

**AMENDMENT TO THE AMENDMENT IN THE NA-  
TURE OF A SUBSTITUTE TO COMMITTEE  
PRINT FOR SUBTITLE E RELATING TO DRUG  
PRICING**

**OFFERED BY M**\_\_ . \_\_\_\_\_

Strike all and insert the following:

- 1                   **Subtitle E—Drug Pricing**  
2                   **PART 1—MEDICARE PARTS B AND D**  
3                   **Subpart A—Medicare Part B Provisions**  
4   **SEC. 30501. IMPROVEMENTS TO MEDICARE SITE-OF-SERV-**  
5                   **ICE TRANSPARENCY.**  
6                   Section 1834(t) of the Social Security Act (42 U.S.C.  
7 1395m(t)) is amended—  
8                   (1) in paragraph (1)—  
9                   (A) in the heading, by striking “IN GEN-  
10 ERAL” and inserting “SITE PAYMENT”;  
11                   (B) in the matter preceding subparagraph  
12 (A)—  
13                   (i) by striking “or to” and inserting “,  
14 to”;  
15                   (ii) by inserting “, or to a physician  
16 for services furnished in a physician’s of-  
17 fice” after “surgical center”; and

1 (iii) by inserting “(or 2022 with re-  
2 spect to a physician for services furnished  
3 in a physician’s office)” after “2018”; and  
4 (C) in subparagraph (A)—

5 (i) by striking “and the” and insert-  
6 ing “, the”; and

7 (ii) by inserting “, and the physician  
8 fee schedule under section 1848 (with re-  
9 spect to the practice expense component of  
10 such payment amount)” after “such sec-  
11 tion”;

12 (2) by redesignating paragraphs (2) through  
13 (4) as paragraphs (3) through (5), respectively; and

14 (3) by inserting after paragraph (1) the fol-  
15 lowing new paragraph:

16 “(2) PHYSICIAN PAYMENT.—Beginning in  
17 2022, the Secretary shall expand the information in-  
18 cluded on the Internet website described in para-  
19 graph (1) to include—

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

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

1 **SEC. 30502. REQUIRING MANUFACTURERS OF CERTAIN SIN-**  
2 **GLE-DOSE CONTAINER OR SINGLE-USE PACK-**  
3 **AGE DRUGS PAYABLE UNDER PART B OF THE**  
4 **MEDICARE PROGRAM TO PROVIDE REFUNDS**  
5 **WITH RESPECT TO DISCARDED AMOUNTS OF**  
6 **SUCH DRUGS.**

7 Section 1847A of the Social Security Act (42 U.S.C.  
8 1395w-3a) is amended by adding at the end the following  
9 new subsection:

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

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

14 “(A) IN GENERAL.—For each calendar  
15 quarter beginning on or after January 1, 2022,  
16 the Secretary shall, with respect to a refundable  
17 single-dose container or single-use package drug  
18 (as defined in paragraph (8)), report to each  
19 manufacturer (as defined in subsection  
20 (c)(6)(A)) of such refundable single-dose con-  
21 tainer or single-use package drug the following  
22 for the calendar quarter:

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

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

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

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

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

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

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

12 “(3) REFUND AMOUNT.—

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

21 “(i) the product of—

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

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

3 “(II)(aa) in the case of a refund-  
4 able single-dose container or single-  
5 use package drug that is a single  
6 source drug or biological, the amount  
7 of payment determined for such drug  
8 or biological under subsection  
9 (b)(1)(B) for such quarter; or

10 “(bb) in the case of a refundable  
11 single-dose container or single-use  
12 package drug that is a biosimilar bio-  
13 logical product, the amount of pay-  
14 ment determined for such product  
15 under subsection (b)(1)(C) for such  
16 quarter; exceeds

17 “(ii) an amount equal to the applica-  
18 ble percentage (as defined in subparagraph  
19 (B)) of the estimated total allowed charges  
20 for such drug under this part during the  
21 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) if applicable, in the case of  
7                               a refundable single-dose container or  
8                               single-use package drug described in  
9                               clause (ii), a percentage specified by  
10                              the Secretary pursuant to such clause.

11                   “(ii) TREATMENT OF DRUGS THAT  
12                   HAVE UNIQUE CIRCUMSTANCES.—In the  
13                   case of a refundable single-dose container  
14                   or single-use package drug that has unique  
15                   circumstances involving similar loss of  
16                   product as that described in paragraph  
17                   (8)(B)(ii), the Secretary, through notice  
18                   and comment rulemaking, may increase  
19                   the applicable percentage otherwise appli-  
20                   cable under clause (i)(I) as determined ap-  
21                   propriate by the Secretary.

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

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

5           “(6) ENFORCEMENT.—

6           “(A) AUDITS.—

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

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

22           “(B) CIVIL MONEY PENALTY.—

23           “(i) IN GENERAL.—The Secretary  
24 shall impose a civil money penalty on a  
25 manufacturer of a refundable single-dose



1 container or single-use package drug who  
2 has failed to comply with the requirement  
3 under paragraph (2) for such drug for a  
4 calendar quarter in an amount equal to the  
5 sum of—

6 “(I) the amount that the manu-  
7 facturer would have paid under such  
8 paragraph with respect to such drug  
9 for such quarter; and

10 “(II) 25 percent of such amount.

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

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

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

23 “(A) IN GENERAL.—Except as provided in  
24 subparagraph (B), in this subsection, the term  
25 ‘refundable single-dose container or single-use

1 package drug’ means a single source drug or bi-  
2 ological (as defined in section 1847A(c)(6)(D))  
3 or a biosimilar biological product (as defined in  
4 section 1847A(c)(6)(H)) for which payment is  
5 made under this part and that is furnished  
6 from a single-dose container or single-use pack-  
7 age.

8 “(B) EXCLUSIONS.—The term ‘refundable  
9 single-dose container or single-use package  
10 drug’ does not include—

11 “(i) a drug or biological that is either  
12 a radiopharmaceutical or an imaging  
13 agent;

14 “(ii) a drug or biological approved by  
15 the Food and Drug Administration for  
16 which dosage and administration instruc-  
17 tions included in the labeling require filtra-  
18 tion during the drug preparation process,  
19 prior to dilution and administration, and  
20 require that any unused portion of such  
21 drug after the filtration process be dis-  
22 carded after the completion of such filtra-  
23 tion process; or

24 “(iii) a drug or biological approved by  
25 the Food and Drug Administration on or

1           after the date of enactment of this sub-  
2           section and with respect to which payment  
3           has been made under this part for fewer  
4           than 18 months.

5           “(9) REPORT TO CONGRESS.—Not later than 3  
6           years after the date of enactment of this subsection,  
7           the Office of the Inspector General, after consulta-  
8           tion with the Centers for Medicare & Medicaid Serv-  
9           ices and the Food and Drug Administration, shall  
10          submit to the Committee on Energy and Commerce  
11          and the Committee on Ways and Means of the  
12          House of Representatives and the Committee on Fi-  
13          nance in the Senate, a report on any impact this  
14          section is reported to have on the licensure, market  
15          entry, market retention, or marketing of biosimilar  
16          biological products. Such report shall be updated pe-  
17          riodically at the direction of the Committee on En-  
18          ergy and Commerce and the Committee on Ways  
19          and Means of the House of Representatives and the  
20          Committee on Finance in the Senate.”.

21 **SEC. 30503. PROVIDING FOR VARIATION IN PAYMENT FOR**  
22 **CERTAIN DRUGS COVERED UNDER PART B**  
23 **OF THE MEDICARE PROGRAM.**

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

1 (1) in paragraph (1)—

2 (A) in subparagraph (A), by inserting after  
3 “or 106 percent” the following: “(or, for a mul-  
4 tiple source drug (other than autologous cellular  
5 immunotherapy) furnished on or after January  
6 1, 2022, the applicable percent specified in  
7 paragraph (9)(A) for the drug and quarter in-  
8 volved)”; and

9 (B) in subparagraph (B) of paragraph (1),  
10 by inserting after “106 percent” the following:  
11 “(or, for a single source drug or biological  
12 (other than autologous cellular immunotherapy)  
13 furnished on or after January 1, 2022, the ap-  
14 plicable percent specified in paragraph (9)(A)  
15 for the drug or biological and quarter in-  
16 volved)”; and

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

19 “(9) APPLICATION OF VARIABLE PERCENTAGES  
20 BASED ON PERCENTILE RANKING OF PER BENE-  
21 FICIARY ALLOWED CHARGES.—

22 “(A) APPLICABLE PERCENT TO BE AP-  
23 PLIED.—

24 “(i) IN GENERAL.—Subject to clauses  
25 (ii), with respect to a drug or biological

1 furnished in a calendar quarter beginning  
2 on or after January 1, 2022, if the Sec-  
3 retary determines that the percentile rank  
4 of a drug or biological under subparagraph  
5 (B)(i)(III), with respect to per beneficiary  
6 allowed charges for all such drugs or  
7 biologicals, is—

8 “(I) at least equal to the 85th  
9 percentile, the applicable percent for  
10 the drug for such quarter under this  
11 subparagraph is 104 percent;

12 “(II) at least equal to the 70th  
13 percentile, but less than the 85th per-  
14 centile, such applicable percent is 106  
15 percent;

16 “(III) at least equal to the 50th  
17 percentile, but less than the 70th per-  
18 centile, such applicable percent is 108  
19 percent; or

20 “(IV) less than the 50th per-  
21 centile, such applicable percent is 110  
22 percent.

23 “(ii) CASES WHERE DATA NOT SUFFI-  
24 CIENTLY AVAILABLE TO COMPUTE PER  
25 BENEFICIARY ALLOWED CHARGES.—Sub-

1           ject to clause (iii), in the case of a drug or  
2           biological furnished for which the amount  
3           of payment is determined under subpara-  
4           graph (A) or (B) of paragraph (1) and not  
5           under subsection (c)(4), for calendar quar-  
6           ters during a period in which data are not  
7           sufficiently available to compute a per ben-  
8           eficiary allowed charges for the drug or bi-  
9           ological, the applicable percent is 106 per-  
10          cent.

11           “(B) DETERMINATION OF PERCENTILE  
12          RANK OF PER BENEFICIARY ALLOWED CHARGES  
13          OF DRUGS.—

14           “(i) IN GENERAL.—With respect to a  
15          calendar quarter beginning on or after  
16          January 1, 2022, for drugs and biologicals  
17          for which the amount of payment is deter-  
18          mined under subparagraph (A) or (B) of  
19          paragraph (1), except for drugs or  
20          biologicals for which data are not suffi-  
21          ciently available, the Secretary shall—

22           “(I) compute the per beneficiary  
23          allowed charges (as defined in sub-  
24          paragraph (C)) for each such drug or  
25          biological;

1                   “(II) adjust such per beneficiary  
2                   allowed charges for the quarter, to the  
3                   extent provided under subparagraph  
4                   (D); and

5                   “(III) array such adjusted per  
6                   beneficiary allowed charges for all  
7                   such drugs or biologicals from high to  
8                   low and rank such drugs or biologicals  
9                   by percentile of such arrayed per ben-  
10                  eficiary allowed charges.

11                  “(ii) FREQUENCY.—The Secretary  
12                  shall make the computations under clause  
13                  (i)(I) every 6 months (or, if necessary, as  
14                  determined by the Secretary, every 9 or 12  
15                  months) and such computations shall apply  
16                  to succeeding calendar quarters until a  
17                  new computation has been made.

18                  “(iii) APPLICABLE DATA PERIOD.—  
19                  For purposes of this paragraph, the term  
20                  ‘applicable data period’ means the most re-  
21                  cent period for which the data necessary  
22                  for making the computations under clause  
23                  (i) are available, as determined by the Sec-  
24                  retary.

1           “(C) PER BENEFICIARY ALLOWED  
2 CHARGES DEFINED.—In this paragraph, the  
3 term ‘per beneficiary allowed charges’ means,  
4 with respect to a drug or biological for which  
5 the amount of payment is determined under  
6 subparagraph (A) or (B) of paragraph (1)—

7           “(i) the allowed charges for the drug  
8 or biological for which payment is so made  
9 for the applicable data period, as estimated  
10 by the Secretary; divided by

11           “(ii) the number of individuals for  
12 whom any payment for the drug or biologi-  
13 cal was made under paragraph (1) for the  
14 applicable data period, as estimated by the  
15 Secretary.

16           “(D) ADJUSTMENT TO REFLECT CHANGES  
17 IN AVERAGE SALES PRICE.—In applying this  
18 paragraph for a particular calendar quarter, the  
19 Secretary shall adjust the per beneficiary al-  
20 lowed charges for a drug or biological by multi-  
21 plying such per beneficiary allowed charges  
22 under subparagraph (C) for the applicable data  
23 period by the ratio of—

24           “(i) the average sales price for the  
25 drug or biological for the most recent cal-



1           endar quarter used under subsection  
2           (c)(5)(B); to

3           “(ii) the average sales price for the  
4           drug or biological for the calendar quarter  
5           (or the weighted average for the quarters  
6           involved) included in the applicable data  
7           period.”.

8           (b) APPLICATION OF JUDICIAL REVIEW PROVI-  
9           SIONS.—Section 1847A(g) of the Social Security Act is  
10          amended—

11           (1) by striking “and” at the end of paragraph  
12           (4);

13           (2) by striking the period at the end of para-  
14           graph (5) and inserting “; and”; and

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

17           “(6) the determination of per beneficiary al-  
18           lowed charges of drugs or biologicals and ranking of  
19           such charges under subsection (b)(9).”.

20           **SEC. 30504. ESTABLISHMENT OF MAXIMUM ADD-ON PAY-**  
21           **MENT FOR DRUGS AND BIOLOGICALS.**

22           (a) IN GENERAL.—Section 1847A of the Social Secu-  
23           rity Act (42 U.S.C. 1395w–3a), as amended by section  
24           103, is further amended—

25           (1) in subsection (b)—

1 (A) in paragraph (1), in the matter pre-  
2 ceeding subparagraph (A), by striking “para-  
3 graph (7)” and inserting “paragraphs (7) and  
4 (10)”; and

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

7 “(10) MAXIMUM ADD-ON PAYMENT AMOUNT.—

8 “(A) IN GENERAL.—In determining the  
9 payment amount under the provisions of sub-  
10 paragraph (A), (B), or (C) of paragraph (1) of  
11 this subsection, subsection (c)(4)(A)(ii), or sub-  
12 section (d)(3)(C) for a drug or biological fur-  
13 nished on or after January 1, 2022, if the ap-  
14 plicable add-on payment (as defined in subpara-  
15 graph (B)) for each drug or biological on a  
16 claim for a date of service exceeds the max-  
17 imum add-on payment amount specified under  
18 subparagraph (C) for the drug or biological,  
19 then the payment amount otherwise determined  
20 for the drug or biological under those provi-  
21 sions, as applicable, shall be reduced by the  
22 amount of such excess.

23 “(B) APPLICABLE ADD-ON PAYMENT DE-  
24 FINED.—In this paragraph, the term ‘applicable  
25 add-on payment’ means the following amounts,

1 determined without regard to the application of  
2 subparagraph (A):

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

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

9 “(II) the amount that would be  
10 applied under such paragraph if ‘100  
11 percent’ were substituted for the ap-  
12 plicable percent (as defined in para-  
13 graph (9)) for such drug.

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

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

20 “(II) the amount that would be  
21 applied under such paragraph if ‘100  
22 percent’ were substituted for the ap-  
23 plicable percent (as defined in para-  
24 graph (9)) for such drug or biological.

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

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

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

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

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

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

20 “(v) In the case of a drug or biologi-  
21 cal to which subsection (d)(3)(C) applies,  
22 an amount equal to the difference be-  
23 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) with respect to a drug or biologi-  
18                               cal (other than autologous cellular  
19                               immunotherapy)—

20                               “(I) for each of 2022 through  
21                               2029, \$1,000; and

22                               “(II) for a subsequent year, the  
23                               amount specified in this subparagraph  
24                               for the preceding year increased by  
25                               the percentage increase in the con-

1 consumer price index for all urban con-  
2 sumers (all items; United States city  
3 average) for the 12-month period end-  
4 ing with June of the previous year; or  
5 “(ii) with respect to a drug or biologi-  
6 cal consisting of autologous cellular  
7 immunotherapy—

8 “(I) for each of 2022 through  
9 2029, \$2,000; and

10 “(II) for a subsequent year, the  
11 amount specified in this subparagraph  
12 for the preceding year increased by  
13 the percentage increase in the con-  
14 sumer price index for all urban con-  
15 sumers (all items; United States city  
16 average) for the 12-month period end-  
17 ing with June of the previous year.

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

21 (2) in subsection (c)(4)(A)(ii), by striking “in  
22 the case” and inserting “subject to subsection  
23 (b)(10), in the case”.

24 (b) CONFORMING AMENDMENTS RELATING TO SEPA-  
25 RATELY PAYABLE DRUGS.—

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

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

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

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

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

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

2 (B) by redesignating clause (vi) as clause

3 (vii); and

4 (C) by inserting after clause (v) the fol-  
5 lowing new clause:

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

16 **SEC. 30505. TREATMENT OF DRUG ADMINISTRATION SERV-**  
17 **ICES FURNISHED BY CERTAIN EXCEPTED**  
18 **OFF-CAMPUS OUTPATIENT DEPARTMENTS OF**  
19 **A PROVIDER.**

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

23 “(G) SPECIAL PAYMENT RULE FOR DRUG  
24 ADMINISTRATION SERVICES FURNISHED BY AN  
25 EXCEPTED DEPARTMENT OF A PROVIDER.—



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

14                   “(ii) APPLICATION WITHOUT REGARD  
15 TO BUDGET NEUTRALITY.—The reductions  
16 made under this subparagraph—

17                                 “(I) shall not be considered an  
18 adjustment under paragraph (2)(E);  
19 and

20                                 “(II) shall not be implemented in  
21 a budget neutral manner.”.

1                   **Subpart B—Drug Price Transparency**

2   **SEC. 30511. REPORTING ON EXPLANATION FOR DRUG**  
3                   **PRICE INCREASES.**

4           (a) IN GENERAL.—Title III of the Public Health  
5 Service Act (42 U.S.C. 241 et seq.) is amended by adding  
6 at the end the following:

7           **“PART W—DRUG PRICE REPORTING; DRUG**  
8                   **VALUE FUND**

9   **“SEC. 39900. REPORTING ON EXPLANATION FOR DRUG**  
10                   **PRICE INCREASES.**

11           “(a) DEFINITIONS.—In this section:

12                   “(1) MANUFACTURER.—The term ‘manufac-  
13 turer’ means the person—

14                           “(A) that holds the application for a drug  
15 approved under section 505 of the Federal  
16 Food, Drug, and Cosmetic Act or licensed  
17 under section 351 of this Act; or

18                           “(B) who is responsible for setting the  
19 wholesale acquisition cost for the drug.

20                   “(2) QUALIFYING DRUG.—The term ‘qualifying  
21 drug’ means any drug that is approved under sub-  
22 section (c) or (j) of section 505 of the Federal Food,  
23 Drug, and Cosmetic Act or licensed under subsection  
24 (a) or (k) of section 351 of this Act—

25                           “(A) that has a wholesale acquisition cost  
26 of \$100 or more, adjusted for inflation occur-

1 ring after the date of enactment of this section,  
2 for a month’s supply or a typical course of  
3 treatment that lasts less than a month, and  
4 is—

5 “(i) subject to section 503(b)(1) of  
6 the Federal Food, Drug, and Cosmetic  
7 Act;

8 “(ii) administered or otherwise dis-  
9 pensed to treat a disease or condition af-  
10 fecting more than 200,000 persons in the  
11 United States; and

12 “(iii) not a vaccine; and

13 “(B) for which, during the previous cal-  
14 endar year, at least 1 dollar of the total amount  
15 of sales were for individuals enrolled under the  
16 Medicare program under title XVIII of the So-  
17 cial Security Act (42 U.S.C. 1395 et seq.) or  
18 under a State Medicaid plan under title XIX of  
19 such Act (42 U.S.C. 1396 et seq.) or under a  
20 waiver of such plan.

21 “(3) WHOLESALE ACQUISITION COST.—The  
22 term ‘wholesale acquisition cost’ has the meaning  
23 given that term in section 1847A(c)(6)(B) of the So-  
24 cial Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).

25 “(b) REPORT.—

1           “(1) REPORT REQUIRED.—The manufacturer of  
2 a qualifying drug shall submit a report to the Sec-  
3 retary for each increase in the price of a qualifying  
4 drug that results in an increase in the wholesale ac-  
5 quisition cost of that drug that is equal to—

6           “(A) 10 percent or more within a single  
7 calendar year beginning on or after January 1,  
8 2021; or

9           “(B) 25 percent or more within three con-  
10 secutive calendar years for which the first such  
11 calendar year begins on or after January 1,  
12 2021.

13           “(2) REPORT DEADLINE.—Each report de-  
14 scribed in paragraph (1) shall be submitted to the  
15 Secretary—

16           “(A) in the case of a report with respect  
17 to an increase in the price of a qualifying drug  
18 that occurs during the period beginning on Jan-  
19 uary 1, 2021, and ending on the day that is 60  
20 days after the date of enactment of this section,  
21 not later than 90 days after such date of enact-  
22 ment; and

23           “(B) in the case of a report with respect  
24 to an increase in the price of a qualifying drug  
25 that occurs after the period described in sub-

1 paragraph (A), not later than 30 days prior to  
2 the planned effective date of such price increase  
3 for such qualifying drug.

