
13                  drug or biological, the period of any  
14                  patents listed in the publication, Ap-  
15                  proved Drug Products With Thera-  
16                  peutic Equivalence Evaluations (re-  
17                  ferred to as the ‘Orange Book’).

18                  “(B) NEGOTIATION.—

19                  “(i) IN GENERAL.—With respect to  
20                  period during which the negotiated price of  
21                  such drug or biological is not more than 75  
22                  percent of the average sales price of such  
23                  drug or biological (as determined on an an-  
24                  nual basis), the Secretary and the manu-  
25                  facturer of a negotiation-eligible drug or

1 biological shall during the negotiation pe-  
2 riod negotiate a maximum allowable cost  
3 for such drug or biological.

4 “(ii) MAXIMUM ALLOWABLE COST.—  
5 In this subparagraph, the term ‘maximum  
6 allowable cost’ means the amount agreed  
7 to by the Secretary and the manufacturer  
8 of a negotiation-eligible drug or biological  
9 for a unit of such drug or biological that  
10 is not less than 65 percent and not more  
11 than 75 percent of the lowest average sales  
12 price of such drug or biological for the pre-  
13 ceding 1-year period.

14 “(iii) EXCLUSIONS.—The maximum  
15 allowable cost under this section shall be  
16 excluded from the calculation of the manu-  
17 facturer’s average sales price under section  
18 1847A(c), average manufacturer price  
19 under section 1927(k)(1), best price under  
20 section 1927(c)(1)(C), and non-Federal av-  
21 erage manufacturer price under 38 U.S.C.  
22 8126(h).”.

## 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 calculating” and inserting “DISCOUNTS TO PURCHASERS AND COUPONS PROVIDED TO PRIVATELY INSURED INDIVIDUALS.—

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

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

“(B) COUPONS PROVIDED TO REDUCE COST-SHARING.—For calendar quarters beginning on or after July 1, 2024, in calculating the manufacturer’s average sales price under this subsection, such price shall include the value (as defined in paragraph (6)(J)) of any coupons provided under a drug coupon program of a manufacturer (as those terms are defined in



1           subparagraphs (K) and (L), respectively, of  
2           paragraph (6)).”; and

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

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

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

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

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

1 respect to a drug or biological, including a bio-  
2 similar biological product, of the manufacturer.

3 “(L) DRUG COUPON PROGRAM.—

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

10 “(ii) EXCLUSIONS.—Such term does  
11 not include—

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

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

1 **SEC. 202. PAYMENT FOR BIOSIMILAR BIOLOGICAL PROD-**  
2 **UCTS DURING INITIAL PERIOD.**

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

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

9 (2) by redesignating subparagraphs (A) and  
10 (B) as clauses (i) and (ii) and moving such clauses  
11 2 ems to the right;

12 (3) by striking “UNAVAILABLE.—In the case”  
13 and inserting “UNAVAILABLE.—

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

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

18 “(B) LIMITATION ON PAYMENT AMOUNT  
19 FOR BIOSIMILAR BIOLOGICAL PRODUCTS DUR-  
20 ING INITIAL PERIOD.—In the case of a bio-  
21 similar biological product furnished on or after  
22 July 1, 2023, in lieu of applying subparagraph  
23 (A) during the initial period described in such  
24 subparagraph with respect to the biosimilar bio-  
25 logical product, the amount payable under this

1 section for the biosimilar biological product is  
 2 the lesser of the following:

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

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

9 **SEC. 203. TEMPORARY INCREASE IN MEDICARE PART B**  
 10 **PAYMENT FOR BIOSIMILAR BIOLOGICAL**  
 11 **PRODUCTS.**

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

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

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

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

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

23 “(B) TEMPORARY PAYMENT INCREASE FOR  
 24 BIOSIMILAR BIOLOGICAL PRODUCTS.—

1 “(i) IN GENERAL.—Beginning Janu-  
2 ary 1, 2023, in the case of a biosimilar bio-  
3 logical product described in paragraph  
4 (1)(C) that is furnished during the applica-  
5 ble 5-year period for such product, the  
6 amount specified in this paragraph for  
7 such product is an amount equal to the  
8 lesser of the following:

9 “(I) The amount specified in sub-  
10 paragraph (A) for such product if  
11 clause (ii) of such subparagraph was  
12 applied by substituting ‘8 percent’ for  
13 ‘6 percent’.

14 “(II) The amount determined  
15 under subsection (b)(1)(B) for the  
16 reference biological product.

17 “(ii) APPLICABLE 5-YEAR PERIOD.—  
18 For purposes of clause (i), the applicable  
19 5-year period for a biosimilar biological  
20 product is—

21 “(I) in the case of such a product  
22 for which payment was made under  
23 this paragraph as of December 31,  
24 2012, the 5-year period beginning on  
25 January 1, 2023; and

1 “(II) in the case of such a prod-  
 2 uct that is not described in subclause  
 3 (I), the 5-year period beginning on the  
 4 first day of the first calendar quarter  
 5 in which payment was made for such  
 6 product under this paragraph.”.

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

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

11 “(x) REBATE BY MANUFACTURERS FOR SINGLE  
 12 SOURCE DRUGS WITH PRICES INCREASING FASTER  
 13 THAN INFLATION.—

14 “(1) REQUIREMENTS.—

15 “(A) SECRETARIAL PROVISION OF INFOR-  
 16 MATION.—Not later than 6 months after the  
 17 end of each calendar quarter beginning on or  
 18 after July 1, 2024, the Secretary shall, for each  
 19 part B rebatable drug, report to each manufac-  
 20 turer of such part B rebatable drug the fol-  
 21 lowing for such calendar quarter:

22 “(i) Information on the total number  
 23 of units of the billing and payment code  
 24 described in subparagraph (A)(i) of para-

1 graph (3) with respect to such drug and  
2 calendar quarter.

3 “(ii) Information on the amount (if  
4 any) of the excess average sales price in-  
5 crease described in subparagraph (A)(ii) of  
6 such paragraph for such drug and calendar  
7 quarter.

8 “(iii) The rebate amount specified  
9 under such paragraph for such part B  
10 rebatable drug and calendar quarter.

11 “(B) MANUFACTURER REQUIREMENT.—  
12 For each calendar quarter beginning on or after  
13 July 1, 2024, the manufacturer of a part B  
14 rebatable drug shall, for such drug, not later  
15 than 30 days after the date of receipt from the  
16 Secretary of the information described in sub-  
17 paragraph (A) for such calendar quarter, pro-  
18 vide to the Secretary a rebate that is equal to  
19 the amount specified in paragraph (3) for such  
20 drug for such calendar quarter.

21 “(2) PART B REBATABLE DRUG DEFINED.—

22 “(A) IN GENERAL.—In this subsection, the  
23 term ‘part B rebatable drug’ means a single  
24 source drug or biological (as defined in sub-  
25 paragraph (D) of section 1847A(c)(6)), includ-

1           ing a biosimilar biological product (as defined  
2           in subparagraph (H) of such section), paid for  
3           under this part, except such term shall not in-  
4           clude such a drug or biological—

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

10                   “(ii) that is a vaccine described in  
11                   subparagraph (A) or (B) of section  
12                   1861(s)(10).

13                   “(B) INCREASE.—The dollar amount ap-  
14                   plied under subparagraph (A)(i)—

15                   “(i) for 2025, shall be the dollar  
16                   amount specified under such subparagraph  
17                   for 2024, increased by the percentage in-  
18                   crease in the consumer price index for all  
19                   urban consumers (United States city aver-  
20                   age) for the 12-month period ending with  
21                   June of the previous year; and

22                   “(ii) for a subsequent year, shall be  
23                   the dollar amount specified in this clause  
24                   (or clause (i)) for the previous year, in-  
25                   creased by the percentage increase in the



1 consumer price index for all urban con-  
2 sumers (United States city average) for  
3 the 12-month period ending with June of  
4 the previous year.

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

8 “(3) REBATE AMOUNT.—

9 “(A) IN GENERAL.—For purposes of para-  
10 graph (1), the amount specified in this para-  
11 graph for a part B rebatable drug assigned to  
12 a billing and payment code for a calendar quar-  
13 ter is, subject to paragraph (4), the amount  
14 equal to the product of—

15 “(i) subject to subparagraphs (B) and  
16 (G), the total number of units of the bill-  
17 ing and payment code for such part B  
18 rebatable drug furnished under this part  
19 during the calendar quarter; and

20 “(ii) the amount (if any) by which—

21 “(I) the payment amount under  
22 subparagraph (B) or (C) of section  
23 1847A(b)(1), as applicable, for such  
24 part B rebatable drug during the cal-  
25 endar quarter; exceeds

1 “(II) the inflation-adjusted pay-  
2 ment amount determined under sub-  
3 paragraph (C) for such part B  
4 rebatable drug during the calendar  
5 quarter.

6 “(B) EXCLUDED UNITS.—For purposes of  
7 subparagraph (A)(i), the total number of units  
8 of the billing and payment code for each part  
9 B rebatable drug furnished during a calendar  
10 quarter shall not include—

11 “(i) units packaged into the payment  
12 for a procedure or service under section  
13 1833(t) or under section 1833(i) (instead  
14 of separately payable under such respective  
15 section);

16 “(ii) units included under the single  
17 payment system for renal dialysis services  
18 under section 1881(b)(14); or

19 “(iii) units of a part B rebatable drug  
20 of a manufacturer furnished to an indi-  
21 vidual, if such manufacturer, with respect  
22 to the furnishing of such units of such  
23 drug, provides for discounts under section  
24 340B of the Public Health Service Act or  
25 for rebates under section 1927.

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

“(i) the payment amount for the billing and payment code for such drug in the payment amount benchmark quarter (as defined in subparagraph (D)); increased by

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

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

“(E) BENCHMARK PERIOD CPI–U.—The term ‘benchmark period CPI–U’ means the consumer price index for all urban consumers (United States city average) for July 2015.

“(F) REBATE PERIOD CPI–U.—The term ‘rebate period CPI–U’ means, with respect to a calendar quarter described in subparagraph

1 (C), the greater of the benchmark period CPI–  
2 U and the consumer price index for all urban  
3 consumers (United States city average) for the  
4 first month of the calendar quarter that is two  
5 calendar quarters prior to such described cal-  
6 endar quarter.

7 “(G) COUNTING UNITS.—

8 “(i) CUT-OFF PERIOD TO COUNT  
9 UNITS.—For purposes of subparagraph  
10 (A)(i), subject to clause (ii), to count the  
11 total number of billing units for a part B  
12 rebatable drug for a quarter, the Secretary  
13 may use a cut-off period in order to ex-  
14 clude from such total number of billing  
15 units for such quarter claims for services  
16 furnished during such quarter that were  
17 not processed at an appropriate time prior  
18 to the end of the cut-off period.

19 “(ii) COUNTING UNITS FOR CLAIMS  
20 PROCESSED AFTER CUT-OFF PERIOD.—If  
21 the Secretary uses a cut-off period pursu-  
22 ant to clause (i), in the case of units of a  
23 part B rebatable drug furnished during a  
24 quarter but pursuant to application of such  
25 cut-off period excluded for purposes of sub-

1 paragraph (A)(i) from the total number of  
2 billing units for the drug for such quarter,  
3 the Secretary shall count such units of  
4 such drug so furnished in the total number  
5 of billing units for such drug for a subse-  
6 quent quarter, as the Secretary determines  
7 appropriate.

8 “(4) SPECIAL TREATMENT OF CERTAIN DRUGS  
9 AND EXEMPTION.—

10 “(A) SUBSEQUENTLY APPROVED DRUGS.—

11 Subject to subparagraph (B), in the case of a  
12 part B rebatable drug first approved or licensed  
13 by the Food and Drug Administration after  
14 July 1, 2015, clause (i) of paragraph (3)(C)  
15 shall be applied as if the term ‘payment amount  
16 benchmark quarter’ were defined under para-  
17 graph (3)(D) as the third full calendar quarter  
18 after the day on which the drug was first mar-  
19 keted and clause (ii) of paragraph (3)(C) shall  
20 be applied as if the term ‘benchmark period  
21 CPI-U’ were defined under paragraph (3)(E)  
22 as if the reference to ‘July 2015’ under such  
23 paragraph were a reference to ‘the first month  
24 of the first full calendar quarter after the day  
25 on which the drug was first marketed’.

1           “(B) TIMELINE FOR PROVISION OF RE-  
2           BATES FOR SUBSEQUENTLY APPROVED  
3           DRUGS.—In the case of a part B rebatable drug  
4           first approved or licensed by the Food and  
5           Drug Administration after July 1, 2015, para-  
6           graph (1)(B) shall be applied as if the reference  
7           to ‘July 1, 2024’ under such paragraph were a  
8           reference to the later of the 6th full calendar  
9           quarter after the day on which the drug was  
10          first marketed or July 1, 2024.

11          “(C) EXEMPTION FOR SHORTAGES.—The  
12          Secretary may reduce or waive the rebate  
13          amount under paragraph (1)(B) with respect to  
14          a part B rebatable drug that is described as  
15          currently in shortage on the shortage list in ef-  
16          fect under section 506E of the Federal Food,  
17          Drug, and Cosmetic Act or in the case of other  
18          exigent circumstances, as determined by the  
19          Secretary.

20          “(D) SELECTED DRUGS.—In the case of a  
21          part B rebatable drug that is a selected drug  
22          (as defined in section 1192(c)) for a price appli-  
23          cability period (as defined in section  
24          1191(b)(2))—

1 “(i) for calendar quarters during such  
2 period for which a maximum fair price (as  
3 defined in section 1191(c)(2)) for such  
4 drug has been determined and is applied  
5 under part E of title XI, the rebate  
6 amount under paragraph (1)(B) shall be  
7 waived; and

8 “(ii) in the case such drug is deter-  
9 mined (pursuant to such section 1192(c))  
10 to no longer be a selected drug, for each  
11 applicable year beginning after the price  
12 applicability period with respect to such  
13 drug, clause (i) of paragraph (3)(C) shall  
14 be applied as if the term ‘payment amount  
15 benchmark quarter’ were defined under  
16 paragraph (3)(D) as the calendar quarter  
17 beginning January 1 of the last year be-  
18 ginning during such price applicability pe-  
19 riod with respect to such selected drug and  
20 clause (ii) of paragraph (3)(C) shall be ap-  
21 plied as if the term ‘benchmark period  
22 CPI-U’ were defined under paragraph  
23 (3)(E) as if the reference to ‘July 2015’  
24 under such paragraph were a reference to

1           the July of the year preceding such last  
2           year.

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

7                   “(A) in computing the amount of any coin-  
8                   surance applicable under this title to an indi-  
9                   vidual with respect to such drug, the computa-  
10                  tion of such coinsurance shall be based on the  
11                  inflation-adjusted payment amount determined  
12                  under paragraph (3)(C) for such part B  
13                  rebatable drug; and

14                   “(B) the amount of such coinsurance is  
15                  equal to 20 percent of such inflation-adjusted  
16                  payment amount so determined.

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

21           “(7) CIVIL MONEY PENALTY.—If a manufac-  
22           turer of a part B rebatable drug has failed to com-  
23           ply with the requirements under paragraph (1)(B)  
24           for such drug for a calendar quarter, the manufac-  
25           turer shall be subject to, in accordance with a proc-



1       ess established by the Secretary pursuant to regula-  
2       tions, a civil money penalty in an amount equal to  
3       at least 125 percent of the amount specified in para-  
4       graph (3) for such drug for such calendar quarter.  
5       The provisions of section 1128A (other than sub-  
6       sections (a) (with respect to amounts of penalties or  
7       additional assessments) and (b)) shall apply to a  
8       civil money penalty under this paragraph in the  
9       same manner as such provisions apply to a penalty  
10      or proceeding under section 1128A(a).

11           “(8) STUDY AND REPORT.—

12                   “(A) STUDY.—The Secretary shall conduct  
13           a study of the feasibility of and operational  
14           issues involved with the following:

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

18                           “(ii) Including drugs and biologicals  
19                           paid for under MA plans under part C in  
20                           the rebate system under this subsection.

21                           “(iii) Including drugs excluded under  
22                           paragraph (2)(A) and units of the billing  
23                           and payment code of the drugs excluded  
24                           under paragraph (3)(B) in the rebate sys-  
25                           tem under this subsection.

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

6           “(9) APPLICATION TO MULTIPLE SOURCE  
 7           DRUGS.—The Secretary may, based on the report  
 8           submitted under paragraph (8) and pursuant to  
 9           rulemaking, apply the provisions of this subsection  
 10          to multiple source drugs (as defined in section  
 11          1847A(c)(6)(C)), including, for purposes of deter-  
 12          mining the rebate amount under paragraph (3), by  
 13          calculating manufacturer-specific average sales  
 14          prices for the benchmark period and the rebate pe-  
 15          riod.”.

16          (b) AMOUNTS PAYABLE; COST-SHARING.—Section  
 17          1833 of the Social Security Act (42 U.S.C. 1395l) is  
 18          amended—

19               (1) in subsection (a)—

20                   (A) in paragraph (1)—

21                           (i) in subparagraph (S), by striking  
 22                           “with respect to” and inserting “subject to  
 23                           subparagraph (DD), with respect to”;

24                           (ii) by striking “and (CC)” and in-  
 25                           serting “(CC)”; and

1 (iii) by inserting before the semicolon  
2 at the end the following: “, and (DD) with  
3 respect to a part B rebatable drug (as de-  
4 fined in paragraph (2) of section 1834(x))  
5 for which the payment amount for a cal-  
6 endar quarter under paragraph  
7 (3)(A)(ii)(I) of such section for such quar-  
8 ter exceeds the inflation-adjusted payment  
9 under paragraph (3)(A)(ii)(II) of such sec-  
10 tion for such quarter, the amounts paid  
11 shall be the difference between (i) the pay-  
12 ment amount under paragraph  
13 (3)(A)(ii)(I) of such section for such drug,  
14 and (ii) 20 percent of the inflation-ad-  
15 justed payment amount under paragraph  
16 (3)(A)(ii)(II) of such section for such  
17 drug”; and

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

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

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

3           “(9) In the case of a part B rebatable drug (as  
4 defined in paragraph (2) of section 1834(x)) for  
5 which payment under this subsection is not pack-  
6 aged into a payment for a covered OPD service (as  
7 defined in subsection (t)(1)(B)) (or group of serv-  
8 ices) furnished on or after July 1, 2024, under the  
9 system under this subsection, in lieu of calculation  
10 of coinsurance and the amount of payment otherwise  
11 applicable under this subsection, the provisions of  
12 section 1834(x)(5), paragraph (1)(DD) of subsection  
13 (a), and the flush left matter following paragraph  
14 (9) of subsection (a), shall, as determined appro-  
15 priate by the Secretary, apply under this subsection  
16 in the same manner as such provisions of section  
17 1834(x)(5) and subsection (a) apply under such sec-  
18 tion and subsection.”; and

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

21           “(F) PART B REBATABLE DRUGS.—In the  
22 case of a part B rebatable drug (as defined in  
23 paragraph (2) of section 1834(x)) for which  
24 payment under this part is not packaged into a  
25 payment for a service furnished on or after July

1           1, 2024, under the system under this sub-  
 2           section, in lieu of calculation of coinsurance and  
 3           the amount of payment otherwise applicable  
 4           under this subsection, the provisions of section  
 5           1834(x)(5), paragraph (1)(DD) of subsection  
 6           (a), and the flush left matter following para-  
 7           graph (9) of subsection (a), shall, as determined  
 8           appropriate by the Secretary, apply under this  
 9           subsection in the same manner as such provi-  
 10          sions of section 1834(x)(5) and subsection (a)  
 11          apply under such section and subsection.”.

12          (c) CONFORMING AMENDMENTS.—

13           (1) TO PART B ASP CALCULATION.—Section  
 14          1847A(c)(3) of the Social Security Act (42 U.S.C.  
 15          1395w–3a(c)(3)) is amended by inserting “or section  
 16          1834(x)” after “section 1927”.

17           (2) EXCLUDING PART B DRUG INFLATION RE-  
 18          BATE FROM BEST PRICE.—Section  
 19          1927(c)(1)(C)(ii)(I) of the Social Security Act (42  
 20          U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is amended by in-  
 21          serting “or section 1834(x)” after “this section”.

22           (3) COORDINATION WITH MEDICAID REBATE IN-  
 23          FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)  
 24          of the Social Security Act (42 U.S.C. 1396r–  
 25          8(b)(3)(D)(i)) is amended by striking “or to carry

1 out section 1847B” and inserting “to carry out sec-  
 2 tion 1847B or section 1834(x)”.

3 **SEC. 205. REQUIRING MANUFACTURERS OF CERTAIN SIN-**  
 4 **GLE-DOSE CONTAINER OR SINGLE-USE PACK-**  
 5 **AGE DRUGS PAYABLE UNDER PART B OF THE**  
 6 **MEDICARE PROGRAM TO PROVIDE REFUNDS**  
 7 **WITH RESPECT TO DISCARDED AMOUNTS OF**  
 8 **SUCH DRUGS.**

9 Section 1847A of the Social Security Act (42 U.S.C.  
 10 1395–3a), as amended by section 206, is amended by add-  
 11 ing at the end the following new subsection:

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

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

16 “(A) IN GENERAL.—For each calendar  
 17 quarter beginning on or after July 1, 2024, the  
 18 Secretary shall, with respect to a refundable  
 19 single-dose container or single-use package drug  
 20 (as defined in paragraph (8)), report to each  
 21 manufacturer (as defined in subsection  
 22 (c)(6)(A)) of such refundable single-dose con-  
 23 tainer or single-use package drug the following  
 24 for the calendar quarter:

1           “(i) Subject to subparagraph (C), in-  
2           formation on the total number of units of  
3           the billing and payment code of such drug,  
4           if any, that were discarded during such  
5           quarter, as determined using a mechanism  
6           such as the JW modifier used as of the  
7           date of enactment of this subsection (or  
8           any such successor modifier that includes  
9           such data as determined appropriate by  
10          the Secretary).

11          “(ii) The refund amount that the  
12          manufacturer is liable for pursuant to  
13          paragraph (3).

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

22          “(C) EXCLUSION OF UNITS OF PACKAGED  
23          DRUGS.—The total number of units of the bill-  
24          ing and payment code of a refundable single-  
25          dose container or single-use package drug of a

1 manufacturer furnished during a calendar quar-  
2 ter for purposes of subparagraph (A)(i), and  
3 the determination of the estimated total allowed  
4 charges for the drug in the quarter for purposes  
5 of paragraph (3)(A)(ii), shall not include such  
6 units that are packaged into the payment  
7 amount for an item or service and are not sepa-  
8 rately payable.

9 “(2) MANUFACTURER REQUIREMENT.—For  
10 each calendar quarter beginning on or after July 1,  
11 2024, the manufacturer of a refundable single-dose  
12 container or single-use package drug shall, for such  
13 drug, provide to the Secretary a refund that is equal  
14 to the amount specified in paragraph (3) for such  
15 drug for such quarter.

16 “(3) REFUND AMOUNT.—

17 “(A) IN GENERAL.—The amount of the re-  
18 fund specified in this paragraph is, with respect  
19 to a refundable single-dose container or single-  
20 use package drug of a manufacturer assigned to  
21 a billing and payment code for a calendar quar-  
22 ter beginning on or after July 1, 2024, an  
23 amount equal to the estimated amount (if any)  
24 by which—

25 “(i) the product of—



1 “(I) the total number of units of  
2 the billing and payment code for such  
3 drug that were discarded during such  
4 quarter (as determined under para-  
5 graph (1)); and

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

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

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

22 “(B) APPLICABLE PERCENTAGE DE-  
23 FINED.—

1 “(i) IN GENERAL.—For purposes of  
2 subparagraph (A)(ii), the term ‘applicable  
3 percentage’ means—

4 “(I) subject to subclause (II), 10  
5 percent; and

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

15 “(ii) TREATMENT OF DRUGS THAT  
16 REQUIRE FILTRATION OR OTHER UNIQUE  
17 CIRCUMSTANCES.—The Secretary, through  
18 notice and comment rulemaking—

19 “(I) in the case of a refundable  
20 single-dose container or single-use  
21 package drug described in subclause  
22 (I) of clause (iii), shall increase the  
23 applicable percentage otherwise appli-  
24 cable under clause (i)(I) as deter-

1           mined appropriate by the Secretary;  
2           and

3                   “(II) in the case of a refundable  
4           single-dose container or single-use  
5           package drug described in subclause  
6           (II) of clause (iii), may increase the  
7           applicable percentage otherwise appli-  
8           cable under clause (i)(I) as deter-  
9           mined appropriate by the Secretary.

10                   “(iii) DRUG DESCRIBED.—For pur-  
11           poses of clause (ii), a refundable single-  
12           dose container or single-use package drug  
13           described in this clause is either of the fol-  
14           lowing:

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

1                   carded after the completion of such  
2                   filtration process.

3                   “(II) Any other refundable sin-  
4                   gle-dose container or single-use pack-  
5                   age drug that has unique cir-  
6                   cumstances involving similar loss of  
7                   product.

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

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

16                  “(6) ENFORCEMENT.—

17                         “(A) AUDITS.—

18                                 “(i) MANUFACTURER AUDITS.—Each  
19                                 manufacturer of a refundable single-dose  
20                                 container or single-use package drug that  
21                                 is required to provide a refund under this  
22                                 subsection shall be subject to periodic  
23                                 audit with respect to such drug and such  
24                                 refunds by the Secretary.

1 “(ii) PROVIDER AUDITS.—The Sec-  
2 retary shall conduct periodic audits of  
3 claims submitted under this part with re-  
4 spect to refundable single-dose container or  
5 single-use package drugs in accordance  
6 with the authority under section 1833(e) to  
7 ensure compliance with the requirements  
8 applicable under this subsection.

9 “(B) CIVIL MONEY PENALTY.—

10 “(i) IN GENERAL.—The Secretary  
11 shall impose a civil money penalty on a  
12 manufacturer of a refundable single-dose  
13 container or single-use package drug who  
14 has failed to comply with the requirement  
15 under paragraph (2) for such drug for a  
16 calendar quarter in an amount equal to the  
17 sum of—

18 “(I) the amount that the manu-  
19 facturer would have paid under such  
20 paragraph with respect to such drug  
21 for such quarter; and

22 “(II) 25 percent of such amount.

23 “(ii) APPLICATION.—The provisions  
24 of section 1128A (other than subsections  
25 (a) and (b)) shall apply to a civil money

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

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

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

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

20 “(B) EXCLUSIONS.—The term ‘refundable  
21 single-dose container or single-use package  
22 drug’ does not include a drug or biological that  
23 is either a radiopharmaceutical or an imaging  
24 agent.”.

1 **SEC. 206. ESTABLISHMENT OF MAXIMUM ADD-ON PAYMENT**  
2 **FOR DRUGS AND BIOLOGICALS.**

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

5 (1) in subsection (b)—

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

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

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

13 “(A) IN GENERAL.—In determining the  
14 payment amount under the provisions of sub-  
15 paragraph (A), (B), or (C) of paragraph (1) of  
16 this subsection, subsection (c)(4)(A)(ii), or sub-  
17 section (d)(3)(C) for a drug or biological fur-  
18 nished on or after January 1, 2024, if the ap-  
19 plicable add-on payment (as defined in subpara-  
20 graph (B)) for each drug or biological on a  
21 claim for a date of service exceeds the max-  
22 imum add-on payment amount specified under  
23 subparagraph (C) for the drug or biological,  
24 then the payment amount otherwise determined  
25 for the drug or biological under those provi-

sions, as applicable, shall be reduced by the amount of such excess.