4 “(c) CONTENTS.—A report under subsection (b), con-  
5 sistent with the standard for disclosures described in sec-  
6 tion 213.3(d) of title 12, Code of Federal Regulations (as  
7 in effect on the date of enactment of this section), shall,  
8 at a minimum, include—

9 “(1) with respect to the qualifying drug—

10 “(A) the percentage by which the manufac-  
11 turer will raise the wholesale acquisition cost of  
12 the drug within the calendar year or three con-  
13 secutive calendar years as described in sub-  
14 section (b)(1)(A) or (b)(1)(B), if applicable, and  
15 the effective date of such price increase;

16 “(B) an explanation for, and description  
17 of, each price increase for such drug that will  
18 occur during the calendar year period described  
19 in subsection (b)(1)(A) or the three consecutive  
20 calendar year period described in subsection  
21 (b)(1)(B), as applicable;

22 “(C) if known and different from the man-  
23 ufacturer of the qualifying drug, the identity  
24 of—

1           “(i) the sponsor or sponsors of any in-  
2           vestigational new drug applications under  
3           section 505(i) of the Federal Food, Drug,  
4           and Cosmetic Act for clinical investigations  
5           with respect to such drug, for which the  
6           full reports are submitted as part of the  
7           application—

8                   “(I) for approval of the drug  
9                   under section 505 of such Act; or

10                   “(II) for licensure of the drug  
11                   under section 351 of this Act; and

12           “(ii) the sponsor of an application for  
13           the drug approved under such section 505  
14           of the Federal Food, Drug, and Cosmetic  
15           Act or licensed under section 351 of this  
16           Act;

17           “(D) a description of the history of the  
18           manufacturer’s price increases for the drug  
19           since the approval of the application for the  
20           drug under section 505 of the Federal Food,  
21           Drug, and Cosmetic Act or the issuance of the  
22           license for the drug under section 351 of this  
23           Act, or since the manufacturer acquired such  
24           approved application or license, if applicable;

1                   “(E) the current wholesale acquisition cost  
2 of the drug;

3                   “(F) the total expenditures of the manu-  
4 facturer on—

5                   “(i) materials and manufacturing for  
6 such drug; and

7                   “(ii) acquiring patents and licensing  
8 for such drug;

9                   “(G) the percentage of total expenditures  
10 of the manufacturer on research and develop-  
11 ment for such drug that was derived from Fed-  
12 eral funds;

13                   “(H) the total expenditures of the manu-  
14 facturer on research and development for such  
15 drug that is necessary to demonstrate that it  
16 meets applicable statutory standards for ap-  
17 proval under section 505 of the Federal Food,  
18 Drug, and Cosmetic Act or licensure under sec-  
19 tion 351 of this Act, as applicable;

20                   “(I) the total expenditures of the manufac-  
21 turer on pursuing new or expanded indications  
22 or dosage changes for such drug under section  
23 505 of the Federal Food, Drug, and Cosmetic  
24 Act or section 351 of this Act;

1           “(J) the total expenditures of the manufac-  
2           turer on carrying out postmarket requirements  
3           related to such drug, including under section  
4           505(o)(3) of the Federal Food, Drug, and Cos-  
5           metic Act;

6           “(K) the total revenue and the net profit  
7           generated from the qualifying drug for each cal-  
8           endar year since the approval of the application  
9           for the drug under section 505 of the Federal  
10          Food, Drug, and Cosmetic Act or the issuance  
11          of the license for the drug under section 351,  
12          or since the manufacturer acquired such ap-  
13          proved application or license; and

14          “(L) the total costs associated with mar-  
15          keting and advertising for the qualifying drug;  
16          “(2) with respect to the manufacturer—

17          “(A) the total revenue and the net profit  
18          of the manufacturer for each of the 1-year pe-  
19          riod described in subsection (b)(1)(A) or the 3-  
20          year period described in subsection (b)(1)(B),  
21          as applicable;

22          “(B) all stock-based performance metrics  
23          used by the manufacturer to determine execu-  
24          tive compensation for each of the 1-year period  
25          described in subsection (b)(1)(A) or the 3-year



1 period described in subsection (b)(1)(B), as ap-  
2 plicable; and

3 “(C) any additional information the manu-  
4 facturer chooses to provide related to drug pric-  
5 ing decisions, such as total expenditures on—

6 “(i) drug research and development;

7 or

8 “(ii) clinical trials, including on drugs  
9 that failed to receive approval by the Food  
10 and Drug Administration; and

11 “(3) such other related information as the Sec-  
12 retary considers appropriate and as specified by the  
13 Secretary through notice-and-comment rulemaking.

14 “(d) INFORMATION PROVIDED.—The manufacturer  
15 of a qualifying drug that is required to submit a report  
16 under subsection (b), shall ensure that such report and  
17 any explanation for, and description of, each price increase  
18 described in subsection (c)(1)(B) shall be truthful, not  
19 misleading, and accurate.

20 “(e) CIVIL MONETARY PENALTY.—Any manufac-  
21 turer of a qualifying drug that fails to submit a report  
22 for the drug as required by this section, following notifica-  
23 tion by the Secretary to the manufacturer that the manu-  
24 facturer is not in compliance with this section, shall be

1 subject to a civil monetary penalty of \$75,000 for each  
2 day on which the violation continues.

3 “(f) FALSE INFORMATION.—Any manufacturer that  
4 submits a report for a drug as required by this section  
5 that knowingly provides false information in such report  
6 is subject to a civil monetary penalty in an amount not  
7 to exceed \$75,000 for each item of false information.

8 “(g) PUBLIC POSTING.—

9 “(1) IN GENERAL.—Subject to paragraph (3),  
10 the Secretary shall post each report submitted under  
11 subsection (b) on the public website of the Depart-  
12 ment of Health and Human Services the day the  
13 price increase of a qualifying drug is scheduled to go  
14 into effect.

15 “(2) FORMAT.—In developing the format in  
16 which reports will be publicly posted under para-  
17 graph (1), the Secretary shall consult with stake-  
18 holders, including beneficiary groups, and shall seek  
19 feedback from consumer advocates and readability  
20 experts on the format and presentation of the con-  
21 tent of such reports to ensure that such reports  
22 are—

23 “(A) user-friendly to the public; and

24 “(B) written in plain language that con-  
25 sumers can readily understand.

1           “(3) PROTECTED INFORMATION.—Nothing in  
2 this section shall be construed to authorize the pub-  
3 lic disclosure of information submitted by a manu-  
4 facturer that is prohibited from disclosure by appli-  
5 cable laws concerning the protection of trade secrets,  
6 commercial information, and other information cov-  
7 ered under such laws.

8 **“SEC. 39900-1. ANNUAL REPORT TO CONGRESS.**

9           “(a) IN GENERAL.—Subject to subsection (b), the  
10 Secretary shall submit to Congress, and post on the public  
11 website of the Department of Health and Human Services  
12 in a way that is user-friendly to the public and written  
13 in plain language that consumers can readily understand,  
14 an annual report—

15           “(1) summarizing the information reported pur-  
16 suant to section 39900;

17           “(2) including copies of the reports and sup-  
18 porting detailed economic analyses submitted pursu-  
19 ant to such section;

20           “(3) detailing the costs and expenditures in-  
21 curred by the Department of Health and Human  
22 Services in carrying out section 39900; and

23           “(4) explaining how the Department of Health  
24 and Human Services is improving consumer and

1 provider information about drug value and drug  
2 price transparency.

3 “(b) PROTECTED INFORMATION.—Nothing in this  
4 section shall be construed to authorize the public disclo-  
5 sure of information submitted by a manufacturer that is  
6 prohibited from disclosure by applicable laws concerning  
7 the protection of trade secrets, commercial information,  
8 and other information covered under such laws.”.

9 (b) EFFECTIVE DATE.—The amendment made by  
10 subsection (a) takes effect on the date of enactment of  
11 this Act.

12 **SEC. 30512. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.**

13 Section 1150A of the Social Security Act (42 U.S.C.  
14 1320b–23) is amended—

15 (1) in subsection (c), in the matter preceding  
16 paragraph (1), by inserting “(other than as per-  
17 mitted under subsection (e))” after “disclosed by the  
18 Secretary”; and

19 (2) by adding at the end the following new sub-  
20 section:

21 “(e) PUBLIC AVAILABILITY OF CERTAIN INFORMA-  
22 TION.—

23 “(1) IN GENERAL.—In order to allow the com-  
24 parison of PBMs’ ability to negotiate rebates, dis-  
25 counts, direct and indirect remuneration fees, ad-

1       ministrative fees, and price concessions and the  
2       amount of such rebates, discounts, direct and indi-  
3       rect remuneration fees, administrative fees, and  
4       price concessions that are passed through to plan  
5       sponsors, beginning January 1, 2022, the Secretary  
6       shall make available on the Internet website of the  
7       Department of Health and Human Services the in-  
8       formation with respect to the second preceding cal-  
9       endar year provided to the Secretary on generic dis-  
10      pensing rates (as described in paragraph (1) of sub-  
11      section (b)) and information provided to the Sec-  
12      retary under paragraphs (2) and (3) of such sub-  
13      section that, as determined by the Secretary, is with  
14      respect to each PBM.

15               “(2) AVAILABILITY OF DATA.—In carrying out  
16      paragraph (1), the Secretary shall ensure the fol-  
17      lowing:

18                       “(A) CONFIDENTIALITY.—The information  
19      described in such paragraph is displayed in a  
20      manner that prevents the disclosure of informa-  
21      tion, with respect to an individual drug or an  
22      individual plan, on rebates, discounts, direct  
23      and indirect remuneration fees, administrative  
24      fees, and price concessions.

1           “(B) CLASS OF DRUG.—The information  
2           described in such paragraph is made available  
3           by class of drug, using an existing classification  
4           system, but only if the class contains such num-  
5           ber of drugs, as specified by the Secretary (but  
6           not fewer than three drugs), to ensure confiden-  
7           tiality of proprietary information or other infor-  
8           mation that is prevented to be disclosed under  
9           subparagraph (A).”.

10 **SEC. 30513. STUDY OF PHARMACEUTICAL SUPPLY CHAIN**  
11 **INTERMEDIARIES AND MERGER ACTIVITY.**

12           (a) INITIAL REPORT.—Not later than 1 year after  
13 the date of enactment of this Act, the Commission shall  
14 submit to the appropriate committees of Congress a report  
15 that—

16           (1) addresses at minimum—

17           (A) whether pharmacy benefit managers—

18           (i) charge payers a higher price than  
19           the reimbursement rate at which the phar-  
20           macy benefit managers reimburse com-  
21           peting pharmacies;

22           (ii) steer patients for anticompetitive  
23           purposes to any pharmacies, including re-  
24           tail, mail-order, or any other type of phar-

1 macy, in which the pharmacy benefit man-  
2 ager has an ownership interest;

3 (iii) audit or review proprietary data,  
4 including acquisition costs, patient infor-  
5 mation, or dispensing information, of com-  
6 peting pharmacies that can be used for  
7 anticompetitive purposes; or

8 (iv) use formulary designs to increase  
9 the market share of higher cost prescrip-  
10 tion drugs and depress the market share of  
11 lower cost prescription drugs (each net of  
12 rebates and discounts);

13 (B) how companies and payers assess the  
14 benefits, costs, and risks of contracting with  
15 intermediaries, including pharmacy services ad-  
16 ministrative organizations, and whether more  
17 information about the roles of intermediaries  
18 should be available to consumers and payers;  
19 and

20 (C) whether there are any specific legal or  
21 regulatory obstacles the Commission currently  
22 faces in ensuring a competitive and transparent  
23 marketplace in the pharmaceutical supply  
24 chain, including the pharmacy benefit manager

1 marketplace and pharmacy services administra-  
2 tive organizations; and

3 (2) provides—

4 (A) observations or conclusions drawn  
5 from the November 2017 roundtable entitled  
6 “Understanding Competition in Prescription  
7 Drug Markets: Entry and Supply Chain Dy-  
8 namics”, and any similar efforts;

9 (B) specific actions the Commission in-  
10 tends to take as a result of the November 2017  
11 roundtable, and any similar efforts, including a  
12 detailed description of relevant forthcoming ac-  
13 tions, additional research or roundtable discus-  
14 sions, consumer education efforts, or enforce-  
15 ment actions; and

16 (C) policy or legislative recommendations  
17 to—

18 (i) improve transparency and competi-  
19 tion in the pharmaceutical supply chain;

20 (ii) prevent and deter anticompetitive  
21 behavior in the pharmaceutical supply  
22 chain; and

23 (iii) best ensure that consumers ben-  
24 efit from any cost savings or efficiencies



1                   that may result from mergers and consoli-  
2                   dations.

3           (b) INTERIM REPORT.—Not later than 180 days  
4 after the date of enactment of this Act, the Commission  
5 shall submit to the appropriate committees of Congress  
6 an interim report on the progress of the report required  
7 by subsection (a), along with preliminary findings and  
8 conclusions based on information collected to that date.

9           (c) DEFINITIONS.—In this section:

10           (1) APPROPRIATE COMMITTEES OF CON-  
11 GRESS.—The term “appropriate committees of Con-  
12 gress” means—

13                   (A) the Committee on Energy and Com-  
14 merce of the House of Representatives;

15                   (B) the Committee on the Judiciary of the  
16 Senate; and

17                   (C) the Committee on the Judiciary of the  
18 House of Representatives.

19           (2) COMMISSION.—The term “Commission”  
20 means the Federal Trade Commission.

1 **SEC. 30514. MAKING PRESCRIPTION DRUG MARKETING**  
2 **SAMPLE INFORMATION REPORTED BY MANU-**  
3 **FACTURERS AVAILABLE TO CERTAIN INDI-**  
4 **VIDUALS AND ENTITIES.**

5 (a) IN GENERAL.—Section 1128H of the Social Secu-  
6 rity Act (42 U.S.C. 1320a–7i) is amended—

7 (1) by redesignating subsection (b) as sub-  
8 section (e); and

9 (2) by inserting after subsection (a) the fol-  
10 lowing new subsections:

11 “(b) DATA SHARING AGREEMENTS.—

12 “(1) IN GENERAL.—The Secretary shall enter  
13 into agreements with the specified data sharing indi-  
14 viduals and entities described in paragraph (2)  
15 under which—

16 “(A) upon request of such an individual or  
17 entity, as applicable, the Secretary makes avail-  
18 able to such individual or entity the information  
19 submitted under subsection (a) by manufactur-  
20 ers and authorized distributors of record; and

21 “(B) such individual or entity agrees to  
22 not disclose publicly or to another individual or  
23 entity any information that identifies a par-  
24 ticular practitioner or health care facility.

25 “(2) SPECIFIED DATA SHARING INDIVIDUALS  
26 AND ENTITIES.—For purposes of paragraph (1), the

1 specified data sharing individuals and entities de-  
2 scribed in this paragraph are the following:

3 “(A) OVERSIGHT AGENCIES.—Health over-  
4 sight agencies (as defined in section 164.501 of  
5 title 45, Code of Federal Regulations), includ-  
6 ing the Centers for Medicare & Medicaid Serv-  
7 ices, the Office of the Inspector General of the  
8 Department of Health and Human Services, the  
9 Government Accountability Office, the Congres-  
10 sional Budget Office, the Medicare Payment  
11 Advisory Commission, and the Medicaid and  
12 CHIP Payment and Access Commission.

13 “(B) RESEARCHERS.—Individuals who  
14 conduct scientific research (as defined in sec-  
15 tion 164.501 of title 45, Code of Federal Regu-  
16 lations) in relevant areas as determined by the  
17 Secretary.

18 “(C) PAYERS.—Private and public health  
19 care payers, including group health plans,  
20 health insurance coverage offered by health in-  
21 surance issuers, Federal health programs, and  
22 State health programs.

23 “(3) EXEMPTION FROM FREEDOM OF INFORMA-  
24 TION ACT.—Except as described in paragraph (1),  
25 the Secretary may not be compelled to disclose the

1 information submitted under subsection (a) to any  
2 individual or entity. For purposes of section 552 of  
3 title 5, United States Code (commonly referred to as  
4 the Freedom of Information Act), this paragraph  
5 shall be considered a statute described in subsection  
6 (b)(3)(B) of such section.

7 “(c) PENALTIES.—

8 “(1) DATA SHARING AGREEMENTS.—Subject to  
9 paragraph (3), any specified data sharing individual  
10 or entity described in subsection (b)(2) that violates  
11 the terms of a data sharing agreement the individual  
12 or entity has with the Secretary under subsection  
13 (b)(1) shall be subject to a civil money penalty of  
14 not less than \$1,000, but not more than \$10,000,  
15 for each such violation. Such penalty shall be im-  
16 posed and collected in the same manner as civil  
17 money penalties under subsection (a) of section  
18 1128A are imposed and collected under that section.

19 “(2) FAILURE TO REPORT.—Subject to para-  
20 graph (3), any manufacturer or authorized dis-  
21 tributor of record of an applicable drug under sub-  
22 section (a) that fails to submit information required  
23 under such subsection in a timely manner in accord-  
24 ance with rules or regulations promulgated to carry  
25 out such subsection shall be subject to a civil money

1 penalty of not less than \$1,000, but not more than  
2 \$10,000, for each such failure. Such penalty shall be  
3 imposed and collected in the same manner as civil  
4 money penalties under subsection (a) of section  
5 1128A are imposed and collected under that section.

6 “(3) LIMITATION.—The total amount of civil  
7 money penalties imposed under paragraph (1) or (2)  
8 with respect to a year and an individual or entity de-  
9 scribed in paragraph (1) or a manufacturer or dis-  
10 tributor described in paragraph (2), respectively,  
11 shall not exceed \$150,000.

12 “(d) DRUG SAMPLE DISTRIBUTION INFORMATION.—

13 “(1) IN GENERAL.—Not later than January 1  
14 of each year (beginning with 2022), the Secretary  
15 shall maintain a list containing information related  
16 to the distribution of samples of applicable drugs.  
17 Such list shall provide the following information with  
18 respect to the preceding year:

19 “(A) The name of the manufacturer or au-  
20 thorized distributor of record of an applicable  
21 drug for which samples were requested or dis-  
22 tributed under this section.

23 “(B) The quantity and class of drug sam-  
24 ples requested.

1                   “(C) The quantity and class of drug sam-  
2                   ples distributed.

3                   “(2) PUBLIC AVAILABILITY.—The Secretary  
4                   shall make the information in such list available to  
5                   the public on the Internet website of the Food and  
6                   Drug Administration.”.

7                   (b) FDA MAINTENANCE OF INFORMATION.—The  
8                   Food and Drug Administration shall maintain information  
9                   available to affected reporting companies to ensure their  
10                  ability to fully comply with the requirements of section  
11                  1128H of the Social Security Act.

12                  (c) PROHIBITION ON DISTRIBUTION OF SAMPLES OF  
13                  OPIOIDS.—Section 503(d) of the Federal Food, Drug, and  
14                  Cosmetic Act (21 U.S.C. 353(d)) is amended—

15                         (1) by moving the margin of paragraph (4) 2  
16                         ems to the left; and

17                         (2) by adding at the end the following:

18                         “(5) No person may distribute a drug sample of a  
19                         drug that is—

20                                 “(A) an applicable drug (as defined in section  
21                                 1128H(e) of the Social Security Act);

22                                 “(B) a controlled substance (as defined in sec-  
23                                 tion 102 of the Controlled Substances Act) for which  
24                                 the findings required under section 202(b)(2) of  
25                                 such Act have been made; and

1           “(C) approved under section 505 for use in the  
2           management or treatment of pain (other than for  
3           the management or treatment of a substance use  
4           disorder).”.

5           (d) MEDPAC REPORT.—Not later than 3 years after  
6           the date of the enactment of this Act, the Medicare Pay-  
7           ment Advisory Commission shall conduct a study on the  
8           impact of drug samples on provider prescribing practices  
9           and health care costs and may, as the Commission deems  
10          appropriate, make recommendations on such study.

11 **SEC. 30515. SENSE OF CONGRESS REGARDING THE NEED**  
12                           **TO EXPAND COMMERCIALLY AVAILABLE**  
13                           **DRUG PRICING COMPARISON PLATFORMS.**

14          It is the sense of Congress that—

15           (1) commercially available drug pricing com-  
16           parison platforms can, at no cost, help patients find  
17           the lowest price for their medications at their local  
18           pharmacy;

19           (2) such platforms should be integrated, to the  
20           maximum extent possible, in the health care delivery  
21           ecosystem; and

22           (3) pharmacy benefit managers should work to  
23           disclose generic and brand name drug prices to such  
24           platforms to ensure that—

1 (A) patients can benefit from the lowest  
2 possible price available to them; and

3 (B) overall drug prices can be reduced as  
4 more educated purchasing decisions are made  
5 based on price transparency.

6 **Subpart C—Medicare Part D Benefit Redesign**

7 **SEC. 30521. MEDICARE PART D BENEFIT REDESIGN.**

8 (a) BENEFIT STRUCTURE REDESIGN.—Section  
9 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–  
10 102(b)) is amended—

11 (1) in paragraph (2)—

12 (A) in subparagraph (A)—

13 (i) in the matter preceding clause (i),  
14 by inserting “for a year preceding 2022  
15 and for costs above the annual deductible  
16 specified in paragraph (1) and up to the  
17 annual out-of-pocket threshold specified in  
18 paragraph (4)(B) for 2022 and each subse-  
19 quent year” after “paragraph (3)”;

20 (ii) in clause (i), by inserting after  
21 “25 percent” the following: “(or, for 2022  
22 and each subsequent year, 15 percent)”;  
23 and



1 (iii) in clause (ii), by inserting “(or,  
2 for 2022 and each subsequent year, 15  
3 percent)” after “25 percent”;

4 (B) in subparagraph (C)—

5 (i) in clause (i), in the matter pre-  
6 ceding subclause (I), by inserting “for a  
7 year preceding 2022,” after “paragraph  
8 (4),”; and

9 (ii) in clause (ii)(III), by striking  
10 “and each subsequent year” and inserting  
11 “and 2021”; and

12 (C) in subparagraph (D)—

13 (i) in clause (i)—

14 (I) in the matter preceding sub-  
15 clause (I), by inserting “for a year  
16 preceding 2022,” after “paragraph  
17 (4),”; and

18 (II) in subclause (I)(bb), by  
19 striking “a year after 2018” and in-  
20 serting “each of years 2018 through  
21 2021”; and

22 (ii) in clause (ii)(V), by striking  
23 “2019 and each subsequent year” and in-  
24 serting “each of years 2019 through  
25 2021”;

1 (2) in paragraph (3)(A)—

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

5 (B) in clause (ii), by striking “for a subse-  
6 quent year” and inserting “for each of years  
7 2007 through 2021”;

8 (3) in paragraph (4)—

9 (A) in subparagraph (A)—

10 (i) in clause (i)—

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

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

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

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

1 (IV) by adding at the end the fol-  
2 lowing:

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

5 (ii) in clause (ii)—

6 (I) by striking “clause (i)(I)” and  
7 inserting “clause (i)(I)(aa)”; and

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

15 (B) in subparagraph (B)—

16 (i) in clause (i)—

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

19 (II) in subclause (VI)—

20 (aa) by striking “for a sub-  
21 sequent year” and inserting “for  
22 2021”; and

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

1 (III) by adding at the end the  
2 following new subclauses:

3 “(VII) for 2022, is equal to  
4 \$3,100; or

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

11 (ii) in clause (ii), by striking “clause  
12 (i)(II)” and inserting “clause (i)”;

13 (C) in subparagraph (C)(i), by striking  
14 “and for amounts” and inserting “and for a  
15 year preceding 2022 for amounts”; and

16 (D) in subparagraph (E), by striking “In  
17 applying” and inserting “For each of 2011  
18 through 2021, in applying”.

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

22 (1) by striking “equal to 80 percent” and in-  
23 serting “equal to—

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

1           (2) in subparagraph (A), as added by para-  
2           graph (1), by striking the period at the end and in-  
3           serting “; and”; and

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

6                   “(B) for 2022 and each subsequent year,  
7           the sum of—

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

19                           “(ii) an amount equal to 30 percent of  
20                           the allowable reinsurance costs (as speci-  
21                           fied in paragraph (2)) attributable to that  
22                           portion of gross covered prescription drug  
23                           costs as specified in paragraph (3) in-  
24                           curred in the coverage year after such indi-  
25                           vidual has incurred costs that exceed the

1           annual out-of-pocket threshold specified in  
2           section 1860D–2(b)(4)(B) with respect to  
3           covered part D drugs that are not applica-  
4           ble drugs (as so defined).”.

5           (c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

11       “(a) ESTABLISHMENT.—The Secretary shall estab-  
12       lish a manufacturer discount program (in this section re-  
13       ferred to as the ‘program’). Under the program, the Sec-  
14       retary shall enter into agreements described in subsection  
15       (b) with manufacturers and provide for the performance  
16       of the duties described in subsection (c). The Secretary  
17       shall establish a model agreement for use under the pro-  
18       gram by not later than January 1, 2023, in consultation  
19       with manufacturers, and allow for comment on such model  
20       agreement.

21       “(b) TERMS OF AGREEMENT.—

22           “(1) IN GENERAL.—

23           “(A) AGREEMENT.—An agreement under  
24           this section shall require the manufacturer to  
25           provide applicable beneficiaries access to dis-

1           counted prices for applicable drugs of the man-  
2           ufacturer that are dispensed on or after Janu-  
3           ary 1, 2024.

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

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

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

25          “(4) LENGTH OF AGREEMENT.—

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

7           “(B) TERMINATION.—

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

23           “(ii) BY A MANUFACTURER.—A man-  
24 ufacturer may terminate an agreement  
25 under this section for any reason. Any



1 such termination shall be effective, with re-  
2 spect to a plan year—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15           “(2) MONITORING COMPLIANCE.—

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

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

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

7           “(d) ADMINISTRATION.—

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

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

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

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

1 individuals or entities the Secretary determines  
2 appropriate;

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

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

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

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

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

4           “(e) ENFORCEMENT.—

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

8           “(2) CIVIL MONEY PENALTY.—

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

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

22                   “(ii) 25 percent of such amount.

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

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

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

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

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

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

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

18           “(C) has incurred costs for covered part D  
19 drugs in the year that are equal to or exceed  
20 the annual deductible specified in section  
21 1860D–2(b)(1) for such year.

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

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

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

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

20          “(iii) is provided through an exception or  
21          appeal.

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



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

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

5           “(4) DISCOUNTED PRICE.—

6           “(A) IN GENERAL.—The term ‘discounted  
7           price’ means, with respect to an applicable drug  
8           of a manufacturer furnished during a year to  
9           an applicable beneficiary, 90 percent of the ne-  
10          gotiated price of such drug.

11          “(B) CLARIFICATION.—Nothing in this  
12          section shall be construed as affecting the re-  
13          sponsibility of an applicable beneficiary for pay-  
14          ment of a dispensing fee for an applicable drug.

15          “(C) SPECIAL CASE FOR CLAIMS SPANNING  
16          DEDUCTIBLE.—In the case where the entire  
17          amount of the negotiated price of an individual  
18          claim for an applicable drug with respect to an  
19          applicable beneficiary does not fall at or above  
20          the annual deductible specified in section  
21          1860D–2(b)(1) for the year, the manufacturer  
22          of the applicable drug shall provide the dis-  
23          counted price under this section on only the  
24          portion of the negotiated price of the applicable

1 drug that falls at or above such annual deduct-  
2 ible.

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

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

18 “(7) QUALIFIED RETIREE PRESCRIPTION DRUG  
19 PLAN.—The term ‘qualified retiree prescription drug  
20 plan’ has the meaning given such term in section  
21 11860D–22(a)(2).”.

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

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

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

6 “(h) SUNSET OF PROGRAM.—

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

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

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

22 (A) in subsection (b)(2)(C)(iii)—

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

1 “(I) the reinsurance”; and

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

4 “(II) for 2024 and each subse-  
5 quent year, the manufacturer dis-  
6 counts provided under section 1860D-  
7 14B subtracted from the actuarial  
8 value to produce such bid; and”; and

9 (B) in subsection (c)(1)(C)—

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

13 “(i) the reinsurance”;

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

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

19 “(ii) for 2024 and each subsequent  
20 year, the manufacturer discounts provided  
21 under section 1860D-14B;”.

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

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

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

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

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

14 (1) in paragraph (2)—

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

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

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

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

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

6 (2) in paragraph (3)—

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

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

14 (e) UPDATING RISK ADJUSTMENT METHODOLOGIES  
15 TO ACCOUNT FOR PART D MODERNIZATION REDESIGN.—

16 Section 1860D–15(c) of the Social Security Act (42  
17 U.S.C. 1395w–115(e)) is amended by adding at the end  
18 the following new paragraph:

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

1           suant to the amendments made by section 121 of  
2           the Lower Costs, More Cures Act of 2021.”.

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

6           (1) in subsection (a)—

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

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

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

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

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

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

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

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

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

9           “(2) the Secretary determines that in the period  
10 beginning on January 1, 2011, and ending on De-  
11 cember 31, 2011 (with respect to paragraphs (1)  
12 through (3) of subsection (a)) or the period begin-  
13 ning on January 1, 2024, and ending December 31,  
14 2024 (with respect to paragraphs (4) through (6) of  
15 such subsection), there were extenuating cir-  
16 cumstances.”.

17           (g) CONFORMING AMENDMENTS.—

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

20           (A) in subsection (a)(2)(A)(i)(I), by strik-  
21 ing “, or an increase in the initial” and insert-  
22 ing “or for a year preceding 2024 an increase  
23 in the initial”;

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



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

4 (ii) by inserting “for a year preceding  
5 2024 or the annual out-of-pocket threshold  
6 specified in subsection (b)(4)(B) for the  
7 year for 2024 and each subsequent year”  
8 after “subsection (b)(3) for the year” each  
9 place it appears; and

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

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

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

19 (A) in paragraph (1)—

20 (i) in subparagraph (C), by striking  
21 “The continuation” and inserting “For a  
22 year preceding 2024, the continuation”;

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

1 (iii) in subparagraph (E), by striking  
2 “The elimination” and inserting “For a  
3 year preceding 2024, the elimination”; and  
4 (B) in paragraph (2)—

5 (i) in subparagraph (C), by striking  
6 “The continuation” and inserting “For a  
7 year preceding 2024, the continuation”;  
8 and

9 (ii) in subparagraph (E)—  
10 (I) by inserting “for a year pre-  
11 ceding 2024,” after “subsection (e)”;  
12 and

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

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

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

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

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

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

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

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

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

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

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

17 (h) EFFECTIVE DATE.—The amendments made by  
18 this section shall apply to plan year 2024 and subsequent  
19 plan years.

20 **Subpart D—Other Medicare Part D Provisions**

21 **SEC. 30531. ALLOWING THE OFFERING OF ADDITIONAL**  
22 **PRESCRIPTION DRUG PLANS UNDER MEDI-**  
23 **CARE PART D.**

24 (a) RESCINDING AND ISSUANCE OF NEW GUID-  
25 ANCE.—Not later than one year after the date of the en-

1 actment of this Act, the Secretary of Health and Human  
2 Services (in this section referred to as the “Secretary”)  
3 shall—

4 (1) rescind sections of any sub-regulatory guid-  
5 ance that limit the number of prescription drug  
6 plans in each PDP region that may be offered by a  
7 PDP sponsor under part D of title XVIII of the So-  
8 cial Security Act (42 U.S.C. 1395w–101 et seq.);  
9 and

10 (2) issue new guidance specifying that a PDP  
11 sponsor may offer up to 4 (or a greater number if  
12 determined appropriate by the Secretary) prescrip-  
13 tion drug plans in each PDP region, except in cases  
14 where the PDP sponsor may offer up to 2 additional  
15 plans in a PDP region pursuant to section 1860D–  
16 11(d)(4) of the Social Security Act (42 U.S.C.  
17 1395w–111(d)(4)), as added by subsection (b).

18 (b) OFFERING OF ADDITIONAL PLANS.—Section  
19 1860D–11(d) of the Social Security Act (42 U.S.C.  
20 1395w–111(d)) is amended by adding at the end the fol-  
21 lowing new paragraph:

22 “(4) OFFERING OF ADDITIONAL PLANS.—

23 “(A) IN GENERAL.—For plan year 2022  
24 and each subsequent plan year, a PDP sponsor  
25 may offer up to 2 additional prescription drug

1 plans in a PDP region (in addition to any limit  
2 established by the Secretary under this part)  
3 provided that the PDP sponsor complies with  
4 subparagraph (B) with respect to at least one  
5 such prescription drug plan.

6 “(B) REQUIREMENTS.—In order to be eli-  
7 gible to offer up to 2 additional plans in a PDP  
8 region pursuant to subparagraph (A), a PDP  
9 sponsor must ensure that, with respect to at  
10 least one such prescription drug plan, the spon-  
11 sor or any entity that provides pharmacy bene-  
12 fits management services under a contract with  
13 any such sponsor or plan does not receive direct  
14 or indirect remuneration, as defined in section  
15 423.308 of title 42, Code of Federal Regula-  
16 tions (or any successor regulation), unless at  
17 least 25 percent of the aggregate reductions in  
18 price or other remuneration received by the  
19 PDP sponsor or entity from drug manufactur-  
20 ers with respect to the plan and plan year—

21 “(i) are reflected at the point-of-sale  
22 to the enrollee; or

23 “(ii) are used to reduce total bene-  
24 ficiary cost-sharing estimated by the PDP  
25 sponsor for prescription drug coverage

1 under the plan in the annual bid submitted  
2 by the PDP sponsor under section 1860D–  
3 11(b).

4 “(C) DEFINITION OF REDUCTIONS IN  
5 PRICE.—For purposes of subparagraph (B), the  
6 term ‘reductions in price’ refers only to collect-  
7 ible amounts, as determined by the Secretary,  
8 which excludes amounts which after adjudica-  
9 tion and reconciliation with pharmacies and  
10 manufacturers are duplicate in nature, contrary  
11 to other contractual clauses, or otherwise ineli-  
12 gible (such as due to beneficiary disenrollment  
13 or coordination of benefits).”.

14 (c) RULE OF CONSTRUCTION.—Nothing in the provi-  
15 sions of, or amendments made by, this section shall be  
16 construed as limiting the ability of the Secretary to in-  
17 crease any limit otherwise applicable on the number of  
18 prescription drug plans that a PDP sponsor may offer,  
19 at the discretion of the PDP sponsor, in a PDP region  
20 under part D of title XVIII of the Social Security Act (42  
21 U.S.C. 1395w–101 et seq.).

1 **SEC. 30532. ALLOWING CERTAIN ENROLLEES OF PRESCRIP-**  
2 **TION DRUG PLANS AND MA-PD PLANS UNDER**  
3 **MEDICARE PROGRAM TO SPREAD OUT COST-**  
4 **SHARING UNDER CERTAIN CIRCUMSTANCES.**

5 (a) STANDARD PRESCRIPTION DRUG COVERAGE.—  
6 Section 1860D–2(b)(2) of the Social Security Act (42  
7 U.S.C. 1395w–102(b)(2)), as amended by section 121, is  
8 further amended—

9 (1) in subparagraph (A), by striking “Subject  
10 to subparagraphs (C) and (D)” and inserting “Sub-  
11 ject to subparagraphs (C), (D), and (E)”; and

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

14 “(E) ENROLLEE OPTION REGARDING  
15 SPREADING COST-SHARING.—

16 “(i) IN GENERAL.—The Secretary  
17 shall establish by regulation a process  
18 under which, with respect to plan year  
19 2022 and subsequent plan years, a pre-  
20 scription drug plan or an MA–PD plan  
21 shall, in the case of a part D eligible indi-  
22 vidual enrolled with such plan for such  
23 plan year with respect to whom the plan  
24 projects that the dispensing of a covered  
25 part D drug to such individual will result  
26 in the individual incurring costs within a

1           30-day period that are equal to a signifi-  
2           cant percentage (as specified by the Sec-  
3           retary pursuant to such regulation) of the  
4           annual out-of-pocket threshold specified in  
5           paragraph (4)(B) for such plan year, pro-  
6           vide such individual with the option to  
7           make the coinsurance payment required  
8           under subparagraph (A) for such costs in  
9           the form of equal monthly installments  
10          over the remainder of such plan year.

11           “(ii) SIGNIFICANT PERCENTAGE LIM-  
12          TATIONS.—In specifying a significant per-  
13          centage pursuant to the regulation estab-  
14          lished by the Secretary under clause (i),  
15          the Secretary may not specify a percentage  
16          that is less than 30 percent or greater  
17          than 100 percent.”.

18          (b) ALTERNATIVE PRESCRIPTION DRUG COV-  
19          ERAGE.—Section 1860D–2(c) of the Social Security Act  
20          (42 U.S.C. 1395w–102(c)) is amended by adding at the  
21          end the following new paragraph:

22           “(4) SAME ENROLLEE OPTION REGARDING  
23          SPREADING COST-SHARING.—For plan year 2022  
24          and subsequent plan years, the coverage provides the  
25          enrollee option regarding spreading cost-sharing de-



1 scribed in and required under subsection  
2 (b)(2)(E).”.

3 **SEC. 30533. ESTABLISHING A MONTHLY CAP ON BENE-**  
4 **FICIARY INCURRED COSTS FOR INSULIN**  
5 **PRODUCTS AND SUPPLIES UNDER A PRE-**  
6 **SCRIPTION DRUG PLAN OR MA-PD PLAN.**

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

10 (1) in subsection (b)(2)—

11 (A) in subparagraph (A), by striking “and  
12 (E)” and inserting “(E), and (F)”;

13 (B) in subparagraph (B), by striking “and  
14 (D)” and inserting “(D), and (F)”;

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

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

19 “(i) IN GENERAL.—The coverage pro-  
20 vides benefits, for costs above the annual  
21 deductible specified in paragraph (1) and  
22 up to the annual out-of-pocket threshold  
23 described in paragraph (4)(B) and with re-  
24 spect to a month (beginning with January  
25 of 2022), with cost sharing that is equal to

1           \$0 for a specified covered part D drug (as  
2           defined in clause (iii)) furnished to an indi-  
3           vidual who has incurred costs during such  
4           month with respect to specified covered  
5           part D drugs equal to—

6                       “(I) for months occurring in  
7                       2022, \$50; or

8                       “(II) for months occurring in a  
9                       subsequent year, the amount applica-  
10                      ble under this clause for months oc-  
11                      curring in the year preceding such  
12                      subsequent year, increased by the an-  
13                      nual percentage increase specified in  
14                      paragraph (6) for such subsequent  
15                      year and rounded to the nearest dol-  
16                      lar.

17                      “(ii) APPLICATION.—The provisions  
18                      of clauses (i) through (iii) of paragraph  
19                      (4)(C) shall apply with respect to the de-  
20                      termination of the incurred costs for speci-  
21                      fied covered part D drugs for purposes of  
22                      clause (i) in the same manner as such pro-  
23                      visions apply with respect to the deter-  
24                      mination of incurred costs for covered part  
25                      D drugs for purposes of paragraph (4)(A).

1                   “(iii) SPECIFIED COVERED PART D  
2                   DRUG.—For purposes of this subpara-  
3                   graph, the term ‘specified covered part D  
4                   drug’ means a covered part D drug that  
5                   is—

6                                   “(I) insulin; or

7                                   “(II) a medical supply associated  
8                   with the injection of insulin (as de-  
9                   fined in regulations of the Secretary  
10                  promulgated pursuant to subsection  
11                  (e)(1)(B)).”; and

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

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

18                  (b) CONFORMING AMENDMENTS.—

19                               (1) IN GENERAL.—Section 1860D–14(a)(1)(D)  
20                  of the Social Security Act (42 U.S.C. 1395w–  
21                  114(a)(1)(D)), as amended by section 121, is fur-  
22                  ther amended—

23                               (A) in clause (ii), by striking “section  
24                  1860D–2(b)(2)” and inserting “section 1860D–  
25                  2(b)(2)(A)”; and

1 (B) in clause (iii), by striking “section  
2 1860D–2(b)(2)” and inserting “section 1860D–  
3 2(b)(2)(A)”.

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

7 **SEC. 30534. GROWTH RATE OF MEDICARE PART D OUT-OF-**  
8 **POCKET COST THRESHOLD.**

9 (a) PROVIDING MEDICARE PART D BENEFICIARIES  
10 WITH CERTAIN 2020 OFFSET PAYMENTS.—Section  
11 1860D–2(b)(4) of the Social Security Act (42 U.S.C.  
12 1395w–102(b)(4)) is amended by adding at the end the  
13 following new subparagraph:

14 “(F) 2020 OFFSET PAYMENTS.—

15 “(i) IN GENERAL.—Subject to clause  
16 (iv), the Secretary shall provide for pay-  
17 ment from the Medicare Prescription Drug  
18 Account as follows:

19 “(I) In the case of a specified in-  
20 dividual (as defined in clause (ii)(I))  
21 who as of the last day of a calendar  
22 quarter in 2020 has incurred costs for  
23 covered part D drugs so that the indi-  
24 vidual has exceeded the annual out-of-  
25 pocket threshold applied under sub-

1 paragraph (B)(i)(V) for 2020, pay-  
2 ment to the individual by not later  
3 than 15th day of the third month fol-  
4 lowing the end of such quarter of the  
5 amount by which such threshold so  
6 applied exceeded the target threshold  
7 for 2020.

8 “(II) In the case of a specified  
9 individual who is not described in sub-  
10 clause (I) and who as of the last day  
11 of 2020 has incurred costs for covered  
12 part D drugs so that the individual  
13 has exceeded the target threshold for  
14 2020, payment to the individual by  
15 not later than December 31, 2021, of  
16 the amount by which such incurred  
17 costs exceeded the target threshold for  
18 2020.

19 “(ii) DEFINITIONS.—For purposes of  
20 this subparagraph:

21 “(I) SPECIFIED INDIVIDUAL.—  
22 The term ‘specified individual’ means  
23 an individual who—

1                   “(aa) is enrolled in a pre-  
2                   scription drug plan or an MA-  
3                   PD plan;

4                   “(bb) is not enrolled in a  
5                   qualified retiree prescription drug  
6                   plan; and

7                   “(cc) is not entitled to an in-  
8                   come-related subsidy under sec-  
9                   tion 1860D-14(a).

10                  “(II) TARGET THRESHOLD FOR  
11                  2020.—The term ‘target threshold for  
12                  2020’ means the annual out-of-pocket  
13                  threshold that would have been ap-  
14                  plied under subparagraph (B)(i) for  
15                  2020 if such threshold had been de-  
16                  termined in accordance with subclause  
17                  (IV) of such subparagraph instead of  
18                  subclause (V) of such subparagraph.

19                  “(iii) NOTIFICATION.—In the case of  
20                  any specified individual who during 2020  
21                  has incurred costs for covered part D  
22                  drugs so that the individual has exceeded  
23                  the target threshold for 2020, the Sec-  
24                  retary shall, not later than September 30,  
25                  2021, provide to such individual a notifica-

1           tion informing such individual of such indi-  
2           vidual’s right to a payment described in  
3           clause (i) and the estimated timing of such  
4           payment.