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

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

“(I) the amount that would otherwise be applied under paragraph (1)(A); and

“(II) the amount that would be applied under such paragraph if ‘100 percent’ were substituted for ‘106 percent’.

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

“(I) the amount that would otherwise be applied under paragraph (1)(B); and

“(II) the amount that would be applied under such paragraph if ‘100



1                   percent’ were substituted for ‘106 per-  
2                   cent’.

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

6                   “(iv) In the case of a drug or biologi-  
7                   cal during the initial period described in  
8                   subsection (c)(4)(A), an amount equal to  
9                   the difference between—

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

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

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

19                   “(bb) any percent in excess  
20                   of 100 percent applied under  
21                   subclause (II) of such subsection.

22                   “(v) In the case of a drug or biologi-  
23                   cal to which subsection (d)(3)(C) applies,  
24                   an amount equal to the difference be-  
25                   tween—

1 “(I) the amount that would oth-  
2 erwise be applied under such sub-  
3 section; and

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

8 “(aa) any percent in excess  
9 of 100 percent applied under  
10 clause (i) of such subsection; or

11 “(bb) ‘103 percent’ in clause  
12 (ii) of such subsection.

13 “(C) MAXIMUM ADD-ON PAYMENT AMOUNT  
14 SPECIFIED.—For purposes of subparagraph  
15 (A), the maximum add-on payment amount  
16 specified in this subparagraph is—

17 “(i) for each of 2024 through 2031,  
18 \$1,000; and

19 “(ii) for a subsequent year, the  
20 amount specified in this subparagraph for  
21 the preceding year increased by the per-  
22 centage increase in the consumer price  
23 index for all urban consumers (all items;  
24 United States city average) for the 12-

1 month period ending with June of the pre-  
 2 vious year.

3 Any amount determined under this subpara-  
 4 graph that is not a multiple of \$10 shall be  
 5 rounded to the nearest multiple of \$10.”; and

6 (2) in subsection (c)(4)(A)(ii), by striking “in  
 7 the case” and inserting “subject to subsection  
 8 (b)(9), in the case”.

9 (b) CONFORMING AMENDMENTS RELATING TO SEPA-  
 10 RATELY PAYABLE DRUGS.—

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

13 (A) in subparagraph (A)(iii)(II), by insert-  
 14 ing “, subject to subparagraph (I)” after “are  
 15 not available”; and

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

18 “(I) APPLICATION OF MAXIMUM ADD-ON  
 19 PAYMENT FOR SEPARATELY PAYABLE DRUGS  
 20 AND BIOLOGICALS.—In establishing the amount  
 21 of payment under subparagraph (A) for a speci-  
 22 fied covered outpatient drug that is furnished  
 23 as part of a covered OPD service (or group of  
 24 services) on or after January 1, 2024, if such  
 25 payment is determined based on the average

1 price for the year established under section  
2 1847A pursuant to clause (iii)(II) of such sub-  
3 paragraph, the provisions of subsection (b)(9)  
4 of section 1847A shall apply to the amount of  
5 payment so established in the same manner as  
6 such provisions apply to the amount of payment  
7 under section 1847A.”.

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

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

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

14 (C) by inserting after clause (v) the fol-  
15 lowing new clause:

16 “(vi) If there is a separate payment under the system  
17 described in clause (i) for a drug or biological furnished  
18 on or after January 1, 2024, the provisions of subsection  
19 (t)(14)(I) shall apply to the establishment of the amount  
20 of payment for the drug or biological under such system  
21 in the same manner in which such provisions apply to the  
22 establishment of the amount of payment under subsection  
23 (t)(14)(A).”.

1 **SEC. 207. TREATMENT OF DRUG ADMINISTRATION SERV-**  
2 **ICES FURNISHED BY CERTAIN EXCEPTED**  
3 **OFF-CAMPUS OUTPATIENT DEPARTMENTS OF**  
4 **A PROVIDER.**

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

8 “(G) SPECIAL PAYMENT RULE FOR DRUG  
9 ADMINISTRATION SERVICES FURNISHED BY AN  
10 EXCEPTED DEPARTMENT OF A PROVIDER.—

11 “(i) IN GENERAL.—In the case of a  
12 covered OPD service that is a drug admin-  
13 istration service (as defined by the Sec-  
14 retary) furnished by a department of a  
15 provider described in clause (ii) or (iv) of  
16 paragraph (21)(B), the payment amount  
17 for such service furnished on or after Jan-  
18 uary 1, 2024, shall be the same payment  
19 amount (as determined in paragraph  
20 (21)(C)) that would apply if the drug ad-  
21 ministration service was furnished by an  
22 off-campus outpatient department of a pro-  
23 vider (as defined in paragraph (21)(B)).

24 “(ii) APPLICATION WITHOUT REGARD  
25 TO BUDGET NEUTRALITY.—The reductions  
26 made under this subparagraph—

1 “(I) shall not be considered an  
2 adjustment under paragraph (2)(E);  
3 and  
4 “(II) shall not be implemented in  
5 a budget neutral manner.”.

6 **SEC. 208. GAO STUDY AND REPORT ON AVERAGE SALES**  
7 **PRICE.**

8 (a) STUDY.—

9 (1) IN GENERAL.—The Comptroller General of  
10 the United States (in this section referred to as the  
11 “Comptroller General”) shall conduct a study on  
12 spending for applicable drugs under part B of title  
13 XVIII of the Social Security Act.

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

17 (A) for which reimbursement under such  
18 part B is based on the average sales price of  
19 the drug or biological; and

20 (B) that account for the largest percentage  
21 of total spending on drugs and biologicals under  
22 such part B (as determined by the Comptroller  
23 General, but in no case less than 25 drugs or  
24 biologicals).

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

3           (A) The extent to which each applicable  
4       drug is paid for—

5                   (i) under such part B for Medicare  
6       beneficiaries; or

7                   (ii) by private payers in the commer-  
8       cial market.

9           (B) Any change in Medicare spending or  
10       Medicare beneficiary cost-sharing that would  
11       occur if the average sales price of an applicable  
12       drug was based solely on payments by private  
13       payers in the commercial market.

14          (C) The extent to which drug manufactur-  
15       ers provide rebates, discounts, or other price  
16       concessions to private payers in the commercial  
17       market for applicable drugs, which the manu-  
18       facturer includes in its average sales price cal-  
19       culation, for—

20                   (i) formulary placement;

21                   (ii) utilization management consider-  
22       ations; or

23                   (iii) other purposes.

1 (D) Barriers to drug manufacturers pro-  
 2 viding such price concessions for applicable  
 3 drugs.

4 (E) Other areas determined appropriate by  
 5 the Comptroller General.

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

12 **SEC. 209. AUTHORITY TO USE ALTERNATIVE PAYMENT FOR**  
 13 **DRUGS AND BIOLOGICALS TO PREVENT PO-**  
 14 **TENTIAL DRUG SHORTAGES.**

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

17 (1) by striking “PAYMENT IN RESPONSE TO  
 18 PUBLIC HEALTH EMERGENCY.—In the case” and  
 19 inserting “PAYMENTS.—

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

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

24 “(2) PREVENTING POTENTIAL DRUG SHORT-  
 25 AGES.—



1           “(A) IN GENERAL.—In the case of a drug  
2           or biological that the Secretary determines is  
3           described in subparagraph (B) for one or more  
4           quarters beginning on or after January 1,  
5           2024, the Secretary may use wholesale acquisi-  
6           tion cost (or other reasonable measure of a  
7           drug or biological price) instead of the manu-  
8           facturer’s average sales price for such quarters  
9           and for subsequent quarters until the end of  
10          the quarter in which such drug or biological is  
11          removed from the drug shortage list under sec-  
12          tion 506E of the Federal Food, Drug, and Cos-  
13          metic Act, or in the case of a drug or biological  
14          described in subparagraph (B)(ii), the date on  
15          which the Secretary determines that the total  
16          manufacturing capacity or the total number of  
17          manufacturers of such drug or biological is suf-  
18          ficient to mitigate a potential shortage of the  
19          drug or biological.

20           “(B) DRUG OR BIOLOGICAL DESCRIBED.—  
21          For purposes of subparagraph (A), a drug or  
22          biological described in this subparagraph is a  
23          drug or biological—

24                   “(i) that is listed on the drug shortage  
25                   list maintained by the Food and Drug Ad-

1           ministration pursuant to section 506E of  
2           the Federal Food, Drug, and Cosmetic  
3           Act, and with respect to which any manu-  
4           facturer of such drug or biological notifies  
5           the Secretary of a permanent discontinu-  
6           ance or an interruption that is likely to  
7           lead to a meaningful disruption in the  
8           manufacturer's supply of that drug pursu-  
9           ant to section 506C(a) of such Act; or

10           “(ii) that—

11                   “(I) is described in section  
12                   506C(a) of such Act;

13                   “(II) was listed on the drug  
14                   shortage list maintained by the Food  
15                   and Drug Administration pursuant to  
16                   section 506E of such Act within the  
17                   preceding 5 years; and

18                   “(III) for which the total manu-  
19                   facturing capacity of all manufactur-  
20                   ers with an approved application for  
21                   such drug or biological that is cur-  
22                   rently marketed or total number of  
23                   manufacturers with an approved ap-  
24                   plication for such drug or biological  
25                   that is currently marketed declines

1                   during a 6-month period, as deter-  
2                   mined by the Secretary.

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

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

23               (c) HHS REPORT AND RECOMMENDATIONS.—

24                   (1) IN GENERAL.—Not later than July 1, 2024,  
25                  the Secretary shall submit to Congress a report on

1 shortages of drugs within the Medicare program  
2 under title XVIII of the Social Security Act (42  
3 U.S.C. 1395 et seq.). The report shall include—

4 (A) an analysis of—

5 (i) the effect of drug shortages on  
6 Medicare beneficiary access, quality, safe-  
7 ty, and out-of-pocket costs;

8 (ii) the effect of drug shortages on  
9 health providers, including hospitals and  
10 physicians, across the Medicare program;

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

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

24 (v) payment structures and incentives  
25 under parts A, B, C, and D of the Medi-

1                   care program and their effect, if any, on  
2                   drug shortages; and

3                   (B) relevant findings and recommendations  
4                   to Congress.

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

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

## 13                   **Subtitle B—Part D**

### 14   **SEC. 221. MEDICARE PART D MODERNIZATION REDESIGN.**

15                  (a) BENEFIT STRUCTURE REDESIGN.—Section  
16   1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–  
17   102(b)) is amended—

18                   (1) in paragraph (2)—

19                   (A) in subparagraph (A), in the matter  
20                   preceding clause (i), by inserting “for a year  
21                   preceding 2024 and for costs above the annual  
22                   deductible specified in paragraph (1) and up to  
23                   the annual out-of-pocket threshold specified in  
24                   paragraph (4)(B) for 2024 and each subsequent  
25                   year” after “paragraph (3)”;

1 (B) in subparagraph (C)—

2 (i) in clause (i), in the matter pre-  
3 ceding subclause (I), by inserting “for a  
4 year preceding 2024,” after “paragraph  
5 (4),”; and

6 (ii) in clause (ii)(III), by striking  
7 “and each subsequent year” and inserting  
8 “, 2021, 2022, and 2023”; and

9 (C) in subparagraph (D)—

10 (i) in clause (i)—

11 (I) in the matter preceding sub-  
12 clause (I), by inserting “for a year  
13 preceding 2024,” after “paragraph  
14 (4),”; and

15 (II) in subclause (I)(bb), by  
16 striking “a year after 2018” and in-  
17 serting “each of years 2018 through  
18 2023”; and

19 (ii) in clause (ii)(V), by striking  
20 “2019 and each subsequent year” and in-  
21 serting “each of years 2019 through  
22 2023”;

23 (2) in paragraph (3)(A)—

1 (A) in the matter preceding clause (i), by  
2 inserting “for a year preceding 2024,” after  
3 “and (4),”; and

4 (B) in clause (ii), by striking “for a subse-  
5 quent year” and inserting “for each of years  
6 2007 through 2023”; and

7 (3) in paragraph (4)—

8 (A) in subparagraph (A)—

9 (i) in clause (i)—

10 (I) by redesignating subclauses  
11 (I) and (II) as items (aa) and (bb),  
12 respectively, and indenting appro-  
13 priately;

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

18 “I for a year preceding 2024, the  
19 greater of—”;

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

24 (IV) by adding at the end the fol-  
25 lowing:

1 “(II) for 2024 and each suc-  
2 ceeding year, \$0.”; and

3 (ii) in clause (ii)—

4 (I) by striking “clause (i)(I)” and  
5 inserting “clause (i)(I)(aa)”; and

6 (II) by adding at the end the fol-  
7 lowing new sentence: “The Secretary  
8 shall continue to calculate the dollar  
9 amounts specified in clause (i)(I)(aa),  
10 including with the adjustment under  
11 this clause, after 2023 for purposes of  
12 section 1860D–14(a)(1)(D)(iii).”;

13 (B) in subparagraph (B)—

14 (i) in clause (i)—

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

17 (II) in subclause (VI)—

18 (aa) by striking “for a sub-  
19 sequent year” and inserting “for  
20 2021, 2022, and 2023”; and

21 (bb) by striking the period  
22 at the end and inserting a semi-  
23 colon; and

24 (III) by adding at the end the  
25 following new subclauses:



1 “(VII) for 2024, is equal to:

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

8 “(bb) \$2,000 for bene-  
9 ficiaries determined to have in-  
10 come that is between 300 to 400  
11 percent of the Federal poverty  
12 line applicable to a family of the  
13 size involved; or

14 “(cc) \$1,200 for bene-  
15 ficiaries determined to have in-  
16 come that is below 300 percent of  
17 the Federal poverty line applica-  
18 ble to a family of the size in-  
19 volved; or

20 “(VIII) for a subsequent year, is  
21 equal to the amount specified in this  
22 subparagraph for the previous year,  
23 increased by the annual percentage in-  
24 crease described in paragraph (6) for  
25 the year involved.”; and

1 (ii) in clause (ii), by striking “clause  
2 (i)(II)” and inserting “clause (i)”;

3 (C) in subparagraph (C)(i), by striking  
4 “and for amounts” and inserting “and for a  
5 year preceding 2024 for amounts”; and

6 (D) in subparagraph (E), by striking “In  
7 applying” and inserting “For each of 2011  
8 through 2023, in applying”.

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

12 (1) in paragraph (1)—

13 (A) by striking “equal to 80 percent” and  
14 inserting “equal to—

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

17 (B) in subparagraph (A), as added by  
18 paragraph (1), by striking the period at the end  
19 and inserting “; and”; and

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

22 “(B) for 2024 and each subsequent year,  
23 the sum of—

24 “(i) an amount equal to the applicable  
25 percentage specified in paragraph (5)(A) of

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

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

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

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

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

3 “(i) for 2024, 60 percent;

4 “(ii) for 2025, 40 percent; and

5 “(iii) for 2026 and each subsequent  
6 year, 20 percent; and

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

9 “(i) for 2024, 80 percent;

10 “(ii) for 2025, 60 percent; and

11 “(iii) for 2026 and each subsequent  
12 year, 40 percent.”.

13 (c) MANUFACTURER DISCOUNT PROGRAM DURING  
14 INITIAL AND CATASTROPHIC PHASES OF COVERAGE.—

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

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

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

1 shall establish a model agreement for use under the pro-  
2 gram by not later than January 1, 2023, in consultation  
3 with manufacturers, and allow for comment on such model  
4 agreement.

5 “(b) TERMS OF AGREEMENT.—

6 “(1) IN GENERAL.—

7 “(A) AGREEMENT.—An agreement under  
8 this section shall require the manufacturer to  
9 provide applicable beneficiaries access to dis-  
10 counted prices for applicable drugs of the man-  
11 ufacturer that are dispensed on or after Janu-  
12 ary 1, 2024.

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

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

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

10           “(4) LENGTH OF AGREEMENT.—

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

17           “(B) TERMINATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

1 “(2) MONITORING COMPLIANCE.—

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

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

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

17 “(d) ADMINISTRATION.—

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

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

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

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

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

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

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

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

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

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

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

20 “(e) ENFORCEMENT.—

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

24 “(2) CIVIL MONEY PENALTY.—

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

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

14                   “(ii) 25 percent of such amount.

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

21           “(f) CLARIFICATION REGARDING AVAILABILITY OF  
22           OTHER COVERED PART D DRUGS.—Nothing in this sec-  
23           tion shall prevent an applicable beneficiary from pur-  
24           chasing a covered part D drug that is not an applicable  
25           drug (including a generic drug or a drug that is not on

1 the formulary of the prescription drug plan or MA–PD  
2 plan that the applicable beneficiary is enrolled in).

3 “(g) DEFINITIONS.—In this section:

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

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

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

11 “(C) has incurred costs for covered part D  
12 drugs in the year that are above the annual de-  
13 ductible specified in section 1860D–2(b)(1) for  
14 such year.

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

18 “(A) approved under a new drug applica-  
19 tion under section 505(c) of the Federal Food,  
20 Drug, and Cosmetic Act or, in the case of a bio-  
21 logic product, licensed under section 351 of the  
22 Public Health Service Act (including a product  
23 licensed under subsection (k) of such section  
24 351); and

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

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

13          “(iii) is provided through an exception or  
14          appeal.

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

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

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

22          “(4) DISCOUNTED PRICE.—

23               “(A) IN GENERAL.—Except as provided in  
24               subparagraph (B), the term ‘discounted price’

1 means 90 percent of the negotiated price of the  
2 applicable drug of a manufacturer.

3 “(B) PHASE-IN FOR CERTAIN DRUGS DIS-  
4 PENSED FOR SUBSIDY ELIGIBLE INDIVID-  
5 UALS.—

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

16 “(ii) SPECIFIED MANUFACTURER.—In  
17 this subparagraph, the term ‘specified  
18 manufacturer’ means a manufacturer of an  
19 applicable drug for which, in the calendar  
20 year 2 years prior to the current plan year  
21 (referred to in this clause as the ‘applicable  
22 period’), the total reimbursement under  
23 this title during the applicable period rep-  
24 resented less than 1 percent of the total re-



1                   imbursement under this title for all pre-  
2                   scription drugs during such period.

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

6                               “(I) for 2024, 98 percent;

7                               “(II) for 2025, 97 percent;

8                               “(III) for 2026, 96 percent;

9                               “(IV) for 2027, 95 percent;

10                              “(V) for 2028, 94 percent;

11                              “(VI) for 2029, 93 percent;

12                              “(VII) for 2030, 92 percent;

13                              “(VIII) for 2031, 91 percent;

14                              and

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

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

21                   “(5) MANUFACTURER.—The term ‘manufac-  
22                   turer’ means any entity which is engaged in the pro-  
23                   duction, preparation, propagation, compounding,  
24                   conversion, or processing of prescription drug prod-  
25                   ucts, either directly or indirectly by extraction from

1 substances of natural origin, or independently by  
 2 means of chemical synthesis, or by a combination of  
 3 extraction and chemical synthesis. Such term does  
 4 not include a wholesale distributor of drugs or a re-  
 5 tail pharmacy licensed under State law.

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

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

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

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

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

24 “(h) SUNSET OF PROGRAM.—

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

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

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

16                 (A) in subsection (b)(2)(C)(iii)—

17                         (i) by striking “assumptions regarding  
18                         the reinsurance” and inserting “assump-  
19                         tions regarding—

20                                 “(I) the reinsurance”; and

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

23                                 “(II) for 2024 and each subse-  
24                         quent year, the manufacturer dis-  
25                         counts provided under section 1860D–

1                   14B subtracted from the actuarial  
 2                   value to produce such bid; and”; and  
 3                   (B) in subsection (c)(1)(C)—

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

7                   “(i) the reinsurance”;

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

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

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

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

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

23                  (B) by adding at the end the following new  
 24                  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”; and

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. 222. MONTHLY OUT-OF-POCKET COST SHARING MAX-**  
 14 **IMUM FOR ENROLLEES WHO INCUR A SIG-**  
 15 **NIFICANT PORTION OF COSTS TOWARDS AN-**  
 16 **NUAL OUT-OF-POCKET THRESHOLD.**

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

20 (1) in paragraph (2)—

21 (A) in subparagraph (A), by striking “and  
 22 (D)” and inserting “, (D), and (E)”; and

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

1                   “(E) MONTHLY OUT-OF-POCKET COST  
2                   SHARING MAXIMUM FOR ENROLLEES WHO  
3                   INCUR A SIGNIFICANT PORTION OF COSTS TO-  
4                   WARDS ANNUAL OUT-OF-POCKET THRESH-  
5                   OLD.—

6                   “(i) ESTABLISHMENT OF PROCESS.—

7                   “(I) IN GENERAL.—For plan  
8                   years beginning on or after January  
9                   1, 2024, the Secretary shall, through  
10                  notice and comment rulemaking, es-  
11                  tablish a process under which each  
12                  PDP sponsor offering a prescription  
13                  drug plan and each MA organization  
14                  offering an MA–PD plan shall each  
15                  plan year automatically enroll applica-  
16                  ble enrollees in the option to have  
17                  their monthly out-of-pocket cost-shar-  
18                  ing under the plan capped and paid in  
19                  monthly installments in accordance  
20                  with this subparagraph (referred to in  
21                  this subparagraph as the ‘monthly  
22                  out-of-pocket cost sharing maximum  
23                  option’).

24                  “(II) OPT OUT.—The process es-  
25                  tablished under this clause shall per-

1 mit an applicable enrollee, prior to the  
2 beginning of the plan year or at any  
3 point during the plan year, to opt out  
4 of enrollment in the monthly out-of-  
5 pocket cost sharing maximum option  
6 and pay any out-of-pocket cost-shar-  
7 ing otherwise applicable for any cov-  
8 ered part D drug in full at the time  
9 of the dispensing of such drug (or at  
10 the time of such opt out in the case  
11 of costs incurred during such enroll-  
12 ment that have not yet been billed to  
13 the enrollee).

14 “(ii) DEFINITIONS.—

15 “(I) APPLICABLE ENROLLEE.—

16 In this subparagraph, the term ‘appli-  
17 cable enrollee’ means any enrollee in a  
18 prescription drug plan or an MA–PD  
19 plan, including an enrollee who is a  
20 subsidy eligible individual (as defined  
21 in paragraph (3) of section 1860D–  
22 14(a)), who incurs or is likely to incur  
23 a significant percentage of costs for  
24 covered part D drugs.

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

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

21                   “(iv) BENEFICIARY MONTHLY PAY-  
22 MENTS.—With respect to an applicable en-  
23 rollee who is enrolled in the monthly out-  
24 of-pocket cost sharing maximum option,  
25 for each month described in clause (iii),

1 the PDP sponsor or MA organization shall  
2 bill such enrollee an amount (not to exceed  
3 the monthly out-of-pocket cost sharing  
4 maximum) for the out-of-pocket costs of  
5 such enrollee in such month.

6 “(v) MONTHLY OUT-OF-POCKET COST  
7 SHARING MAXIMUM DEFINED.—In this  
8 subparagraph, the term ‘monthly out-of-  
9 pocket cost sharing maximum’ means, with  
10 respect to an enrollee—

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

14 “(aa) the annual out-of-  
15 pocket threshold specified in  
16 paragraph (4)(B) minus the in-  
17 curred costs of the enrollee as de-  
18 scribed in paragraph (4)(C); di-  
19 vided by

20 “(bb) the number of months  
21 remaining in the plan year; and

22 “(II) for a subsequent month, an  
23 amount determined by calculating—

24 “(aa) the sum of any re-  
25 maining out-of-pocket costs owed

1 by the enrollee from a previous  
2 month that have not yet been  
3 billed to the enrollee and any ad-  
4 ditional costs incurred by the en-  
5 rollee; divided by

6 “(bb) the number of months  
7 remaining in the plan year.

8 “(vi) ADDITIONAL REQUIREMENTS.—  
9 The following requirements shall apply  
10 with respect to the monthly out-of-pocket  
11 cost sharing maximum option under this  
12 subparagraph:

13 “(I) SECRETARIAL RESPONSIBIL-  
14 ITIES.—The Secretary shall provide  
15 information to part D eligible individ-  
16 uals on the monthly out-of-pocket cost  
17 sharing maximum option through edu-  
18 cational materials, including through  
19 the notices provided under section  
20 1804(a).

21 “(II) PDP SPONSOR AND MA OR-  
22 GANIZATION RESPONSIBILITIES.—  
23 Each PDP sponsor offering a pre-  
24 scription drug plan or MA organiza-  
25 tion offering an MA–PD plan—



1 “(aa) shall not limit the ap-  
2 plication of the monthly out-of-  
3 pocket cost sharing maximum op-  
4 tion to certain covered part D  
5 drugs;

6 “(bb) shall, prior to the plan  
7 year, notify prospective enrollees  
8 of such option, including the  
9 availability of the opt out under  
10 clause (i)(II);

11 “(cc) shall include informa-  
12 tion on such option in enrollee  
13 educational materials, including  
14 the availability of the opt out  
15 under clause (i)(II);

16 “(dd) shall have in place a  
17 mechanism to notify a pharmacy  
18 during the plan year when an en-  
19 rollee incurs out-of-pocket costs  
20 with respect to covered part D  
21 drugs that make it likely the en-  
22 rollee is an applicable enrollee;

23 “(ee) shall provide that a  
24 pharmacy, after receiving a noti-  
25 fication described in item (dd)

1 with respect to an enrollee, in-  
2 forms the enrollee of such notifi-  
3 cation;

4 “(ff) shall ensure that the  
5 application of this subparagraph  
6 has no effect on the amount paid  
7 to pharmacies (or the timing of  
8 such payments) with respect to  
9 covered part D drugs dispensed  
10 to the enrollee; and

11 “(gg) shall have in place a  
12 financial reconciliation process to  
13 correct inaccuracies in payments  
14 made by an enrollee under this  
15 subparagraph with respect to  
16 covered part D drugs during the  
17 plan year.

18 “(III) FAILURE TO PAY AMOUNT  
19 BILLED UNDER MONTHLY OUT-OF-  
20 POCKET COST SHARING MAXIMUM OP-  
21 TION.—If an applicable enrollee fails  
22 to pay the amount billed for a month  
23 as required under this subparagraph,  
24 the applicable enrollee’s enrollment in  
25 the monthly out-of-pocket cost sharing

1 maximum option shall be terminated  
2 and the enrollee shall pay the cost-  
3 sharing otherwise applicable for any  
4 covered part D drugs subsequently  
5 dispensed to the enrollee up to the an-  
6 nual out-of-pocket threshold specified  
7 in paragraph (4)(B).

8 “(IV) CLARIFICATION REGARD-  
9 ING PAST DUE AMOUNTS.—Nothing in  
10 this subparagraph shall be construed  
11 as prohibiting a PDP sponsor or an  
12 MA organization from billing an en-  
13 rollee for an amount owed under this  
14 subparagraph.

15 “(V) TREATMENT OF UNSET-  
16 TLED BALANCES.—Any unsettled bal-  
17 ances with respect to amounts owed  
18 under this subparagraph shall be  
19 treated as plan losses and the Sec-  
20 retary shall not be liable for any such  
21 balances outside of those assumed as  
22 losses estimated in plan bids.”; and

23 (2) in paragraph (4)—

24 (A) in subparagraph (C), by striking “and  
25 subject to subparagraph (F)” and inserting

1 “and subject to subparagraphs (F) and (G”;  
2 and

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

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

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

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

1 **SEC. 223. PUBLIC DISCLOSURE OF DRUG DISCOUNTS AND**  
2 **OTHER PHARMACY BENEFIT MANAGER (PBM)**  
3 **PROVISIONS.**

4 (a) PUBLIC DISCLOSURE OF DRUG DISCOUNTS.—

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

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

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

12 “(e) PUBLIC AVAILABILITY OF CERTAIN INFORMA-  
13 TION.—

14 “(1) IN GENERAL.—Subject to paragraphs (2)  
15 and (3), in order to allow patients and employers to  
16 compare PBMs’ ability to negotiate rebates, dis-  
17 counts, and price concessions and the amount of  
18 such rebates, discounts, and price concessions that  
19 are passed through to plan sponsors, not later than  
20 July 1, 2025, the Secretary shall make available on  
21 the Internet website of the Department of Health  
22 and Human Services the information provided to the  
23 Secretary and described in paragraphs (2) and (3)  
24 of subsection (b) with respect to each PBM.

25 “(2) LAG IN DATA.—The information made  
26 available in a plan year under paragraph (1) shall

1 not include information with respect to such plan  
 2 year or the two preceding plan years.

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

10 (2) EFFECTIVE DATE.—The amendment made  
 11 by paragraph (1)(A) shall take effect on January 1,  
 12 2025.

13 (b) PLAN AUDIT OF PHARMACY BENEFIT MANAGER  
 14 DATA.—Section 1860D–2(d)(3) of the Social Security Act  
 15 (42 U.S.C. 1395w–102(d)(3)) is amended—

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

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

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

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

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

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

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

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

17 “(I) be conducted by an inde-  
18 pendent third party; and

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

1 “(iii) REBATE AGREEMENTS.—A PDP  
2 sponsor and an MA organization shall re-  
3 quire pharmacy benefit managers to make  
4 rebate contracts with drug manufacturers  
5 made on their behalf available under audits  
6 described in clause (i).

7 “(iv) CONFIDENTIALITY AGREE-  
8 MENTS.—Audits described in clause (i)  
9 shall be subject to confidentiality agree-  
10 ments to prevent, except as required under  
11 clause (vii), the redisclosure of data trans-  
12 mitted under the audit.

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

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



1 “(vii) SUBMISSION OF AUDIT REPORTS  
2 TO THE SECRETARY.—

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

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

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

1 “(viii) NOTICE OF NONCOMPLI-  
2 ANCE.—A PDP sponsor and an MA orga-  
3 nization shall notify the Secretary if any  
4 pharmacy benefit manager is not com-  
5 plying with requests for access to informa-  
6 tion required under an audit under clause  
7 (i).

8 “(ix) CIVIL MONETARY PENALTIES.—

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

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

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

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

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

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

11                   “(B) TO PHARMACIES.—

12                           “(i) IN GENERAL.—For plan year  
13 2025 and subsequent plan years, a PDP  
14 sponsor offering a prescription drug plan  
15 and an MA organization offering an MA-  
16 PD plan shall report any pharmacy price  
17 concession or incentive payment that oc-  
18 curs with respect to a pharmacy after pay-  
19 ment for covered part D drugs at the  
20 point-of-sale, including by an intermediary  
21 organization with which a PDP sponsor or  
22 MA organization has contracted, to the  
23 pharmacy.

24                           “(ii) TIMING.—The reporting of price  
25 concessions and incentive payments to a

pharmacy under clause (i) shall be made on a periodic basis (but in no case less frequently than annually).

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

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

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

“(iii) DISCLOSURE OF CONFLICTS OF INTEREST.—With respect to plan year 2025 and subsequent plan years, a PDP sponsor of a prescription drug plan and an MA organization offering an MA–PD plan shall, as part of its bid submission under section 1860D–11(b), provide the Secretary with a completed statement of financial conflicts of interest, including with

1 manufacturers, from each member of any  
2 pharmacy and therapeutic committee used  
3 by the sponsor or organization pursuant to  
4 this paragraph.”.

5 (2) INCLUSION IN BID.—Section 1860D–  
6 11(b)(2) of the Social Security Act (42 U.S.C.  
7 1395w–111(b)(2)) is amended—

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

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

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

15 (e) INFORMATION ON DIRECT AND INDIRECT REMU-  
16 NERATION REQUIRED TO BE INCLUDED IN BID.—Section  
17 1860D–11(b) of the Social Security Act (42 U.S.C.  
18 1395w–111(b)) is amended—

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

25 (2) in paragraph (2)(C)—

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

3 (B) in clause (iv), by striking the period at  
4 the end and inserting the following: “, and, with  
5 respect to plan year 2025 and subsequent plan  
6 years, actual and projected administrative ex-  
7 penses assumed in the bid, categorized by the  
8 type of such expense, including actual and pro-  
9 jected price concessions retained by a pharmacy  
10 benefit manager; and”; and

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

13 “(v) with respect to plan year 2025  
14 and subsequent plan years, actual and pro-  
15 jected direct and indirect remuneration,  
16 categorized as received from each of the  
17 following:

18 “(I) A pharmacy.

19 “(II) A manufacturer.

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

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

1 **SEC. 224. PUBLIC DISCLOSURE OF DIRECT AND INDIRECT**  
2 **REMUNERATION REVIEW AND AUDIT RE-**  
3 **SULTS.**

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

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

10 “(1) DIR REVIEW RESULTS.—

11 “(A) IN GENERAL.—Except as provided in  
12 subparagraph (B), in 2023 and each subse-  
13 quent year, the Secretary shall make available  
14 to the public on the Internet website of the  
15 Centers for Medicare & Medicaid Services infor-  
16 mation on discrepancies related to summary  
17 and detailed DIR reports submitted by PDP  
18 sponsors pursuant to section 1860D–15 across  
19 all prescription drug plans based on the most  
20 recent data available. Information made avail-  
21 able under this subparagraph shall include the  
22 following:

23 “(i) The number of potential errors  
24 identified by the Secretary for PDP spon-  
25 sors to review.

1                   “(ii) The extent to which PDP spon-  
2                   sors resubmitted DIR reports to make  
3                   changes for previous contract years.

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

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

16                  “(2) FINANCIAL AUDIT RESULTS.—In 2023 and  
17                  each subsequent year, the Secretary shall make  
18                  available to the public on the Internet website of the  
19                  Centers for Medicare & Medicaid Services the results  
20                  of DIR audits required under section 1860D–  
21                  12(b)(3)(C). Information made available under this  
22                  paragraph shall include the following:

23                         “(A) With respect to the year, the number  
24                         of PDP sponsors that received each of the fol-  
25                         lowing:



1 “(i) A notice of observations or find-  
2 ings that required the sponsor to make  
3 DIR report corrections.

4 “(ii) An unqualified audit opinion that  
5 renders the audit closed.

6 “(iii) A qualified audit opinion that  
7 requires the sponsor to submit a corrective  
8 action plan to the Secretary.

9 “(iv) An adverse opinion, with a de-  
10 scription of the types of actions that the  
11 Secretary takes when issuing an adverse  
12 opinion.

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

14 “(i) The number of PDP sponsors  
15 that reopened a previously closed reconcili-  
16 ation as a result of an audit, including as  
17 a result of DIR changes.

18 “(ii) The extent to which the Sec-  
19 retary recouped an overpayment or made  
20 an underpayment as a result of a reopen-  
21 ing of a previously closed reconciliation.

22 “(3) DEFINITION OF DIR.—For purposes of  
23 this subsection, the term ‘DIR’ means direct and in-  
24 direct remuneration as defined in section 423.308 of

1 title 42, Code of Federal Regulations, or any suc-  
 2 cessor regulation.”.

3 **SEC. 225. IMPROVEMENTS TO PROVISION OF PARTS A AND**  
 4 **B CLAIMS DATA TO PRESCRIPTION DRUG**  
 5 **PLANS.**

6 (a) DATA USE.—

7 (1) IN GENERAL.—Paragraph (6) of section  
 8 1860D–4(c) of the Social Security Act (42 U.S.C.  
 9 1395w–104(c)), as added by section 50354 of divi-  
 10 sion E of the Bipartisan Budget Act of 2018 (Public  
 11 Law 115–123), relating to providing prescription  
 12 drug plans with parts A and B claims data to pro-  
 13 mote the appropriate use of medications and im-  
 14 prove health outcomes, is amended—

15 (A) in subparagraph (B)—

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

20 (ii) by striking “PURPOSES.—A PDP  
 21 sponsor” and inserting “PURPOSES.—

22 “(i) IN GENERAL.—A PDP sponsor.”;  
 23 and

24 (iii) by adding at the end the fol-  
 25 lowing new clause:

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

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

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

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

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

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

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

21 “(ii) MANNER OF PROVISION.—

22 “(I) IN GENERAL.—Such data  
 23 may be provided pursuant to this  
 24 paragraph in the same manner as  
 25 data under the Part D Enhanced

1 Medication Therapy Management  
 2 model tested under section 1115A,  
 3 through Application Programming  
 4 Interface, or in another manner as de-  
 5 termined by the Secretary.

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

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

13 **SEC. 226. MEDICARE PART D REBATE BY MANUFACTURERS.**

14 (a) IN GENERAL.—Part D of title XVIII of the Social  
 15 Security Act is amended by inserting after section 1860D–  
 16 14A (42 U.S.C. 1395w–114a) the following new section:

17 **“SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN**  
 18 **DRUGS WITH PRICES INCREASING FASTER**  
 19 **THAN INFLATION.**

20 “(a) IN GENERAL.—

21 “(1) IN GENERAL.—Subject to the provisions of  
 22 this section, in order for coverage to be available  
 23 under this part for a part D rebatable drug (as de-  
 24 fined in subsection (h)(1)) of a manufacturer (as de-  
 25 fined in section 1927(k)(5)) dispensed during an ap-

1       plicable year, the manufacturer must have entered  
 2       into and have in effect an agreement described in  
 3       subsection (b).

4           “(2) AUTHORIZING COVERAGE FOR DRUGS NOT  
 5       COVERED UNDER AGREEMENTS.—Paragraph (1)  
 6       shall not apply to the dispensing of a covered part  
 7       D drug if—

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

11          “(B) the Secretary determines that in the  
 12      period beginning on January 1, 2025, and end-  
 13      ing on December 31, 2025, there were extenu-  
 14      ating circumstances.

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

18      “(b) AGREEMENTS.—

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

23          “(A) SECRETARIAL PROVISION OF INFOR-  
 24      MATION.—Not later than 9 months after the  
 25      end of each applicable year with respect to

1           which the agreement is in effect, the Secretary,  
2           for each part D rebatable drug of the manufac-  
3           turer, shall report to the manufacturer the fol-  
4           lowing for such year:

5                   “(i) Information on the total number  
6                   of units (as defined in subsection (h)(2))  
7                   for each dosage form and strength with re-  
8                   spect to such part D rebatable drug and  
9                   year.

10                   “(ii) Information on the amount (if  
11                   any) of the excess average manufacturer  
12                   price increase described in subsection  
13                   (c)(1)(B) for each dosage form and  
14                   strength with respect to such drug and  
15                   year.

16                   “(iii) The rebate amount specified  
17                   under subsection (c) for each dosage form  
18                   and strength with respect to such drug and  
19                   year.

20                   “(B) MANUFACTURER REQUIREMENTS.—

21           For each applicable year with respect to which  
22           the agreement is in effect, the manufacturer of  
23           the part D rebatable drug, for each dosage  
24           form and strength with respect to such drug,  
25           not later than 30 days after the date of receipt

1 from the Secretary of the information described  
2 in subparagraph (A) for such year, shall pro-  
3 vide to the Secretary a rebate that is equal to  
4 the amount specified in subsection (c) for such  
5 dosage form and strength with respect to such  
6 drug for such year.

7 “(2) LENGTH OF AGREEMENT.—

8 “(A) IN GENERAL.—An agreement under  
9 this section, with respect to a part D rebatable  
10 drug, shall be effective for an initial period of  
11 not less than one year and shall be automati-  
12 cally renewed for a period of not less than one  
13 year unless terminated under subparagraph  
14 (B).

15 “(B) TERMINATION.—

16 “(i) BY SECRETARY.—The Secretary  
17 may provide for termination of an agree-  
18 ment under this section for violation of the  
19 requirements of the agreement or other  
20 good cause shown. Such termination shall  
21 not be effective earlier than 30 days after  
22 the date of notice of such termination. The  
23 Secretary shall provide, upon request, a  
24 manufacturer with a hearing concerning  
25 such a termination, but such hearing shall

1 not delay the effective date of the termi-  
2 nation.

3 “(ii) BY A MANUFACTURER.—A man-  
4 ufacturer may terminate an agreement  
5 under this section for any reason. Any  
6 such termination shall be effective, with re-  
7 spect to a plan year—

8 “(I) if the termination occurs be-  
9 fore January 30 of the plan year, as  
10 of the day after the end of the plan  
11 year; and

12 “(II) if the termination occurs on  
13 or after January 30 of the plan year,  
14 as of the day after the end of the suc-  
15 ceeding plan year.

16 “(C) EFFECTIVENESS OF TERMINATION.—  
17 Any termination under this paragraph shall not  
18 affect rebates due under the agreement under  
19 this section before the effective date of its ter-  
20 mination.

21 “(D) DELAY BEFORE REENTRY.—In the  
22 case of any agreement under this section with  
23 a manufacturer that is terminated in a plan  
24 year, the Secretary may not enter into another  
25 such agreement with the manufacturer (or a



1 successor manufacturer) before the subsequent  
2 plan year, unless the Secretary finds good cause  
3 for an earlier reinstatement of such an agree-  
4 ment.

5 “(c) REBATE AMOUNT.—

6 “(1) IN GENERAL.—For purposes of this sec-  
7 tion, the amount specified in this subsection for a  
8 dosage form and strength with respect to a part D  
9 rebatable drug and applicable year is, subject to sub-  
10 paragraphs (B) and (C) of paragraph (5), the  
11 amount equal to the product of—

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

15 “(B) the amount (if any) by which—

16 “(i) the annual manufacturer price  
17 (as determined in paragraph (2)) paid for  
18 such dosage form and strength with re-  
19 spect to such part D rebatable drug for the  
20 year; exceeds

21 “(ii) the inflation-adjusted payment  
22 amount determined under paragraph (3)  
23 for such dosage form and strength with re-  
24 spect to such part D rebatable drug for the  
25 year.

1           “(2) DETERMINATION OF ANNUAL MANUFAC-  
2           TURER PRICE.—The annual manufacturer price de-  
3           termined under this paragraph for a dosage form  
4           and strength, with respect to a part D rebatable  
5           drug and an applicable year, is the sum of the prod-  
6           ucts of—

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

12                  “(B) the ratio of—

13                          “(i) the total number of units of such  
14                          dosage form and strength dispensed during  
15                          each such calendar quarter of such year; to

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

19           “(3) DETERMINATION OF INFLATION-ADJUSTED  
20           PAYMENT AMOUNT.—The inflation-adjusted payment  
21           amount determined under this paragraph for a dos-  
22           age form and strength with respect to a part D  
23           rebatable drug for an applicable year, subject to sub-  
24           paragraphs (A) and (D) of paragraph (5), is—

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

5           “(B) the percentage by which the applica-  
6 ble year CPI-U (as defined in subsection  
7 (h)(5)) for the applicable year exceeds the  
8 benchmark period CPI-U (as defined in sub-  
9 section (h)(4)).

10          “(4) DETERMINATION OF BENCHMARK YEAR  
11 MANUFACTURER PRICE.—The benchmark year man-  
12 ufacturer price determined under this paragraph for  
13 a dosage form and strength, with respect to a part  
14 D rebatable drug and an applicable year, is the sum  
15 of the products of—

16           “(A) the average manufacturer price (as  
17 defined in subsection (h)(6)) of such dosage  
18 form and strength, as calculated for a unit of  
19 such drug, with respect to each of the calendar  
20 quarters of the payment amount benchmark  
21 year (as defined in subsection (h)(3)); and

22           “(B) the ratio of—

23           “(i) the total number of units of such  
24 dosage form and strength dispensed during

1 each such calendar quarter of such pay-  
2 ment amount benchmark year; to

3 “(ii) the total number of units of such  
4 dosage form and strength dispensed during  
5 such payment amount benchmark year.

6 “(5) SPECIAL TREATMENT OF CERTAIN DRUGS  
7 AND EXEMPTION.—

8 “(A) SUBSEQUENTLY APPROVED DRUGS.—

9 In the case of a part D rebatable drug first ap-  
10 proved or licensed by the Food and Drug Ad-  
11 ministration after January 1, 2016, subpara-  
12 graphs (A) and (B) of paragraph (4) shall be  
13 applied as if the term ‘payment amount bench-  
14 mark year’ were defined under subsection  
15 (h)(3) as the first calendar year beginning after  
16 the day on which the drug was first marketed  
17 by any manufacturer and subparagraph (B) of  
18 paragraph (3) shall be applied as if the term  
19 ‘benchmark period CPI-U’ were defined under  
20 subsection (h)(4) as if the reference to ‘January  
21 2016’ under such subsection were a reference to  
22 ‘January of the first year beginning after the  
23 date on which the drug was first marketed by  
24 any manufacturer’.

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

9           “(C) TREATMENT OF NEW FORMULA-  
10          TIONS.—

11           “(i) IN GENERAL.—In the case of a  
12          part D rebtable drug that is a line exten-  
13          sion of a part D rebtable drug that is an  
14          oral solid dosage form, the Secretary shall  
15          establish a formula for determining the  
16          amount specified in this subsection with  
17          respect to such part D rebtable drug and  
18          an applicable year with consideration of  
19          the original part D rebtable drug.

20           “(ii) LINE EXTENSION DEFINED.—In  
21          this subparagraph, the term ‘line exten-  
22          sion’ means, with respect to a part D  
23          rebtable drug, a new formulation of the  
24          drug (as determined by the Secretary),  
25          such as an extended release formulation,

1 but does not include an abuse-deterrent  
2 formulation of the drug (as determined by  
3 the Secretary), regardless of whether such  
4 abuse-deterrent formulation is an extended  
5 release formulation.

6 “(D) SELECTED DRUGS.—In the case of a  
7 part D 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 plan years during such period  
12 for which a maximum fair price (as defined  
13 in section 1191(c)(2)) for such drug has  
14 been determined and is applied under part  
15 E of title XI, the rebate under subsection  
16 (b)(1)(B) shall be waived; and

17 “(ii) in the case such drug is deter-  
18 mined (pursuant to such section 1192(c))  
19 to no longer be a selected drug, for each  
20 applicable year beginning after the price  
21 applicability period with respect to such  
22 drug, subparagraphs (A) and (B) of para-  
23 graph (4) shall be applied as if the term  
24 ‘payment amount benchmark year’ were  
25 defined under subsection (h)(3) as the last

1           year beginning during such price applica-  
2           bility period with respect to such selected  
3           drug and subparagraph (B) of paragraph  
4           (3) shall be applied as if the term ‘bench-  
5           mark period CPI–U’ were defined under  
6           subsection (h)(4) as if the reference to  
7           ‘January 2016’ under such subsection were  
8           a reference to January of the last year be-  
9           ginning during such price applicability pe-  
10          riod with respect to such drug.

11       “(d) REBATE DEPOSITS.—Amounts paid as rebates  
12       under subsection (c) shall be deposited into the Medicare  
13       Prescription Drug Account in the Federal Supplementary  
14       Medical Insurance Trust Fund established under section  
15       1841.

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

19       “(f) CIVIL MONEY PENALTY.—In the case of a man-  
20       ufacturer of a part D rebatable drug with an agreement  
21       in effect under this section who has failed to comply with  
22       the terms of the agreement under subsection (b)(1)(B)  
23       with respect to such drug for an applicable year, the Sec-  
24       retary may impose a civil money penalty on such manufac-  
25       turer in an amount equal to 125 percent of the amount

1 specified in subsection (c) for such drug for such year.  
 2 The provisions of section 1128A (other than subsections  
 3 (a) (with respect to amounts of penalties or additional as-  
 4 sessments) and (b)) shall apply to a civil money penalty  
 5 under this subsection in the same manner as such provi-  
 6 sions apply to a penalty or proceeding under section  
 7 1128A(a).

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

10 “(1) The determination of units under this sec-  
 11 tion.

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

14 “(3) The calculation of the rebate amount  
 15 under this section.

16 “(h) DEFINITIONS.—In this section:

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

18 “(A) IN GENERAL.—The term ‘part D  
 19 rebatable drug’ means a drug or biological that  
 20 would (without application of this section) be a  
 21 covered part D drug, except such term shall,  
 22 with respect to an applicable year, not include  
 23 such a drug or biological if the average annual  
 24 total cost under this part for such year per in-  
 25 dividual who uses such a drug or biological, as



determined by the Secretary, is less than, subject to subparagraph (B), \$100, as determined by the Secretary using the most recent data available or, if data is not available, as estimated by the Secretary.

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

“(i) for 2026, shall be the dollar amount specified under such subparagraph for 2025, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period beginning with January of 2025; and

“(ii) for a subsequent year, shall be the dollar amount specified in this subparagraph 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 beginning with January 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.

1           “(2) UNIT DEFINED.—The term ‘unit’ means,  
2           with respect to a part D rebatable drug, the lowest  
3           identifiable quantity (such as a capsule or tablet,  
4           milligram of molecules, or grams) of the part D  
5           rebatable drug that is dispensed to individuals under  
6           this part.

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

10          “(4) BENCHMARK PERIOD CPI-U.—The term  
11          ‘benchmark period CPI-U’ means the consumer  
12          price index for all urban consumers (United States  
13          city average) for January 2016.

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

19          “(6) AVERAGE MANUFACTURER PRICE.—The  
20          term ‘average manufacturer price’ has the meaning,  
21          with respect to a part D rebatable drug of a manu-  
22          facturer, given such term in section 1927(k)(1), with  
23          respect to a covered outpatient drug of a manufac-  
24          turer for a rebate period under section 1927.”.

25          (b) 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)), as amended by section 201(c)(1),  
 4       is further amended by striking “section 1927 or sec-  
 5       tion 1834(x)” and inserting “section 1927, section  
 6       1834(x), or section 1860D–14B”.

7           (2) EXCLUDING PART D DRUG INFLATION RE-  
 8       BATE           FROM           BEST           PRICE.—Section  
 9       1927(c)(1)(C)(ii)(I) of the Social Security Act (42  
 10      U.S.C. 1396r–8(c)(1)(C)(ii)(I)), as amended by sec-  
 11      tion 201(c)(2), is further amended by striking “or  
 12      section 1834(x)” and inserting “, section 1834(x), or  
 13      section 1860D–14B”.

14          (3) COORDINATION WITH MEDICAID REBATE IN-  
 15      FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)  
 16      of the Social Security Act (42 U.S.C. 1396r–  
 17      8(b)(3)(D)(i)), as amended by section 201(c)(3), is  
 18      further amended by striking “or section 1834(x)”  
 19      and inserting “, section 1834(x), or section 1860D–  
 20      14B”.

21 **SEC. 227. PROHIBITING BRANDING ON PART D BENEFIT**  
 22 **CARDS.**

23          (a) IN GENERAL.—Section 1851(j)(2)(B) of the So-  
 24      cial Security Act (42 U.S.C. 1395w–21(j)(2)(B)) is  
 25      amended by striking “co-branded network provider” and

1 inserting “co-branded, co-owned, or affiliated network pro-  
 2 vider, pharmacy, or pharmacy benefit manager”.

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

6 **SEC. 228. REQUIRING PRESCRIPTION DRUG PLANS AND**  
 7 **MA-PD PLANS TO REPORT POTENTIAL**  
 8 **FRAUD, WASTE, AND ABUSE TO THE SEC-**  
 9 **RETARY OF HHS.**

10 Section 1860D–4 of the Social Security Act (42  
 11 U.S.C. 1395w–104), as amended by section 225, is  
 12 amended by adding at the end the following new sub-  
 13 section:

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

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

22 “(2) any steps made by the PDP sponsor after  
 23 identifying such activities to take corrective ac-  
 24 tions.”.

1 **SEC. 229. ESTABLISHMENT OF PHARMACY QUALITY MEAS-**  
2 **URES UNDER MEDICARE PART D.**

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

7 “(8) APPLICATION OF PHARMACY QUALITY  
8 MEASURES.—

9 “(A) IN GENERAL.—A PDP sponsor that  
10 implements incentive payments to a pharmacy  
11 or price concessions paid by a pharmacy based  
12 on quality measures shall use measures estab-  
13 lished or approved by the Secretary under sub-  
14 paragraph (B) with respect to payment for cov-  
15 ered part D drugs dispensed by such pharmacy.

16 “(B) STANDARD PHARMACY QUALITY  
17 MEASURES.—The Secretary shall establish or  
18 approve standard quality measures from a con-  
19 sensus and evidence-based organization for pay-  
20 ments described in subparagraph (A). Such  
21 measures shall focus on patient health outcomes  
22 and be based on proven criteria measuring  
23 pharmacy performance.

24 “(C) EFFECTIVE DATE.—The requirement  
25 under subparagraph (A) shall take effect for  
26 plan years beginning on or after January 1,

2026, or such earlier date specified by the Secretary if the Secretary determines there are sufficient measures established or approved under subparagraph (B) to meet the requirement under subparagraph (A).”.

**SEC. 230. ADDITION OF NEW MEASURES BASED ON ACCESS TO BIOSIMILAR BIOLOGICAL PRODUCTS TO THE 5-STAR RATING SYSTEM UNDER MEDICARE ADVANTAGE.**

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

“(E) ADDITION OF NEW MEASURES BASED ON ACCESS TO BIOSIMILAR BIOLOGICAL PRODUCTS.—

“(i) IN GENERAL.—For 2028 and subsequent years, the Secretary shall add a new set of measures to the 5-star rating system based on access to biosimilar biological products covered under part B and, in the case of MA–PD plans, such products that are covered part D drugs. Such measures shall assess the impact a plan’s benefit structure may have on enrollees’ utilization of or ability to access biosimilar

1 biological products, including in compari-  
2 son to the reference biological product, and  
3 shall include measures, as applicable, with  
4 respect to the following:

5 “(I) COVERAGE.—Assessing  
6 whether a biosimilar biological prod-  
7 uct is on the plan formulary in lieu of  
8 or in addition to the reference biologi-  
9 cal product.

10 “(II) PREFERENCING.—Assess-  
11 ing tier placement or cost-sharing for  
12 a biosimilar biological product relative  
13 to the reference biological product.

14 “(III) UTILIZATION MANAGE-  
15 MENT TOOLS.—Assessing whether and  
16 how utilization management tools are  
17 used with respect to a biosimilar bio-  
18 logical product relative to the ref-  
19 erence biological product.

20 “(IV) UTILIZATION.—Assessing  
21 the percentage of enrollees prescribed  
22 the biosimilar biological product and  
23 the percentage of enrollees prescribed  
24 the reference biological product when

1 the reference biological product is also  
2 on the plan formulary.

3 “(ii) DEFINITIONS.—In this subpara-  
4 graph, the terms ‘biosimilar biological  
5 product’ and ‘reference biological product’  
6 have the meaning given those terms in sec-  
7 tion 1847A(c)(6).

8 “(iii) PROTECTING PATIENT INTER-  
9 ESTS.—In developing such measures, the  
10 Secretary shall ensure that each measure  
11 developed to address coverage,  
12 preferencing, or utilization management is  
13 constructed such that patients retain ac-  
14 cess to appropriate therapeutic options  
15 without undue administrative burden.”.

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



1 manner as such provisions apply to the 5-star rating sys-  
2 tem under such section 1853(o)(4).