5           “(iv) CLARIFICATION.—The Secretary  
6           shall provide only 1 payment under this  
7           subparagraph with respect to any indi-  
8           vidual.

9           “(v) IMPLEMENTATION.—The Sec-  
10          retary may implement this subparagraph  
11          by program instruction or otherwise.”.

12          (b) REDUCED GROWTH RATE FOR 2021 OF MEDI-  
13          CARE PART D OUT-OF-POCKET COST THRESHOLD.—Sec-  
14          tion 1860D–2(b)(4)(B)(i) of the Social Security Act (42  
15          U.S.C. 1395w–102(b)(4)(B)(i)) is amended—

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

18           (2) by redesignating subclause (VI) as sub-  
19           clause (VIII); and

20           (3) by inserting after subclause (V) the fol-  
21           lowing new subclauses:

22                   “(VI) for 2021, is equal to the  
23                   amount that would have been applied  
24                   under this subparagraph for 2020 if  
25                   such amount had been determined in

1                   accordance with subclause (IV) in-  
2                   stead of subclause (V), increased by  
3                   the lesser of—

4                                 “(aa) the annual percentage  
5                                 increase described in paragraph  
6                                 (7) for 2021, plus 2 percentage  
7                                 points; or

8                                 “(bb) the annual percentage  
9                                 increase described in paragraph  
10                                (6) for 2021;

11                               “(VII) for 2022, is equal to the  
12                               amount that would have been applied  
13                               under this subparagraph for 2022 if  
14                               the amendments made by section  
15                               1101(d)(1) of the Health Care and  
16                               Education Reconciliation Act of 2010  
17                               and by section 134 of the Lower  
18                               Costs, More Cures Act of 2021 had  
19                               not been enacted; or”.

20                               **PART 2—MEDICAID**

21                               **SEC. 30601. MEDICAID PHARMACY AND THERAPEUTICS**

22                               **COMMITTEE IMPROVEMENTS.**

23                               (a) IN GENERAL.—Subparagraph (A) of section  
24                               1927(d)(4) of the Social Security Act (42 U.S.C. 1396r–  
25                               8(d)(4)) is amended to read as follows:



1           “(A)(i) The formulary is developed and re-  
2 viewed by a pharmacy and therapeutics com-  
3 mittee consisting of physicians, pharmacists,  
4 and other appropriate individuals appointed by  
5 the Governor of the State.

6           “(ii) Subject to clause (vi), the State estab-  
7 lishes and implements a conflict of interest pol-  
8 icy for the pharmacy and therapeutics com-  
9 mittee that—

10                   “(I) is publicly accessible;

11                   “(II) requires all committee members  
12 to complete, on at least an annual basis, a  
13 disclosure of relationships, associations,  
14 and financial dealings that may affect their  
15 independence of judgement in committee  
16 matters; and

17                   “(III) contains clear processes, such  
18 as recusal from voting or discussion, for  
19 those members who report a conflict of in-  
20 terest, along with appropriate processes to  
21 address any instance where a member fails  
22 to report a conflict of interest.

23           “(iii) The membership of the pharmacy  
24 and therapeutics committee—

1                   “(I) includes at least 1 actively prac-  
2                   ticing physician and at least 1 actively  
3                   practicing pharmacist, each of whom—

4                                 “(aa) is independent and free of  
5                                 conflict with respect to manufacturers  
6                                 and Medicaid participating plans or  
7                                 subcontractors, including pharmacy  
8                                 benefit managers; and

9                                 “(bb) has expertise in the care of  
10                                1 or more Medicaid-specific popu-  
11                                lations such as elderly or disabled in-  
12                                dividuals, children with complex med-  
13                                ical needs, or low-income individuals  
14                                with chronic illnesses; and

15                                “(II) is made publicly available.

16                                “(iv) At the option of the State, the  
17                                State’s drug use review board established under  
18                                subsection (g)(3) may serve as the pharmacy  
19                                and therapeutics committee provided the State  
20                                ensures that such board meets the requirements  
21                                of clauses (ii) and (iii).

22                                “(v) The State reviews and has final ap-  
23                                proval of the formulary established by the phar-  
24                                macy and therapeutics committee.

1           “(vi) If the Secretary determines it appro-  
2           priate or necessary based on the findings and  
3           recommendations of the Comptroller General of  
4           the United States in the report submitted to  
5           Congress under section 203 of the Lower Costs,  
6           More Cures Act of 2021, the Secretary shall  
7           issue guidance that States must follow for es-  
8           tablishing conflict of interest policies for the  
9           pharmacy and therapeutics committee in ac-  
10          cordance with the requirements of clause (ii),  
11          including appropriate standards and require-  
12          ments for identifying, addressing, and reporting  
13          on conflicts of interest.”.

14          (b) APPLICATION TO MEDICAID MANAGED CARE OR-  
15          GANIZATIONS.—Clause (xiii) of section 1903(m)(2)(A) of  
16          the Social Security Act (42 U.S.C. 1396b(m)(2)(A)) is  
17          amended—

18                 (1) by striking “and (III)” and inserting  
19                 “(III)”;

20                 (2) by striking the period at the end and insert-  
21                 ing “, and (IV) any formulary used by the entity for  
22                 covered outpatient drugs dispensed to individuals eli-  
23                 gible for medical assistance who are enrolled with  
24                 the entity is developed and reviewed by a pharmacy  
25                 and therapeutics committee that meets the require-

1           ments of clauses (ii) and (iii) of section  
2           1927(d)(4)(A).”; and

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

4           (c) EFFECTIVE DATE.—The amendments made by  
5 this section shall take effect on the date that is 1 year  
6 after the date of enactment of this Act.

7 **SEC. 30602. GAO REPORT ON CONFLICTS OF INTEREST IN**  
8                           **STATE MEDICAID PROGRAM DRUG USE RE-**  
9                           **VIEW BOARDS AND PHARMACY AND THERA-**  
10                           **PEUTICS (P&T) COMMITTEES.**

11           (a) INVESTIGATION.—The Comptroller General of the  
12 United States shall conduct an investigation of potential  
13 or existing conflicts of interest among members of State  
14 Medicaid program State drug use review boards (in this  
15 section referred to as “DUR Boards”) and pharmacy and  
16 therapeutics committees (in this section referred to as  
17 “P&T Committees”).

18           (b) REPORT.—Not later than 24 months after the  
19 date of enactment of this Act, the Comptroller General  
20 shall submit to Congress a report on the investigation con-  
21 ducted under subsection (a) that includes the following:

22                   (1) A description outlining how DUR Boards  
23                   and P&T Committees operate in States, including  
24                   details with respect to—

1 (A) the structure and operation of DUR  
2 Boards and statewide P&T Committees;

3 (B) States that operate separate P&T  
4 Committees for their fee-for-service Medicaid  
5 program and their Medicaid managed care or-  
6 ganizations or other Medicaid managed care ar-  
7 rangements (collectively referred to in this sec-  
8 tion as “Medicaid MCOs”); and

9 (C) States that allow Medicaid MCOs to  
10 have their own P&T Committees and the extent  
11 to which pharmacy benefit managers administer  
12 or participate in such P&T Committees.

13 (2) A description outlining the differences be-  
14 tween DUR Boards established in accordance with  
15 section 1927(g)(3) of the Social Security Act (42  
16 U.S.C. 1396r(g)(3)) and P&T Committees.

17 (3) A description outlining the tools P&T Com-  
18 mittees may use to determine Medicaid drug cov-  
19 erage and utilization management policies.

20 (4) An analysis of whether and how States or  
21 P&T Committees establish participation and inde-  
22 pendence requirements for DUR Boards and P&T  
23 Committees, including with respect to entities with  
24 connections with drug manufacturers, State Med-  
25 icaid programs, managed care organizations, and

1 other entities or individuals in the pharmaceutical  
2 industry.

3 (5) A description outlining how States, DUR  
4 Boards, or P&T Committees define conflicts of inter-  
5 est.

6 (6) A description of how DUR Boards and P&T  
7 Committees address conflicts of interest, including  
8 who is responsible for implementing such policies.

9 (7) A description of the tools, if any, States use  
10 to ensure that there are no conflicts of interest on  
11 DUR Boards and P&T Committees.

12 (8) An analysis of the effectiveness of tools  
13 States use to ensure that there are no conflicts of  
14 interest on DUR Boards and P&T Committees and,  
15 if applicable, recommendations as to how such tools  
16 could be improved.

17 (9) A review of strategies States may use to  
18 guard against conflicts of interest on DUR Boards  
19 and P&T Committees and to ensure compliance with  
20 the requirements of titles XI and XIX of the Social  
21 Security Act (42 U.S.C. 1301 et seq., 1396 et seq.)  
22 and access to effective, clinically appropriate, and  
23 medically necessary drug treatments for Medicaid  
24 beneficiaries, including recommendations for such

1 legislative and administrative actions as the Comp-  
2 troller General determines appropriate.

3 **SEC. 30603. ENSURING THE ACCURACY OF MANUFACTURER**  
4 **PRICE AND DRUG PRODUCT INFORMATION**  
5 **UNDER THE MEDICAID DRUG REBATE PRO-**  
6 **GRAM.**

7 (a) **AUDIT OF MANUFACTURER PRICE AND DRUG**  
8 **PRODUCT INFORMATION.—**

9 (1) **IN GENERAL.—**Subparagraph (B) of section  
10 1927(b)(3) of the Social Security Act (42 U.S.C.  
11 1396r–8(b)(3)) is amended to read as follows:

12 “(B) **AUDITS AND SURVEYS OF MANUFAC-**  
13 **TURER PRICE AND DRUG PRODUCT INFORMA-**  
14 **TION.—**

15 “(i) **AUDITS.—**The Secretary shall  
16 conduct ongoing audits of the price and  
17 drug product information reported by man-  
18 ufacturers under subparagraph (A) for the  
19 most recently ended rebate period to en-  
20 sure the accuracy and timeliness of such  
21 information. In conducting such audits, the  
22 Secretary may employ evaluations, surveys,  
23 statistical sampling, predictive analytics  
24 and other relevant tools and methods.

1                   “(ii) VERIFICATIONS SURVEYS OF AV-  
2                   ERAGE MANUFACTURER PRICE AND MANU-  
3                   FACTURER’S AVERAGE SALES PRICE.—In  
4                   addition to the audits required under  
5                   clause (i), the Secretary may survey whole-  
6                   salers and manufacturers (including manu-  
7                   facturers that directly distribute their cov-  
8                   ered outpatient drugs (in this subpara-  
9                   graph referred to as ‘direct sellers’)), when  
10                  necessary, to verify manufacturer prices  
11                  and manufacturer’s average sales prices  
12                  (including wholesale acquisition cost) to  
13                  make payment reported under subpara-  
14                  graph (A).

15                  “(iii) PENALTIES.—In addition to  
16                  other penalties as may be prescribed by  
17                  law, including under subparagraph (C) of  
18                  this paragraph, the Secretary may impose  
19                  a civil monetary penalty in an amount not  
20                  to exceed \$185,000 on an annual basis on  
21                  a wholesaler, manufacturer, or direct sell-  
22                  er, if the wholesaler, manufacturer, or di-  
23                  rect seller of a covered outpatient drug re-  
24                  fuses a request for information about  
25                  charges or prices by the Secretary in con-



1           nection with an audit or survey under this  
2           subparagraph or knowingly provides false  
3           information. The provisions of section  
4           1128A (other than subsections (a) (with  
5           respect to amounts of penalties or addi-  
6           tional assessments) and (b)) shall apply to  
7           a civil money penalty under this clause in  
8           the same manner as such provisions apply  
9           to a penalty or proceeding under section  
10          1128A(a).

11                   “(iv) REPORTS.—

12                           “(I) REPORT TO CONGRESS.—

13           The Secretary shall, not later than 18  
14           months after date of enactment of  
15           this subparagraph, submit a report to  
16           the Committee on Energy and Com-  
17           merce of the House of Representatives  
18           and the Committee on Finance of the  
19           Senate regarding additional regulatory  
20           or statutory changes that may be re-  
21           quired in order to ensure accurate and  
22           timely reporting and oversight of  
23           manufacturer price and drug product  
24           information, including whether  
25           changes should be made to reasonable

1 assumption requirements to ensure  
2 such assumptions are reasonable and  
3 accurate or whether another method-  
4 ology for ensuring accurate and timely  
5 reporting of price and drug product  
6 information should be considered to  
7 ensure the integrity of the drug rebate  
8 program under this section.

9 “(II) ANNUAL REPORTS.—The  
10 Secretary shall, on at least an annual  
11 basis, submit a report to the Com-  
12 mittee on Energy and Commerce of  
13 the House of Representatives and the  
14 Committee on Finance of the Senate  
15 summarizing the results of the audits  
16 and surveys conducted under this sub-  
17 paragraph during the period that is  
18 the subject of the report.

19 “(III) CONTENT.—Each report  
20 submitted under subclause (II) shall,  
21 with respect to the period that is the  
22 subject of the report, include sum-  
23 maries of—

24 “(aa) error rates in the  
25 price, drug product, and other

1 relevant information supplied by  
2 manufacturers under subpara-  
3 graph (A);

4 “(bb) the timeliness with  
5 which manufacturers, whole-  
6 salers, and direct sellers provide  
7 information required under sub-  
8 paragraph (A) or under clause (i)  
9 or (ii) of this subparagraph;

10 “(cc) the number of manu-  
11 facturers, wholesalers, and direct  
12 sellers and drug products audited  
13 under this subparagraph;

14 “(dd) the types of price and  
15 drug product information re-  
16 viewed under the audits con-  
17 ducted under this subparagraph;

18 “(ee) the tools and meth-  
19 odologies employed in such au-  
20 dits;

21 “(ff) the findings of such  
22 audits, including which manufac-  
23 turers, if any, were penalized  
24 under this subparagraph; and

1 “(gg) such other relevant in-  
2 formation as the Secretary shall  
3 deem appropriate.

4 “(IV) PROTECTION OF INFORMA-  
5 TION.—In preparing a report required  
6 under subclause (II), the Secretary  
7 shall redact such proprietary informa-  
8 tion as the Secretary determines ap-  
9 propriate to prevent disclosure of, and  
10 to safeguard, such information.

11 “(v) APPROPRIATIONS.—Out of any  
12 funds in the Treasury not otherwise appro-  
13 priated, there is appropriated to the Sec-  
14 retary \$2,000,000 for fiscal year 2022 and  
15 each fiscal year thereafter to carry out this  
16 subparagraph.”.

17 (2) EFFECTIVE DATE.—The amendments made  
18 by this subsection shall take effect on the first day  
19 of the first fiscal quarter that begins after the date  
20 of enactment of this Act.

21 (b) INCREASED PENALTIES FOR NONCOMPLIANCE  
22 WITH REPORTING REQUIREMENTS.—

23 (1) INCREASED PENALTY FOR LATE REPORTING  
24 OF INFORMATION.—Section 1927(b)(3)(C)(i) of the  
25 Social Security Act (42 U.S.C. 1396r–8(b)(3)(C)(i))

1 is amended by striking “increased by \$10,000 for  
2 each day in which such information has not been  
3 provided and such amount shall be paid to the  
4 Treasury” and inserting “, for each covered out-  
5 patient drug with respect to which such information  
6 is not provided, \$50,000 for the first day that such  
7 information is not provided on a timely basis and  
8 \$19,000 for each subsequent day that such informa-  
9 tion is not provided”.

10 (2) INCREASED PENALTY FOR KNOWINGLY RE-  
11 PORTING FALSE INFORMATION.—Section  
12 1927(b)(3)(C)(ii) of the Social Security Act (42  
13 U.S.C. 1396r–8(b)(3)(C)(ii)) is amended by striking  
14 “\$100,000” and inserting “\$500,000”.

15 (3) EFFECTIVE DATE.—The amendments made  
16 by this subsection shall take effect on the first day  
17 of the first fiscal quarter that begins after the date  
18 of enactment of this Act.

19 **SEC. 30604. IMPROVING TRANSPARENCY AND PREVENTING**  
20 **THE USE OF ABUSIVE SPREAD PRICING AND**  
21 **RELATED PRACTICES IN MEDICAID.**

22 (a) PASS-THROUGH PRICING REQUIRED.—

23 (1) IN GENERAL.—Section 1927(e) of the So-  
24 cial Security Act (42 U.S.C. 1396r–8(e)) is amended  
25 by adding at the end the following:

1           “(6) PASS-THROUGH PRICING REQUIRED.—A  
2           contract between the State and a pharmacy benefit  
3           manager (referred to in this paragraph as a ‘PBM’),  
4           or a contract between the State and a managed care  
5           entity or other specified entity (as such terms are  
6           defined in section 1903(m)(9)(D)) that includes pro-  
7           visions making the entity responsible for coverage of  
8           covered outpatient drugs dispensed to individuals en-  
9           rolled with the entity, shall require that payment for  
10          such drugs and related administrative services (as  
11          applicable), including payments made by a PBM on  
12          behalf of the State or entity, is based on a pass-  
13          through pricing model under which—

14                   “(A) any payment made by the entity of  
15                   the PBM (as applicable) for such a drug—

16                           “(i) is limited to—

17                                   “(I) ingredient cost; and

18                                   “(II) a professional dispensing  
19                                   fee that is not less than the profes-  
20                                   sional dispensing fee that the State  
21                                   plan or waiver would pay if the plan  
22                                   or waiver was making the payment di-  
23                                   rectly;

1           “(ii) is passed through in its entirety  
2           by the entity or PBM to the pharmacy  
3           that dispenses the drug; and

4           “(iii) is made in a manner that is con-  
5           sistent with section 1902(a)(30)(A) and  
6           sections 447.512, 447.514, and 447.518 of  
7           title 42, Code of Federal Regulations (or  
8           any successor regulation), as if such re-  
9           quirements applied directly to the entity or  
10          the PBM;

11          “(B) payment to the entity or the PBM  
12          (as applicable) for administrative services per-  
13          formed by the entity or PBM is limited to a  
14          reasonable administrative fee that covers the  
15          reasonable cost of providing such services;

16          “(C) the entity or the PBM (as applicable)  
17          shall make available to the State, and the Sec-  
18          retary upon request, all costs and payments re-  
19          lated to covered outpatient drugs and accom-  
20          panying administrative services incurred, re-  
21          ceived, or made by the entity or the PBM, in-  
22          cluding ingredient costs, professional dispensing  
23          fees, administrative fees, post-sale and post-in-  
24          voice fees. Discounts, or related adjustments

1 such as direct and indirect remuneration fees,  
2 and any and all remuneration; and

3 “(D) any form of spread pricing whereby  
4 any amount charged or claimed by the entity or  
5 the PBM (as applicable) is in excess of the  
6 amount paid to the pharmacies on behalf of the  
7 entity, including any post-sale or post-invoice  
8 fees, discounts, or related adjustments such as  
9 direct and indirect remuneration fees or assess-  
10 ments (after allowing for a reasonable adminis-  
11 trative fee as described in subparagraph (B)) is  
12 not allowable for purposes of claiming Federal  
13 matching payments under this title.”.

14 (2) CONFORMING AMENDMENT.—Clause (xiii)  
15 of section 1903(m)(2)(A) of such Act (42 U.S.C.  
16 1396b(m)(2)(A)), as amended by section 202, is fur-  
17 ther amended—

18 (A) by striking “and (IV)” and inserting  
19 “(IV)”; and

20 (B) by inserting before the period at the  
21 end the following: “, and (V) pharmacy benefit  
22 management services provided by the entity, or  
23 provided by a pharmacy benefit manager on be-  
24 half of the entity under a contract or other ar-  
25 rangement between the entity and the phar-



1           macy benefit manager, shall comply with the re-  
2           quirements of section 1927(e)(6)”.

3           (3) EFFECTIVE DATE.—The amendments made  
4           by this subsection apply to contracts between States  
5           and managed care entities, other specified entities,  
6           or pharmacy benefits managers that are entered into  
7           or renewed on or after the date that is 18 months  
8           after the date of enactment of this Act.

9           (b) SURVEY OF RETAIL PRICES.—

10           (1) IN GENERAL.—Section 1927(f) of the Social  
11           Security Act (42 U.S.C. 1396r–8(f)) is amended—

12           (A) by striking “and” after the semicolon  
13           at the end of paragraph (1)(A)(i) and all that  
14           precedes it through “(1)” and inserting the fol-  
15           lowing:

16           “(1) SURVEY OF RETAIL PRICES.—The Sec-  
17           retary shall conduct a survey of retail community  
18           drug prices, to include at least the national average  
19           drug acquisition cost, as follows:

20           “(A) USE OF VENDOR.—The Secretary  
21           may contract services for—

22           “(i) with respect to retail community  
23           pharmacies, the determination on a month-  
24           ly basis of retail survey prices of the na-  
25           tional average drug acquisition cost for

1 covered outpatient drugs for such phar-  
2 macies, net of all discounts and rebates (to  
3 the extent any information with respect to  
4 such discounts and rebates is available),  
5 the average reimbursement received for  
6 such drugs by such pharmacies from all  
7 sources of payment, including third par-  
8 ties, and, to the extent available, the usual  
9 and customary charges to consumers for  
10 such drugs; and”;

11 (B) by adding at the end of paragraph (1)  
12 the following:

13 “(F) SURVEY REPORTING.—In order to  
14 meet the requirement of section 1902(a)(54), a  
15 State shall require that any retail community  
16 pharmacy in the State that receives any pay-  
17 ment, administrative fee, discount, or rebate re-  
18 lated to the dispensing of covered outpatient  
19 drugs to individuals receiving benefits under  
20 this title, regardless of whether such payment,  
21 fee, discount, or rebate is received from the  
22 State or a managed care entity directly or from  
23 a pharmacy benefit manager or another entity  
24 that has a contract with the State or a man-

1 aged care entity, shall respond to surveys of re-  
2 tail prices conducted under this subsection.