3 **SEC. 231. HHS STUDY AND REPORT ON THE INFLUENCE OF**  
4 **PHARMACEUTICAL MANUFACTURER THIRD-**  
5 **PARTY REIMBURSEMENT HUBS ON HEALTH**  
6 **CARE PROVIDERS WHO PRESCRIBE THEIR**  
7 **DRUGS AND BIOLOGICALS.**

8 (a) STUDY.—

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

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

19 (A) The influence of pharmaceutical manu-  
20 facturer distribution models that provide third-  
21 party reimbursement hub services to health care  
22 providers who prescribe the manufacturer’s  
23 drugs and biologicals, including—

24 (i) the operations of pharmaceutical  
25 manufacturer distribution models that pro-

1           vide reimbursement hub services for health  
2           care providers who prescribe the manufac-  
3           turer's products;

4                   (ii) Federal laws affecting these phar-  
5           maceutical manufacturer distribution mod-  
6           els; and

7                   (iii) whether hub services could im-  
8           properly incentivize health care providers  
9           to deem a drug or biological as medically  
10          necessary under section 423.578 of title  
11          42, Code of Federal Regulations.

12          (B) Other areas determined appropriate by  
13          the Secretary.

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

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

1 **SEC. 232. DEFINITION OF STRENGTH FOR THE PURPOSES**  
 2 **OF DETERMINING INTERCHANGEABILITY OF**  
 3 **BIOLOGICAL AND BIOSIMILAR PRODUCTS.**

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

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

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

15 **Subtitle C—Miscellaneous**

16 **SEC. 233. DRUG MANUFACTURER PRICE TRANSPARENCY.**

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

20 **“SEC. 1128L. DRUG MANUFACTURER PRICE TRANS-**  
 21 **PARENCY.**

22 “(a) IN GENERAL.—

23 “(1) DETERMINATIONS.—Beginning July 1,  
 24 2025, the Secretary shall make determinations as to  
 25 whether a drug is an applicable drug as described in  
 26 subsection (b).

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

8       “(b) APPLICABLE DRUG DESCRIBED.—

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

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

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

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

19           “(I) during 2023, of at least 100  
 20      percent since the date of the enact-  
 21      ment of this section;

22           “(II) during 2024, of at least  
 23      100 percent in the preceding 12  
 24      months or of at least 150 percent in  
 25      the preceding 24 months;

1 “(III) during 2025, of at least  
2 100 percent in the preceding 12  
3 months or of at least 200 percent in  
4 the preceding 36 months;

5 “(IV) during 2026, of at least  
6 100 percent in the preceding 12  
7 months or of at least 250 percent in  
8 the preceding 48 months; or

9 “(V) on or after January 1,  
10 2027, of at least 100 percent in the  
11 preceding 12 months or of at least  
12 300 percent in the preceding 60  
13 months.

14 “(B) HIGH SPENDING WITH INCREASE.—

15 The drug—

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

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

1                   “(I) during 2023, of at least 15  
2                   percent since the date of the enact-  
3                   ment of this section;

4                   “(II) during 2024, of at least 15  
5                   percent in the preceding 12 months or  
6                   of at least 20 percent in the preceding  
7                   24 months;

8                   “(III) during 2025, of at least 15  
9                   percent in the preceding 12 months or  
10                  of at least 30 percent in the preceding  
11                  36 months;

12                  “(IV) during 2026, of at least 15  
13                  percent in the preceding 12 months or  
14                  of at least 40 percent in the preceding  
15                  48 months; or

16                  “(V) on or after January 1,  
17                  2027, of at least 15 percent in the  
18                  preceding 12 months or of at least 50  
19                  percent in the preceding 60 months.

20                  “(C) HIGH LAUNCH PRICE FOR NEW  
21                  DRUGS.—In the case of a drug that is marketed  
22                  for the first time on or after January 1, 2023,  
23                  and for which the manufacturer has established  
24                  the first wholesale acquisition cost on or after  
25                  such date, such wholesale acquisition cost for a

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

6 “(2) SPECIAL RULES.—

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

17 “(B) DRUGS WITH HIGH LAUNCH PRICES  
18 ANNUALLY REPORT UNTIL A THERAPEUTIC  
19 EQUIVALENT IS AVAILABLE.—In the case of a  
20 drug that the Secretary determines is an appli-  
21 cable drug described in subparagraph (C) of  
22 paragraph (1), such drug shall remain de-  
23 scribed in such subparagraph (C) (and the  
24 manufacturer of such drug shall annually re-  
25 port the justification under subsection (c)(2))

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

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

8           “(c) JUSTIFICATION DESCRIBED.—

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 “(d) TIMING.—

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

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

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

8            “(3) POSTING ON INTERNET WEBSITE.—

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

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

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

12       “(f) PENALTIES.—

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

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

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

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

11 “(g) DEFINITIONS.—In this section:

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

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

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

1 **SEC. 234. STRENGTHENING AND EXPANDING PHARMACY**  
2 **BENEFIT MANAGERS TRANSPARENCY RE-**  
3 **QUIREMENTS.**

4 Section 1150A of the Social Security Act (42 U.S.C.  
5 1320b–23), as amended by section 223, is amended—

6 (1) in subsection (a)—

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

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

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

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

16 (2) in subsection (b)—

17 (A) in paragraph (2)—

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

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

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

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

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

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

12 “(A) PDP sponsors;

13 “(B) qualified health benefit plans;

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

16 “(D) drug manufacturers.”;

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

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

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

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

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

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

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

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

15 “(A) PBM rebates;

16 “(B) administrative fees;

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

19 “(D) generic dispensing rates; and

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

22 “(2) REPORT.—Not later than July 1, 2023,  
23 and annually thereafter, the Inspector General of the  
24 Department of Health and Human Services shall  
25 submit to Congress a report containing the results



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

7 **SEC. 235. PRESCRIPTION DRUG PRICING DASHBOARDS.**

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

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

11 “(a) IN GENERAL.—Beginning not later than Janu-  
 12 ary 1, 2023, the Secretary shall establish, and annually  
 13 update, internet website-based dashboards, through which  
 14 beneficiaries, clinicians, researchers, and the public can re-  
 15 view information on spending for, and utilization of, pre-  
 16 scription drugs and biologicals (and related supplies and  
 17 mechanisms of delivery) covered under each of parts B  
 18 and D of title XVIII and under a State program under  
 19 title XIX, including information on trends of such spend-  
 20 ing and utilization over time.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12                  “(1) IN GENERAL.—The dashboard established  
13                  under subsection (a) for title XIX shall provide the  
14                  information described in paragraph (2).

15                  “(2) INFORMATION DESCRIBED.—The informa-  
16                  tion described in this paragraph is the following in-  
17                  formation with respect to covered outpatient drugs  
18                  under such title:

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

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

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

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

11   **SEC. 236. IMPROVING COORDINATION BETWEEN THE FOOD**  
 12                           **AND DRUG ADMINISTRATION AND THE CEN-**  
 13                           **TERS FOR MEDICARE & MEDICAID SERVICES.**

14          (a) IN GENERAL.—

15               (1) PUBLIC MEETING.—

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

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

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

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

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

(iii) representatives of commercial health insurance payers;

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

(v) stakeholders representing patients and with expertise in the utilization of patient experience data in medical product development.



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

3 (i) the status of the drug and medical  
4 device development pipeline related to the  
5 availability of novel medical products;

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

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

16 (iv) trends in the differences in the  
17 data necessary to determine the safety and  
18 effectiveness of a novel medical product  
19 and the data necessary to determine  
20 whether a novel medical product meets the  
21 reasonable and necessary requirements for  
22 coverage and payment under title XVIII of  
23 the Social Security Act pursuant to section  
24 1862(a)(1)(A) of such Act (42 U.S.C.  
25 1395y(a)(1)(A));

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

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

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

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

19 (A) DRAFT GUIDANCE.—Not later than 18  
20 months after the public meeting under para-  
21 graph (1), the Secretary shall update the final  
22 guidance titled “National Coverage Determina-  
23 tions with Data Collection as a Condition of  
24 Coverage: Coverage with Evidence Develop-  
25 ment” to address any opportunities to improve

1 the availability and coordination of information  
2 as described in clauses (iv) through (vi) of para-  
3 graph (1)(C).

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

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

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

23 (2) Recommendations to—

24 (A) incorporate patient experience data  
25 (such as the impact of a disease or condition on

1 the lives of patients and patient treatment pref-  
2 erences) into the coverage and payment proc-  
3 esses within the Centers for Medicare & Med-  
4 icaid Services;

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

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

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

21 (c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For  
22 purposes of this section, a novel medical product described  
23 in this subsection is a medical product, including a drug,  
24 biological (including gene and cell therapy), or medical de-  
25 vice, that has been designated as a breakthrough therapy

1 under section 506(a) of the Federal Food, Drug, and Cos-  
 2 metic Act (21 U.S.C. 356(a)), a breakthrough device  
 3 under section 515B of such Act (21 U.S.C. 360e–3), or  
 4 a regenerative advanced therapy under section 506(g) of  
 5 such Act (21 U.S.C. 356(g)).

6 **SEC. 237. PATIENT CONSULTATION IN MEDICARE NA-**  
 7 **TIONAL AND LOCAL COVERAGE DETERMINA-**  
 8 **TIONS IN ORDER TO MITIGATE BARRIERS TO**  
 9 **INCLUSION OF SUCH PERSPECTIVES.**

10 Section 1862(l) of the Social Security Act (42 U.S.C.  
 11 1395y(l)) is amended by adding at the end the following  
 12 new paragraph:

13 “(7) PATIENT CONSULTATION IN NATIONAL  
 14 AND LOCAL COVERAGE DETERMINATIONS.—The Sec-  
 15 retary may consult with patients and organizations  
 16 representing patients in making national and local  
 17 coverage determinations.”.

18 **SEC. 238. GAO STUDY ON INCREASES TO MEDICARE AND**  
 19 **MEDICAID SPENDING DUE TO COPAYMENT**  
 20 **COUPONS AND OTHER PATIENT ASSISTANCE**  
 21 **PROGRAMS.**

22 (a) STUDY.—The Comptroller General of the United  
 23 States shall conduct a study on the impact of copayment  
 24 coupons and other patient assistance programs on pre-  
 25 scription drug pricing and expenditures within the Medi-

1 care and Medicaid programs. The study shall assess the  
2 following:

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

6 (2) The impact copayment coupons and other  
7 patient assistance programs have in the Medicare  
8 Part D program established under part D of title  
9 XVIII of the Social Security Act (42 U.S.C. 1395w-  
10 101 et seq.) on utilization of higher-cost brand drugs  
11 and lower utilization of generic drugs in that pro-  
12 gram.

13 (3) The extent to which manufacturers report  
14 or obtain tax benefits, including deductions of busi-  
15 ness expenses and charitable contributions, for any  
16 of the following:

17 (A) Offering copayment coupons or other  
18 patient assistance programs.

19 (B) Sponsoring manufacturer patient as-  
20 sistance programs.

21 (C) Paying for sponsorships at outreach  
22 and advocacy events organized by patient as-  
23 sistance programs.

24 (4) The efficacy of oversight conducted to en-  
25 sure that independent charity patient assistance pro-

grams adhere to guidance from the Office of the Inspector General of the Department of Health and Human Services on avoiding waste, fraud, and abuse.

(b) DEFINITIONS.—In this section:

(1) INDEPENDENT CHARITY PATIENT ASSISTANCE PROGRAM.—The term “independent charity patient assistance program” means any organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of such Code and which is not a private foundation (as defined in section 509(a) of such Code) that offers patient assistance.

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

(3) MANUFACTURER PATIENT ASSISTANCE PROGRAM.—The term “manufacturer patient assistance program” means an organization, including a private foundation (as so defined), that is sponsored by, or receives funding from, a manufacturer and that offers patient assistance. Such term does not include an independent charity patient assistance program.

1           (4) PATIENT ASSISTANCE.—The term “patient  
2           assistance” means assistance provided to offset the  
3           cost of drugs for individuals. Such term includes free  
4           products, coupons, rebates, copay or discount cards,  
5           and other means of providing assistance to individ-  
6           uals related to drug costs, as determined by the Sec-  
7           retary of Health and Human Services.

8           (c) REPORT.—Not later than 24 months after the  
9           date of the enactment of this Act, the Comptroller General  
10          of the United States shall submit to Congress a report  
11          describing the findings of the study required under sub-  
12          section (a).

13       **SEC. 239. MEDPAC REPORT ON SHIFTING COVERAGE OF**  
14                               **CERTAIN MEDICARE PART B DRUGS TO MEDI-**  
15                               **CARE PART D.**

16          (a) STUDY.—The Medicare Payment Advisory Com-  
17          mission (in this section referred to as the “Commission”)  
18          shall conduct a study on shifting coverage of certain drugs  
19          and biologicals for which payment is currently made under  
20          part B of title XVIII of the Social Security Act (42 U.S.C.  
21          1395j et seq.) to part D of such title (42 U.S.C. 1395w-  
22          21 et seq.). Such study shall include an analysis of—

23               (1) differences in program structures and pay-  
24               ment methods for drugs and biologicals covered  
25               under such parts B and D, including effects of such



1 a shift on program spending, beneficiary cost-shar-  
2 ing liability, and utilization management techniques  
3 for such drugs and biologicals; and

4 (2) the feasibility and policy implications of  
5 shifting coverage of drugs and biologicals for which  
6 payment is currently made under such part B to  
7 such part D.

8 (b) REPORT.—

9 (1) IN GENERAL.—Not later than June 30,  
10 2024, the Commission shall submit to Congress a re-  
11 port containing the results of the study conducted  
12 under subsection (a).

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

16 (A) formulary design under such part D;

17 (B) the ability of the benefit structure  
18 under such part D to control total spending on  
19 drugs and biologicals for which payment is cur-  
20 rently made under such part B;

21 (C) changes to the bid process under such  
22 part D, if any, that may be necessary to inte-  
23 grate coverage of such drugs and biologicals  
24 into such part D; and

1 (D) any other changes to the program that  
2 Congress should consider in determining wheth-  
3 er to shift coverage of such drugs and  
4 biologicals from such part B to such part D.

5 **SEC. 240. TAKING STEPS TO FULFILL TREATY OBLIGATIONS**  
6 **TO TRIBAL COMMUNITIES.**

7 (a) GAO STUDY.—The Comptroller General shall  
8 conduct a study regarding access to, and the cost of, pre-  
9 scription drugs among Indians. The study shall include—  
10 (1) a review of what Indian health programs  
11 pay for prescription drugs on reservations and in  
12 urban centers relative to other consumers;  
13 (2) recommendations to align the value of pre-  
14 scription drug discounts available under the Med-  
15 icaid drug rebate program established under section  
16 1927 of the Social Security Act (42 U.S.C. 1396r–  
17 8) with prescription drug discounts available to  
18 Tribal communities through the purchased/referred  
19 care program of the Indian Health Service for physi-  
20 cian administered drugs; and  
21 (3) an examination of how Tribal communities  
22 and urban Indian organizations utilize the Medicare  
23 part D program established under title XVIII of the  
24 Social Security Act (42 U.S.C. 1395w–101 et seq.)

1 and recommendations to improve enrollment among  
 2 Indians in that program.

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

9 (c) DEFINITIONS.—In this section:

10 (1) COMPTROLLER GENERAL.—The term  
 11 “Comptroller General” means the Comptroller Gen-  
 12 eral of the United States.

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

18 **SEC. 241. ESTABLISHING A MONTHLY CAP ON BENEFICIARY**  
 19 **INCURRED COSTS FOR INSULIN PRODUCTS**  
 20 **AND SUPPLIES UNDER A PRESCRIPTION**  
 21 **DRUG PLAN OR MA-PD PLAN.**

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

25 (1) in subsection (b)(2)—

1 (A) in subparagraph (A), by striking “and  
2 (E)” and inserting “(E), and (F)”;

3 (B) in subparagraph (B), by striking “and  
4 (D)” and inserting “(D), and (F)”;

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

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

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

21 “(I) for months occurring in  
22 2022, \$50; or

23 “(II) for months occurring in a  
24 subsequent year, the amount applica-  
25 ble under this clause for months oc-

1 curring in the year preceding such  
2 subsequent year, increased by the an-  
3 nual percentage increase specified in  
4 paragraph (6) for such subsequent  
5 year and rounded to the nearest dol-  
6 lar.

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

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

21 “(I) insulin; or

22 “(II) a medical supply associated  
23 with the injection of insulin (as de-  
24 fined in regulations of the Secretary

1 promulgated pursuant to subsection  
2 (e)(1)(B)).”; and

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

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

9 (b) CONFORMING AMENDMENTS.—

10 (1) IN GENERAL.—Section 1860D–14(a)(1)(D)  
11 of the Social Security Act (42 U.S.C. 1395w–  
12 114(a)(1)(D)), as amended by section 121, is fur-  
13 ther amended—

14 (A) in clause (ii), by striking “section  
15 1860D–2(b)(2)” and inserting “section 1860D–  
16 2(b)(2)(A)”; and

17 (B) in clause (iii), by striking “section  
18 1860D–2(b)(2)” and inserting “section 1860D–  
19 2(b)(2)(A)”.

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

# **TITLE III—MEDICAID**

## **SEC. 301. MEDICAID PHARMACY AND THERAPEUTICS COMMITTEE IMPROVEMENTS.**

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

“(A)(i) The formulary is developed and reviewed by a pharmacy and therapeutics committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State.

“(ii) Subject to clause (vi), the State establishes and implements a conflict of interest policy for the pharmacy and therapeutics committee that—

“(I) is publicly accessible;

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

“(III) contains clear processes, such as recusal from voting or discussion, for those members who report a conflict of in-

1           terest, along with appropriate processes to  
2           address any instance where a member fails  
3           to report a conflict of interest.

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

6                   “(I) includes at least 1 actively prac-  
7                   ticing physician and at least 1 actively  
8                   practicing pharmacist, each of whom—

9                           “(aa) is independent and free of  
10                           conflict with respect to manufacturers  
11                           and Medicaid participating plans or  
12                           subcontractors, including pharmacy  
13                           benefit managers; and

14                           “(bb) has expertise in the care of  
15                           1 or more Medicaid-specific popu-  
16                           lations such as elderly or disabled in-  
17                           dividuals, children with complex med-  
18                           ical needs, or low-income individuals  
19                           with chronic illnesses; and

20                           “(II) is made publicly available.

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



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

3 “(v) The State reviews and has final ap-  
4 proval of the formulary established by the phar-  
5 macy and therapeutics committee.

6 “(vi) If the Secretary determines it appro-  
7 priate or necessary based on the findings and  
8 recommendations of the Comptroller General of  
9 the United States in the report submitted to  
10 Congress under section 303 of the Reduced  
11 Costs and Continued Cures Act of 2021, the  
12 Secretary shall issue guidance that States must  
13 follow for establishing conflict of interest poli-  
14 cies for the pharmacy and therapeutics com-  
15 mittee in accordance with the requirements of  
16 clause (ii), including appropriate standards and  
17 requirements for identifying, addressing, and  
18 reporting on conflicts of interest.”.

19 (b) APPLICATION TO MEDICAID MANAGED CARE OR-  
20 GANIZATIONS.—Clause (xiii) of section 1903(m)(2)(A) of  
21 the Social Security Act (42 U.S.C. 1396b(m)(2)(A)) is  
22 amended—

23 (1) by striking “and (III)” and inserting  
24 “(III)”;

1           (2) by striking the period at the end and insert-  
 2           ing “, and (IV) any formulary used by the entity for  
 3           covered outpatient drugs dispensed to individuals eli-  
 4           gible for medical assistance who are enrolled with  
 5           the entity is developed and reviewed by a pharmacy  
 6           and therapeutics committee that meets the require-  
 7           ments of clauses (ii) and (iii) of section  
 8           1927(d)(4)(A).”; and

9           (3) by moving the left margin 2 ems to the left.

10          (c) EFFECTIVE DATE.—The amendments made by  
 11 this section shall take effect on the date that is 1 year  
 12 after the date of enactment of this Act.

13 **SEC. 302. IMPROVING REPORTING REQUIREMENTS AND DE-**  
 14 **VELOPING STANDARDS FOR THE USE OF**  
 15 **DRUG USE REVIEW BOARDS IN STATE MED-**  
 16 **ICAID PROGRAMS.**

17          (a) IN GENERAL.—Section 1927(g)(3) of the Social  
 18 Security Act (42 U.S.C. 1396r–8(g)(3)) is amended—

19           (1) by amending subparagraph (B) to read as  
 20 follows:

21           “(B) MEMBERSHIP.—

22           “(i) IN GENERAL.—The membership  
 23 of the DUR Board shall include health  
 24 care professionals who have recognized

1 knowledge and expertise in one or more of  
2 the following:

3 “(I) The clinically appropriate  
4 prescribing of covered outpatient  
5 drugs.

6 “(II) The clinically appropriate  
7 dispensing and monitoring of covered  
8 outpatient drugs.

9 “(III) Drug use review, evalua-  
10 tion, and intervention.

11 “(IV) Medical quality assurance.

12 “(ii) MEMBERSHIP REQUIREMENTS.—  
13 The membership of the DUR Board  
14 shall—

15 “(I) be made up of at least  $\frac{1}{3}$   
16 but no more than 51 percent members  
17 who are licensed and actively prac-  
18 ticing physicians and at least  $\frac{1}{3}$  mem-  
19 bers who are licensed and actively  
20 practicing pharmacists;

21 “(II) include at least 1 licensed  
22 and actively practicing physician and  
23 at least 1 licensed and actively prac-  
24 ticing pharmacist, each of whom—

1           “(aa) is independent and  
2           free of any conflict, including  
3           with respect to manufacturers,  
4           Medicaid managed care entities,  
5           or pharmacy benefit managers;  
6           and

7           “(bb) has expertise in the  
8           care of 1 or more categories of  
9           individuals who are likely to be  
10          eligible for benefits under this  
11          title, including elderly or disabled  
12          individuals, children with complex  
13          medical needs, or low-income in-  
14          dividuals with chronic illnesses;  
15          and

16          “(III) be made publicly available.

17          “(iii) CONFLICT OF INTEREST POL-  
18          ICY.—The State shall establish and imple-  
19          ment a conflict of interest policy for the  
20          DUR Board that—

21                 “(I) is publicly accessible;

22                 “(II) requires all board members  
23                 to complete, on at least an annual  
24                 basis, a disclosure of relationships, as-  
25                 sociations, and financial dealings that

1                   may affect their independence of  
2                   judgement in board matters; and

3                   “(III) contains clear processes,  
4                   such as recusal from voting or discus-  
5                   sion, for those members who report a  
6                   conflict of interest, along with appro-  
7                   priate processes to address any in-  
8                   stance where a member fails to report  
9                   a conflict of interest.”; and

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

12                   “(E)   DUR   BOARD   MEMBERSHIP   RE-  
13       PORTS.—

14                   “(i)   DUR   BOARD   REPORTS.—Each  
15                   State shall require the DUR Board to pre-  
16                   pare and submit to the State an annual re-  
17                   port on the DUR Board membership. Each  
18                   such report shall include any conflicts of  
19                   interest with respect to members of the  
20                   DUR Board that the DUR Board recorded  
21                   or was aware of during the period that is  
22                   the subject of the report, and the process  
23                   applied to address such conflicts of inter-  
24                   est, in addition to any other information  
25                   required by the State.

1 “(ii) INCLUSION OF DUR BOARD MEM-  
2 BERSHIP INFORMATION IN STATE RE-  
3 PORTS.—Each annual State report to the  
4 Secretary required under subparagraph  
5 (D) shall include—

6 “(I) the number of individuals  
7 serving on the State’s DUR Board;

8 “(II) the names and professions  
9 of the individuals serving on such  
10 DUR Board;

11 “(III) any conflicts of interest or  
12 recusals with respect to members of  
13 such DUR Board reported by the  
14 DUR Board or that the State was  
15 aware of during the period that is the  
16 subject of the report; and

17 “(IV) whether the State has  
18 elected for such DUR Board to serve  
19 as the committee responsible for de-  
20 veloping a State formulary under sub-  
21 section (d)(4)(A).”.

22 (b) MANAGED CARE REQUIREMENTS.—Section  
23 1932(i) of the Social Security Act (42 U.S.C. 1396u–2(i))  
24 is amended—

1           (1) by striking “section 483.3(s)(4)” and in-  
2       serting “section 438.3(s)(4)”;

3           (2) by striking “483.3(s)(5)” and inserting  
4       “438.3(s)(5)”; and

5           (3) by adding at the end the following: “Such  
6       a managed care entity shall not be considered to be  
7       in compliance with the requirement of such section  
8       438.3(s)(5) that the entity provide a detailed de-  
9       scription of its drug utilization review activities un-  
10      less the entity includes a description of the prospec-  
11      tive drug review activities described in paragraph  
12      (2)(A) of section 1927(g) and the activities listed in  
13      paragraph (3)(C) of section 1927(g), makes the un-  
14      derlying drug utilization review data available to the  
15      State and the Secretary, and provides such other in-  
16      formation as deemed appropriate by the Secretary.”.

17       (c) DEVELOPMENT OF NATIONAL STANDARDS FOR  
18   MEDICAID DRUG USE REVIEW.—The Secretary of Health  
19   and Human Services may promulgate regulations or guid-  
20   ance establishing national standards for Medicaid drug  
21   use review programs under section 1927(g) of the Social  
22   Security Act (42 U.S.C. 1396r–8) and drug utilization re-  
23   view activities and requirements under section 1932(i) of  
24   such Act (42 U.S.C. 1396u–2(i)), for the purpose of align-

1 ing review criteria for prospective and retrospective drug  
2 use review across all State Medicaid programs.

3 (d) CMS GUIDANCE.—Not later than 18 months  
4 after the date of enactment of this Act, the Secretary of  
5 Health and Human Services shall issue guidance—

6 (1) outlining steps that States must take to  
7 come into compliance with statutory and regulatory  
8 requirements for prospective and retrospective drug  
9 use review under section 1927(g) of the Social Secu-  
10 rity Act (42 U.S.C. 1396r–8(g)) and drug utilization  
11 review activities and requirements under section  
12 1932(i) of such Act (42 U.S.C. 1396u–2(i)) (includ-  
13 ing with respect to requirements that were in effect  
14 before the date of enactment of this Act); and

15 (2) describing the actions that the Secretary  
16 will take to enforce such requirements.

17 (e) EFFECTIVE DATE.—The amendments made by  
18 this section shall take effect on the date that is 1 year  
19 after the date of enactment of this Act.

20 **SEC. 303. GAO REPORT ON CONFLICTS OF INTEREST IN**  
21 **STATE MEDICAID PROGRAM DRUG USE RE-**  
22 **VIEW BOARDS AND PHARMACY AND THERA-**  
23 **PEUTICS (P&T) COMMITTEES.**

24 (a) INVESTIGATION.—The Comptroller General of the  
25 United States shall conduct an investigation of potential



1 or existing conflicts of interest among members of State  
2 Medicaid program State drug use review boards (in this  
3 section referred to as “DUR Boards”) and pharmacy and  
4 therapeutics committees (in this section referred to as  
5 “P&T Committees”).

6 (b) REPORT.—Not later than 24 months after the  
7 date of enactment of this Act, the Comptroller General  
8 shall submit to Congress a report on the investigation con-  
9 ducted under subsection (a) that includes the following:

10 (1) A description outlining how DUR Boards  
11 and P&T Committees operate in States, including  
12 details with respect to—

13 (A) the structure and operation of DUR  
14 Boards and statewide P&T Committees;

15 (B) States that operate separate P&T  
16 Committees for their fee-for-service Medicaid  
17 program and their Medicaid managed care or-  
18 ganizations or other Medicaid managed care ar-  
19 rangements (collectively referred to in this sec-  
20 tion as “Medicaid MCOs”); and

21 (C) States that allow Medicaid MCOs to  
22 have their own P&T Committees and the extent  
23 to which pharmacy benefit managers administer  
24 or participate in such P&T Committees.