3 “(G) SURVEY INFORMATION.—Information  
4 on retail community prices obtained under this  
5 paragraph shall be made publicly available and  
6 shall include at least the following:

7 “(i) The monthly response rate of the  
8 survey including a list of pharmacies not in  
9 compliance with subparagraph (F).

10 “(ii) The sampling frame and number  
11 of pharmacies sampled monthly.

12 “(iii) Characteristics of reporting  
13 pharmacies, including type (such as inde-  
14 pendent or chain), geographic or regional  
15 location, and dispensing volume.

16 “(iv) Reporting of a separate national  
17 average drug acquisition cost for each drug  
18 for independent retail pharmacies and  
19 chain operated pharmacies.

20 “(v) Information on price concessions  
21 including on and off invoice discounts, re-  
22 bates, and other price concessions.

23 “(vi) Information on average profes-  
24 sional dispensing fees paid.

25 “(H) PENALTIES.—

1           “(i) FAILURE TO PROVIDE TIMELY IN-  
2           FORMATION.—A retail community phar-  
3           macy that fails to respond to a survey con-  
4           ducted under this subsection on a timely  
5           basis may be subject to a civil monetary  
6           penalty in the amount of \$10,000 for each  
7           day in which such information has not  
8           been provided.

9           “(ii) FALSE INFORMATION.—A retail  
10          community pharmacy that knowingly pro-  
11          vides false information in response to a  
12          survey conducted under this subsection  
13          may be subject to a civil money penalty in  
14          an amount not to exceed \$100,000 for  
15          each item of false information.

16          “(iii) OTHER PENALTIES.—Any civil  
17          money penalties imposed under this sub-  
18          paragraph shall be in addition to other  
19          penalties as may be prescribed by law. The  
20          provisions of section 1128A (other than  
21          subsections (a) and (b)) shall apply to a  
22          civil money penalty under this subpara-  
23          graph in the same manner as such provi-  
24          sions apply to a penalty or proceedings  
25          under section 1128A(a).

1                   “(I) REPORT ON SPECIALTY PHAR-  
2                   MACIES.—

3                   “(i) IN GENERAL.—Not later than 1  
4                   year after the effective date of this sub-  
5                   paragraph, the Secretary shall submit a re-  
6                   port to Congress examining specialty drug  
7                   coverage and reimbursement under this  
8                   title.

9                   “(ii) CONTENT OF REPORT.—Such re-  
10                  port shall include a description of how  
11                  State Medicaid programs define specialty  
12                  drugs, how much State Medicaid programs  
13                  pay for specialty drugs, how States and  
14                  managed care plans determine payment for  
15                  specialty drugs, the settings in which spe-  
16                  cialty drugs are dispensed (such as retail  
17                  community pharmacies or specialty phar-  
18                  macies), whether acquisition costs for spe-  
19                  cialty drugs are captured in the national  
20                  average drug acquisition cost survey, and  
21                  recommendations as to whether specialty  
22                  pharmacies should be included in the sur-  
23                  vey of retail prices to ensure national aver-  
24                  age drug acquisition costs capture drugs

1 sold at specialty pharmacies and how such  
2 specialty pharmacies should be defined.”;

3 (C) in paragraph (2)—

4 (i) in subparagraph (A), by inserting  
5 “, including payments rates under Med-  
6 icaid managed care plans,” after “under  
7 this title”; and

8 (ii) in subparagraph (B), by inserting  
9 “and the basis for such dispensing fees”  
10 before the semicolon; and

11 (D) in paragraph (4), by inserting “, and  
12 \$5,000,000 for fiscal year 2022 and each fiscal  
13 year thereafter,” after “2010”.

14 (2) EFFECTIVE DATE.—The amendments made  
15 by this subsection take effect on the 1st day of the  
16 1st quarter that begins on or after the date that is  
17 18 months after the date of enactment of this Act.

18 (c) MANUFACTURER REPORTING OF WHOLESALE  
19 ACQUISITION COST.—Section 1927(b)(3) of such Act (42  
20 U.S.C. 1396r–8(b)(3)), as amended by section 141, is fur-  
21 ther amended—

22 (1) in subparagraph (A)(i)—

23 (A) in subclause (I), by striking “and”  
24 after the semicolon;

1 (B) in subclause (II), by adding “and”  
2 after the semicolon;

3 (C) by moving the left margins of sub-  
4 clauses (I) and (II) 2 ems to the right; and

5 (D) by adding at the end the following:

6 “(III) in the case of rebate peri-  
7 ods that begin on or after the date of  
8 enactment of this subclause, on the  
9 wholesale acquisition cost (as defined  
10 in section 1847A(c)(6)(B)) for cov-  
11 ered outpatient drugs for the rebate  
12 period under the agreement (including  
13 for all such drugs that are sold under  
14 a new drug application approved  
15 under section 505(c) of the Federal  
16 Food, Drug, and Cosmetic Act);”;

17 (2) in subparagraph (D)—

18 (A) in the matter preceding clause (i), by  
19 inserting “and clause (vii) of this subpara-  
20 graph” after “1847A”;

21 (B) in clause (vi), by striking “and” after  
22 the comma;

23 (C) in clause (vii), by striking the period  
24 and inserting “, and”; and

1 (D) by inserting after clause (vii) the fol-  
2 lowing:

3 “(viii) to the Secretary to disclose  
4 (through a website accessible to the public)  
5 the most recently reported wholesale acqui-  
6 sition cost (as defined in section  
7 1847A(c)(6)(B)) for each covered out-  
8 patient drug (including for all such drugs  
9 that are sold under a new drug application  
10 approved under section 505(c) of the Fed-  
11 eral Food, Drug, and Cosmetic Act), as re-  
12 ported under subparagraph (A)(i)(III).”.

13 **SEC. 30605. T-MSIS DRUG DATA ANALYTICS REPORTS.**

14 (a) IN GENERAL.—Not later than May 1 of each cal-  
15 endar year beginning with calendar year 2023, the Sec-  
16 retary of Health and Human Services (in this section re-  
17 ferred to as the “Secretary”) shall publish on a website  
18 of the Centers for Medicare & Medicaid Services that is  
19 accessible to the public a report of the most recently avail-  
20 able data on provider prescribing patterns under the Med-  
21 icaid program.

22 (b) CONTENT OF REPORT.—

23 (1) REQUIRED CONTENT.—Each report re-  
24 quired under subsection (a) for a calendar year shall  
25 include the following information with respect to



1 each State (and, to the extent available, with respect  
2 to Puerto Rico, the United States Virgin Islands,  
3 Guam, the Northern Mariana Islands, and American  
4 Samoa):

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

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

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

17 (iii) by episodes of care for—

18 (I) each chronic disease category,  
19 as defined by the Secretary, that is  
20 represented in the 10 conditions that  
21 accounted for the greatest share of  
22 total spending under the plan or waiv-  
23 er during the year that is the subject  
24 of the report;

25 (II) procedural groupings; and

1 (III) rare disease diagnosis codes;  
2 (iv) by patient demographic character-  
3 istics, including race (to the extent that  
4 the Secretary determines that there is suf-  
5 ficient data available with respect to such  
6 characteristic in a majority of States), gen-  
7 der, and age;  
8 (v) by patient high-utilizer or risk sta-  
9 tus; and  
10 (vi) by high and low resource settings  
11 by facility and place of service categories,  
12 as determined by the Secretary.

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

22 (2) ADDITIONAL CONTENT.—A report required  
23 under subsection (a) for a calendar year may include  
24 State-specific information about prescription utiliza-

1           tion management tools under State Medicaid plans  
2           or waivers of such plans, including—

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

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

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

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

22                  (E) a comparison of the prescription utili-  
23                  zation management tools applicable under the  
24                  State Medicaid plan or waiver by patient high-  
25                  utilizer or risk status.

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

4                   (A) analyses of national, State, and local  
5                   patterns of Medicaid population-based pre-  
6                   scribing behaviors; and

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

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

15                  (1) be prepared using data and definitions from  
16                  the Transformed Medicaid Statistical Information  
17                  System (T-MSIS) data set (or a successor data set)  
18                  that is not more than 24 months old on the date  
19                  that the report is published; and

20                  (2) as appropriate, include a description with  
21                  respect to each State of the quality and complete-  
22                  ness of the data, as well as any necessary caveats  
23                  describing the limitations of the data reported to the  
24                  Secretary by the State that are sufficient to commu-  
25                  nicate the appropriate uses for the information.

1 (d) PREPARATION OF REPORT.—Each report re-  
2 quired under subsection (a) shall be prepared by the Ad-  
3 ministrator for the Centers for Medicare & Medicaid Serv-  
4 ices.

5 (e) APPROPRIATION.—For fiscal year 2022 and each  
6 fiscal year thereafter, there is appropriated to the Sec-  
7 retary \$2,000,000 to carry out this section.

8 **SEC. 30606. RISK-SHARING VALUE-BASED PAYMENT AGREE-**  
9 **MENTS FOR COVERED OUTPATIENT DRUGS**  
10 **UNDER MEDICAID.**

11 (a) IN GENERAL.—Section 1927 of the Social Secu-  
12 rity Act (42 U.S.C. 1396r–8) is amended by adding at  
13 the end the following new subsection:

14 “(1) STATE OPTION TO PAY FOR COVERED OUT-  
15 PATIENT DRUGS THROUGH RISK-SHARING VALUE-BASED  
16 AGREEMENTS.—

17 “(1) IN GENERAL.—Beginning January 1,  
18 2022, a State shall have the option to pay (whether  
19 on a fee-for-service or managed care basis) for cov-  
20 ered outpatient drugs that are potentially curative  
21 treatments intended for one-time use that are ad-  
22 ministered to individuals under this title by entering  
23 into a risk-sharing value-based payment agreement  
24 with the manufacturer of the drug in accordance  
25 with the requirements of this subsection.

1           “(2) SECRETARIAL APPROVAL.—

2                   “(A) IN GENERAL.—A State shall submit a  
3 request to the Secretary to enter into a risk-  
4 sharing value based payment agreement, and  
5 the Secretary shall not approve a proposed risk-  
6 sharing value-based payment agreement be-  
7 tween a State and a manufacturer for payment  
8 for a covered outpatient drug of the manufac-  
9 turer unless the following requirements are met:

10                   “(i) MANUFACTURER IS PARTY TO RE-  
11 BATE AGREEMENT AND IN COMPLIANCE  
12 WITH REQUIREMENTS.—The manufacturer  
13 has a rebate agreement in effect as re-  
14 quired under subsections (a) and (b) of  
15 this section and is in compliance with all  
16 applicable requirements under this title.

17                   “(ii) NO INCREASE TO PROJECTED  
18 NET FEDERAL SPENDING.—

19                   “(I) IN GENERAL.—The Chief  
20 Actuary certifies that the projected  
21 payments for each covered outpatient  
22 drug under such proposed agreement  
23 would not result in greater estimated  
24 Federal spending under this title than  
25 the net Federal spending that would

1 result in the absence of the agree-  
2 ment.

3 “(II) NET FEDERAL SPENDING  
4 DEFINED.—For purposes of this sub-  
5 section, the term ‘net Federal spend-  
6 ing’ means the amount of Federal  
7 payments the Chief Actuary estimates  
8 would be made under this title for ad-  
9 ministering a covered outpatient drug  
10 to an individual eligible for medical  
11 assistance under a State plan or a  
12 waiver of such plan, reduced by the  
13 amount of all rebates the Chief Actu-  
14 ary estimates would be paid with re-  
15 spect to the administering of such  
16 drug, including all rebates under this  
17 title and any supplemental or other  
18 additional rebates, in the absence of  
19 such an agreement.

20 “(III) INFORMATION.—The Chief  
21 Actuary shall make the certifications  
22 required under this clause based on  
23 the most recently available and reli-  
24 able drug pricing and product infor-  
25 mation. The State and manufacturer

1 shall provide the Secretary and the  
2 Chief Actuary with all necessary infor-  
3 mation required to make the estimates  
4 needed for such certifications.

5 “(iii) LAUNCH AND LIST PRICE JUS-  
6 TIFICATIONS.—The manufacturer submits  
7 all relevant information and supporting  
8 documentation necessary for pricing deci-  
9 sions as deemed appropriate by the Sec-  
10 retary, which shall be truthful and non-  
11 misleading, including manufacturer infor-  
12 mation and supporting documentation for  
13 launch price or list price increases, and  
14 any applicable justification required under  
15 section 1128L.

16 “(iv) CONFIDENTIALITY OF INFORMA-  
17 TION; PENALTIES.—The provisions of sub-  
18 paragraphs (C) and (D) of subsection  
19 (b)(3) shall apply to a manufacturer that  
20 fails to submit the information and docu-  
21 mentation required under clauses (ii) and  
22 (iii) on a timely basis, or that knowingly  
23 provides false or misleading information, in  
24 the same manner as such provisions apply



1 to a manufacturer with a rebate agreement  
2 under this section.

3 “(B) CONSIDERATION OF STATE REQUEST  
4 FOR APPROVAL.—

5 “(i) IN GENERAL.—The Secretary  
6 shall treat a State request for approval of  
7 a risk-sharing value-based payment agree-  
8 ment in the same manner that the Sec-  
9 retary treats a State plan amendment, and  
10 subpart B of part 430 of title 42, Code of  
11 Federal Regulations, including, subject to  
12 clause (ii), the timing requirements of sec-  
13 tion 430.16 of such title (as in effect on  
14 the date of enactment of this subsection),  
15 shall apply to a request for approval of a  
16 risk-sharing value-based payment agree-  
17 ment in the same manner as such subpart  
18 applies to a State plan amendment.

19 “(ii) TIMING.—The Secretary shall  
20 consult with the Commissioner of Food  
21 and Drugs as required under subpara-  
22 graph (C) and make a determination on  
23 whether to approve a request from a State  
24 for approval of a proposed risk-sharing  
25 value-based payment agreement (or request

1 additional information necessary to allow  
2 the Secretary to make a determination  
3 with respect to such request for approval)  
4 within the time period, to the extent prac-  
5 ticable, specified in section 430.16 of title  
6 42, Code of Federal Regulations (as in ef-  
7 fect on the date of enactment of this sub-  
8 section), but in no case shall the Secretary  
9 take more than 180 days after the receipt  
10 of such request for approval or response to  
11 such request for additional information to  
12 make such a determination (or request ad-  
13 ditional information).

14 “(C) CONSULTATION WITH THE COMMIS-  
15 SIONER OF FOOD AND DRUGS.—In considering  
16 whether to approve a risk-sharing value-based  
17 payment agreement, the Secretary, to the ex-  
18 tent necessary, shall consult with the Commis-  
19 sioner of Food and Drugs to determine whether  
20 the relevant clinical parameters specified in  
21 such agreement are appropriate.

22 “(3) INSTALLMENT-BASED PAYMENT STRUC-  
23 TURE.—

24 “(A) IN GENERAL.—A risk-sharing value-  
25 based payment agreement shall provide for a

1 payment structure under which, for every in-  
2 stallment year of the agreement (subject to sub-  
3 paragraph (B)), the State shall pay the total in-  
4 stallment year amount in equal installments to  
5 be paid at regular intervals over a period of  
6 time that shall be specified in the agreement.

7 “(B) REQUIREMENTS FOR INSTALLMENT  
8 PAYMENTS.—

9 “(i) TIMING OF FIRST PAYMENT.—

10 The State shall make the first of the in-  
11 stallment payments described in subpara-  
12 graph (A) for an installment year not later  
13 than 30 days after the end of such year.

14 “(ii) LENGTH OF INSTALLMENT PE-  
15 RIOD.—The period of time over which the  
16 State shall make the installment payments  
17 described in subparagraph (A) for an in-  
18 stallment year shall not be longer than 5  
19 years.

20 “(iii) NONPAYMENT OR REDUCED  
21 PAYMENT OF INSTALLMENTS FOLLOWING  
22 A FAILURE TO MEET CLINICAL PARAM-  
23 ETER.—If, prior to the payment date (as  
24 specified in the agreement) of any install-  
25 ment payment described in subparagraph

1 (A) or any other alternative date or time  
2 frame (as otherwise specified in the agree-  
3 ment), the covered outpatient drug which  
4 is subject to the agreement fails to meet a  
5 relevant clinical parameter of the agree-  
6 ment, the agreement shall provide that—

7 “(I) the installment payment  
8 shall not be made; or

9 “(II) the installment payment  
10 shall be reduced by a percentage spec-  
11 ified in the agreement that is based  
12 on the outcome achieved by the drug  
13 relative to the relevant clinical param-  
14 eter.

15 “(4) NOTICE OF INTENT.—

16 “(A) IN GENERAL.—Subject to subpara-  
17 graph (B), a manufacturer of a covered out-  
18 patient drug shall not be eligible to enter into  
19 a risk-sharing value-based payment agreement  
20 under this subsection with respect to such drug  
21 unless the manufacturer notifies the Secretary  
22 that the manufacturer is interested in entering  
23 into such an agreement with respect to such  
24 drug. The decision to submit and timing of a  
25 request to enter into a proposed risk-sharing

1 value-based payment agreement shall remain  
2 solely within the discretion of the State and  
3 shall only be effective upon Secretarial approval  
4 as required under this subsection.

5 “(B) TREATMENT OF SUBSEQUENTLY AP-  
6 PROVED DRUGS.—

7 “(i) IN GENERAL.—In the case of a  
8 manufacturer of a covered outpatient drug  
9 approved under section 505 of the Federal  
10 Food, Drug, and Cosmetic Act or licensed  
11 under section 351 of the Public Health  
12 Service Act after the date of enactment of  
13 this subsection, not more than 90 days  
14 after meeting with the Food and Drug Ad-  
15 ministration following phase II clinical  
16 trials for such drug (or, in the case of a  
17 drug described in clause (ii), not later than  
18 March 31, 2022), the manufacturer must  
19 notify the Secretary of the manufacturer’s  
20 intent to enter into a risk-sharing value-  
21 based payment agreement under this sub-  
22 section with respect to such drug. If no  
23 such meeting has occurred, the Secretary  
24 may use discretion as to whether a poten-  
25 tially curative treatment intended for one-

1 time use may qualify for a risk-sharing  
2 value-based payment agreement under this  
3 section. A manufacturer notification of in-  
4 terest shall not have any influence on a de-  
5 cision for approval by the Food and Drug  
6 Administration.

7 “(ii) APPLICATION TO CERTAIN SUB-  
8 SEQUENTLY APPROVED DRUGS.—A drug  
9 described in this clause is a covered out-  
10 patient drug of a manufacturer—

11 “(I) that is approved under sec-  
12 tion 505 of the Federal Food, Drug,  
13 and Cosmetic Act or licensed under  
14 section 351 of the Public Health Serv-  
15 ice Act after the date of enactment of  
16 this subsection; and

17 “(II) with respect to which, as of  
18 January 1, 2022, more than 90 days  
19 have passed after the manufacturer’s  
20 meeting with the Food and Drug Ad-  
21 ministration following phase II clinical  
22 trials for such drug.

23 “(iii) PARALLEL APPROVAL.—The  
24 Secretary, in coordination with the Admin-  
25 istrator of the Centers for Medicare &

1 Medicaid Services and the Commissioner of  
2 Food and Drugs, shall, to the extent prac-  
3 ticable, approve a State’s request to enter  
4 into a proposed risk-sharing value-based  
5 payment agreement that otherwise meets  
6 the requirements of this subsection at the  
7 time that such a drug is approved by the  
8 Food and Drug Administration to help  
9 provide that no State that wishes to enter  
10 into such an agreement is required to pay  
11 for the drug in full at one time if the State  
12 is seeking to pay over a period of time as  
13 outlined in the proposed agreement.

14 “(iv) RULE OF CONSTRUCTION.—  
15 Nothing in this paragraph shall be applied  
16 or construed to modify or affect the time-  
17 frames or factors involved in the Sec-  
18 retary’s determination of whether to ap-  
19 prove or license a drug under section 505  
20 of the Federal Food, Drug, and Cosmetic  
21 Act or section 351 of the Public Health  
22 Service Act.

23 “(5) SPECIAL PAYMENT RULES.—

24 “(A) IN GENERAL.—Except as otherwise  
25 provided in this paragraph, with respect to an

1 individual who is administered a unit of a cov-  
2 ered outpatient drug that is purchased under a  
3 State plan by a State Medicaid agency under a  
4 risk-sharing value-based payment agreement in  
5 an installment year, the State shall remain lia-  
6 ble to the manufacturer of such drug for pay-  
7 ment for such unit without regard to whether  
8 the individual remains enrolled in the State  
9 plan under this title (or a waiver of such plan)  
10 for each installment year for which the State is  
11 to make installment payments for covered out-  
12 patient drugs purchased under the agreement  
13 in such year.

14 “(B) DEATH.—In the case of an individual  
15 described in subparagraph (A) who dies during  
16 the period described in such subparagraph, the  
17 State plan shall not be liable for any remaining  
18 payment for the unit of the covered outpatient  
19 drug administered to the individual which is  
20 owed under the agreement described in such  
21 subparagraph.

22 “(C) WITHDRAWAL OF APPROVAL.—In the  
23 case of a covered outpatient drug that is the  
24 subject of a risk-sharing value-based agreement  
25 between a State and a manufacturer under this



1 subsection, including a drug approved in ac-  
2 cordance with section 506(c) of the Federal  
3 Food, Drug, and Cosmetic Act, and such drug  
4 is the subject of an application that has been  
5 withdrawn by the Secretary, the State plan  
6 shall not be liable for any remaining payment  
7 that is owed under the agreement.

8 “(D) ALTERNATIVE ARRANGEMENT UNDER  
9 AGREEMENT.—Subject to approval by the Sec-  
10 retary, the terms of a proposed risk-sharing  
11 value-based payment agreement submitted for  
12 approval by a State may provide that subpara-  
13 graph (A) shall not apply.

14 “(E) GUIDANCE.—Not later than January  
15 1, 2022, the Secretary shall issue guidance to  
16 States establishing a process for States to no-  
17 tify the Secretary when an individual who is ad-  
18 ministered a unit of a covered outpatient drug  
19 that is purchased by a State plan under a risk-  
20 sharing value-based payment agreement ceases  
21 to be enrolled under the State plan under this  
22 title (or a waiver of such plan) or dies before  
23 the end of the installment period applicable to  
24 such unit under the agreement.

1           “(6) TREATMENT OF PAYMENTS UNDER RISK-  
2 SHARING VALUE-BASED AGREEMENTS FOR PUR-  
3 POSES OF AVERAGE MANUFACTURER PRICE; BEST  
4 PRICE.—The Secretary shall treat any payments  
5 made to the manufacturer of a covered outpatient  
6 drug under a risk-sharing value-based payment  
7 agreement under this subsection during a rebate pe-  
8 riod in the same manner that the Secretary treats  
9 payments made under a State supplemental rebate  
10 agreement under sections 447.504(c)(19) and  
11 447.505(e)(7) of title 42, Code of Federal Regula-  
12 tions (or any successor regulations), for purposes of  
13 determining average manufacturer price and best  
14 price under this section with respect to the covered  
15 outpatient drug and a rebate period and for pur-  
16 poses of offsets required under subsection (b)(1)(B).

17           “(7) ASSESSMENTS AND REPORT TO CON-  
18 GRESS.—

19           “(A) ASSESSMENTS.—

20           “(i) IN GENERAL.—Not later than  
21 180 days after the end of each assessment  
22 period of any risk-sharing value-based pay-  
23 ment agreement for a State approved  
24 under this subsection, the Secretary shall  
25 conduct an evaluation of such agreement

1           which shall include an evaluation by the  
2           Chief Actuary to determine whether pro-  
3           gram spending under the risk-sharing  
4           value-based payment agreement aligned  
5           with the projections for the agreement  
6           made under paragraph (2)(A)(ii), including  
7           an assessment of whether actual Federal  
8           spending under this title under the agree-  
9           ment was less or more than net Federal  
10          spending would have been in the absence  
11          of the agreement.

12                   “(ii) ASSESSMENT PERIOD.—For pur-  
13                   poses of clause (i)—

14                           “(I) the first assessment period  
15                           for a risk-sharing value-based pay-  
16                           ment agreement shall be the period of  
17                           time over which payments are sched-  
18                           uled to be made under the agreement  
19                           for the first 10 individuals who are  
20                           administered covered outpatient drugs  
21                           under the agreement except that such  
22                           period shall not exceed the 5-year pe-  
23                           riod after the date on which the Sec-  
24                           retary approves the agreement; and

1                   “(II) each subsequent assessment  
2                   period for a risk-sharing value-based  
3                   payment agreement shall be the 5-  
4                   year period following the end of the  
5                   previous assessment period.

6                   “(B) RESULTS OF ASSESSMENTS.—

7                   “(i) TERMINATION OPTION.—If the  
8                   Secretary determines as a result of the as-  
9                   sessment by the Chief Actuary under sub-  
10                  paragraph (A) that the actual Federal  
11                  spending under this title for any covered  
12                  outpatient drug that was the subject of the  
13                  State’s risk-sharing value-based payment  
14                  agreement was greater than the net Fed-  
15                  eral spending that would have resulted in  
16                  the absence of the agreement, the Sec-  
17                  retary may terminate approval of such  
18                  agreement and shall immediately conduct  
19                  an assessment under this paragraph of any  
20                  other ongoing risk-sharing value-based  
21                  payment agreement to which the same  
22                  manufacturer is a party.

23                  “(ii) REPAYMENT REQUIRED.—

24                  “(I) IN GENERAL.—If the Sec-  
25                  retary determines as a result of the

1 assessment by the Chief Actuary  
2 under subparagraph (A) that the Fed-  
3 eral spending under the risk-sharing  
4 value-based agreement for a covered  
5 outpatient drug that was subject to  
6 such agreement was greater than the  
7 net Federal spending that would have  
8 resulted in the absence of the agree-  
9 ment, the manufacturer shall repay  
10 the difference to the State and Fed-  
11 eral governments in a timely manner  
12 as determined by the Secretary.

13 “(II) TERMINATION FOR FAIL-  
14 URE TO PAY.—The failure of a manu-  
15 facturer to make repayments required  
16 under subclause (I) in a timely man-  
17 ner shall result in immediate termi-  
18 nation of all risk-sharing value-based  
19 agreements to which the manufacturer  
20 is a party.

21 “(III) ADDITIONAL PEN-  
22 ALTIES.—In the case of a manufac-  
23 turer that fails to make repayments  
24 required under subclause (I), the Sec-  
25 retary may treat such manufacturer

1 in the same manner as a manufac-  
2 turer that fails to pay required re-  
3 bates under this section, and the Sec-  
4 retary may—

5 “(aa) suspend or terminate  
6 the manufacturer’s rebate agree-  
7 ment under this section; and

8 “(bb) pursue any other rem-  
9 edy that would be available if the  
10 manufacturer had failed to pay  
11 required rebates under this sec-  
12 tion.

13 “(C) REPORT TO CONGRESS.—Not later  
14 than 5 years after the first risk-sharing value-  
15 based payment agreement is approved under  
16 this subsection, the Secretary shall submit to  
17 Congress and make available to the public a re-  
18 port that includes—

19 “(i) an assessment of the impact of  
20 risk-sharing value-based payment agree-  
21 ments on access for individuals who are eli-  
22 gible for benefits under a State plan or  
23 waiver under this title to medically nec-  
24 essary covered outpatient drugs and re-  
25 lated treatments;

1 “(ii) an analysis of the impact of such  
2 agreements on overall State and Federal  
3 spending under this title;

4 “(iii) an assessment of the impact of  
5 such agreements on drug prices, including  
6 launch price and price increases; and

7 “(iv) such recommendations to Con-  
8 gress as the Secretary deems appropriate.

9 “(8) GUIDANCE AND REGULATIONS.—

10 “(A) IN GENERAL.—Not later than Janu-  
11 ary 1, 2022, the Secretary shall issue guidance  
12 to States seeking to enter into risk-sharing  
13 value-based payment agreements under this  
14 subsection that includes a model template for  
15 such agreements. The Secretary may issue any  
16 additional guidance or promulgate regulations  
17 as necessary to implement and enforce the pro-  
18 visions of this subsection.

19 “(B) MODEL AGREEMENTS.—

20 “(i) IN GENERAL.—If a State ex-  
21 presses an interest in pursuing a risk-shar-  
22 ing value-based payment agreement under  
23 this subsection with a manufacturer for  
24 the purchase of a covered outpatient drug,  
25 the Secretary may share with such State

1 any risk-sharing value-based agreement be-  
2 tween a State and the manufacturer for  
3 the purchase of such drug that has been  
4 approved under this subsection. While such  
5 shared agreement may serve as a template  
6 for a State that wishes to propose, the use  
7 of a previously approved agreement shall  
8 not affect the submission and approval  
9 process for approval of a proposed risk-  
10 sharing value-based payment agreement  
11 under this subsection, including the re-  
12 quirements under paragraph (2)(A).

13 “(ii) CONFIDENTIALITY.—In the case  
14 of a risk-sharing value-based payment  
15 agreement that is disclosed to a State by  
16 the Secretary under this subparagraph and  
17 that is only in effect with respect to a sin-  
18 gle State, the confidentiality of information  
19 provisions described in subsection  
20 (b)(3)(D) shall apply to such information.

21 “(C) OIG CONSULTATION.—

22 “(i) IN GENERAL.—The Secretary  
23 shall consult with the Office of the Inspec-  
24 tor General of the Department of Health  
25 and Human Services to determine whether



1           there are potential program integrity con-  
2           cerns with agreement approvals or tem-  
3           plates and address accordingly.

4           “(ii) ~~OIG~~ POLICY UPDATES AS NEC-  
5           CESSARY.—The Inspector General of the  
6           Department of Health and Human Serv-  
7           ices shall review and update, as necessary,  
8           any policies or guidelines of the Office of  
9           the Inspector General of the Department  
10          of Human Services (including policies re-  
11          lated to the enforcement of section 1128B)  
12          to accommodate the use of risk-sharing  
13          value-based payment agreements in accord-  
14          ance with this section.

15          “(9) RULES OF CONSTRUCTION.—

16          “(A) MODIFICATIONS.—Nothing in this  
17          subsection or any regulations promulgated  
18          under this subsection shall prohibit a State  
19          from requesting a modification from the Sec-  
20          retary to the terms of a risk-sharing value-  
21          based payment agreement. A modification that  
22          is expected to result in any increase to pro-  
23          jected net State or Federal spending under the  
24          agreement shall be subject to recertification by  
25          the Chief Actuary as described in paragraph

1           (2)(A)(ii) before the modification may be ap-  
2           proved.

3           “(B) REBATE AGREEMENTS.—Nothing in  
4           this subsection shall be construed as requiring  
5           a State to enter into a risk-sharing value-based  
6           payment agreement or as limiting or super-  
7           seding the ability of a State to enter into a sup-  
8           plemental rebate agreement for a covered out-  
9           patient drug.

10          “(C) FFP FOR PAYMENTS UNDER RISK-  
11          SHARING VALUE-BASED PAYMENT AGREE-  
12          MENTS.—Federal financial participation shall  
13          be available under this title for any payment  
14          made by a State to a manufacturer for a cov-  
15          ered outpatient drug under a risk-sharing  
16          value-based payment agreement in accordance  
17          with this subsection, except that no Federal fi-  
18          nancial participation shall be available for any  
19          payment made by a State to a manufacturer  
20          under such an agreement on and after the ef-  
21          fective date of a disapproval of such agreement  
22          by the Secretary.

23          “(D) CONTINUED APPLICATION OF OTHER  
24          PROVISIONS.—Except as expressly provided in  
25          this subsection, nothing in this subsection or in

1 any regulations promulgated under this sub-  
2 section shall affect the application of any other  
3 provision of this Act.

4 “(10) APPROPRIATIONS.—For fiscal year 2022  
5 and each fiscal year thereafter, there are appro-  
6 priated to the Secretary \$5,000,000 for the purpose  
7 of carrying out this subsection.

8 “(11) DEFINITIONS.—In this subsection:

9 “(A) CHIEF ACTUARY.—The term ‘Chief  
10 Actuary’ means the Chief Actuary of the Cen-  
11 ters for Medicare & Medicaid Services.

12 “(B) INSTALLMENT YEAR.—The term ‘in-  
13 stallment year’ means, with respect to a risk-  
14 sharing value-based payment agreement, a 12-  
15 month period during which a covered outpatient  
16 drug is administered under the agreement.

17 “(C) POTENTIALLY CURATIVE TREATMENT  
18 INTENDED FOR ONE-TIME USE.—The term ‘po-  
19 tentially curative treatment intended for one-  
20 time use’ means a treatment that consists of  
21 the administration of a covered outpatient drug  
22 that—

23 “(i) is a form of gene therapy for a  
24 rare disease, as defined by the Commis-  
25 sioner of Food and Drugs, designated

1 under section 526 of the Federal Food,  
2 Drug, and Cosmetics Act, and approved  
3 under section 505 of such Act or licensed  
4 under subsection (a) or (k) of section 351  
5 of the Public Health Service Act to treat  
6 a serious or life-threatening disease or con-  
7 dition;

8 “(ii) if administered in accordance  
9 with the labeling of such drug, is expected  
10 to result in either—

11 “(I) the cure of such disease or  
12 condition; or

13 “(II) a reduction in the symp-  
14 toms of such disease or condition to  
15 the extent that such disease or condi-  
16 tion is not expected to lead to early  
17 mortality; and

18 “(iii) is expected to achieve a result  
19 described in clause (ii), which may be  
20 achieved over an extended period of time,  
21 after not more than 3 administrations.

22 “(D) RELEVANT CLINICAL PARAMETER.—  
23 The term ‘relevant clinical parameter’ means,  
24 with respect to a covered outpatient drug that

1 is the subject of a risk-sharing value-based pay-  
2 ment agreement—

3 “(i) a clinical endpoint specified in the  
4 drug’s labeling or supported by one or  
5 more of the compendia described in section  
6 1861(t)(2)(B)(ii)(I) that—

7 “(I) is able to be measured or  
8 evaluated on an annual basis for each  
9 year of the agreement on an inde-  
10 pendent basis by a provider or other  
11 entity; and

12 “(II) is required to be achieved  
13 (based on observed metrics in patient  
14 populations) under the terms of the  
15 agreement; or

16 “(ii) a surrogate endpoint (as defined  
17 in section 507(e)(9) of the Federal Food,  
18 Drug, and Cosmetic Act), including those  
19 developed by patient-focused drug develop-  
20 ment tools, that—

21 “(I) is able to be measured or  
22 evaluated on an annual basis for each  
23 year of the agreement on an inde-  
24 pendent basis by a provider or other  
25 entity; and

1                                   “(II) has been qualified by the  
2                                   Food and Drug Administration.

3                                   “(E) RISK-SHARING VALUE-BASED PAY-  
4                                   MENT AGREEMENT.—The term ‘risk-sharing  
5                                   value-based payment agreement’ means an  
6                                   agreement between a State plan and a manu-  
7                                   facturer—

8                                   “(i) for the purchase of a covered out-  
9                                   patient drug of the manufacturer that is a  
10                                   potentially curative treatment intended for  
11                                   one-time use;

12                                   “(ii) under which payment for such  
13                                   drug shall be made pursuant to an install-  
14                                   ment-based payment structure that meets  
15                                   the requirements of paragraph (3);

16                                   “(iii) which conditions payment on the  
17                                   achievement of at least 2 relevant clinical  
18                                   parameters (as defined in subparagraph  
19                                   (C));

20                                   “(iv) which provides that—

21                                   “(I) the State plan will directly  
22                                   reimburse the manufacturer for the  
23                                   drug; or

1                   “(II) a third party will reimburse  
2                   the manufacture in a manner ap-  
3                   proved by the Secretary; and

4                   “(v) is approved by the Secretary in  
5                   accordance with paragraph (2).

6                   “(F)     TOTAL     INSTALLMENT     YEAR  
7                   AMOUNT.—The term ‘total installment year  
8                   amount’ means, with respect to a risk-sharing  
9                   value-based payment agreement for the pur-  
10                  chase of a covered outpatient drug and an in-  
11                  stallment year, an amount equal to the product  
12                  of—

13                  “(i) the unit price of the drug charged  
14                  under the agreement; and

15                  “(ii) the number of units of such drug  
16                  administered under the agreement during  
17                  such installment year.”.

18                  (b) CONFORMING AMENDMENTS.—

19                  (1) Section 1903(i)(10)(A) of the Social Secu-  
20                  rity Act (42 U.S.C. 1396b(i)(10)(A)) is amended by  
21                  striking “or unless section 1927(a)(3) applies” and  
22                  inserting “, section 1927(a)(3) applies with respect  
23                  to such drugs, or such drugs are the subject of a  
24                  risk-sharing value-based payment agreement under  
25                  section 1927(l)”.

1           (2) Section 1927(b) of the Social Security Act  
2           (42 U.S.C. 1396r–8(b)) is amended—

3                   (A) in paragraph (1)(A), by inserting “(ex-  
4                   cept for drugs for which payment is made by a  
5                   State under a risk-sharing value-based payment  
6                   agreement under subsection (l))” after “under  
7                   the State plan for such period”; and

8                   (B) in paragraph (3)—

9                           (i) in subparagraph (C)(i), by insert-  
10                           ing “or subsection (l)(2)(A)” after “sub-  
11                           paragraph (A)”; and

12                           (ii) in subparagraph (D), in the mat-  
13                           ter preceding clause (i), by inserting “,  
14                           under subsection (l)(2)(A),” after “under  
15                           this paragraph”.

16   **SEC. 30607. APPLYING MEDICAID DRUG REBATE REQUIRE-**  
17                   **MENT TO DRUGS PROVIDED AS PART OF OUT-**  
18                   **PATIENT HOSPITAL SERVICES.**

19           (a) IN GENERAL.—Section 1927(k)(3) of the Social  
20   Security Act (42 U.S.C. 1396r–8(k)(3)) is amended to  
21   read as follows:

22                   “(3) LIMITING DEFINITION.—

23                           “(A) IN GENERAL.—The term ‘covered  
24                           outpatient drug’ does not include any drug, bio-  
25                           logical product, or insulin provided as part of,



1 or as incident to and in the same setting as,  
2 any of the following (and for which payment  
3 may be made under this title as part of pay-  
4 ment for the following and not as direct reim-  
5 bursement for the drug):

6 “(i) Inpatient hospital services.

7 “(ii) Hospice services.

8 “(iii) Dental services, except that  
9 drugs for which the State plan authorizes  
10 direct reimbursement to the dispensing  
11 dentist are covered outpatient drugs.

12 “(iv) Physicians’ services.

13 “(v) Outpatient hospital services.

14 “(vi) Nursing facility services and  
15 services provided by an intermediate care  
16 facility for the mentally retarded.

17 “(vii) Other laboratory and x-ray serv-  
18 ices.

19 “(viii) Renal dialysis.

20 “(B) OTHER EXCLUSIONS.—Such term  
21 also does not include any such drug or product  
22 for which a National Drug Code number is not  
23 required by the Food and Drug Administration  
24 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 for which the State is  
6 the primary payer under this title or a dem-  
7 onstration project concerning this title, and that  
8 is provided on an outpatient basis as part of, or  
9 as incident to and in the same setting as, de-  
10 scribed in clause (iv) or (v) of subparagraph (A)  
11 and for which payment is made as part of pay-  
12 ment for such services.

13 “(D) NO EFFECT ON BEST PRICE.—Any  
14 drug, biological product, or insulin excluded  
15 from the definition of such term as a result of  
16 this paragraph shall be treated as a covered  
17 outpatient drug for purposes of determining the  
18 best price (as defined in subsection (c)(1)(C))  
19 for such drug, biological product, or insulin.”.

20 (b) EFFECTIVE DATE; IMPLEMENTATION GUID-  
21 ANCE.—

22 (1) IN GENERAL.—The amendment made by  
23 subsection (a) shall take effect on the date that is  
24 1 year after the date of enactment of this Act.

1           (2) IMPLEMENTATION AND GUIDANCE.—Not  
2 later than 1 year after the date of enactment of this  
3 Act, the Secretary of Health and Human Services  
4 shall issue guidance and relevant informational bul-  
5 letins for States, manufacturers (as defined in sec-  
6 tion 1927(k)(5) of the Social Security Act (42  
7 U.S.C. 1396r–8(k)(5))), and other relevant stake-  
8 holders, including health care providers, regarding  
9 implementation of the amendment made by sub-  
10 section (a).

### 11       **PART 3—FOOD AND DRUG ADMINISTRATION**

#### 12                       **Subpart A—Pay-for-Delay**

##### 13       **SEC. 30701. UNLAWFUL AGREEMENTS.**

14       (a) AGREEMENTS PROHIBITED.—Subject to sub-  
15 sections (b) and (c), it shall be unlawful for an NDA or  
16 BLA holder and a subsequent filer (or for two subsequent  
17 filers) to enter into, or carry out, an agreement resolving  
18 or settling a covered patent infringement claim on a final  
19 or interim basis if under such agreement—

20           (1) a subsequent filer directly or indirectly re-  
21 ceives from such holder (or in the case of such an  
22 agreement between two subsequent filers, the other  
23 subsequent filer) anything of value, including a li-  
24 cense; and

1           (2) the subsequent filer agrees to limit or fore-  
2           go research on, or development, manufacturing,  
3           marketing, or sales, for any period of time, of the  
4           covered product that is the subject of the application  
5           described in subparagraph (A) or (B) of subsection  
6           (g)(8).

7           (b) EXCLUSION.—It shall not be unlawful under sub-  
8           section (a) if a party to an agreement described in such  
9           subsection demonstrates by clear and convincing evidence  
10          that the value described in subsection (a)(1) is compensa-  
11          tion solely for other goods or services that the subsequent  
12          filer has promised to provide.

13          (c) LIMITATION.—Nothing in this section shall pro-  
14          hibit an agreement resolving or settling a covered patent  
15          infringement claim in which the consideration granted by  
16          the NDA or BLA holder to the subsequent filer (or from  
17          one subsequent filer to another) as part of the resolution  
18          or settlement includes only one or more of the following:

19                (1) The right to market the covered product  
20                that is the subject of the application described in  
21                subparagraph (A) or (B) of subsection (g)(8) in the  
22                United States before the expiration of—

23                        (A) any patent that is the basis of the cov-  
24                        ered patent infringement claim; or

1 (B) any patent right or other statutory ex-  
2 clusivity that would prevent the marketing of  
3 such covered product.

4 (2) A payment for reasonable litigation ex-  
5 penses not to exceed \$7,500,000 in the aggregate.