1           (2) A description outlining the differences be-  
2       tween DUR Boards established in accordance with  
3       section 1927(g)(3) of the Social Security Act (42  
4       U.S.C. 1396r(g)(3)) and P&T Committees.

5           (3) A description outlining the tools P&T Com-  
6       mittees may use to determine Medicaid drug cov-  
7       erage and utilization management policies.

8           (4) An analysis of whether and how States or  
9       P&T Committees establish participation and inde-  
10      pendence requirements for DUR Boards and P&T  
11      Committees, including with respect to entities with  
12      connections with drug manufacturers, State Med-  
13      icaid programs, managed care organizations, and  
14      other entities or individuals in the pharmaceutical  
15      industry.

16          (5) A description outlining how States, DUR  
17      Boards, or P&T Committees define conflicts of inter-  
18      est.

19          (6) A description of how DUR Boards and P&T  
20      Committees address conflicts of interest, including  
21      who is responsible for implementing such policies.

22          (7) A description of the tools, if any, States use  
23      to ensure that there are no conflicts of interest on  
24      DUR Boards and P&T Committees.

1           (8) An analysis of the effectiveness of tools  
2       States use to ensure that there are no conflicts of  
3       interest on DUR Boards and P&T Committees and,  
4       if applicable, recommendations as to how such tools  
5       could be improved.

6           (9) A review of strategies States may use to  
7       guard against conflicts of interest on DUR Boards  
8       and P&T Committees and to ensure compliance with  
9       the requirements of titles XI and XIX of the Social  
10      Security Act (42 U.S.C. 1301 et seq., 1396 et seq.)  
11      and access to effective, clinically appropriate, and  
12      medically necessary drug treatments for Medicaid  
13      beneficiaries, including recommendations for such  
14      legislative and administrative actions as the Comp-  
15      troller General determines appropriate.

16 **SEC. 304. ENSURING THE ACCURACY OF MANUFACTURER**  
17 **PRICE AND DRUG PRODUCT INFORMATION**  
18 **UNDER THE MEDICAID DRUG REBATE PRO-**  
19 **GRAM.**

20       (a) AUDIT OF MANUFACTURER PRICE AND DRUG  
21       PRODUCT INFORMATION.—

22           (1) IN GENERAL.—Subparagraph (B) of section  
23       1927(b)(3) of the Social Security Act (42 U.S.C.  
24       1396r–8(b)(3)) is amended to read as follows:

1           “(B) AUDITS AND SURVEYS OF MANUFAC-  
2           TURER PRICE AND DRUG PRODUCT INFORMA-  
3           TION.—

4                   “(i) AUDITS.—The Secretary shall  
5                   conduct ongoing audits of the price and  
6                   drug product information reported by man-  
7                   ufacturers under subparagraph (A) for the  
8                   most recently ended rebate period to en-  
9                   sure the accuracy and timeliness of such  
10                  information. In conducting such audits, the  
11                  Secretary may employ evaluations, surveys,  
12                  statistical sampling, predictive analytics,  
13                  and other relevant tools and methods.

14                  “(ii) VERIFICATIONS SURVEYS OF AV-  
15                  ERAGE MANUFACTURER PRICE AND MANU-  
16                  FACTURER’S AVERAGE SALES PRICE.—In  
17                  addition to the audits required under  
18                  clause (i), the Secretary may survey whole-  
19                  salers and manufacturers (including manu-  
20                  facturers that directly distribute their cov-  
21                  ered outpatient drugs (in this subpara-  
22                  graph referred to as ‘direct sellers’)), when  
23                  necessary, to verify manufacturer prices  
24                  and manufacturer’s average sales prices  
25                  (including wholesale acquisition cost) to

1 make payment reported under subpara-  
2 graph (A).

3 “(iii) PENALTIES.—In addition to  
4 other penalties as may be prescribed by  
5 law, including under subparagraph (C) of  
6 this paragraph, the Secretary may impose  
7 a civil monetary penalty in an amount not  
8 to exceed \$185,000 on an annual basis on  
9 a wholesaler, manufacturer, or direct sell-  
10 er, if the wholesaler, manufacturer, or di-  
11 rect seller of a covered outpatient drug re-  
12 fuses a request for information about  
13 charges or prices by the Secretary in con-  
14 nection with an audit or survey under this  
15 subparagraph or knowingly provides false  
16 information. The provisions of section  
17 1128A (other than subsections (a) (with  
18 respect to amounts of penalties or addi-  
19 tional assessments) and (b)) shall apply to  
20 a civil money penalty under this clause in  
21 the same manner as such provisions apply  
22 to a penalty or proceeding under section  
23 1128A(a).

24 “(iv) REPORTS.—

1 “(I) REPORT TO CONGRESS.—

2 The Secretary shall, not later than 18  
3 months after date of enactment of  
4 this subparagraph, submit a report to  
5 the Committee on Energy and Com-  
6 merce of the House of Representatives  
7 and the Committee on Finance of the  
8 Senate regarding additional regulatory  
9 or statutory changes that may be re-  
10 quired in order to ensure accurate and  
11 timely reporting and oversight of  
12 manufacturer price and drug product  
13 information, including whether  
14 changes should be made to reasonable  
15 assumption requirements to ensure  
16 such assumptions are reasonable and  
17 accurate or whether another method-  
18 ology for ensuring accurate and timely  
19 reporting of price and drug product  
20 information should be considered to  
21 ensure the integrity of the drug rebate  
22 program under this section.

23 “(II) ANNUAL REPORTS.—The  
24 Secretary shall, on at least an annual  
25 basis, submit a report to the Com-

1 mittee on Energy and Commerce of  
2 the House of Representatives and the  
3 Committee on Finance of the Senate  
4 summarizing the results of the audits  
5 and surveys conducted under this sub-  
6 paragraph during the period that is  
7 the subject of the report.

8 “(III) CONTENT.—Each report  
9 submitted under subclause (II) shall,  
10 with respect to the period that is the  
11 subject of the report, include sum-  
12 maries of—

13 “(aa) error rates in the  
14 price, drug product, and other  
15 relevant information supplied by  
16 manufacturers under subpara-  
17 graph (A);

18 “(bb) the timeliness with  
19 which manufacturers, whole-  
20 salers, and direct sellers provide  
21 information required under sub-  
22 paragraph (A) or under clause (i)  
23 or (ii) of this subparagraph;

24 “(cc) the number of manu-  
25 facturers, wholesalers, and direct

1 sellers and drug products audited  
2 under this subparagraph;

3 “(dd) the types of price and  
4 drug product information re-  
5 viewed under the audits con-  
6 ducted under this subparagraph;

7 “(ee) the tools and meth-  
8 odologies employed in such au-  
9 dits;

10 “(ff) the findings of such  
11 audits, including which manufac-  
12 turers, if any, were penalized  
13 under this subparagraph; and

14 “(gg) such other relevant in-  
15 formation as the Secretary shall  
16 deem appropriate.

17 “(IV) PROTECTION OF INFORMA-  
18 TION.—In preparing a report required  
19 under subclause (II), the Secretary  
20 shall redact such proprietary informa-  
21 tion as the Secretary determines ap-  
22 propriate to prevent disclosure of, and  
23 to safeguard, such information.

24 “(v) APPROPRIATIONS.—Out of any  
25 funds in the Treasury not otherwise appro-



1            appropriated, there is appropriated to the Sec-  
2            retary \$2,000,000 for fiscal year 2023 and  
3            each fiscal year thereafter to carry out this  
4            subparagraph.”.

5            (2) EFFECTIVE DATE.—The amendments made  
6            by this subsection shall take effect on the first day  
7            of the first fiscal quarter that begins after the date  
8            of enactment of this Act.

9            (b) INCREASED PENALTIES FOR NONCOMPLIANCE  
10          WITH REPORTING REQUIREMENTS.—

11           (1) INCREASED PENALTY FOR LATE REPORTING  
12           OF INFORMATION.—Section 1927(b)(3)(C)(i) of the  
13           Social Security Act (42 U.S.C. 1396r–8(b)(3)(C)(i))  
14           is amended by striking “increased by \$10,000 for  
15           each day in which such information has not been  
16           provided and such amount shall be paid to the  
17           Treasury” and inserting “, for each covered out-  
18           patient drug with respect to which such information  
19           is not provided, \$50,000 for the first day that such  
20           information is not provided on a timely basis and  
21           \$19,000 for each subsequent day that such informa-  
22           tion is not provided”.

23           (2) INCREASED PENALTY FOR KNOWINGLY RE-  
24           PORTING           FALSE           INFORMATION.—Section  
25           1927(b)(3)(C)(ii) of the Social Security Act (42

1 U.S.C. 1396r–8(b)(3)(C)(ii)) is amended by striking  
2 “\$100,000” and inserting “\$500,000”.

3 (3) EFFECTIVE DATE.—The amendments made  
4 by this subsection shall take effect on the first day  
5 of the first fiscal quarter that begins after the date  
6 of enactment of this Act.

7 **SEC. 305. T-MSIS DRUG DATA ANALYTICS REPORTS.**

8 (a) IN GENERAL.—Not later than May 1 of each cal-  
9 endar year beginning with calendar year 2024, the Sec-  
10 retary of Health and Human Services (in this section re-  
11 ferred to as the “Secretary”) shall publish on a website  
12 of the Centers for Medicare & Medicaid Services that is  
13 accessible to the public a report of the most recently avail-  
14 able data on provider prescribing patterns under the Med-  
15 icaid program.

16 (b) CONTENT OF REPORT.—

17 (1) REQUIRED CONTENT.—Each report re-  
18 quired under subsection (a) for a calendar year shall  
19 include the following information with respect to  
20 each State (and, to the extent available, with respect  
21 to Puerto Rico, the United States Virgin Islands,  
22 Guam, the Northern Mariana Islands, and American  
23 Samoa):

24 (A) A comparison of covered outpatient  
25 drug (as defined in section 1927(k)(2) of the

1 Social Security Act (42 U.S.C. 1396r–8(k)(2)))  
2 prescribing patterns under the State Medicaid  
3 plan or waiver of such plan (including drugs  
4 prescribed on a fee-for-service basis and drugs  
5 prescribed under managed care arrangements  
6 under such plan or waiver)—

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

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

11 (iii) by episodes of care for—

12 (I) each chronic disease category,  
13 as defined by the Secretary, that is  
14 represented in the 10 conditions that  
15 accounted for the greatest share of  
16 total spending under the plan or waiv-  
17 er during the year that is the subject  
18 of the report;

19 (II) procedural groupings; and

20 (III) rare disease diagnosis codes;

21 (iv) by patient demographic character-  
22 istics, including race (to the extent that  
23 the Secretary determines that there is suf-  
24 ficient data available with respect to such

characteristic in a majority of States), gender, and age;

(v) by patient high-utilizer or risk status; and

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

(B) In the case of medical assistance for covered outpatient drugs (as so defined) provided under a State Medicaid plan or waiver of such plan in a managed care setting, an analysis of the differences in managed care prescribing patterns when a covered outpatient drug is prescribed in a managed care setting as compared to when the drug is prescribed in a fee-for-service setting.

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

(A) a description of prescription utilization management tools under State programs to provide long-term services and supports under a State Medicaid plan or a waiver of such plan;

1 (B) a comparison of prescription utilization  
2 management tools applicable to populations cov-  
3 ered under a State Medicaid plan waiver under  
4 section 1115 of the Social Security Act (42  
5 U.S.C. 1315) and the models applicable to pop-  
6 ulations that are not covered under the waiver;

7 (C) a comparison of the prescription utili-  
8 zation management tools employed by different  
9 Medicaid managed care organizations, phar-  
10 macy benefit managers, and related entities  
11 within the State;

12 (D) a comparison of the prescription utili-  
13 zation management tools applicable to each en-  
14 rollment category under a State Medicaid plan  
15 or waiver; and

16 (E) a comparison of the prescription utili-  
17 zation management tools applicable under the  
18 State Medicaid plan or waiver by patient high-  
19 utilizer or risk status.

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

23 (A) analyses of national, State, and local  
24 patterns of Medicaid population-based pre-  
25 scribing behaviors; and

1 (B) recommendations for administrative or  
2 legislative action to improve the effectiveness of,  
3 and reduce costs for, covered outpatient drugs  
4 under Medicaid while ensuring timely bene-  
5 ficiary access to medically necessary covered  
6 outpatient drugs.

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

9 (1) be prepared using data and definitions from  
10 the Transformed Medicaid Statistical Information  
11 System (“T-MSIS”) data set (or a successor data  
12 set) that is not more than 24 months old on the date  
13 that the report is published; and

14 (2) as appropriate, include a description with  
15 respect to each State of the quality and complete-  
16 ness of the data, as well as any necessary caveats  
17 describing the limitations of the data reported to the  
18 Secretary by the State that are sufficient to commu-  
19 nicate the appropriate uses for the information.

20 (d) PREPARATION OF REPORT.—Each report re-  
21 quired under subsection (a) shall be prepared by the Ad-  
22 ministrator for the Centers for Medicare & Medicaid Serv-  
23 ices.

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

4 **SEC. 306. RISK-SHARING VALUE-BASED PAYMENT AGREE-**  
5 **MENTS FOR COVERED OUTPATIENT DRUGS**  
6 **UNDER MEDICAID.**

7 (a) IN GENERAL.—Section 1927 of the Social Secu-  
8 rity Act (42 U.S.C. 1396r–8) is amended by adding at  
9 the end the following new subsection:

10 “(l) STATE OPTION TO PAY FOR COVERED OUT-  
11 PATIENT DRUGS THROUGH RISK-SHARING VALUE-BASED  
12 AGREEMENTS.—

13 “(1) IN GENERAL.—Beginning January 1,  
14 2025, a State shall have the option to pay (whether  
15 on a fee-for-service or managed care basis) for cov-  
16 ered outpatient drugs that are potentially curative  
17 treatments intended for one-time use that are ad-  
18 ministered to individuals under this title by entering  
19 into a risk-sharing value-based payment agreement  
20 with the manufacturer of the drug in accordance  
21 with the requirements of this subsection.

22 “(2) SECRETARIAL APPROVAL.—

23 “(A) IN GENERAL.—A State shall submit a  
24 request to the Secretary to enter into a risk-  
25 sharing value based payment agreement, and

1 the Secretary shall not approve a proposed risk-  
2 sharing value-based payment agreement be-  
3 tween a State and a manufacturer for payment  
4 for a covered outpatient drug of the manufac-  
5 turer unless the following requirements are met:

6 “(i) MANUFACTURER IS PARTY TO RE-  
7 BATE AGREEMENT AND IN COMPLIANCE  
8 WITH REQUIREMENTS.—The manufacturer  
9 has a rebate agreement in effect as re-  
10 quired under subsections (a) and (b) of  
11 this section and is in compliance with all  
12 applicable requirements under this title.

13 “(ii) NO INCREASE TO PROJECTED  
14 NET FEDERAL SPENDING.—

15 “(I) IN GENERAL.—The Chief  
16 Actuary certifies that the projected  
17 payments for each covered outpatient  
18 drug under such proposed agreement  
19 would not result in greater estimated  
20 Federal spending under this title than  
21 the net Federal spending that would  
22 result in the absence of the agree-  
23 ment.

24 “(II) NET FEDERAL SPENDING  
25 DEFINED.—For purposes of this sub-



1 section, the term ‘net Federal spend-  
2 ing’ means the amount of Federal  
3 payments the Chief Actuary estimates  
4 would be made under this title for ad-  
5 ministering a covered outpatient drug  
6 to an individual eligible for medical  
7 assistance under a State plan or a  
8 waiver of such plan, reduced by the  
9 amount of all rebates the Chief Actu-  
10 ary estimates would be paid with re-  
11 spect to the administering of such  
12 drug, including all rebates under this  
13 title and any supplemental or other  
14 additional rebates, in the absence of  
15 such an agreement.

16 “(III) INFORMATION.—The Chief  
17 Actuary shall make the certifications  
18 required under this clause based on  
19 the most recently available and reli-  
20 able drug pricing and product infor-  
21 mation. The State and manufacturer  
22 shall provide the Secretary and the  
23 Chief Actuary with all necessary infor-  
24 mation required to make the estimates  
25 needed for such certifications.

1           “(iii) LAUNCH AND LIST PRICE JUS-  
2           TIFICATIONS.—The manufacturer submits  
3           all relevant information and supporting  
4           documentation necessary for pricing deci-  
5           sions as deemed appropriate by the Sec-  
6           retary, which shall be truthful and non-  
7           misleading, including manufacturer infor-  
8           mation and supporting documentation for  
9           launch price or list price increases, and  
10          any applicable justification required under  
11          section 1128L.

12          “(iv) CONFIDENTIALITY OF INFORMA-  
13          TION; PENALTIES.—The provisions of sub-  
14          paragraphs (C) and (D) of subsection  
15          (b)(3) shall apply to a manufacturer that  
16          fails to submit the information and docu-  
17          mentation required under clauses (ii) and  
18          (iii) on a timely basis, or that knowingly  
19          provides false or misleading information, in  
20          the same manner as such provisions apply  
21          to a manufacturer with a rebate agreement  
22          under this section.

23          “(B) CONSIDERATION OF STATE REQUEST  
24          FOR APPROVAL.—

1           “(i) IN GENERAL.—The Secretary  
2           shall treat a State request for approval of  
3           a risk-sharing value-based payment agree-  
4           ment in the same manner that the Sec-  
5           retary treats a State plan amendment, and  
6           subpart B of part 430 of title 42, Code of  
7           Federal Regulations, including, subject to  
8           clause (ii), the timing requirements of sec-  
9           tion 430.16 of such title (as in effect on  
10          the date of enactment of this subsection),  
11          shall apply to a request for approval of a  
12          risk-sharing value-based payment agree-  
13          ment in the same manner as such subpart  
14          applies to a State plan amendment.

15          “(ii) TIMING.—The Secretary shall  
16          consult with the Commissioner of Food  
17          and Drugs as required under subpara-  
18          graph (C) and make a determination on  
19          whether to approve a request from a State  
20          for approval of a proposed risk-sharing  
21          value-based payment agreement (or request  
22          additional information necessary to allow  
23          the Secretary to make a determination  
24          with respect to such request for approval)  
25          within the time period, to the extent prac-

1            ticable, specified in section 430.16 of title  
2            42, Code of Federal Regulations (as in ef-  
3            fect on the date of enactment of this sub-  
4            section), but in no case shall the Secretary  
5            take more than 180 days after the receipt  
6            of such request for approval or response to  
7            such request for additional information to  
8            make such a determination (or request ad-  
9            ditional information).

10           “(C) CONSULTATION WITH THE COMMIS-  
11           SIONER OF FOOD AND DRUGS.—In considering  
12           whether to approve a risk-sharing value-based  
13           payment agreement, the Secretary, to the ex-  
14           tent necessary, shall consult with the Commis-  
15           sioner of Food and Drugs to determine whether  
16           the relevant clinical parameters specified in  
17           such agreement are appropriate.

18           “(3) INSTALLMENT-BASED PAYMENT STRUC-  
19           TURE.—

20           “(A) IN GENERAL.—A risk-sharing value-  
21           based payment agreement shall provide for a  
22           payment structure under which, for every in-  
23           stallment year of the agreement (subject to sub-  
24           paragraph (B)), the State shall pay the total in-  
25           stallment year amount in equal installments to

1 be paid at regular intervals over a period of  
2 time that shall be specified in the agreement.

3 “(B) REQUIREMENTS FOR INSTALLMENT  
4 PAYMENTS.—

5 “(i) TIMING OF FIRST PAYMENT.—

6 The State shall make the first of the in-  
7 stallment payments described in subpara-  
8 graph (A) for an installment year not later  
9 than 30 days after the end of such year.

10 “(ii) LENGTH OF INSTALLMENT PE-

11 RIOD.—The period of time over which the  
12 State shall make the installment payments  
13 described in subparagraph (A) for an in-  
14 stallment year shall not be longer than 5  
15 years.

16 “(iii) NONPAYMENT OR REDUCED

17 PAYMENT OF INSTALLMENTS FOLLOWING  
18 A FAILURE TO MEET CLINICAL PARAM-  
19 ETER.—If, prior to the payment date (as  
20 specified in the agreement) of any install-  
21 ment payment described in subparagraph  
22 (A) or any other alternative date or time  
23 frame (as otherwise specified in the agree-  
24 ment), the covered outpatient drug which  
25 is subject to the agreement fails to meet a

1 relevant clinical parameter of the agree-  
2 ment, the agreement shall provide that—

3 “(I) the installment payment  
4 shall not be made; or

5 “(II) the installment payment  
6 shall be reduced by a percentage spec-  
7 ified in the agreement that is based  
8 on the outcome achieved by the drug  
9 relative to the relevant clinical param-  
10 eter.

11 “(4) NOTICE OF INTENT.—

12 “(A) IN GENERAL.—Subject to subpara-  
13 graph (B), a manufacturer of a covered out-  
14 patient drug shall not be eligible to enter into  
15 a risk-sharing value-based payment agreement  
16 under this subsection with respect to such drug  
17 unless the manufacturer notifies the Secretary  
18 that the manufacturer is interested in entering  
19 into such an agreement with respect to such  
20 drug. The decision to submit and timing of a  
21 request to enter into a proposed risk-sharing  
22 value-based payment agreement shall remain  
23 solely within the discretion of the State and  
24 shall only be effective upon Secretarial approval  
25 as required under this subsection.

1           “(B) TREATMENT OF SUBSEQUENTLY AP-  
2           PROVED DRUGS.—

3                   “(i) IN GENERAL.—In the case of a  
4           manufacturer of a covered outpatient drug  
5           approved under section 505 of the Federal  
6           Food, Drug, and Cosmetic Act or licensed  
7           under section 351 of the Public Health  
8           Service Act after the date of enactment of  
9           this subsection, not more than 90 days  
10          after meeting with the Food and Drug Ad-  
11          ministration following phase II clinical  
12          trials for such drug (or, in the case of a  
13          drug described in clause (ii), not later than  
14          March 31, 2025), the manufacturer must  
15          notify the Secretary of the manufacturer’s  
16          intent to enter into a risk-sharing value-  
17          based payment agreement under this sub-  
18          section with respect to such drug. If no  
19          such meeting has occurred, the Secretary  
20          may use discretion as to whether a poten-  
21          tially curative treatment intended for one-  
22          time use may qualify for a risk-sharing  
23          value-based payment agreement under this  
24          section. A manufacturer notification of in-  
25          terest shall not have any influence on a de-

1 cision for approval by the Food and Drug  
2 Administration.

3 “(ii) APPLICATION TO CERTAIN SUB-  
4 SEQUENTLY APPROVED DRUGS.—A drug  
5 described in this clause is a covered out-  
6 patient drug of a manufacturer—

7 “(I) that is approved under sec-  
8 tion 505 of the Federal Food, Drug,  
9 and Cosmetic Act or licensed under  
10 section 351 of the Public Health Serv-  
11 ice Act after the date of enactment of  
12 this subsection; and

13 “(II) with respect to which, as of  
14 January 1, 2025, more than 90 days  
15 have passed after the manufacturer’s  
16 meeting with the Food and Drug Ad-  
17 ministration following phase II clinical  
18 trials for such drug.

19 “(iii) PARALLEL APPROVAL.—The  
20 Secretary, in coordination with the Admin-  
21 istrator of the Centers for Medicare &  
22 Medicaid Services and the Commissioner of  
23 Food and Drugs, shall, to the extent prac-  
24 ticable, approve a State’s request to enter  
25 into a proposed risk-sharing value-based



1 payment agreement that otherwise meets  
2 the requirements of this subsection at the  
3 time that such a drug is approved by the  
4 Food and Drug Administration to help  
5 provide that no State that wishes to enter  
6 into such an agreement is required to pay  
7 for the drug in full at one time if the State  
8 is seeking to pay over a period of time as  
9 outlined in the proposed agreement.

10 “(iv) RULE OF CONSTRUCTION.—  
11 Nothing in this paragraph shall be applied  
12 or construed to modify or affect the time-  
13 frames or factors involved in the Sec-  
14 retary’s determination of whether to ap-  
15 prove or license a drug under section 505  
16 of the Federal Food, Drug, and Cosmetic  
17 Act or section 351 of the Public Health  
18 Service Act.

19 “(5) SPECIAL PAYMENT RULES.—

20 “(A) IN GENERAL.—Except as otherwise  
21 provided in this paragraph, with respect to an  
22 individual who is administered a unit of a cov-  
23 ered outpatient drug that is purchased under a  
24 State plan by a State Medicaid agency under a  
25 risk-sharing value-based payment agreement in

1 an installment year, the State shall remain lia-  
2 ble to the manufacturer of such drug for pay-  
3 ment for such unit without regard to whether  
4 the individual remains enrolled in the State  
5 plan under this title (or a waiver of such plan)  
6 for each installment year for which the State is  
7 to make installment payments for covered out-  
8 patient drugs purchased under the agreement  
9 in such year.

10 “(B) DEATH.—In the case of an individual  
11 described in subparagraph (A) who dies during  
12 the period described in such subparagraph, the  
13 State plan shall not be liable for any remaining  
14 payment for the unit of the covered outpatient  
15 drug administered to the individual which is  
16 owed under the agreement described in such  
17 subparagraph.

18 “(C) WITHDRAWAL OF APPROVAL.—In the  
19 case of a covered outpatient drug that is the  
20 subject of a risk-sharing value-based agreement  
21 between a State and a manufacturer under this  
22 subsection, including a drug approved in ac-  
23 cordance with section 506(c) of the Federal  
24 Food, Drug, and Cosmetic Act, and such drug  
25 is the subject of an application that has been

1           withdrawn by the Secretary, the State plan  
2           shall not be liable for any remaining payment  
3           that is owed under the agreement.

4           “(D) ALTERNATIVE ARRANGEMENT UNDER  
5           AGREEMENT.—Subject to approval by the Sec-  
6           retary, the terms of a proposed risk-sharing  
7           value-based payment agreement submitted for  
8           approval by a State may provide that subpara-  
9           graph (A) shall not apply.

10          “(E) GUIDANCE.—Not later than January  
11          1, 2025, the Secretary shall issue guidance to  
12          States establishing a process for States to no-  
13          tify the Secretary when an individual who is ad-  
14          ministered a unit of a covered outpatient drug  
15          that is purchased by a State plan under a risk-  
16          sharing value-based payment agreement ceases  
17          to be enrolled under the State plan under this  
18          title (or a waiver of such plan) or dies before  
19          the end of the installment period applicable to  
20          such unit under the agreement.

21          “(6) TREATMENT OF PAYMENTS UNDER RISK-  
22          SHARING VALUE-BASED AGREEMENTS FOR PUR-  
23          POSES OF AVERAGE MANUFACTURER PRICE; BEST  
24          PRICE.—The Secretary shall treat any payments  
25          made to the manufacturer of a covered outpatient

1 drug under a risk-sharing value-based payment  
2 agreement under this subsection during a rebate pe-  
3 riod in the same manner that the Secretary treats  
4 payments made under a State supplemental rebate  
5 agreement under sections 447.504(c)(19) and  
6 447.505(c)(7) of title 42, Code of Federal Regula-  
7 tions (or any successor regulations) for purposes of  
8 determining average manufacturer price and best  
9 price under this section with respect to the covered  
10 outpatient drug and a rebate period and for pur-  
11 poses of offsets required under subsection (b)(1)(B).