6 (3) A covenant not to sue on any claim that  
7 such covered product infringes a patent.

8 (d) ENFORCEMENT BY FEDERAL TRADE COMMIS-  
9 SION.—

10 (1) GENERAL APPLICATION.—The requirements  
11 of this section apply, according to their terms, to an  
12 NDA or BLA holder or subsequent filer that is—

13 (A) a person, partnership, or corporation  
14 over which the Commission has authority pur-  
15 suant to section 5(a)(2) of the Federal Trade  
16 Commission Act (15 U.S.C. 45(a)(2)); or

17 (B) a person, partnership, or corporation  
18 over which the Commission would have author-  
19 ity pursuant to such section but for the fact  
20 that such person, partnership, or corporation is  
21 not organized to carry on business for its own  
22 profit or that of its members.

23 (2) UNFAIR OR DECEPTIVE ACTS OR PRACTICES  
24 ENFORCEMENT AUTHORITY.—

1 (A) IN GENERAL.—A violation of this sec-  
2 tion shall be treated as an unfair or deceptive  
3 act or practice in violation of section 5(a)(1) of  
4 the Federal Trade Commission Act (15 U.S.C.  
5 45(a)(1)).

6 (B) POWERS OF COMMISSION.—Except as  
7 provided in subparagraph (C) and paragraphs  
8 (1)(B) and (3)—

9 (i) the Commission shall enforce this  
10 section in the same manner, by the same  
11 means, and with the same jurisdiction,  
12 powers, and duties as though all applicable  
13 terms and provisions of the Federal Trade  
14 Commission Act (15 U.S.C. 41 et seq.)  
15 were incorporated into and made a part of  
16 this section; and

17 (ii) any NDA or BLA holder or subse-  
18 quent filer that violates this section shall  
19 be subject to the penalties and entitled to  
20 the privileges and immunities provided in  
21 the Federal Trade Commission Act.

22 (C) JUDICIAL REVIEW.—In the case of a  
23 cease and desist order issued by the Commis-  
24 sion under section 5 of the Federal Trade Com-  
25 mission Act (15 U.S.C. 45) for violation of this

1 section, a party to such order may obtain judi-  
2 cial review of such order as provided in such  
3 section 5, except that—

4 (i) such review may only be obtained  
5 in—

6 (I) the United States Court of  
7 Appeals for the District of Columbia  
8 Circuit;

9 (II) the United States Court of  
10 Appeals for the circuit in which the  
11 ultimate parent entity, as defined in  
12 section 801.1(a)(3) of title 16, Code  
13 of Federal Regulations, or any suc-  
14 cessor thereto, of the NDA or BLA  
15 holder (if any such holder is a party  
16 to such order) is incorporated as of  
17 the date that the application described  
18 in subparagraph (A) or (B) of sub-  
19 section (g)(8) or an approved applica-  
20 tion that is deemed to be a license for  
21 a biological product under section  
22 351(k) of the Public Health Service  
23 Act (42 U.S.C. 262(k)) pursuant to  
24 section 7002(e)(4) of the Biologics  
25 Price Competition and Innovation Act

1 of 2009 (Public Law 111–148; 124  
2 Stat. 817) is submitted to the Com-  
3 missioner of Food and Drugs; or

4 (III) the United States Court of  
5 Appeals for the circuit in which the  
6 ultimate parent entity, as so defined,  
7 of any subsequent filer that is a party  
8 to such order is incorporated as of the  
9 date that the application described in  
10 subparagraph (A) or (B) of subsection  
11 (g)(8) is submitted to the Commis-  
12 sioner of Food and Drugs; and

13 (ii) the petition for review shall be  
14 filed in the court not later than 30 days  
15 after such order is served on the party  
16 seeking review.

17 (3) ADDITIONAL ENFORCEMENT AUTHORITY.—

18 (A) CIVIL PENALTY.—The Commission  
19 may commence a civil action to recover a civil  
20 penalty in a district court of the United States  
21 against any NDA or BLA holder or subsequent  
22 filer that violates this section.

23 (B) SPECIAL RULE FOR RECOVERY OF  
24 PENALTY IF CEASE AND DESIST ORDER  
25 ISSUED.—



1 (i) IN GENERAL.—If the Commission  
2 has issued a cease and desist order in a  
3 proceeding under section 5 of the Federal  
4 Trade Commission Act (15 U.S.C. 45) for  
5 violation of this section—

6 (I) the Commission may com-  
7 mence a civil action under subpara-  
8 graph (A) to recover a civil penalty  
9 against any party to such order at  
10 any time before the expiration of the  
11 1-year period beginning on the date  
12 on which such order becomes final  
13 under section 5(g) of such Act (15  
14 U.S.C. 45(g)); and

15 (II) in such civil action, the find-  
16 ings of the Commission as to the ma-  
17 terial facts in such proceeding shall be  
18 conclusive, unless—

19 (aa) the terms of such order  
20 expressly provide that the Com-  
21 mission’s findings shall not be  
22 conclusive; or

23 (bb) such order became final  
24 by reason of section 5(g)(1) of  
25 such Act (15 U.S.C. 45(g)(1)), in

1 which case such findings shall be  
2 conclusive if supported by evi-  
3 dence.

4 (ii) RELATIONSHIP TO PENALTY FOR  
5 VIOLATION OF AN ORDER.—The penalty  
6 provided in clause (i) for violation of this  
7 section is separate from and in addition to  
8 any penalty that may be incurred for viola-  
9 tion of an order of the Commission under  
10 section 5(l) of the Federal Trade Commis-  
11 sion Act (15 U.S.C. 45(l)).

12 (C) AMOUNT OF PENALTY.—

13 (i) IN GENERAL.—The amount of a  
14 civil penalty imposed in a civil action under  
15 subparagraph (A) on a party to an agree-  
16 ment described in subsection (a) shall be  
17 sufficient to deter violations of this section,  
18 but in no event greater than—

19 (I) if such party is the NDA or  
20 BLA holder (or, in the case of an  
21 agreement between two subsequent fil-  
22 ers, the subsequent filer who gave the  
23 value described in subsection (a)(1)),  
24 the greater of—

1 (aa) 3 times the value re-  
2 ceived by such NDA or BLA  
3 holder (or by such subsequent  
4 filer) that is reasonably attrib-  
5 utable to the violation of this sec-  
6 tion; or

7 (bb) 3 times the value given  
8 to the subsequent filer (or to the  
9 other subsequent filer) reason-  
10 ably attributable to the violation  
11 of this section; and

12 (II) if such party is the subse-  
13 quent filer (or, in the case of an  
14 agreement between two subsequent fil-  
15 ers, the subsequent filer who received  
16 the value described in subsection  
17 (a)(1)), 3 times the value received by  
18 such subsequent filer that is reason-  
19 ably attributable to the violation of  
20 this section.

21 (ii) FACTORS FOR CONSIDERATION.—  
22 In determining such amount, the court  
23 shall take into account—

24 (I) the nature, circumstances, ex-  
25 tent, and gravity of the violation;

1 (II) with respect to the violator,  
2 the degree of culpability, any history  
3 of violations, the ability to pay, any  
4 effect on the ability to continue doing  
5 business, profits earned by the NDA  
6 or BLA holder (or, in the case of an  
7 agreement between two subsequent fil-  
8 ers, the subsequent filer who gave the  
9 value described in subsection (a)(1)),  
10 compensation received by the subse-  
11 quent filer (or, in the case of an  
12 agreement between two subsequent fil-  
13 ers, the subsequent filer who received  
14 the value described in subsection  
15 (a)(1)), and the amount of commerce  
16 affected; and

17 (III) other matters that justice  
18 requires.

19 (D) INJUNCTIONS AND OTHER EQUITABLE  
20 RELIEF.—In a civil action under subparagraph  
21 (A), the United States district courts are em-  
22 powered to grant mandatory injunctions and  
23 such other and further equitable relief as they  
24 deem appropriate.

1           (4) REMEDIES IN ADDITION.—Remedies pro-  
2           vided in this subsection are in addition to, and not  
3           in lieu of, any other remedy provided by Federal  
4           law.

5           (5) PRESERVATION OF AUTHORITY OF COMMIS-  
6           SION.—Nothing in this section shall be construed to  
7           affect any authority of the Commission under any  
8           other provision of law.

9           (e) FEDERAL TRADE COMMISSION RULEMAKING.—  
10          The Commission may, in its discretion, by rule promul-  
11          gated under section 553 of title 5, United States Code,  
12          exempt from this section certain agreements described in  
13          subsection (a) if the Commission finds such agreements  
14          to be in furtherance of market competition and for the  
15          benefit of consumers.

16          (f) ANTITRUST LAWS.—Nothing in this section shall  
17          modify, impair, limit, or supersede the applicability of the  
18          antitrust laws as defined in subsection (a) of the first sec-  
19          tion of the Clayton Act (15 U.S.C. 12(a)), and of section  
20          5 of the Federal Trade Commission Act (15 U.S.C. 45)  
21          to the extent that such section 5 applies to unfair methods  
22          of competition. Nothing in this section shall modify, im-  
23          pair, limit, or supersede the right of a subsequent filer  
24          to assert claims or counterclaims against any person,

1 under the antitrust laws or other laws relating to unfair  
2 competition.

3 (g) DEFINITIONS.—In this section:

4 (1) AGREEMENT RESOLVING OR SETTLING A  
5 COVERED PATENT INFRINGEMENT CLAIM.—The  
6 term “agreement resolving or settling a covered pat-  
7 ent infringement claim” means any agreement  
8 that—

9 (A) resolves or settles a covered patent in-  
10 fringement claim; or

11 (B) is contingent upon, provides for a con-  
12 tingent condition for, or is otherwise related to  
13 the resolution or settlement of a covered patent  
14 infringement claim.

15 (2) COMMISSION.—The term “Commission”  
16 means the Federal Trade Commission.

17 (3) COVERED PATENT INFRINGEMENT CLAIM.—  
18 The term “covered patent infringement claim”  
19 means an allegation made by the NDA or BLA hold-  
20 er to a subsequent filer (or, in the case of an agree-  
21 ment between two subsequent filers, by one subse-  
22 quent filer to another), whether or not included in  
23 a complaint filed with a court of law, that—

24 (A) the submission of the application de-  
25 scribed in subparagraph (A) or (B) of para-

1 graph (9), or the manufacture, use, offering for  
2 sale, sale, or importation into the United States  
3 of a covered product that is the subject of such  
4 an application—

5 (i) in the case of an agreement be-  
6 tween an NDA or BLA holder and a sub-  
7 sequent filer, infringes any patent owned  
8 by, or exclusively licensed to, the NDA or  
9 BLA holder of the covered product; or

10 (ii) in the case of an agreement be-  
11 tween two subsequent filers, infringes any  
12 patent owned by the subsequent filer; or

13 (B) in the case of an agreement between  
14 an NDA or BLA holder and a subsequent filer,  
15 the covered product to be manufactured under  
16 such application uses a covered product as  
17 claimed in a published patent application.

18 (4) COVERED PRODUCT.—The term “covered  
19 product” means a drug (as defined in section 201(g)  
20 of the Federal Food, Drug, and Cosmetic Act (21  
21 U.S.C. 321(g))), including a biological product (as  
22 defined in section 351(i) of the Public Health Serv-  
23 ice Act (42 U.S.C. 262(i))).

24 (5) NDA OR BLA HOLDER.—The term “NDA  
25 or BLA holder” means—

1 (A) the holder of—

2 (i) an approved new drug application  
3 filed under section 505(b)(1) of the Fed-  
4 eral Food, Drug, and Cosmetic Act (21  
5 U.S.C. 355(b)(1)) for a covered product;

6 or

7 (ii) a biologics license application filed  
8 under section 351(a) of the Public Health  
9 Service Act (42 U.S.C. 262(a)) with re-  
10 spect to a biological product;

11 (B) a person owning or controlling enforce-  
12 ment of the patent on—

13 (i) the list published under section  
14 505(j)(7) of the Federal Food, Drug, and  
15 Cosmetic Act (21 U.S.C. 355(j)(7)) in con-  
16 nection with the application described in  
17 subparagraph (A)(i); or

18 (ii) any list published under section  
19 351 of the Public Health Service Act (42  
20 U.S.C. 262) comprised of patents associ-  
21 ated with biologics license applications filed  
22 under section 351(a) of such Act (42  
23 U.S.C. 262(a)); or

24 (C) the predecessors, subsidiaries, divi-  
25 sions, groups, and affiliates controlled by, con-



1 trolling, or under common control with any en-  
2 tity described in subparagraph (A) or (B) (such  
3 control to be presumed by direct or indirect  
4 share ownership of 50 percent or greater), as  
5 well as the licensees, licensors, successors, and  
6 assigns of each of the entities.

7 (6) PATENT.—The term “patent” means a pat-  
8 ent issued by the United States Patent and Trade-  
9 mark Office.

10 (7) STATUTORY EXCLUSIVITY.—The term  
11 “statutory exclusivity” means those prohibitions on  
12 the submission or approval of drug applications  
13 under clauses (ii) through (iv) of section  
14 505(c)(3)(E) (5- and 3-year exclusivity), clauses (ii)  
15 through (iv) of section 505(j)(5)(F) (5-year and 3-  
16 year exclusivity), section 505(j)(5)(B)(iv) (180-day  
17 exclusivity), section 527 (orphan drug exclusivity),  
18 section 505A (pediatric exclusivity), or section 505E  
19 (qualified infectious disease product exclusivity) of  
20 the Federal Food, Drug, and Cosmetic Act (21  
21 U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 355(j)(5)(F),  
22 360cc, 355a, 355f), or prohibitions on the submis-  
23 sion or licensing of biologics license applications  
24 under section 351(k)(6) (interchangeable biological  
25 product exclusivity) or section 351(k)(7) (biological

1 product reference product exclusivity) of the Public  
2 Health Service Act (42 U.S.C. 262(k)(6), (7)).

3 (8) SUBSEQUENT FILER.—The term “subse-  
4 quent filer” means—

5 (A) in the case of a drug, a party that  
6 owns or controls an abbreviated new drug appli-  
7 cation submitted pursuant to section 505(j) of  
8 the Federal Food, Drug, and Cosmetic Act (21  
9 U.S.C. 355(j)) or a new drug application sub-  
10 mitted pursuant to section 505(b)(2) of the  
11 Federal Food, Drug, and Cosmetic Act (21  
12 U.S.C. 355(b)(2)) and filed under section  
13 505(b)(1) of such Act (21 U.S.C. 355(b)(1)) or  
14 has the exclusive rights to distribute the cov-  
15 ered product that is the subject of such applica-  
16 tion; or

17 (B) in the case of a biological product, a  
18 party that owns or controls an application filed  
19 with the Food and Drug Administration under  
20 section 351(k) of the Public Health Service Act  
21 (42 U.S.C. 262(k)) or has the exclusive rights  
22 to distribute the biological product that is the  
23 subject of such application.

1 (h) EFFECTIVE DATE.—This section applies with re-  
2 spect to agreements described in subsection (a) entered  
3 into on or after the date of the enactment of this Act.

4 **SEC. 30702. NOTICE AND CERTIFICATION OF AGREEMENTS.**

5 (a) NOTICE OF ALL AGREEMENTS.—Section 1111(7)  
6 of the Medicare Prescription Drug, Improvement, and  
7 Modernization Act of 2003 (21 U.S.C. 355 note) is  
8 amended by inserting “or the owner of a patent for which  
9 a claim of infringement could reasonably be asserted  
10 against any person for making, using, offering to sell, sell-  
11 ing, or importing into the United States a biological prod-  
12 uct that is the subject of a biosimilar biological product  
13 application” before the period at the end.

14 (b) CERTIFICATION OF AGREEMENTS.—Section 1112  
15 of such Act (21 U.S.C. 355 note) is amended by adding  
16 at the end the following:

17 “(d) CERTIFICATION.—The Chief Executive Officer  
18 or the company official responsible for negotiating any  
19 agreement under subsection (a) or (b) that is required to  
20 be filed under subsection (c) shall, within 30 days of such  
21 filing, execute and file with the Assistant Attorney General  
22 and the Commission a certification as follows: ‘I declare  
23 that the following is true, correct, and complete to the best  
24 of my knowledge: The materials filed with the Federal  
25 Trade Commission and the Department of Justice under

1 section 1112 of the Medicare Prescription Drug, Improve-  
2 ment, and Modernization Act of 2003, with respect to the  
3 agreement referenced in this certification—’ ‘

4 “(1) represent the complete, final, and exclu-  
5 sive agreement between the parties;

6 “(2) include any ancillary agreements that are  
7 contingent upon, provide a contingent condition for,  
8 were entered into within 30 days of, or are otherwise  
9 related to, the referenced agreement; and

10 “(3) include written descriptions of any oral  
11 agreements, representations, commitments, or prom-  
12 ises between the parties that are responsive to sub-  
13 section (a) or (b) of such section 1112 and have not  
14 been reduced to writing.’”.

15 **SEC. 30703. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

16 Section 505(j)(5)(D)(i)(V) of the Federal Food,  
17 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))  
18 is amended by inserting “section 301 of the Lower Costs,  
19 More Cures Act of 2021 or” after “that the agreement  
20 has violated”.

21 **SEC. 30704. COMMISSION LITIGATION AUTHORITY.**

22 Section 16(a)(2) of the Federal Trade Commission  
23 Act (15 U.S.C. 56(a)(2)) is amended—

24 (1) in subparagraph (D), by striking “or” after  
25 the semicolon;

1           (2) in subparagraph (E), by moving the margin  
2           2 ems to the left and inserting “or” after the semi-  
3           colon; and

4           (3) by inserting after subparagraph (E) the fol-  
5           lowing:

6           “(F) under section 301(d)(3)(A) of the Lower  
7           Costs, More Cures Act of 2021;”.

8   **SEC. 30705. STATUTE OF LIMITATIONS.**

9           (a) IN GENERAL.—Except as provided in subsection  
10          (b), the Commission shall commence any administrative  
11          proceeding or civil action to enforce section 301 of this  
12          Act not later than 6 years after the date on which the  
13          parties to the agreement file the Notice of Agreement as  
14          provided by section 1112(c)(2) and (d) of the Medicare  
15          Prescription Drug, Improvement, and Modernization Act  
16          of 2003 (21 U.S.C. 355 note).

17          (b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND  
18          DESIST ORDER.—If the Commission has issued a cease  
19          and desist order under section 5 of the Federal Trade  
20          Commission Act (15 U.S.C. 45) for violation of section  
21          301 of this Act and the proceeding for the issuance of  
22          such order was commenced within the period required by  
23          subsection (a) of this section, such subsection does not  
24          prohibit the commencement, after such period, of a civil  
25          action under section 301(d)(3)(A) against a party to such

1 order or a civil action under subsection (l) of such section  
2 5 for violation of such order.

3 **Subpart B—Advancing Education on Biosimilars**

4 **SEC. 30711. EDUCATION ON BIOLOGICAL PRODUCTS.**

5 (a) WEBSITE; CONTINUING EDUCATION.—Subpart 1  
6 of part F of title III of the Public Health Service Act (42  
7 U.S.C. 262 et seq.) is amended by adding at the end the  
8 following:

9 **“SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.**

10 “(a) INTERNET WEBSITE.—

11 “(1) IN GENERAL.—The Secretary shall main-  
12 tain and operate an internet website to provide edu-  
13 cational materials for health care providers, patients,  
14 and caregivers, regarding the meaning of the terms,  
15 and the standards for review and licensing of, bio-  
16 logical products, including biosimilar biological prod-  
17 ucts and interchangeable biosimilar biological prod-  
18 ucts.

19 “(2) CONTENT.—Educational materials pro-  
20 vided under paragraph (1) may include—

21 “(A) explanations of key statutory and  
22 regulatory terms, including ‘biosimilar’ and  
23 ‘interchangeable’, and clarification regarding  
24 the use of interchangeable biosimilar biological  
25 products;

1           “(B) information related to development  
2           programs for biological products, including bio-  
3           similar biological products and interchangeable  
4           biosimilar biological products and relevant clin-  
5           ical considerations for prescribers, which may  
6           include, as appropriate and applicable, informa-  
7           tion related to the comparability of such biologi-  
8           cal products;

9           “(C) an explanation of the process for re-  
10          porting adverse events for biological products,  
11          including biosimilar biological products and  
12          interchangeable biosimilar biological products;  
13          and

14          “(D) an explanation of the relationship be-  
15          tween biosimilar biological products and inter-  
16          changeable biosimilar biological products li-  
17          censed under section 351(k) and reference  
18          products (as defined in section 351(i)), includ-  
19          ing the standards for review and licensing of  
20          each such type of biological product.

21          “(3) FORMAT.—The educational materials pro-  
22          vided under paragraph (1) may be—

23                 “(A) in formats such as webinars, con-  
24                 tinuing medical education modules, videos, fact  
25                 sheets, infographics, stakeholder toolkits, or

1 other formats as appropriate and applicable;  
2 and

3 “(B) tailored for the unique needs of  
4 health care providers, patients, caregivers, and  
5 other audiences, as the Secretary determines  
6 appropriate.

7 “(4) OTHER INFORMATION.—In addition to the  
8 information described in paragraph (2), the Sec-  
9 retary shall continue to publish the following infor-  
10 mation:

11 “(A) The action package of each biological  
12 product licensed under subsection (a) or (k).

13 “(B) The summary review of each biologi-  
14 cal product licensed under subsection (a) or (k).

15 “(5) CONFIDENTIAL AND TRADE SECRET IN-  
16 FORMATION.—This subsection does not authorize  
17 the disclosure of any trade secret, confidential com-  
18 mercial or financial information, or other matter de-  
19 scribed in section 552(b) of title 5.