12 “(7) ASSESSMENTS AND REPORT TO CON-  
13 GRESS.—

14 “(A) ASSESSMENTS.—

15 “(i) IN GENERAL.—Not later than  
16 180 days after the end of each assessment  
17 period of any risk-sharing value-based pay-  
18 ment agreement for a State approved  
19 under this subsection, the Secretary shall  
20 conduct an evaluation of such agreement  
21 which shall include an evaluation by the  
22 Chief Actuary to determine whether pro-  
23 gram spending under the risk-sharing  
24 value-based payment agreement aligned  
25 with the projections for the agreement

1 made under paragraph (2)(A)(ii), including  
2 an assessment of whether actual Federal  
3 spending under this title under the agree-  
4 ment was less or more than net Federal  
5 spending would have been in the absence  
6 of the agreement.

7 “(ii) ASSESSMENT PERIOD.—For pur-  
8 poses of clause (i)—

9 “(I) the first assessment period  
10 for a risk-sharing value-based pay-  
11 ment agreement shall be the period of  
12 time over which payments are sched-  
13 uled to be made under the agreement  
14 for the first 10 individuals who are  
15 administered covered outpatient drugs  
16 under the agreement except that such  
17 period shall not exceed the 5-year pe-  
18 riod after the date on which the Sec-  
19 retary approves the agreement; and

20 “(II) each subsequent assessment  
21 period for a risk-sharing value-based  
22 payment agreement shall be the 5-  
23 year period following the end of the  
24 previous assessment period.

25 “(B) RESULTS OF ASSESSMENTS.—

1           “(i) TERMINATION OPTION.—If the  
2           Secretary determines as a result of the as-  
3           sessment by the Chief Actuary under sub-  
4           paragraph (A) that the actual Federal  
5           spending under this title for any covered  
6           outpatient drug that was the subject of the  
7           State’s risk-sharing value-based payment  
8           agreement was greater than the net Fed-  
9           eral spending that would have resulted in  
10          the absence of the agreement, the Sec-  
11          retary may terminate approval of such  
12          agreement and shall immediately conduct  
13          an assessment under this paragraph of any  
14          other ongoing risk-sharing value-based  
15          payment agreement to which the same  
16          manufacturer is a party.

17          “(ii) REPAYMENT REQUIRED.—

18               “(I) IN GENERAL.—If the Sec-  
19               retary determines as a result of the  
20               assessment by the Chief Actuary  
21               under subparagraph (A) that the Fed-  
22               eral spending under the risk-sharing  
23               value-based agreement for a covered  
24               outpatient drug that was subject to  
25               such agreement was greater than the

1 net Federal spending that would have  
2 resulted in the absence of the agree-  
3 ment, the manufacturer shall repay  
4 the difference to the State and Fed-  
5 eral governments in a timely manner  
6 as determined by the Secretary.

7 “(II) TERMINATION FOR FAIL-  
8 URE TO PAY.—The failure of a manu-  
9 facturer to make repayments required  
10 under subclause (I) in a timely man-  
11 ner shall result in immediate termi-  
12 nation of all risk-sharing value-based  
13 agreements to which the manufacturer  
14 is a party.

15 “(III) ADDITIONAL PEN-  
16 ALTIES.—In the case of a manufac-  
17 turer that fails to make repayments  
18 required under subclause (I), the Sec-  
19 retary may treat such manufacturer  
20 in the same manner as a manufac-  
21 turer that fails to pay required re-  
22 bates under this section, and the Sec-  
23 retary may—

1                   “(aa) suspend or terminate  
2                   the manufacturer’s rebate agree-  
3                   ment under this section; and

4                   “(bb) pursue any other rem-  
5                   edy that would be available if the  
6                   manufacturer had failed to pay  
7                   required rebates under this sec-  
8                   tion.

9                   “(C) REPORT TO CONGRESS.—Not later  
10                  than 5 years after the first risk-sharing value-  
11                  based payment agreement is approved under  
12                  this subsection, the Secretary shall submit to  
13                  Congress and make available to the public a re-  
14                  port that includes—

15                  “(i) an assessment of the impact of  
16                  risk-sharing value-based payment agree-  
17                  ments on access for individuals who are eli-  
18                  gible for benefits under a State plan or  
19                  waiver under this title to medically nec-  
20                  essary covered outpatient drugs and re-  
21                  lated treatments;

22                  “(ii) an analysis of the impact of such  
23                  agreements on overall State and Federal  
24                  spending under this title;



1 “(iii) an assessment of the impact of  
2 such agreements on drug prices, including  
3 launch price and price increases; and

4 “(iv) such recommendations to Con-  
5 gress as the Secretary deems appropriate.

6 “(8) GUIDANCE AND REGULATIONS.—

7 “(A) IN GENERAL.—Not later than Janu-  
8 ary 1, 2025, the Secretary shall issue guidance  
9 to States seeking to enter into risk-sharing  
10 value-based payment agreements under this  
11 subsection that includes a model template for  
12 such agreements. The Secretary may issue any  
13 additional guidance or promulgate regulations  
14 as necessary to implement and enforce the pro-  
15 visions of this subsection.

16 “(B) MODEL AGREEMENTS.—

17 “(i) IN GENERAL.—If a State ex-  
18 presses an interest in pursuing a risk-shar-  
19 ing value-based payment agreement under  
20 this subsection with a manufacturer for  
21 the purchase of a covered outpatient drug,  
22 the Secretary may share with such State  
23 any risk-sharing value-based agreement be-  
24 tween a State and the manufacturer for  
25 the purchase of such drug that has been

1 approved under this subsection. While such  
2 shared agreement may serve as a template  
3 for a State that wishes to propose, the use  
4 of a previously approved agreement shall  
5 not affect the submission and approval  
6 process for approval of a proposed risk-  
7 sharing value-based payment agreement  
8 under this subsection, including the re-  
9 quirements under paragraph (2)(A).

10 “(ii) CONFIDENTIALITY.—In the case  
11 of a risk-sharing value-based payment  
12 agreement that is disclosed to a State by  
13 the Secretary under this subparagraph and  
14 that is only in effect with respect to a sin-  
15 gle State, the confidentiality of information  
16 provisions described in subsection  
17 (b)(3)(D) shall apply to such information.

18 “(C) OIG CONSULTATION.—

19 “(i) IN GENERAL.—The Secretary  
20 shall consult with the Office of the Inspec-  
21 tor General of the Department of Health  
22 and Human Services to determine whether  
23 there are potential program integrity con-  
24 cerns with agreement approvals or tem-  
25 plates and address accordingly.

1                   “(ii) OIG POLICY UPDATES AS NEC-  
2                   CESSARY.—The Inspector General of the  
3                   Department of Health and Human Serv-  
4                   ices shall review and update, as necessary,  
5                   any policies or guidelines of the Office of  
6                   the Inspector General of the Department  
7                   of Human Services (including policies re-  
8                   lated to the enforcement of section 1128B)  
9                   to accommodate the use of risk-sharing  
10                  value-based payment agreements in accord-  
11                  ance with this section.

12               “(9) RULES OF CONSTRUCTION.—

13               “(A) MODIFICATIONS.—Nothing in this  
14               subsection or any regulations promulgated  
15               under this subsection shall prohibit a State  
16               from requesting a modification from the Sec-  
17               retary to the terms of a risk-sharing value-  
18               based payment agreement. A modification that  
19               is expected to result in any increase to pro-  
20               jected net State or Federal spending under the  
21               agreement shall be subject to recertification by  
22               the Chief Actuary as described in paragraph  
23               (2)(A)(ii) before the modification may be ap-  
24               proved.

1           “(B) REBATE AGREEMENTS.—Nothing in  
2           this subsection shall be construed as requiring  
3           a State to enter into a risk-sharing value-based  
4           payment agreement or as limiting or super-  
5           seding the ability of a State to enter into a sup-  
6           plemental rebate agreement for a covered out-  
7           patient drug.

8           “(C) FFP FOR PAYMENTS UNDER RISK-  
9           SHARING VALUE-BASED PAYMENT AGREE-  
10          MENTS.—Federal financial participation shall  
11          be available under this title for any payment  
12          made by a State to a manufacturer for a cov-  
13          ered outpatient drug under a risk-sharing  
14          value-based payment agreement in accordance  
15          with this subsection, except that no Federal fi-  
16          nancial participation shall be available for any  
17          payment made by a State to a manufacturer  
18          under such an agreement on and after the ef-  
19          fective date of a disapproval of such agreement  
20          by the Secretary.

21          “(D) CONTINUED APPLICATION OF OTHER  
22          PROVISIONS.—Except as expressly provided in  
23          this subsection, nothing in this subsection or in  
24          any regulations promulgated under this sub-

1 section shall affect the application of any other  
2 provision of this Act.

3 “(10) APPROPRIATIONS.—For fiscal year 2023  
4 and each fiscal year thereafter, there are appro-  
5 priated to the Secretary \$5,000,000 for the purpose  
6 of carrying out this subsection.

7 “(11) DEFINITIONS.—In this subsection:

8 “(A) CHIEF ACTUARY.—The term ‘Chief  
9 Actuary’ means the Chief Actuary of the Cen-  
10 ters for Medicare & Medicaid Services.

11 “(B) INSTALLMENT YEAR.—The term ‘in-  
12 stallment year’ means, with respect to a risk-  
13 sharing value-based payment agreement, a 12-  
14 month period during which a covered outpatient  
15 drug is administered under the agreement.

16 “(C) POTENTIALLY CURATIVE TREATMENT  
17 INTENDED FOR ONE-TIME USE.—The term ‘po-  
18 tentially curative treatment intended for one-  
19 time use’ means a treatment that consists of  
20 the administration of a covered outpatient drug  
21 that—

22 “(i) is a form of gene therapy for a  
23 rare disease, as defined by the Commis-  
24 sioner of Food and Drugs, designated  
25 under section 526 of the Federal Food,

1 Drug, and Cosmetics Act, and approved  
2 under section 505 of such Act or licensed  
3 under subsection (a) or (k) of section 351  
4 of the Public Health Service Act to treat  
5 a serious or life-threatening disease or con-  
6 dition;

7 “(ii) if administered in accordance  
8 with the labeling of such drug, is expected  
9 to result in either—

10 “(I) the cure of such disease or  
11 condition; or

12 “(II) a reduction in the symp-  
13 toms of such disease or condition to  
14 the extent that such disease or condi-  
15 tion is not expected to lead to early  
16 mortality; and

17 “(iii) is expected to achieve a result  
18 described in clause (ii), which may be  
19 achieved over an extended period of time,  
20 after not more than 3 administrations.

21 “(D) RELEVANT CLINICAL PARAMETER.—

22 The term ‘relevant clinical parameter’ means,  
23 with respect to a covered outpatient drug that  
24 is the subject of a risk-sharing value-based pay-  
25 ment agreement—

1 “(i) a clinical endpoint specified in the  
2 drug’s labeling or supported by one or  
3 more of the compendia described in section  
4 1861(t)(2)(B)(ii)(I) that—

5 “(I) is able to be measured or  
6 evaluated on an annual basis for each  
7 year of the agreement on an inde-  
8 pendent basis by a provider or other  
9 entity; and

10 “(II) is required to be achieved  
11 (based on observed metrics in patient  
12 populations) under the terms of the  
13 agreement; or

14 “(ii) a surrogate endpoint (as defined  
15 in section 507(e)(9) of the Federal Food,  
16 Drug, and Cosmetic Act), including those  
17 developed by patient-focused drug develop-  
18 ment tools, that—

19 “(I) is able to be measured or  
20 evaluated on an annual basis for each  
21 year of the agreement on an inde-  
22 pendent basis by a provider or other  
23 entity; and

24 “(II) has been qualified by the  
25 Food and Drug Administration.

1           “(E) RISK-SHARING VALUE-BASED PAY-  
2           MENT AGREEMENT.—The term ‘risk-sharing  
3           value-based payment agreement’ means an  
4           agreement between a State plan and a manu-  
5           facturer—

6                   “(i) for the purchase of a covered out-  
7                   patient drug of the manufacturer that is a  
8                   potentially curative treatment intended for  
9                   one-time use;

10                   “(ii) under which payment for such  
11                   drug shall be made pursuant to an install-  
12                   ment-based payment structure that meets  
13                   the requirements of paragraph (3);

14                   “(iii) which conditions payment on the  
15                   achievement of at least 2 relevant clinical  
16                   parameters (as defined in subparagraph  
17                   (C));

18                   “(iv) which provides that—

19                           “(I) the State plan will directly  
20                           reimburse the manufacturer for the  
21                           drug; or

22                           “(II) a third party will reimburse  
23                           the manufacture in a manner ap-  
24                           proved by the Secretary; and



1 “(v) is approved by the Secretary in  
2 accordance with paragraph (2).

3 “(F) TOTAL INSTALLMENT YEAR  
4 AMOUNT.—The term ‘total installment year  
5 amount’ means, with respect to a risk-sharing  
6 value-based payment agreement for the pur-  
7 chase of a covered outpatient drug and an in-  
8 stallment year, an amount equal to the product  
9 of—

10 “(i) the unit price of the drug charged  
11 under the agreement; and

12 “(ii) the number of units of such drug  
13 administered under the agreement during  
14 such installment year.”.

15 (b) CONFORMING AMENDMENTS.—

16 (1) Section 1903(i)(10)(A) of the Social Secu-  
17 rity Act (42 U.S.C. 1396b(i)(10)(A)) is amended by  
18 striking “or unless section 1927(a)(3) applies” and  
19 inserting “, section 1927(a)(3) applies with respect  
20 to such drugs, or such drugs are the subject of a  
21 risk-sharing value-based payment agreement under  
22 section 1927(l)”.

23 (2) Section 1927(b) of the Social Security Act  
24 (42 U.S.C. 1396r–8(b)) is amended—

(A) in paragraph (1)(A), by inserting “(except for drugs for which payment is made by a State under a risk-sharing value-based payment agreement under subsection (l))” after “under the State plan for such period”; and

(B) in paragraph (3)—

(i) in subparagraph (C)(i), by inserting “or subsection (l)(2)(A)” after “subparagraph (A)”; and

(ii) in subparagraph (D), in the matter preceding clause (i), by inserting “, under subsection (l)(2)(A),” after “under this paragraph”.

**SEC. 307. MODIFICATION OF MAXIMUM REBATE AMOUNT  
UNDER MEDICAID DRUG REBATE PROGRAM.**

(a) IN GENERAL.—Subparagraph (D) of section 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)) is amended to read as follows:

“(D) MAXIMUM REBATE AMOUNT.—

“(i) IN GENERAL.—Except as provided in clause (ii), in no case shall the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator

multiple source drug for a rebate period  
exceed—

“(I) for rebate periods beginning  
after December 31, 2009, and before  
September 30, 2025, 100 percent of  
the average manufacturer price of the  
drug; and

“(II) for rebate periods beginning  
on or after October 1, 2025, 125 per-  
cent of the average manufacturer  
price of the drug.

“(ii) NO MAXIMUM AMOUNT FOR  
DRUGS IF AMP INCREASES OUTPACE IN-  
FLATION.—

“(I) IN GENERAL.—If the aver-  
age manufacturer price with respect  
to each dosage form and strength of  
a single source drug or an innovator  
multiple source drug increases on or  
after October 1, 2024, and such in-  
creased average manufacturer price  
exceeds the inflation-adjusted average  
manufacturer price determined with  
respect to such drug under subclause  
(II) for the rebate period, clause (i)

1 shall not apply and there shall be no  
2 limitation on the sum of the amounts  
3 applied under paragraph (1)(A)(ii)  
4 and this paragraph for the rebate pe-  
5 riod with respect to each dosage form  
6 and strength of the single source drug  
7 or innovator multiple source drug.

8 “(II) INFLATION-ADJUSTED AV-  
9 ERAGE MANUFACTURER PRICE DE-  
10 FINED.—In this clause, the term ‘in-  
11 flation-adjusted average manufacturer  
12 price’ means, with respect to a single  
13 source drug or an innovator multiple  
14 source drug and a rebate period, the  
15 average manufacturer price for each  
16 dosage form and strength of the drug  
17 for the calendar quarter beginning  
18 July 1, 1990 (without regard to  
19 whether or not the drug has been sold  
20 or transferred to an entity, including  
21 a division or subsidiary of the manu-  
22 facturer, after the first day of such  
23 quarter), increased by the percentage  
24 by which the consumer price index for  
25 all urban consumers (United States

1 city average) for the month before the  
 2 month in which the rebate period be-  
 3 gins exceeds such index for September  
 4 1990.”.

5 (b) TREATMENT OF SUBSEQUENTLY APPROVED  
 6 DRUGS.—Section 1927(c)(2)(B) of the Social Security Act  
 7 (42 U.S.C. 1396r–8(c)(2)(B)) is amended by inserting  
 8 “and clause (ii)(II) of subparagraph (D)” after “clause  
 9 (ii)(II) of subparagraph (A)”.

10 (c) TECHNICAL AMENDMENTS.—Section  
 11 1927(c)(3)(C)(ii)(IV) of the Social Security Act (42  
 12 U.S.C. 1396r–9(c)(3)(C)(ii)(IV)) is amended—

13 (1) by striking “subparagraph (A)” and insert-  
 14 ing “paragraph (3)(A)”; and

15 (2) by striking “this subparagraph” and insert-  
 16 ing “paragraph (3)(C)”.

17 **SEC. 308. APPLYING MEDICAID DRUG REBATE REQUIRE-**  
 18 **MENT TO DRUGS PROVIDED AS PART OF OUT-**  
 19 **PATIENT HOSPITAL SERVICES.**

20 (a) IN GENERAL.—Section 1927(k)(3) of the Social  
 21 Security Act (42 U.S.C. 1396r–8(k)(3)) is amended to  
 22 read as follows:

23 “(3) LIMITING DEFINITION.—

24 “(A) IN GENERAL.—The term ‘covered  
 25 outpatient drug’ does not include any drug, bio-

1           logical product, or insulin provided as part of,  
2           or as incident to and in the same setting as,  
3           any of the following (and for which payment  
4           may be made under this title as part of pay-  
5           ment for the following and not as direct reim-  
6           bursement for the drug):

7                   “(i) Inpatient hospital services.

8                   “(ii) Hospice services.

9                   “(iii) Dental services, except that  
10           drugs for which the State plan authorizes  
11           direct reimbursement to the dispensing  
12           dentist are covered outpatient drugs.

13                   “(iv) Physicians’ services.

14                   “(v) Outpatient hospital services.

15                   “(vi) Nursing facility services and  
16           services provided by an intermediate care  
17           facility for the mentally retarded.

18                   “(vii) Other laboratory and x-ray serv-  
19           ices.

20                   “(viii) Renal dialysis.

21                   “(B) OTHER EXCLUSIONS.—Such term  
22           also does not include any such drug or product  
23           for which a National Drug Code number is not  
24           required by the Food and Drug Administration  
25           or a drug or biological used for a medical indi-

1 cation which is not a medically accepted indica-  
 2 tion.

3 “(C) STATE OPTION.—At the option of a  
 4 State, such term may include any drug, biologi-  
 5 cal product, or insulin provided on an out-  
 6 patient basis as part of, or as incident to and  
 7 in the same setting as, described in clause (iv)  
 8 or (v) of subparagraph (A) (such as a drug, bi-  
 9 ological product, or insulin being provided as  
 10 part of a bundled payment).

11 “(D) NO EFFECT ON BEST PRICE.—Any  
 12 drug, biological product, or insulin excluded  
 13 from the definition of such term as a result of  
 14 this paragraph shall be treated as a covered  
 15 outpatient drug for purposes of determining the  
 16 best price (as defined in subsection (c)(1)(C))  
 17 for such drug, biological product, or insulin.”.

18 (b) EFFECTIVE DATE; IMPLEMENTATION GUID-  
 19 ANCE.—

20 (1) IN GENERAL.—The amendment made by  
 21 subsection (a) shall take effect on the date that is  
 22 1 year after the date of enactment of this Act.

23 (2) IMPLEMENTATION AND GUIDANCE.—Not  
 24 later than 1 year after the date of enactment of this  
 25 Act, the Secretary of Health and Human Services

1 shall issue guidance and relevant informational bul-  
 2 letins for States, manufacturers (as defined in sec-  
 3 tion 1927(k)(5) of the Social Security Act (42  
 4 U.S.C. 1396r–8(k)(5)), and other relevant stake-  
 5 holders, including health care providers, regarding  
 6 implementation of the amendment made by sub-  
 7 section (a).

8 **TITLE IV—ADDRESSING INTER-**  
 9 **MEDIARIES AND DRUG COM-**  
 10 **PETITION**

11 **SEC. 401. HEALTH PLAN OVERSIGHT OF PHARMACY BEN-**  
 12 **EFIT MANAGER SERVICES.**

13 Subpart II of part A of title XXVII of the Public  
 14 Health Service Act (42 U.S.C. 300gg–11 et seq.) is  
 15 amended by adding at the end the following:

16 **“SEC. 2729A. HEALTH PLAN OVERSIGHT OF PHARMACY**  
 17 **BENEFIT MANAGER SERVICES.**

18 “(a) IN GENERAL.—A group health plan or health  
 19 insurance issuer offering group or individual health insur-  
 20 ance coverage or an entity or subsidiary providing phar-  
 21 macy benefits management services shall not enter into  
 22 a contract with a drug manufacturer, distributor, whole-  
 23 saler, subcontractor, rebate aggregator, or any associated  
 24 third party that limits the disclosure of information to  
 25 plan sponsors in such a manner that prevents the plan



1 or coverage, or an entity or subsidiary providing pharmacy  
2 benefits management services on behalf of a plan or cov-  
3 erage from making the reports described in subsection (b).

4 “(b) REPORTS TO GROUP PLAN SPONSORS.—

5 “(1) IN GENERAL.—Beginning with the first  
6 plan year that begins after the date of enactment of  
7 this section, not less frequently than once every six  
8 months, a health insurance issuer offering group  
9 health insurance coverage or an entity providing  
10 pharmacy benefits management services on behalf of  
11 a group health plan shall submit to the self-funded  
12 group health plan and at the request of any other  
13 group health plan a report in accordance with this  
14 subsection and make such report available to the  
15 plan sponsor in a machine-readable format. Each  
16 such report shall include, with respect to the applica-  
17 ble group health plan or health insurance coverage—

18 “(A) information collected from drug man-  
19 ufacturers by such issuer or entity on the total  
20 amount of copayment assistance dollars paid, or  
21 copayment cards applied, that were funded by  
22 the drug manufacturer with respect to the en-  
23 rollees in such plan or coverage;

24 “(B) a list of each covered drug dispensed  
25 during the reporting period, including, with re-

1 spect to each such drug during the reporting  
2 period—

3 “(i) the brand name, chemical entity,  
4 and National Drug Code;

5 “(ii) the number of enrollees for  
6 whom the drug was filled during the plan  
7 year, the total number of prescription fills  
8 for the drug (including original prescrip-  
9 tions and refills), and the total number of  
10 dosage units of the drug dispensed across  
11 the plan year, including whether the dis-  
12 pensing channel was by retail, mail order,  
13 or specialty pharmacy;

14 “(iii) the wholesale acquisition cost,  
15 listed as cost per days supply and cost per  
16 pill, or in the case of a drug in another  
17 form, per dose;

18 “(iv) the total out-of-pocket spending  
19 by enrollees on such drug, including en-  
20 rollee spending through copayments, coin-  
21 surance, and deductibles; and

22 “(v) for any drug for which gross  
23 spending of the group health plan or  
24 health insurance coverage exceeded  
25 \$10,000 during the reporting period—

1                   “(I) a list of all other available  
2                   drugs in the same therapeutic cat-  
3                   egory or class, including brand name  
4                   drugs and biological products and ge-  
5                   neric drugs or biosimilar biological  
6                   products that are in the same thera-  
7                   peutic category or class; and

8                   “(II) the rationale for preferred  
9                   formulary placement of a particular  
10                  drug or drugs in that therapeutic cat-  
11                  egory or class;

12                  “(C) a list of each therapeutic category or  
13                  class of drugs that were dispensed under the  
14                  health plan or health insurance coverage during  
15                  the reporting period, and, with respect to each  
16                  such therapeutic category or class of drugs,  
17                  during the reporting period—

18                         “(i) total gross spending by the plan,  
19                         before manufacturer rebates, fees, or other  
20                         manufacturer remuneration;

21                         “(ii) the number of enrollees who  
22                         filled a prescription for a drug in that cat-  
23                         egory or class;

24                         “(iii) if applicable to that category or  
25                         class, a description of the formulary tiers

1 and utilization mechanisms (such as prior  
2 authorization or step therapy) employed  
3 for drugs in that category or class;

4 “(iv) the total out-of-pocket spending  
5 by enrollees, including enrollee spending  
6 through copayments, coinsurance, and  
7 deductibles; and

8 “(v) for each therapeutic category or  
9 class under which three or more drugs are  
10 marketed and available—

11 “(I) the amount received, or ex-  
12 pected to be received, from drug man-  
13 ufacturers in rebates, fees, alternative  
14 discounts, or other remuneration—

15 “(aa) to be paid by drug  
16 manufacturers for claims in-  
17 curred during the reporting pe-  
18 riod; or

19 “(bb) that is related to utili-  
20 zation of drugs, in such thera-  
21 peutic category or class;

22 “(II) the total net spending by  
23 the health plan or health insurance  
24 coverage on that category or class of  
25 drugs; and

1                   “(III) the net price per dosage  
2                   unit or course of treatment incurred  
3                   by the health plan or health insurance  
4                   coverage and its enrollees, after man-  
5                   ufacturer rebates, fees, and other re-  
6                   muneration for drugs dispensed within  
7                   such therapeutic category or class  
8                   during the reporting period;

9                   “(D) total gross spending on prescription  
10                  drugs by the plan or coverage during the re-  
11                  porting period, before rebates and other manu-  
12                  facturer fees or remuneration;

13                  “(E) total amount received, or expected to  
14                  be received, by the health plan or health insur-  
15                  ance coverage in drug manufacturer rebates,  
16                  fees, alternative discounts, and all other remu-  
17                  neration received from the manufacturer or any  
18                  third party related to utilization of drug or  
19                  drug spending under that health plan or health  
20                  insurance coverage during the reporting period;

21                  “(F) the total net spending on prescription  
22                  drugs by the health plan or health insurance  
23                  coverage during the reporting period; and

24                  “(G) amounts paid directly or indirectly in  
25                  rebates, fees, or any other type of remuneration

1 to brokers, consultants, advisors, or any other  
2 individual or firm who referred the group health  
3 plan's or health insurance issuer's business to  
4 the pharmacy benefit manager.

5 “(2) PRIVACY REQUIREMENTS.—Health insur-  
6 ance issuers offering group health insurance cov-  
7 erage and entities providing pharmacy benefits man-  
8 agement services on behalf of a group health plan  
9 shall provide information under paragraph (1) in a  
10 manner consistent with the privacy, security, and  
11 breach notification regulations promulgated under  
12 section 264(c) of the Health Insurance Portability  
13 and Accountability Act of 1996 (or successor regula-  
14 tions), and shall restrict the use and disclosure of  
15 such information according to such privacy regula-  
16 tions.

17 “(3) DISCLOSURE AND REDISCLOSURE.—

18 “(A) LIMITATION TO BUSINESS ASSOCI-  
19 ATES.—A group health plan receiving a report  
20 under paragraph (1) may disclose such informa-  
21 tion only to business associates of such plan as  
22 defined in section 160.103 of title 45, Code of  
23 Federal Regulations (or successor regulations).

24 “(B) CLARIFICATION REGARDING PUBLIC  
25 DISCLOSURE OF INFORMATION.—Nothing in

1           this section prevents a health insurance issuer  
2           offering group health insurance coverage or an  
3           entity providing pharmacy benefits management  
4           services on behalf of a group health plan from  
5           placing reasonable restrictions on the public dis-  
6           closure of the information contained in a report  
7           described in paragraph (1).

8           “(c) ENFORCEMENT.—

9           “(1) IN GENERAL.—The Secretary, in consulta-  
10          tion with the Secretary of Labor and the Secretary  
11          of the Treasury, shall enforce this section.

12          “(2) FAILURE TO PROVIDE TIMELY INFORMA-  
13          TION.—A health insurance issuer or an entity pro-  
14          viding pharmacy benefit management services that  
15          violates subsection (a) or fails to provide information  
16          required under subsection (b) or a drug manufac-  
17          turer that fails to provide information under sub-  
18          section (b)(1)(A), in a timely manner shall be sub-  
19          ject to a civil monetary penalty in the amount of  
20          \$10,000 for each day during which such violation  
21          continues or such information is not disclosed or re-  
22          ported.

23          “(3) FALSE INFORMATION.—A health insurance  
24          issuer, entity providing pharmacy benefit manage-  
25          ment services, or drug manufacturer that knowingly

1 provides false information under this section shall be  
2 subject to a civil money penalty in an amount not  
3 to exceed \$100,000 for each item of false informa-  
4 tion. Such civil money penalty shall be in addition to  
5 other penalties as may be prescribed by law.

6 “(4) PROCEDURE.—The provisions of section  
7 1128A of the Social Security Act, other than sub-  
8 sections (a) and (b) and the first sentence of sub-  
9 section (c)(1) of such section shall apply to civil  
10 monetary penalties under this subsection in the  
11 same manner as such provisions apply to a penalty  
12 or proceeding under section 1128A of the Social Se-  
13 curity Act.

14 “(5) SAFE HARBOR.—The Secretary may waive  
15 penalties under paragraph (2), or extend the period  
16 of time for compliance with a requirement of this  
17 section, for an entity in violation of this section that  
18 has made a good-faith effort to comply with this sec-  
19 tion.

20 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-  
21 tion shall be construed to prohibit entities providing phar-  
22 macy benefits management services from retaining bona  
23 fide service fees, provided that such fees are transparent  
24 to group health plans and health insurance issuers and



1 are not linked directly to the price or formulary placement  
2 or position of a drug.

3 “(e) DEFINITIONS.—In this section—

4 “(1) the term ‘similarly situated pharmacy’  
5 means, with respect to a particular pharmacy, an-  
6 other pharmacy that is approximately the same size  
7 (as measured by the number of prescription drugs  
8 dispensed), and that serves patients in the same geo-  
9 graphical area, whether through physical locations or  
10 mail order;

11 “(2) the term ‘wholesale acquisition cost’ has  
12 the meaning given such term in section  
13 1847A(c)(6)(B) of the Social Security Act; and

14 “(3) the term ‘bona fide service fees’ means  
15 fees paid by a manufacturer, customer, or client  
16 (other than a group health plan or health insurance  
17 issuer) of an entity providing pharmacy benefit man-  
18 agement services, to an entity providing pharmacy  
19 benefit management services, that represent fair  
20 market value for bona fide, itemized services actually  
21 performed on behalf of the manufacturer, customer,  
22 or client would otherwise perform or contract for in  
23 the absence of the service arrangement, without  
24 prior consent for any specific arrangements.”.

1 **SEC. 402. STUDY OF PHARMACEUTICAL SUPPLY CHAIN**  
2 **INTERMEDIARIES AND MERGER ACTIVITY.**

3 (a) INITIAL REPORT.—Not later than 1 year after  
4 the date of enactment of this Act, the Commission shall  
5 submit to the appropriate committees of Congress a report  
6 that—

7 (1) addresses at minimum—

8 (A) whether pharmacy benefit managers—

9 (i) charge payers a higher price than  
10 the reimbursement rate at which the phar-  
11 macy benefit managers reimburse com-  
12 peting pharmacies;

13 (ii) steer patients for anticompetitive  
14 purposes to any pharmacies, including re-  
15 tail, mail-order, or any other type of phar-  
16 macy, in which the pharmacy benefit man-  
17 ager has an ownership interest;

18 (iii) audit or review proprietary data,  
19 including acquisition costs, patient infor-  
20 mation, or dispensing information, of com-  
21 peting pharmacies that can be used for  
22 anticompetitive purposes; or

23 (iv) use formulary designs to increase  
24 the market share of higher cost prescrip-  
25 tion drugs and depress the market share of

1 lower cost prescription drugs (each net of  
2 rebates and discounts);

3 (B) how companies and payers assess the  
4 benefits, costs, and risks of contracting with  
5 intermediaries, including pharmacy services ad-  
6 ministrative organizations, and whether more  
7 information about the roles of intermediaries  
8 should be available to consumers and payers;  
9 and

10 (C) whether there are any specific legal or  
11 regulatory obstacles the Commission currently  
12 faces in ensuring a competitive and transparent  
13 marketplace in the pharmaceutical supply  
14 chain, including the pharmacy benefit manager  
15 marketplace and pharmacy services administra-  
16 tive organizations; and

17 (2) provides—

18 (A) observations or conclusions drawn  
19 from the November 2017 roundtable entitled  
20 “Understanding Competition in Prescription  
21 Drug Markets: Entry and Supply Chain Dy-  
22 namics”, and any similar efforts;

23 (B) specific actions the Commission in-  
24 tends to take as a result of the November 2017  
25 roundtable, and any similar efforts, including a

1 detailed description of relevant forthcoming ac-  
2 tions, additional research or roundtable discus-  
3 sions, consumer education efforts, or enforce-  
4 ment actions; and

5 (C) policy or legislative recommendations  
6 to—

7 (i) improve transparency and competi-  
8 tion in the pharmaceutical supply chain;

9 (ii) prevent and deter anticompetitive  
10 behavior in the pharmaceutical supply  
11 chain; and

12 (iii) best ensure that consumers ben-  
13 efit from any cost savings or efficiencies  
14 that may result from mergers and consoli-  
15 dations.

16 (b) INTERIM REPORT.—Not later than 180 days  
17 after the date of enactment of this Act, the Commission  
18 shall submit to the appropriate committees of Congress  
19 an interim report on the progress of the report required  
20 by subsection (a), along with preliminary findings and  
21 conclusions based on information collected to that date.

22 (c) DEFINITIONS.—In this section:

23 (1) APPROPRIATE COMMITTEES OF CON-  
24 GRESS.—The term “appropriate committees of Con-  
25 gress” means—

1 (A) the Committee on Energy and Com-  
2 merce of the House of Representatives;

3 (B) the Committee on the Judiciary of the  
4 Senate; and

5 (C) the Committee on the Judiciary of the  
6 House of Representatives.

7 (2) COMMISSION.—The term “Commission”  
8 means the Federal Trade Commission.

9 **SEC. 403. REQUIREMENT THAT DIRECT-TO-CONSUMER AD-**  
10 **VERTISEMENTS FOR PRESCRIPTION DRUGS**  
11 **AND BIOLOGICAL PRODUCTS INCLUDE**  
12 **TRUTHFUL AND NON-MISLEADING PRICING**  
13 **INFORMATION.**

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

16 **“SEC. 1150D. REQUIREMENT THAT DIRECT-TO-CONSUMER**  
17 **ADVERTISEMENTS FOR PRESCRIPTION**  
18 **DRUGS AND BIOLOGICAL PRODUCTS IN-**  
19 **CLUDE TRUTHFUL AND NON-MISLEADING**  
20 **PRICING INFORMATION.**

21 “(a) IN GENERAL.—The Secretary shall require that  
22 each direct-to-consumer advertisement for a prescription  
23 drug or biological product for which payment is available  
24 under title XVIII or XIX includes an appropriate dislo-

1 sure of truthful and non-misleading pricing information  
 2 with respect to the drug or product.

3 “(b) DETERMINATION BY CMS.—The Secretary, act-  
 4 ing through the Administrator of the Centers for Medicare  
 5 & Medicaid Services, shall determine the components of  
 6 the requirement under subsection (a), such as the forms  
 7 of advertising, the manner of disclosure, the price point  
 8 listing, and the price information for disclosure.”.

9 **SEC. 404. CHANGE CONDITIONS OF FIRST GENERIC EXCLU-**  
 10 **SIVITY TO SPUR ACCESS AND COMPETITION.**

11 Clause (iv) of section 505(j)(5)(B) of the Federal  
 12 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B))  
 13 is amended—

14 (1) in subclause (I), after “180 days after the  
 15 date of the first commercial marketing of the drug  
 16 (including the commercial marketing of the listed  
 17 drug) by any first applicant” by inserting “or by an  
 18 applicant whose application is approved pursuant to  
 19 subclause (III)”; and

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

22 “(III) APPLICANT APPROVAL.—An applica-  
 23 tion containing a certification described in para-  
 24 graph (2)(A)(vii)(IV) that is for a drug for  
 25 which a first applicant has submitted an appli-

1 cation containing such a certification can be ap-  
2 proved notwithstanding the eligibility of a first  
3 applicant for the 180-day exclusivity period de-  
4 scribed in subclause (II)(aa) if each of the fol-  
5 lowing conditions is met:

6 “(aa) The approval of such an appli-  
7 cation could be made effective, but for the  
8 eligibility of a first applicant for 180-day  
9 exclusivity under this clause.

10 “(bb) At least 30 months have passed  
11 since the date of submission of an applica-  
12 tion for the drug by at least one first ap-  
13 plicant.

14 “(cc) Approval of an application for  
15 the drug submitted by at least one first ap-  
16 plicant is not precluded under clause (iii).

17 “(dd) No application for the drug  
18 submitted by any first applicant is ap-  
19 proved at the time the conditions under  
20 items (aa), (bb), and (cc) are all met, re-  
21 gardless of whether such an application is  
22 subsequently approved.”.

1 **SEC. 405. ENDING THE PRACTICE PREVENTING MARKET**  
2 **COMPETITION KNOWN AS “PAY-FOR-DELAY”.**

3 (a) CONGRESSIONAL FINDINGS AND DECLARATION  
4 OF PURPOSES.—

5 (1) FINDINGS.—Congress finds the following:

6 (A) In 1984, the Drug Price Competition  
7 and Patent Term Restoration Act (Public Law  
8 98–417) (referred to in this Act as the “1984  
9 Act”), was enacted with the intent of facili-  
10 tating the early entry of generic drugs while  
11 preserving incentives for innovation.

12 (B) Prescription drugs make up approxi-  
13 mately 10 percent of the national health care  
14 spending.

15 (C) Initially, the 1984 Act was successful  
16 in facilitating generic competition to the benefit  
17 of consumers and health care payers, although  
18 88 percent of all prescriptions dispensed in the  
19 United States are generic drugs, they account  
20 for only 28 percent of all expenditures.

21 (D) Generic drugs cost substantially less  
22 than brand name drugs, with discounts off the  
23 brand price averaging 80 to 85 percent.

24 (E) Federal dollars currently account for  
25 over 40 percent of the \$325,000,000,000 spent



1 on retail prescription drugs, and this share is  
2 expected to rise to 47 percent by 2025.

3 (F)(i) In recent years, the intent of the  
4 1984 Act has been subverted by certain settle-  
5 ment agreements in which brand name compa-  
6 nies transfer value to their potential generic  
7 competitors to settle claims that the generic  
8 company is infringing the branded company's  
9 patents.

10 (ii) These “reverse payment” settlement  
11 agreements—

12 (I) allow a branded company to share  
13 its monopoly profits with the generic com-  
14 pany as a way to protect the branded com-  
15 pany's monopoly; and

16 (II) have unduly delayed the mar-  
17 keting of low-cost generic drugs contrary  
18 to free competition, the interests of con-  
19 sumers, and the principles underlying anti-  
20 trust law.

21 (iii) Because of the price disparity between  
22 brand name and generic drugs, such agree-  
23 ments are more profitable for both the brand  
24 and generic manufacturers than competition

1 and will become increasingly common unless  
2 prohibited.

3 (iv) These agreements result in consumers  
4 losing the benefits that the 1984 Act was in-  
5 tended to provide.

6 (G) In 2010, the Biologics Price Competi-  
7 tion and Innovation Act (Public Law 111–148)  
8 (referred to in this Act as the “BPCIA”), was  
9 enacted with the intent of facilitating the early  
10 entry of biosimilar and interchangeable follow-  
11 on versions of branded biological products while  
12 preserving incentives for innovation.

13 (H) Biological drugs play an important  
14 role in treating many serious illnesses, from  
15 cancers to genetic disorders. They are also ex-  
16 pensive, representing more than 40 percent of  
17 all prescription drug spending.

18 (I) Competition from biosimilar and inter-  
19 changeable biological products promises to  
20 lower drug costs and increase patient access to  
21 biological medicines. But “reverse payment”  
22 settlement agreements also threaten to delay  
23 the entry of biosimilar and interchangeable bio-  
24 logical products, which would undermine the  
25 goals of BPCIA.

1           (2) PURPOSES.—The purposes of this Act  
2     are—

3           (A) to enhance competition in the pharma-  
4           ceutical market by stopping anticompetitive  
5           agreements between brand name and generic  
6           drug and biosimilar biological product manufac-  
7           turers that limit, delay, or otherwise prevent  
8           competition from generic drugs and biosimilar  
9           biological products; and

10          (B) to support the purpose and intent of  
11          antitrust law by prohibiting anticompetitive  
12          practices in the pharmaceutical industry that  
13          harm consumers.

14     (b) UNLAWFUL COMPENSATION FOR DELAY.—

15          (1) IN GENERAL.—The Federal Trade Commis-  
16          sion Act (15 U.S.C. 44 et seq.) is amended by in-  
17          serting after section 26 (15 U.S.C. 57c–2) the fol-  
18          lowing:

19     **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS**  
20                 **AND BIOSIMILARS.**

21          “(a) IN GENERAL.—

22                 “(1) ENFORCEMENT PROCEEDING.—The Com-  
23                 mission may initiate a proceeding to enforce the pro-  
24                 visions of this section against the parties to any  
25                 agreement resolving or settling, on a final or interim

1 basis, a patent claim, in connection with the sale of  
2 a drug product or biological product.

3 “(2) PRESUMPTION AND VIOLATION.—

4 “(A) IN GENERAL.—Subject to subpara-  
5 graph (B), in such a proceeding, an agreement  
6 shall be presumed to have anticompetitive ef-  
7 fects and shall be a violation of this section if—

8 “(i) an ANDA filer or a biosimilar bi-  
9 ological product application filer receives  
10 anything of value, including an exclusive li-  
11 cense; and

12 “(ii) the ANDA filer or biosimilar bio-  
13 logical product application filer agrees to  
14 limit or forgo research, development, man-  
15 ufacturing, marketing, or sales of the  
16 ANDA product or biosimilar biological  
17 product, as applicable, for any period of  
18 time.

19 “(B) EXCEPTION.—Subparagraph (A)  
20 shall not apply if the parties to such agreement  
21 demonstrate by clear and convincing evidence  
22 that—

23 “(i) the value described in subpara-  
24 graph (A)(i) is compensation solely for  
25 other goods or services that the ANDA

1                   filer or biosimilar biological product appli-  
2                   cation filer has promised to provide; or

3                   “(ii) the procompetitive benefits of the  
4                   agreement outweigh the anticompetitive ef-  
5                   fects of the agreement.

6           “(b) LIMITATIONS.—In determining whether the set-  
7   tling parties have met their burden under subsection  
8   (a)(2)(B), the fact finder shall not presume—

9                   “(1) that entry would not have occurred until  
10           the expiration of the relevant patent or statutory ex-  
11           clusivity; or

12                   “(2) that the agreement’s provision for entry of  
13           the ANDA product or biosimilar biological product  
14           prior to the expiration of the relevant patent or stat-  
15           utory exclusivity means that the agreement is pro-  
16           competitive.

17           “(c) EXCLUSIONS.—Nothing in this section shall pro-  
18   hibit a resolution or settlement of a patent infringement  
19   claim in which the consideration that the ANDA filer or  
20   biosimilar biological product application filer, respectively,  
21   receives as part of the resolution or settlement includes  
22   only one or more of the following:

23                   “(1) The right to market and secure final ap-  
24           proval in the United States for the ANDA product

1 or biosimilar biological product at a date, whether  
2 certain or contingent, prior to the expiration of—

3 “(A) any patent that is the basis for the  
4 patent infringement claim; or

5 “(B) any patent right or other statutory  
6 exclusivity that would prevent the marketing of  
7 such ANDA product or biosimilar biological  
8 product.

9 “(2) A payment for reasonable litigation ex-  
10 penses not to exceed—

11 “(A) for calendar year 2021, \$7,500,000;

12 or

13 “(B) for calendar year 2022 and each sub-  
14 sequent calendar year, the amount determined  
15 for the preceding calendar year adjusted to re-  
16 flect the percentage increase (if any) in the  
17 Producer Price Index for Legal Services pub-  
18 lished by the Bureau of Labor Statistics of the  
19 Department of Labor for the most recent cal-  
20 endar year.

21 “(3) A covenant not to sue on any claim that  
22 the ANDA product or biosimilar biological product  
23 infringes a United States patent.

24 “(d) ENFORCEMENT.—

1           “(1) ENFORCEMENT.—A violation of this sec-  
2           tion shall be treated as an unfair method of competi-  
3           tion under section 5(a)(1).

4           “(2) JUDICIAL REVIEW.—

5                 “(A) IN GENERAL.—Any party that is sub-  
6           ject to a final order of the Commission, issued  
7           in an administrative adjudicative proceeding  
8           under the authority of subsection (a)(1), may,  
9           within 30 days of the issuance of such order,  
10          petition for review of such order in—

11                   “(i) the United States Court of Ap-  
12                  peals for the District of Columbia Circuit;

13                   “(ii) the United States Court of Ap-  
14                  peals for the circuit in which the ultimate  
15                  parent entity, as defined in section  
16                  801.1(a)(3) of title 16, Code of Federal  
17                  Regulations, or any successor thereto, of  
18                  the NDA holder or biological product li-  
19                  cense holder is incorporated as of the date  
20                  that the NDA or biological product license  
21                  application, as applicable, is filed with the  
22                  Commissioner of Food and Drugs; or

23                   “(iii) the United States Court of Ap-  
24                  peals for the circuit in which the ultimate  
25                  parent entity of the ANDA filer or bio-

1 similar biological product application filer  
2 is incorporated as of the date that the  
3 ANDA or biosimilar biological product ap-  
4 plication is filed with the Commissioner of  
5 Food and Drugs.

6 “(B) TREATMENT OF FINDINGS.—In a  
7 proceeding for judicial review of a final order of  
8 the Commission, the findings of the Commis-  
9 sion as to the facts, if supported by evidence,  
10 shall be conclusive.

11 “(e) ANTITRUST LAWS.—Nothing in this section  
12 shall modify, impair, limit, or supersede the applicability  
13 of the antitrust laws as defined in subsection (a) of the  
14 first section of the Clayton Act (15 U.S.C. 12(a)), and  
15 of section 5 of this Act to the extent that section 5 applies  
16 to unfair methods of competition. Nothing in this section  
17 shall modify, impair, limit, or supersede the right of an  
18 ANDA filer or biosimilar biological product application  
19 filer to assert claims or counterclaims against any person,  
20 under the antitrust laws or other laws relating to unfair  
21 competition.

22 “(f) PENALTIES.—

23 “(1) FORFEITURE.—Each party that violates or  
24 assists in the violation of this section shall forfeit  
25 and pay to the United States a civil penalty suffi-



1       cient to deter violations of this section, but in no  
2       event greater than 3 times the value received by the  
3       party that is reasonably attributable to the violation  
4       of this section. If no such value has been received by  
5       the NDA holder, the biological product license hold-  
6       er, the ANDA filer, or the biosimilar biological prod-  
7       uct application filer, the penalty to the NDA holder,  
8       the biological product license holder, the ANDA  
9       filer, or the biosimilar biological product application  
10      filer shall be sufficient to deter violations, but in no  
11      event shall be greater than 3 times the value given  
12      to an ANDA filer or biosimilar biological product  
13      application filer reasonably attributable to the viola-  
14      tion of this section. Such penalty shall accrue to the  
15      United States and may be recovered in a civil action  
16      brought by the Commission, in its own name by any  
17      of its attorneys designated by it for such purpose, in  
18      a district court of the United States against any  
19      party that violates this section. In such actions, the  
20      United States district courts are empowered to grant  
21      mandatory injunctions and such other and further  
22      equitable relief as they deem appropriate.

23               “(2) CEASE AND DESIST.—

24                       “(A) IN GENERAL.—If the Commission has  
25                       issued a cease and desist order with respect to

1 a party in an administrative adjudicative pro-  
2 ceeding under the authority of subsection  
3 (a)(1), an action brought pursuant to para-  
4 graph (1) may be commenced against such  
5 party at any time before the expiration of 1  
6 year after such order becomes final pursuant to  
7 section 5(g).

8 “(B) EXCEPTION.—In an action under  
9 subparagraph (A), the findings of the Commis-  
10 sion as to the material facts in the administra-  
11 tive adjudicative proceeding with respect to the  
12 violation of this section by a party shall be con-  
13 clusive unless—

14 “(i) the terms of such cease and de-  
15 sist order expressly provide that the Com-  
16 mission’s findings shall not be conclusive;  
17 or

18 “(ii) the order became final by reason  
19 of section 5(g)(1), in which case such find-  
20 ing shall be conclusive if supported by evi-  
21 dence.

22 “(3) CIVIL PENALTY.—In determining the  
23 amount of the civil penalty described in this section,  
24 the court shall take into account—

1           “(A) the nature, circumstances, extent,  
2           and gravity of the violation;

3           “(B) with respect to the violator, the de-  
4           gree of culpability, any history of violations, the  
5           ability to pay, any effect on the ability to con-  
6           tinue doing business, profits earned by the  
7           NDA holder, the biological product license hold-  
8           er, the ANDA filer, or the biosimilar biological  
9           product application filer, compensation received  
10          by the ANDA filer or biosimilar biological prod-  
11          uct application filer, and the amount of com-  
12          merce affected; and

13          “(C) other matters that justice requires.

14          “(4) REMEDIES IN ADDITION.—Remedies pro-  
15          vided in this subsection are in addition to, and not  
16          in lieu of, any other remedy provided by Federal  
17          law. Nothing in this paragraph shall be construed to  
18          affect any authority of the Commission under any  
19          other provision of law.

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

21               “(1) AGREEMENT.—The term ‘agreement’  
22               means anything that would constitute an agreement  
23               under section 1 of the Sherman Act (15 U.S.C. 1)  
24               or section 5 of this Act.

1           “(2) AGREEMENT RESOLVING OR SETTling A  
2           PATENT INFRINGEMENT CLAIM.—The term ‘agree-  
3           ment resolving or settling a patent infringement  
4           claim’ includes any agreement that is entered into  
5           within 30 days of the resolution or the settlement of  
6           the claim, or any other agreement that is contingent  
7           upon, provides a contingent condition for, or is oth-  
8           erwise related to the resolution or settlement of the  
9           claim.

10           “(3) ANDA.—The term ‘ANDA’ means an ab-  
11           breviated new drug application filed under section  
12           505(j) of the Federal Food, Drug, and Cosmetic Act  
13           (21 U.S.C. 355(j)) or a new drug application filed  
14           under section 505(b)(2) of the Federal Food, Drug,  
15           and Cosmetic Act (21 U.S.C. 355(b)(2)).

16           “(4) ANDA FILER.—The term ‘ANDA filer’  
17           means a party that owns or controls an ANDA filed  
18           with the Food and Drug Administration or has the  
19           exclusive rights under such ANDA to distribute the  
20           ANDA product.

21           “(5) ANDA PRODUCT.—The term ‘ANDA  
22           product’ means the product to be manufactured  
23           under the ANDA that is the subject of the patent  
24           infringement claim.

1           “(6) BIOLOGICAL PRODUCT.—The term ‘bio-  
2       logical product’ has the meaning given such term in  
3       section 351(i)(1) of the Public Health Service Act  
4       (42 U.S.C. 262(i)(1)).

5           “(7) BIOLOGICAL PRODUCT LICENSE APPLICA-  
6       TION.—The term ‘biological product license applica-  
7       tion’ means an application under section 351(a) of  
8       the Public Health Service Act (42 U.S.C. 262(a)).

9           “(8) BIOLOGICAL PRODUCT LICENSE HOLD-  
10      ER.—The term ‘biological product license holder’  
11      means—

12           “(A) the holder of an approved biological  
13      product license application for a biological prod-  
14      uct;

15           “(B) a person owning or controlling en-  
16      forcement of any patents that claim the biologi-  
17      cal product that is the subject of such approved  
18      application; or

19           “(C) the predecessors, subsidiaries, divi-  
20      sions, groups, and affiliates controlled by, con-  
21      trolling, or under common control with any of  
22      the entities described in subparagraphs (A) and  
23      (B) (such control to be presumed by direct or  
24      indirect share ownership of 50 percent or great-

1           er), as well as the licensees, licensors, succes-  
2           sors, and assigns of each of the entities.

3           “(9) BIOSIMILAR BIOLOGICAL PRODUCT.—The  
4           term ‘biosimilar biological product’ means the prod-  
5           uct to be manufactured under the biosimilar biologi-  
6           cal product application that is the subject of the pat-  
7           ent infringement claim.

8           “(10) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-  
9           CATION.—The term ‘biosimilar biological product ap-  
10          plication’ means an application under section 351(k)  
11          of the Public Health Service Act (42 U.S.C. 262(k))  
12          for licensure of a biological product as biosimilar to,  
13          or interchangeable with, a reference product.

14          “(11) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-  
15          CATION FILER.—The term ‘biosimilar biological  
16          product application filer’ means a party that owns or  
17          controls a biosimilar biological product application  
18          filed with the Food and Drug Administration or has  
19          the exclusive rights under such application to dis-  
20          tribute the biosimilar biological product.

21          “(12) DRUG PRODUCT.—The term ‘drug prod-  
22          uct’ has the meaning given such term in section  
23          314.3(b) of title 21, Code of Federal Regulations (or  
24          any successor regulation).

1           “(13) MARKET.—The term ‘market’ means the  
2           promotion, offering for sale, selling, or distribution  
3           of a drug product.

4           “(14) NDA.—The term ‘NDA’ means a new  
5           drug application filed under section 505(b) of the  
6           Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
7           355(b)).

8           “(15) NDA HOLDER.—The term ‘NDA holder’  
9           means—

10                   “(A) the holder of an approved NDA appli-  
11                   cation for a drug product;

12                   “(B) a person owning or controlling en-  
13                   forcement of the patent listed in the Approved  
14                   Drug Products With Therapeutic Equivalence  
15                   Evaluations (commonly known as the ‘FDA Or-  
16                   ange Book’) in connection with the NDA; or

17                   “(C) the predecessors, subsidiaries, divi-  
18                   sions, groups, and affiliates controlled by, con-  
19                   trolling, or under common control with any of  
20                   the entities described in subparagraphs (A) and  
21                   (B) (such control to be presumed by direct or  
22                   indirect share ownership of 50 percent or great-  
23                   er), as well as the licensees, licensors, succes-  
24                   sors, and assigns of each of the entities.

1           “(16) PARTY.—The term ‘party’ means any  
2           person, partnership, corporation, or other legal enti-  
3           ty.

4           “(17) PATENT INFRINGEMENT.—The term  
5           ‘patent infringement’ means infringement of any  
6           patent or of any filed patent application, including  
7           any extension, reissue, renewal, division, continu-  
8           ation, continuation in part, reexamination, patent  
9           term restoration, patents of addition, and extensions  
10          thereof.