20 “(b) CONTINUING EDUCATION.—The Secretary shall  
21 advance education and awareness among health care pro-  
22 viders regarding biological products, including biosimilar  
23 biological products and interchangeable biosimilar biologi-  
24 cal products, as appropriate, including by developing or  
25 improving continuing education programs that advance



1 the education of such providers on the prescribing of, and  
2 relevant clinical considerations with respect to, biological  
3 products, including biosimilar biological products and  
4 interchangeable biosimilar biological products.”.

5 (b) APPLICATION UNDER THE MEDICARE MERIT-  
6 BASED INCENTIVE PAYMENT SYSTEM.—Section  
7 1848(q)(5)(C) of the Social Security Act (42 U.S.C.  
8 1395w–4(q)(5)(C)) is amended by adding at the end the  
9 following new clause:

10 “(iv) CLINICAL MEDICAL EDUCATION  
11 PROGRAM ON BIOSIMILAR BIOLOGICAL  
12 PRODUCTS.—Completion of a clinical med-  
13 ical education program developed or im-  
14 proved under section 352A(b) of the Public  
15 Health Service Act by a MIPS eligible pro-  
16 fessional during a performance period shall  
17 earn such eligible professional one-half of  
18 the highest potential score for the perform-  
19 ance category described in paragraph  
20 (2)(A)(iii) for such performance period. A  
21 MIPS eligible professional may only count  
22 the completion of such a program for pur-  
23 poses of such category one time during the  
24 eligible professional’s lifetime.”.

1                   **Subpart C—Other Provisions**

2   **SEC. 30721. CLARIFYING THE MEANING OF NEW CHEMICAL**  
3                   **ENTITY.**

4           Chapter V of the Federal Food, Drug, and Cosmetic  
5 Act is amended—

6                   (1) in section 505 (21 U.S.C. 355)—

7                           (A) in subsection (c)(3)(E)—

8                                   (i) in clause (ii), by striking “active  
9 ingredient (including any ester or salt of  
10 the active ingredient)” and inserting “ac-  
11 tive moiety (as defined by the Secretary in  
12 section 314.3 of title 21, Code of Federal  
13 Regulations (or any successor regula-  
14 tions))”; and

15                                   (ii) in clause (iii), by striking “active  
16 ingredient (including any ester or salt of  
17 the active ingredient)” and inserting “ac-  
18 tive moiety (as defined by the Secretary in  
19 section 314.3 of title 21, Code of Federal  
20 Regulations (or any successor regula-  
21 tions))”;

22                           (B) in subsection (j)(5)(F)—

23                                   (i) in clause (ii), by striking “active  
24 ingredient (including any ester or salt of  
25 the active ingredient)” and inserting “ac-  
26 tive moiety (as defined by the Secretary in

1 section 314.3 of title 21, Code of Federal  
2 Regulations (or any successor regula-  
3 tions))”; and

4 (ii) in clause (iii), by striking “active  
5 ingredient (including any ester or salt of  
6 the active ingredient)” and inserting “ac-  
7 tive moiety (as defined by the Secretary in  
8 section 314.3 of title 21, Code of Federal  
9 Regulations (or any successor regula-  
10 tions))”;

11 (C) in subsection (l)(2)(A)(i), by striking  
12 “active ingredient (including any ester or salt of  
13 the active ingredient)” and inserting “active  
14 moiety (as defined by the Secretary in section  
15 314.3 of title 21, Code of Federal Regulations  
16 (or any successor regulations))”;

17 (D) in subsection (s), in the matter pre-  
18 ceding paragraph (1), by striking “active ingre-  
19 dient (including any ester or salt of the active  
20 ingredient)” and inserting “active moiety (as  
21 defined by the Secretary in section 314.3 of  
22 title 21, Code of Federal Regulations (or any  
23 successor regulations))”; and

24 (E) in subsection (u)(1), in the matter pre-  
25 ceding subparagraph (A)—

1 (i) by striking “active ingredient (in-  
2 cluding any ester or salt of the active in-  
3 gredient)” and inserting “active moiety (as  
4 defined by the Secretary in section 314.3  
5 of title 21, Code of Federal Regulations (or  
6 any successor regulations))”; and

7 (ii) by striking “same active ingre-  
8 dient” and inserting “same active moiety”;

9 (2) in section 512(c)(2)(F) (21 U.S.C.  
10 360b(c)(2)(F))—

11 (A) in clause (i), by striking “active ingre-  
12 dient (including any ester or salt of the active  
13 ingredient)” and inserting “active moiety (as  
14 defined by the Secretary in section 314.3 of  
15 title 21, Code of Federal Regulations (or any  
16 successor regulations))”;

17 (B) in clause (ii), by striking “active ingre-  
18 dient (including any ester or salt of the active  
19 ingredient)” and inserting “active moiety (as  
20 defined by the Secretary in section 314.3 of  
21 title 21, Code of Federal Regulations (or any  
22 successor regulations))”; and

23 (C) in clause (v), by striking “active ingre-  
24 dient (including any ester or salt of the active  
25 ingredient)” and inserting “active moiety (as

1 defined by the Secretary in section 314.3 of  
2 title 21, Code of Federal Regulations (or any  
3 successor regulations))”;

4 (3) in section 524(a)(4)(C) (21 U.S.C.  
5 360n(a)(4)(C)), by striking “active ingredient (in-  
6 cluding any ester or salt of the active ingredient)”  
7 and inserting “active moiety (as defined by the Sec-  
8 retary in section 314.3 of title 21, Code of Federal  
9 Regulations (or any successor regulations))”;

10 (4) in section 529(a)(4)(A)(ii) (21 U.S.C.  
11 360ff(a)(4)(A)(ii)), by striking “active ingredient  
12 (including any ester or salt of the active ingredient)”  
13 and inserting “active moiety (as defined by the Sec-  
14 retary in section 314.3 of title 21, Code of Federal  
15 Regulations (or any successor regulations))”; and

16 (5) in section 565A(a)(4)(D) (21 U.S.C.  
17 360bbb-4a(a)(4)(D)), by striking “active ingredient  
18 (including any ester or salt of the active ingredient)”  
19 and inserting “active moiety (as defined by the Sec-  
20 retary in section 314.3 of title 21, Code of Federal  
21 Regulations (or any successor regulations))”.

1                   **PART 4—REVENUE PROVISION**

2   **SEC. 30731. SAFE HARBOR FOR HIGH DEDUCTIBLE HEALTH**  
3                   **PLANS WITHOUT DEDUCTIBLE FOR INSULIN.**

4           (a) **IN GENERAL.**—Section 223(c)(2)(C) of the Inter-  
5   nal Revenue Code of 1986 is amended by inserting “or  
6   for insulin or any device for the delivery of insulin” before  
7   the period at the end.

8           (b) **EFFECTIVE DATE.**—The amendment made by  
9   this section shall apply to months beginning after the date  
10   of the enactment of this Act.

11                   **PART 5—MISCELLANEOUS**

12   **SEC. 30741. PAYMENT FOR BIOSIMILAR BIOLOGICAL PROD-**  
13                   **UCTS DURING INITIAL PERIOD.**

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

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

20                   (2) by redesignating subparagraphs (A) and  
21           (B) as clauses (i) and (ii) and moving such clauses  
22           2 ems to the right;

23                   (3) by striking “UNAVAILABLE.—In the case”  
24           and inserting “UNAVAILABLE.—

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

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

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

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

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

19 **SEC. 30742. GAO STUDY AND REPORT ON AVERAGE SALES**  
20 **PRICE.**

21 (a) STUDY.—

22 (1) IN GENERAL.—The Comptroller General of  
23 the United States (in this section referred to as the  
24 “Comptroller General”) shall conduct a study on

1 spending for applicable drugs under part B of title  
2 XVIII of the Social Security Act.

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

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

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

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

16 (A) The extent to which each applicable  
17 drug is paid for—

18 (i) under such part B for Medicare  
19 beneficiaries; or

20 (ii) by private payers in the commer-  
21 cial market.

22 (B) Any change in Medicare spending or  
23 Medicare beneficiary cost-sharing that would  
24 occur if the average sales price of an applicable



1 drug was based solely on payments by private  
2 payers in the commercial market.

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

9 (i) formulary placement;

10 (ii) utilization management consider-  
11 ations; or

12 (iii) other purposes.

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

16 (E) Other areas determined appropriate by  
17 the Comptroller General.

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

1 **SEC. 30743. REQUIRING PRESCRIPTION DRUG PLANS AND**  
2 **MA-PD PLANS TO REPORT POTENTIAL**  
3 **FRAUD, WASTE, AND ABUSE TO THE SEC-**  
4 **RETARY OF HHS.**

5 Section 1860D–4 of the Social Security Act (42  
6 U.S.C. 1395w–104) is amended by adding at the end the  
7 following new subsection:

8 “(p) REPORTING POTENTIAL FRAUD, WASTE, AND  
9 ABUSE.—Beginning January 1, 2022, the PDP sponsor  
10 of a prescription drug plan shall report to the Secretary,  
11 as specified by the Secretary—

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

16 “(2) any steps made by the PDP sponsor after  
17 identifying such activities to take corrective ac-  
18 tions.”.

19 **SEC. 30744. ESTABLISHMENT OF PHARMACY QUALITY**  
20 **MEASURES UNDER MEDICARE PART D.**

21 Section 1860D–4(c) of the Social Security Act (42  
22 U.S.C. 1395w–104(c)) is amended by adding at the end  
23 the following new paragraph:

24 “(8) APPLICATION OF PHARMACY QUALITY  
25 MEASURES.—

1           “(A) IN GENERAL.—A PDP sponsor that  
2 implements incentive payments to a pharmacy  
3 or price concessions paid by a pharmacy based  
4 on quality measures shall use measures estab-  
5 lished or approved by the Secretary under sub-  
6 paragraph (B) with respect to payment for cov-  
7 ered part D drugs dispensed by such pharmacy.

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

16           “(C) EFFECTIVE DATE.—The requirement  
17 under subparagraph (A) shall take effect for  
18 plan years beginning on or after January 1,  
19 2023, or such earlier date specified by the Sec-  
20 retary if the Secretary determines there are suf-  
21 ficient measures established or approved under  
22 subparagraph (B) to meet the requirement  
23 under subparagraph (A).”.

1 **SEC. 30745. IMPROVING COORDINATION BETWEEN THE**  
2 **FOOD AND DRUG ADMINISTRATION AND THE**  
3 **CENTERS FOR MEDICARE & MEDICAID SERV-**  
4 **ICES.**

5 (a) IN GENERAL.—

6 (1) PUBLIC MEETING.—

7 (A) IN GENERAL.—Not later than 12  
8 months after the date of the enactment of this  
9 Act, the Secretary of Health and Human Serv-  
10 ices (referred to in this section as the “Sec-  
11 retary”) shall convene a public meeting for the  
12 purposes of discussing and providing input on  
13 improvements to coordination between the Food  
14 and Drug Administration and the Centers for  
15 Medicare & Medicaid Services in preparing for  
16 the availability of novel medical products de-  
17 scribed in subsection (c) on the market in the  
18 United States.

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

21 (i) representatives of relevant Federal  
22 agencies, including representatives from  
23 each of the medical product centers within  
24 the Food and Drug Administration and  
25 representatives from the coding, coverage,

1 and payment offices within the Centers for  
2 Medicare & Medicaid Services;

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

7 (iii) representatives of commercial  
8 health insurance payers;

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

12 (v) stakeholders representing patients  
13 and with expertise in the utilization of pa-  
14 tient experience data in medical product  
15 development.

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

18 (i) the status of the drug and medical  
19 device development pipeline related to the  
20 availability of novel medical products;

21 (ii) the anticipated expertise necessary  
22 to review the safety and effectiveness of  
23 such products at the Food and Drug Ad-  
24 ministration and current gaps in such ex-  
25 pertise, if any;

- 1 (iii) the expertise necessary to make  
2 coding, coverage, and payment decisions  
3 with respect to such products within the  
4 Centers for Medicare & Medicaid Services,  
5 and current gaps in such expertise, if any;
- 6 (iv) trends in the differences in the  
7 data necessary to determine the safety and  
8 effectiveness of a novel medical product  
9 and the data necessary to determine  
10 whether a novel medical product meets the  
11 reasonable and necessary requirements for  
12 coverage and payment under title XVIII of  
13 the Social Security Act pursuant to section  
14 1862(a)(1)(A) of such Act (42 U.S.C.  
15 1395y(a)(1)(A));
- 16 (v) the availability of information for  
17 sponsors of such novel medical products to  
18 meet each of those requirements; and
- 19 (vi) the coordination of information  
20 related to significant clinical improvement  
21 over existing therapies for patients between  
22 the Food and Drug Administration and the  
23 Centers for Medicare & Medicaid Services  
24 with respect to novel medical products.

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

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

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

20 (B) FINAL GUIDANCE.—Not later than 12  
21 months after issuing draft guidance under sub-  
22 paragraph (A), the Secretary shall finalize the  
23 updated guidance to address any such opportu-  
24 nities.

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

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

15 (2) Recommendations to—

16 (A) incorporate patient experience data  
17 (such as the impact of a disease or condition on  
18 the lives of patients and patient treatment pref-  
19 erences) into the coverage and payment proc-  
20 esses within the Centers for Medicare & Med-  
21 icaid Services;

22 (B) decrease the length of time to make  
23 national and local coverage determinations  
24 under the Medicare program (as those terms  
25 are defined in subparagraph (A) and (B), re-



1           spectively, of section 1862(l)(6) of the Social  
2           Security Act (42 U.S.C. 1395y(l)(6));

3           (C) streamline the coverage process under  
4           the Medicare program and incorporate input  
5           from relevant stakeholders into such coverage  
6           determinations; and

7           (D) identify potential mechanisms to incor-  
8           porate novel payment designs similar to those  
9           in development in commercial insurance plans  
10          and State plans under title XIX of such Act  
11          (42 U.S.C. 1396 et seq.) into the Medicare pro-  
12          gram.

13          (c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For  
14          purposes of this section, a novel medical product described  
15          in this subsection is a medical product, including a drug,  
16          biological (including gene and cell therapy), or medical de-  
17          vice, that has been designated as a breakthrough therapy  
18          under section 506(a) of the Federal Food, Drug, and Cos-  
19          metic Act (21 U.S.C. 356(a)), a breakthrough device  
20          under section 515B of such Act (21 U.S.C. 360e–3), or  
21          a regenerative advanced therapy under section 506(g) of  
22          such Act (21 U.S.C. 356(g)).

1 **SEC. 30746. PATIENT CONSULTATION IN MEDICARE NA-**  
2 **TIONAL AND LOCAL COVERAGE DETERMINA-**  
3 **TIONS IN ORDER TO MITIGATE BARRIERS TO**  
4 **INCLUSION OF SUCH PERSPECTIVES.**

5 Section 1862(l) of the Social Security Act (42 U.S.C.  
6 1395y(l)) is amended by adding at the end the following  
7 new paragraph:

8 “(7) PATIENT CONSULTATION IN NATIONAL  
9 AND LOCAL COVERAGE DETERMINATIONS.—The Sec-  
10 retary may consult with patients and organizations  
11 representing patients in making national and local  
12 coverage determinations.”.

13 **SEC. 30747. 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  
26 a shift on program spending, beneficiary cost-shar-

1       ing liability, and utilization management techniques  
2       for such drugs and biologicals; and

3           (2) the feasibility and policy implications of  
4       shifting coverage of drugs and biologicals for which  
5       payment is currently made under such part B to  
6       such part D.

7       (b) REPORT.—

8           (1) IN GENERAL.—Not later than June 30,  
9       2023, the Commission shall submit to Congress a re-  
10      port containing the results of the study conducted  
11      under subsection (a).

12           (2) CONTENTS.—The report under paragraph  
13      (1) shall include information, and recommendations  
14      as the Commission deems appropriate, regarding—

15           (A) formulary design under such part D;

16           (B) the ability of the benefit structure  
17      under such part D to control total spending on  
18      drugs and biologicals for which payment is cur-  
19      rently made under such part B;

20           (C) changes to the bid process under such  
21      part D, if any, that may be necessary to inte-  
22      grate coverage of such drugs and biologicals  
23      into such part D;

24           (D) any other changes to the program that  
25      Congress should consider in determining wheth-

1 er to shift coverage of such drugs and  
2 biologicals from such part B to such part D;  
3 and

4 (E) the feasibility and policy implications  
5 of creating a methodology to preserve the  
6 healthcare provider's ability to take title of the  
7 drug, including a methodology under which—

8 (i) prescription drug plans negotiate  
9 reimbursement rates and other arrange-  
10 ments with drug manufacturers on behalf  
11 of a wholesaler;

12 (ii) wholesalers purchase the drugs  
13 from the manufacturers at the negotiated  
14 rate and ship them through distributors to  
15 physicians to administer to patients;

16 (iii) physicians and hospitals purchase  
17 the drug from the wholesaler via the dis-  
18 tributor;

19 (iv) after administering the drug, the  
20 physician submits a claim to the MAC for  
21 their drug administration fee;

22 (v) to be reimbursed for the purchase  
23 of the drug from the distributor, the physi-  
24 cian furnishes the claim for the drug itself  
25 to the wholesaler and the wholesaler would

1 refund the cost of the drug to the physi-  
2 cian; and

3 (vi) the wholesaler passes this claim to  
4 the PDP to receive reimbursement.

5 **SEC. 30748. REQUIREMENT THAT DIRECT-TO-CONSUMER**  
6 **ADVERTISEMENTS FOR PRESCRIPTION**  
7 **DRUGS AND BIOLOGICAL PRODUCTS IN-**  
8 **CLUDE TRUTHFUL AND NON-MISLEADING**  
9 **PRICING INFORMATION.**

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

12 **“SEC. 1150C. REQUIREMENT THAT DIRECT-TO-CONSUMER**  
13 **ADVERTISEMENTS FOR PRESCRIPTION**  
14 **DRUGS AND BIOLOGICAL PRODUCTS IN-**  
15 **CLUDE TRUTHFUL AND NON-MISLEADING**  
16 **PRICING INFORMATION.**

17 “(a) IN GENERAL.—The Secretary shall require that  
18 each direct-to-consumer advertisement for a prescription  
19 drug or biological product for which payment is available  
20 under title XVIII or XIX includes an appropriate disclo-  
21 sure of truthful and non-misleading pricing information  
22 with respect to the drug or product.

23 “(b) DETERMINATION BY CMS.—The Secretary, act-  
24 ing through the Administrator of the Centers for Medicare  
25 & Medicaid Services, shall determine the components of

1 the requirement under subsection (a), such as the forms  
2 of advertising, the manner of disclosure, the price point  
3 listing, and the price information for disclosure.”.

4 **SEC. 30749. CHIEF PHARMACEUTICAL NEGOTIATOR AT THE**  
5 **OFFICE OF THE UNITED STATES TRADE REP-**  
6 **RESENTATIVE.**

7 (a) IN GENERAL.—Section 141 of the Trade Act of  
8 1974 (19 U.S.C. 2171) is amended—

9 (1) in subsection (b)(2)—

10 (A) by striking “and one Chief Innovation  
11 and Intellectual Property Negotiator” and in-  
12 serting “one Chief Innovation and Intellectual  
13 Property Negotiator, and one Chief Pharma-  
14 ceutical Negotiator”;

15 (B) by striking “or the Chief Innovation  
16 and Intellectual Property Negotiator” and in-  
17 serting “the Chief Innovation and Intellectual  
18 Property Negotiator, or the Chief Pharma-  
19 ceutical Negotiator”; and

20 (C) by striking “and the Chief Innovation  
21 and Intellectual Property Negotiator” and in-  
22 serting “the Chief Innovation and Intellectual  
23 Property Negotiator, and the Chief Pharma-  
24 ceutical Negotiator”; and

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

3           “(7) The principal function of the Chief Phar-  
4 maceutical Negotiator shall be to conduct trade ne-  
5 gotiations and to enforce trade agreements relating  
6 to United States pharmaceutical products and serv-  
7 ices. The Chief Pharmaceutical Negotiator shall be  
8 a vigorous advocate on behalf of United States phar-  
9 maceutical interests. The Chief Pharmaceutical Ne-  
10 gotiator shall perform such other functions as the  
11 United States Trade Representative may direct.”.

12       (b) COMPENSATION.—Section 5314 of title 5, United  
13 States Code, is amended by striking “Chief Innovation  
14 and Intellectual Property Negotiator, Office of the United  
15 States Trade Representative.” and inserting the following:

16           “Chief Innovation and Intellectual Property Ne-  
17 gotiator, Office of the United States Trade Rep-  
18 resentative.

19           “Chief Pharmaceutical Negotiator, Office of the  
20 United States Trade Representative.”.

21       (c) REPORT REQUIRED.—Not later than the date  
22 that is one year after the appointment of the first Chief  
23 Pharmaceutical Negotiator pursuant to paragraph (2) of  
24 section 141(b) of the Trade Act of 1974, as amended by  
25 subsection (a), and annually thereafter, the United States

1 Trade Representative shall submit to the Committee on  
2 Finance of the Senate and the Committee on Ways and  
3 Means of the House of Representatives a report describing  
4 in detail—

5           (1) enforcement actions taken by the United  
6           States Trade Representative during the one-year pe-  
7           riod preceding the submission of the report to en-  
8           sure the protection of United States pharmaceutical  
9           products and services; and

10           (2) other actions taken by the United States  
11           Trade Representative to advance United States  
12           pharmaceutical products and services.