11          “(18) PATENT INFRINGEMENT CLAIM.—The  
12          term ‘patent infringement claim’ means any allega-  
13          tion made to an ANDA filer or biosimilar biological  
14          product application filer, whether or not included in  
15          a complaint filed with a court of law, that its ANDA  
16          or ANDA product, or biosimilar biological product li-  
17          cense application or biosimilar biological product,  
18          may infringe any patent held by, or exclusively li-  
19          censed to, the NDA holder, biological product license  
20          holder, ANDA filer, or biosimilar biological product  
21          application filer of the drug product or biological  
22          product, as applicable.

23          “(19) STATUTORY EXCLUSIVITY.—The term  
24          ‘statutory exclusivity’ means those prohibitions on  
25          the approval of drug applications under clauses (ii)



1 through (iv) of section 505(c)(3)(E) (5- and 3-year  
2 data exclusivity), section 527 (orphan drug exclu-  
3 sivity), or section 505A (pediatric exclusivity) of the  
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
5 355(c)(3)(E), 360cc, 355a), or on the licensing of  
6 biological product applications under section  
7 351(k)(7) (12-year exclusivity) or paragraph (2) or  
8 (3) of section 351(m) (pediatric exclusivity) of the  
9 Public Health Service Act (42 U.S.C. 262) or under  
10 section 527 of the Federal Food, Drug, and Cos-  
11 metic Act (21 U.S.C. 360cc) (orphan drug exclu-  
12 sivity).”.

13 (2) EFFECTIVE DATE.—Section 27 of the Fed-  
14 eral Trade Commission Act, as added by this sec-  
15 tion, shall apply to all agreements described in sec-  
16 tion 27(a)(1) of that Act entered into on or after the  
17 date of enactment of this Act.

18 (c) CERTIFICATION OF AGREEMENTS.—

19 (1) NOTICE OF ALL AGREEMENTS.—Section  
20 1111(7) of the Medicare Prescription Drug, Im-  
21 provement, and Modernization Act of 2003 (21  
22 U.S.C. 355 note) is amended by inserting “, or the  
23 owner of a patent for which a claim of infringement  
24 could reasonably be asserted against any person for  
25 making, using, offering to sell, selling, or importing

1       into the United States a biological product that is  
2       the subject of a biosimilar biological product applica-  
3       tion” before the period at the end.

4               (2) CERTIFICATION OF AGREEMENTS.—Section  
5       1112 of the Medicare Prescription Drug, Improve-  
6       ment, and Modernization Act of 2003 (21 U.S.C.  
7       355 note) is amended by adding at the end the fol-  
8       lowing:

9       “(d) CERTIFICATION.—The Chief Executive Officer  
10      or the company official responsible for negotiating any  
11      agreement under subsection (a) or (b) that is required to  
12      be filed under subsection (c), within 30 days after such  
13      filing, shall execute and file with the Assistant Attorney  
14      General and the Commission a certification as follows: ‘I  
15      declare that the following is true, correct, and complete  
16      to the best of my knowledge: The materials filed with the  
17      Federal Trade Commission and the Department of Justice  
18      under section 1112 of subtitle B of title XI of the Medi-  
19      care Prescription Drug, Improvement, and Modernization  
20      Act of 2003, with respect to the agreement referenced in  
21      this certification—

22               “(1) represent the complete, final, and exclu-  
23      sive agreement between the parties;

24               “(2) include any ancillary agreements that are  
25      contingent upon, provide a contingent condition for,

1 or are otherwise related to, the referenced agree-  
2 ment; and

3 ““(3) include written descriptions of any oral  
4 agreements, representations, commitments, or prom-  
5 ises between the parties that are responsive to sub-  
6 section (a) or (b) of such section 1112 and have not  
7 been reduced to writing.’”.

8 (d) NOTIFICATION OF AGREEMENTS.—Section 1112  
9 of the Medicare Prescription Drug, Improvement, and  
10 Modernization Act of 2003 (21 U.S.C. 355 note), as  
11 amended by section 4(b), is further amended by adding  
12 at the end the following:

13 “(e) RULE OF CONSTRUCTION.—

14 “(1) IN GENERAL.—An agreement that is re-  
15 quired under subsection (a) or (b) shall include  
16 agreements resolving any outstanding disputes, in-  
17 cluding agreements resolving or settling a Patent  
18 Trial and Appeal Board proceeding.

19 “(2) DEFINITION.—For purposes of subpara-  
20 graph (A), the term ‘Patent Trial and Appeal Board  
21 proceeding’ means a proceeding conducted by the  
22 Patent Trial and Appeal Board of the United States  
23 Patent and Trademark Office, including an inter  
24 partes review instituted under chapter 31 of title 35,  
25 United States Code, a post-grant review instituted

1 under chapter 32 of that title (including a pro-  
2 ceeding instituted pursuant to the transitional pro-  
3 gram for covered business method patents, as de-  
4 scribed in section 18 of the Leahy-Smith America  
5 Invents Act (35 U.S.C. 321 note)), and a derivation  
6 proceeding instituted under section 135 of that  
7 title.”.

8 (e) FORFEITURE OF 180-DAY EXCLUSIVITY PE-  
9 RIOD.—Section 505(j)(5)(D)(i)(V) of the Federal Food,  
10 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))  
11 is amended by inserting “section 27 of the Federal Trade  
12 Commission Act or” after “that the agreement has vio-  
13 lated”.

14 (f) COMMISSION LITIGATION AUTHORITY.—Section  
15 16(a)(2) of the Federal Trade Commission Act (15 U.S.C.  
16 56(a)(2)) is amended—

17 (1) in subparagraph (D), by striking “or” after  
18 the semicolon;

19 (2) in subparagraph (E), by inserting “or”  
20 after the semicolon; and

21 (3) inserting after subparagraph (E) the fol-  
22 lowing:

23 “(F) under section 27,”.

24 (g) REPORT ON ADDITIONAL EXCLUSION.—

1           (1) IN GENERAL.—Not later than 1 year after  
2           the date of enactment of this Act, the Federal Trade  
3           Commission shall submit to the Committee on the  
4           Judiciary of the Senate and the Committee on the  
5           Judiciary of the House of Representatives a rec-  
6           ommendation, and the Commission’s basis for such  
7           recommendation, regarding a potential amendment  
8           to include in section 27(c) of the Federal Trade  
9           Commission Act (as added by section 3 of this Act)  
10          an additional exclusion for consideration granted by  
11          an NDA holder to a ANDA filer or by a biological  
12          product license holder to a biosimilar biological prod-  
13          uct application filer as part of the resolution or set-  
14          tlement, a release, waiver, or limitation of a claim  
15          for damages or other monetary relief.

16          (2) DEFINITIONS.—In this section, the terms  
17          “ANDA filer”, “biological product license holder”,  
18          “biosimilar biological product application filer”, and  
19          “NDA holder” have the meanings given such terms  
20          in section 27(g) of the Federal Trade Commission  
21          Act (as added by section 3 of this Act).

22          (h) STATUTE OF LIMITATIONS.—The Federal Trade  
23          Commission shall commence any enforcement proceeding  
24          described in section 27 of the Federal Trade Commission  
25          Act, as added by section 3, except for an action described

1 in section 27(f)(2) of the Federal Trade Commission Act,  
2 not later than 6 years after the date on which the parties  
3 to the agreement file the certification under section  
4 1112(d) of the Medicare Prescription Drug Improvement  
5 and Modernization Act of 2003 (21 U.S.C. 355 note).

6 (i) SEVERABILITY.—If any provision of this Act, an  
7 amendment made by this Act, or the application of such  
8 provision or amendment to any person or circumstance is  
9 held to be unconstitutional, the remainder of this Act, the  
10 amendments made by this Act, and the application of the  
11 provisions of such Act or amendments to any person or  
12 circumstance shall not be affected.

13 **SEC. 406. EMPOWERING THE FTC TO PREVENT “PRODUCT**  
14 **HOPPING”.**

15 (a) IN GENERAL.—The Federal Trade Commission  
16 Act (15 U.S.C. 41 et seq.) is amended by inserting after  
17 section 26 (15 U.S.C. 57c–2) the following:

18 **“SEC. 27. PRODUCT HOPPING.**

19 “(a) DEFINITIONS.—In this section:

20 “(1) ABBREVIATED NEW DRUG APPLICATION.—

21 The term ‘abbreviated new drug application’ means  
22 an application under subsection (b)(2) or (j) of sec-  
23 tion 505 of the Federal Food, Drug, and Cosmetic  
24 Act (21 U.S.C. 355).

1           “(2) BIOSIMILAR BIOLOGICAL PRODUCT.—The  
2           term ‘biosimilar biological product’ means a biologi-  
3           cal product licensed under section 351(k) of the  
4           Public Health Service Act (42 U.S.C. 262(k)).

5           “(3) BIOSIMILAR BIOLOGICAL PRODUCT LI-  
6           CENSE APPLICATION.—The term ‘biosimilar biologi-  
7           cal product license application’ means an application  
8           submitted under section 351(k) of the Public Health  
9           Service Act (42 U.S.C. 262(k)).

10          “(4) FOLLOW-ON PRODUCT.—The term ‘follow-  
11          on product’—

12                 “(A) means a drug approved through an  
13                 application or supplement to an application sub-  
14                 mitted under section 505(b) of the Federal  
15                 Food, Drug, and Cosmetic Act (21 U.S.C.  
16                 355(b)) or a biological product licensed through  
17                 an application or supplement to an application  
18                 submitted under section 351(a) of the Public  
19                 Health Service Act (42 U.S.C. 262(a)) for a  
20                 change, modification, or reformulation to the  
21                 same manufacturer’s previously approved drug  
22                 or biological product that treats the same med-  
23                 ical condition; and

24                 “(B) excludes such an application or sup-  
25                 plement to an application for a change, modi-

1           fication, or reformulation of a drug or biological  
2           product that is requested by the Secretary or  
3           necessary to comply with law, including sections  
4           505A and 505B of the Federal Food, Drug,  
5           and Cosmetic Act (21 U.S.C. 355a, 355c).

6           “(5) GENERIC DRUG.—The term ‘generic drug’  
7           means a drug approved under an application sub-  
8           mitted under subsection (b)(2) or (j) of section 505  
9           of the Federal Food, Drug, and Cosmetic Act (21  
10          U.S.C. 355).

11          “(6) LISTED DRUG.—The term ‘listed drug’  
12          means a drug listed under section 505(j)(7) of the  
13          Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
14          355(j)(7)).

15          “(7) MANUFACTURER.—The term ‘manufac-  
16          turer’ means the holder, licensee, or assignee of—

17               “(A) an approved application for a drug  
18               under section 505(c) of the Federal Food,  
19               Drug, and Cosmetic Act (21 U.S.C. 355(c)); or

20               “(B) a biological product license under sec-  
21               tion 351(a) of the Public Health Service Act  
22               (42 U.S.C. 262(a)).

23          “(8) REFERENCE PRODUCT.—The term ‘ref-  
24          erence product’ has the meaning given the term in



1 section 351(i) of the Public Health Service Act (42  
2 U.S.C. 262(i)).

3 “(9) ULTIMATE PARENT ENTITY.—The term  
4 ‘ultimate parent entity’ has the meaning given the  
5 term in section 801.1 of title 16, Code of Federal  
6 Regulations, or any successor regulation.

7 “(b) PROHIBITION ON PRODUCT HOPPING.—

8 “(1) PRIMA FACIE.—Except as provided in  
9 paragraph (2), a manufacturer of a reference prod-  
10 uct or listed drug shall be considered to have en-  
11 gaged in an unfair method of competition in or af-  
12 fecting commerce in violation of section 5(a) if the  
13 Commission demonstrates by a preponderance of the  
14 evidence in a proceeding initiated by the Commission  
15 under subsection (c)(1)(A), or in a suit brought  
16 under subparagraph (B) or (C) of subsection (c)(1),  
17 that, during the period beginning on the date on  
18 which the manufacturer of the reference product or  
19 listed drug first receives notice that an applicant has  
20 submitted to the Commissioner of Food and Drugs  
21 an abbreviated new drug application or biosimilar bi-  
22 ological product license application and ending on  
23 the date that is 180 days after the date on which  
24 that generic drug or biosimilar biological product is

1 first marketed, the manufacturer engaged in either  
2 of the following actions:

3 “(A) The manufacturer engaged in a hard  
4 switch, which shall be established by dem-  
5 onstrating that the manufacturer engaged in ei-  
6 ther of the following actions:

7 “(i) Upon the request of the manufac-  
8 turer of the listed drug or reference prod-  
9 uct, the Commissioner of Food and Drugs  
10 withdrew the approval of the application  
11 for the listed drug or reference product or  
12 placed the listed drug or reference product  
13 on the discontinued products list and the  
14 manufacturer marketed or sold a follow-on  
15 product.

16 “(ii) The manufacturer of the listed  
17 drug or reference product—

18 “(I)(aa) announced withdrawal  
19 of, discontinuance of the manufacture  
20 of, or intent to withdraw the applica-  
21 tion with respect to the drug or ref-  
22 erence product in a manner that im-  
23 pedes competition from a generic drug  
24 or a biosimilar biological product, as

1 established by objective circumstances;  
2 or

3 “(bb) destroyed the inventory of  
4 the listed drug or reference product in  
5 a manner that impedes competition  
6 from a generic drug or a biosimilar bi-  
7 ological product, which may be estab-  
8 lished by objective circumstances; and

9 “(II) marketed or sold a follow-  
10 on product.

11 “(B) The manufacturer engaged in a soft  
12 switch, which shall be established by dem-  
13 onstrating that the manufacturer engaged in  
14 both of the following actions:

15 “(i) The manufacturer took actions  
16 with respect to the listed drug or reference  
17 product other than those described in sub-  
18 paragraph (A) that unfairly disadvantage  
19 the listed drug or reference product rel-  
20 ative to the follow-on product described in  
21 clause (ii) in a manner that impedes com-  
22 petition from a generic drug or a bio-  
23 similar biological product that is highly  
24 similar to, and has no clinically meaningful  
25 difference with respect to safety, purity,

1 and potency from, the reference product,  
2 which may be established by objective cir-  
3 cumstances.

4 “(ii) The manufacturer marketed or  
5 sold a follow-on product.

6 “(2) JUSTIFICATION.—

7 “(A) IN GENERAL.—Subject to paragraph  
8 (3), the actions described in paragraph (1) by  
9 a manufacturer of a listed drug or reference  
10 product shall not be considered to be an unfair  
11 method of competition in or affecting commerce  
12 if—

13 “(i) the manufacturer demonstrates to  
14 the Commission or a district court of the  
15 United States, as applicable, by a prepon-  
16 derance of the evidence in a proceeding ini-  
17 tiated by the Commission under subsection  
18 (c)(1)(A), or in a suit brought under sub-  
19 paragraph (B) or (C) of subsection (c)(1),  
20 that—

21 “(I) the manufacturer would  
22 have taken the actions regardless of  
23 whether a generic drug that ref-  
24 erences the listed drug or biosimilar  
25 biological product that references the

1 reference product had already entered  
2 the market; and

3 “(II)(aa) with respect to a hard  
4 switch under paragraph (1)(A), the  
5 manufacturer took the action for rea-  
6 sons relating to the safety risk to pa-  
7 tients of the listed drug or reference  
8 product;

9 “(bb) with respect to an action  
10 described in item (aa) or (bb) of para-  
11 graph (1)(A)(ii)(I), there is a supply  
12 disruption that—

13 “(AA) is outside of the con-  
14 trol of the manufacturer;

15 “(BB) prevents the produc-  
16 tion or distribution of the appli-  
17 cable listed drug or reference  
18 product; and

19 “(CC) cannot be remedied  
20 by reasonable efforts; or

21 “(cc) with respect to a soft  
22 switch under paragraph (1)(B), the  
23 manufacturer had legitimate pro-com-  
24 petitive reasons, apart from the finan-

1                   cial effects of reduced competition, to  
2                   take the action.

3                   “(B) RULE OF CONSTRUCTION.—Nothing  
4                   in subparagraph (A) may be construed to limit  
5                   the information that the Commission may oth-  
6                   erwise obtain in any proceeding or action insti-  
7                   tuted with respect to a violation of this section.

8                   “(3) RESPONSE.—With respect to a justifica-  
9                   tion offered by a manufacturer under paragraph (2),  
10                  the Commission may—

11                  “(A) rebut any evidence presented by a  
12                  manufacturer during that justification; or

13                  “(B) establish by a preponderance of the  
14                  evidence that, on balance, the pro-competitive  
15                  benefits from the conduct described in subpara-  
16                  graph (A) or (B) of paragraph (1), as applica-  
17                  ble, do not outweigh any anticompetitive effects  
18                  of the conduct, even in consideration of the jus-  
19                  tification so offered.

20                  “(c) ENFORCEMENT.—

21                  “(1) IN GENERAL.—If the Commission has rea-  
22                  son to believe that any manufacturer has violated, is  
23                  violating, or is about to violate this section, the  
24                  Commission may take any of the following actions:

25                  “(A) Institute a proceeding—

1 “(i) that, except as provided in para-  
2 graph (2), complies with the requirements  
3 under section 5(b); and

4 “(ii) in which the Commission may  
5 impose on the manufacturer any penalty  
6 that the Commission may impose for a vio-  
7 lation of section 5.

8 “(B) In the same manner and to the same  
9 extent as provided in section 13(b), bring suit  
10 in a district court of the United States to tem-  
11 porarily enjoin the action of the manufacturer.

12 “(C) Bring suit in a district court of the  
13 United States, in which the Commission may  
14 seek—

15 “(i) to permanently enjoin the action  
16 of the manufacturer;

17 “(ii) any of the remedies described in  
18 paragraph (3); and

19 “(iii) any other equitable remedy, in-  
20 cluding ancillary equitable relief.

21 “(2) JUDICIAL REVIEW.—

22 “(A) IN GENERAL.—Notwithstanding any  
23 provision of section 5, any manufacturer that is  
24 subject to a final order of the Commission that  
25 is issued in a proceeding instituted under para-

graph (1)(A) may, not later than 30 days after the date on which the Commission issues the order, petition for review of the order in—

“(i) the United States Court of Appeals for the District of Columbia Circuit; or

“(ii) the court of appeals of the United States for the circuit in which the ultimate parent entity of the manufacturer is incorporated.

“(B) TREATMENT OF FINDINGS.—In a review of an order issued by the Commission conducted by a court of appeals of the United States under subparagraph (A), the factual findings of the Commission shall be conclusive if those facts are supported by the evidence.

“(3) EQUITABLE REMEDIES.—

“(A) DISGORGEMENT.—

“(i) IN GENERAL.—In a suit brought under paragraph (1)(C), the Commission may seek, and the court may order, disgorgement of any unjust enrichment that a person obtained as a result of the violation that gives rise to the suit.



1           “(ii) CALCULATION.—Any disgorge-  
2           ment that is ordered with respect to a per-  
3           son under clause (i) shall be offset by any  
4           amount of restitution ordered under sub-  
5           paragraph (B).

6           “(iii) LIMITATIONS PERIOD.—The  
7           Commission may seek disgorgement under  
8           this subparagraph not later than 5 years  
9           after the latest date on which the person  
10          from which the disgorgement is sought re-  
11          ceives any unjust enrichment from the ef-  
12          fects of the violation that gives rise to the  
13          suit in which the Commission seeks the  
14          disgorgement.

15          “(B) RESTITUTION.—

16               “(i) IN GENERAL.—In a suit brought  
17               under paragraph (1)(C), the Commission  
18               may seek, and the court may order, res-  
19               titution with respect to the violation that  
20               gives rise to the suit.

21               “(ii) LIMITATIONS PERIOD.—The  
22               Commission may seek restitution under  
23               this subparagraph not later than 5 years  
24               after the latest date on which the person  
25               from which the restitution is sought re-

1 ceives any unjust enrichment from the ef-  
2 fects of the violation that gives rise to the  
3 suit in which the Commission seeks the  
4 restitution.

5 “(4) RULES OF CONSTRUCTION.—Nothing in  
6 this subsection may be construed as—

7 “(A) requiring the Commission to bring a  
8 suit seeking a temporary injunction under para-  
9 graph (1)(B) before bringing a suit seeking a  
10 permanent injunction under paragraph (1)(C);  
11 or

12 “(B) affecting any other authority of the  
13 Commission under this Act to seek relief or ob-  
14 tain a remedy with respect to a violation of this  
15 Act.”.

16 (b) APPLICABILITY.—Section 27 of the Federal  
17 Trade Commission Act, as added by subsection (a), shall  
18 apply with respect to any—

19 (1) conduct that occurs on or after the date of  
20 enactment of this Act; and

21 (2) action or proceeding that is commenced on  
22 or after the date of enactment of this Act.

23 (c) ANTITRUST LAWS.—Nothing in this section, or  
24 the amendments made by this section, shall modify, im-  
25 pair, limit, or supersede the applicability of the antitrust

1 laws as defined in subsection (a) of the first section of  
 2 the Clayton Act (15 U.S.C. 12(a)), and of section 5 of  
 3 the Federal Trade Commission Act (15 U.S.C. 45) to the  
 4 extent that it applies to unfair methods of competition.

5 (d) RULEMAKING.—The Federal Trade Commission  
 6 may issue rules under section 553 of title 5, United States  
 7 Code, to carry out section 27 of the Federal Trade Com-  
 8 mission Act, as added by subsection (a), including by de-  
 9 fining any terms used in such section 27 (other than terms  
 10 that are defined in subsection (a) of such section 27).

11 **SEC. 407. PROMOTING COMPETITION BY LIMITING PATENT**  
 12 **THICKETS.**

13 (a) IN GENERAL.—Section 271(e) of title 35, United  
 14 States Code, is amended—

15 (1) in paragraph (2)(C), in the flush text fol-  
 16 lowing clause (ii), by adding at the end the fol-  
 17 lowing: “With respect to a submission described in  
 18 clause (ii), the act of infringement shall extend to  
 19 any patent that claims the biological product, a  
 20 method of using the biological product, or a method  
 21 or product used to manufacture the biological prod-  
 22 uct.”; and

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

24 “(7)(A) Subject to subparagraphs (C), (D), and (E),  
 25 if the sponsor of an approved application for a reference

1 product, as defined in section 351(i) of the Public Health  
2 Service Act (42 U.S.C. 262(i)) (referred to in this para-  
3 graph as the ‘reference product sponsor’), brings an action  
4 for infringement under this section against an applicant  
5 for approval of a biological product under section 351(k)  
6 of such Act that references that reference product (re-  
7 ferred to in this paragraph as the ‘subsection (k) appli-  
8 cant’), the reference product sponsor may assert in the  
9 action a total of not more than 20 patents of the type  
10 described in subparagraph (B), not more than 10 of which  
11 shall have issued after the date specified in section  
12 351(l)(7)(A) of such Act.

13 “(B) The patents described in this subparagraph are  
14 patents that satisfy each of the following requirements:

15 “(i) Patents that claim the biological product  
16 that is the subject of an application under section  
17 351(k) of the Public Health Service Act (42 U.S.C.  
18 262(k)) (or a use of that product) or a method or  
19 product used in the manufacture of such biological  
20 product.

21 “(ii) Patents that are included on the list of  
22 patents described in section 351(l)(3)(A) of the Pub-  
23 lic Health Service Act (42 U.S.C. 262(l)(3)(A)), in-  
24 cluding as provided under section 351(l)(7) of such  
25 Act.

1 “(iii) Patents that—

2 “(I) have an actual filing date of more  
3 than 4 years after the date on which the ref-  
4 erence product is approved; or

5 “(II) include a claim to a method in a  
6 manufacturing process that is not used by the  
7 reference product sponsor.

8 “(C) The court in which an action described in sub-  
9 paragraph (A) is brought may increase the number of pat-  
10 ents limited under that subparagraph—

11 “(i) if the request to increase that number is  
12 made without undue delay; and

13 “(ii)(I) if the interest of justice so requires; or

14 “(II) for good cause shown, which—

15 “(aa) shall be established if the subsection  
16 (k) applicant fails to provide information re-  
17 quired under section 351(l)(2)(A) of the Public  
18 Health Service Act (42 U.S.C. 262(l)(2)(A))  
19 that would enable the reference product sponsor  
20 to form a reasonable belief with respect to  
21 whether a claim of infringement under this sec-  
22 tion could reasonably be asserted; and

23 “(bb) may be established—

24 “(AA) if there is a material change to  
25 the biological product (or process with re-

1           spect to the biological product) of the sub-  
2           section (k) applicant that is the subject of  
3           the application;

4           “(BB) if, with respect to a patent on  
5           the supplemental list described in section  
6           351(l)(7)(A) of Public Health Service Act  
7           (42 U.S.C. 262(l)(7)(A)), the patent would  
8           have issued before the date specified in  
9           such section 351(l)(7)(A) but for the fail-  
10          ure of the Office to issue the patent or a  
11          delay in the issuance of the patent, as de-  
12          scribed in paragraph (1) of section 154(b)  
13          and subject to the limitations under para-  
14          graph (2) of such section 154(b); or

15          “(CC) for another reason that shows  
16          good cause, as determined appropriate by  
17          the court.

18          “(D) In determining whether good cause has been  
19          shown for the purposes of subparagraph (C)(ii)(II), a  
20          court may consider whether the reference product sponsor  
21          has provided a reasonable description of the identity and  
22          relevance of any information beyond the subsection (k) ap-  
23          plication that the court believes is necessary to enable the  
24          court to form a belief with respect to whether a claim of

1 infringement under this section could reasonably be as-  
 2 serted.

3 “(E) The limitation imposed under subparagraph  
 4 (A)—

5 “(i) shall apply only if the subsection (k) appli-  
 6 cant completes all actions required under paragraphs  
 7 (2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of  
 8 section 351(l) of the Public Health Service Act (42  
 9 U.S.C. 262(l)); and

10 “(ii) shall not apply with respect to any patent  
 11 that claims, with respect to a biological product, a  
 12 method for using that product in therapy, diagnosis,  
 13 or prophylaxis, such as an indication or method of  
 14 treatment or other condition of use.”.

15 (b) APPLICABILITY.—The amendments made by sub-  
 16 section (a) shall apply with respect to an application sub-  
 17 mitted under section 351(k) of the Public Health Service  
 18 Act (42 U.S.C. 262(k)) on or after the date of enactment  
 19 of this Act.

## 20 **TITLE V—BENEFICIARY COST** 21 **SHARING FAIRNESS**

### 22 **SEC. 501. REPEALING OF RULE BY THE DEPARTMENT OF** 23 **HEALTH AND HUMAN SERVICES.**

24 The final rule of the Department of Health and  
 25 Human Services titled “Fraud And Abuse; Removal of

1 Safe Harbor Protection for Rebates Involving Prescription  
2 Pharmaceuticals And Creation of New Safe Harbor Pro-  
3 tection for Certain Point-of-Sale Reductions in Price on  
4 Prescription Pharmaceuticals and Certain Pharmacy Ben-  
5 efit Manager Service Fees; Additional Delayed Effective  
6 Date” published on November 30, 2020 (85 Fed. Reg.  
7 76666–76731), shall have no force or effect of law.

8 **SEC. 502. DEFINING COST UNDER PRESCRIPTION DRUG**  
9 **PLANS UNDER PART D OF MEDICARE.**

10 Section 1860D–2(b)(2)(A) of the Social Security Act  
11 (42 U.S.C. 1395w–102(b)(2)(A)) is amended—

12 (1) in clause (i), by inserting “of the net costs  
13 to the plan, inclusive of all direct and indirect remu-  
14 nation, including rebates paid by manufacturers to  
15 the plan sponsor, either directly or through a phar-  
16 macy benefit manager or other third party” before  
17 the semicolon; and

18 (2) in clause (ii), by inserting “net” before  
19 “costs”.

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