

116TH CONGRESS  
1ST SESSION

# S. 3129

To provide for certain reforms with respect to the Medicare program under title XVIII of the Social Security Act, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

DECEMBER 19, 2019

Mr. CRAPO (for himself, Mr. ENZI, Mr. BURR, Mr. BARRASSO, Mr. TILLIS, and Mr. RISCH) introduced the following bill; which was read twice and referred to the Committee on Finance

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## A BILL

To provide for certain reforms with respect to the Medicare program under title XVIII of the Social Security Act, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Lower Costs, More  
5 Cures Act of 2019”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents for this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

### Subtitle A—Medicare Part B Provisions

- Sec. 101. Improvements to Medicare site-of-service transparency.
- Sec. 102. Requiring manufacturers of certain single-dose container or single-use package drugs payable under part B of the Medicare program to provide refunds with respect to discarded amounts of such drugs.
- Sec. 103. Providing for variation in payment for certain drugs covered under part B of the Medicare program.
- Sec. 104. Establishment of maximum add-on payment for drugs and biologicals.
- Sec. 105. Treatment of drug administration services furnished by certain excepted off-campus outpatient departments of a provider.
- Sec. 106. Payment for biosimilar biological products during initial period.
- Sec. 107. Education on biological and biosimilar products.
- Sec. 108. GAO study and report on average sales price.

### Subtitle B—Medicare Part D Provisions

- Sec. 111. Medicare part D benefit redesign.
- Sec. 112. Transitional coverage and retroactive Medicare part D coverage for certain low-income beneficiaries.
- Sec. 113. Allowing the offering of additional prescription drug plans under Medicare part D.
- Sec. 114. Allowing certain enrollees of prescription drug plans and MA–PD plans under the Medicare program to spread out cost-sharing under certain circumstances.
- Sec. 115. Establishing a monthly cap on beneficiary incurred costs for insulin products and supplies under a prescription drug plan or MA–PD plan.
- Sec. 116. Growth rate of Medicare part D out-of-pocket cost threshold.
- Sec. 117. Requiring prescription drug plan sponsors to include real-time benefit information as part of such sponsor’s electronic prescription program under the Medicare program.
- Sec. 118. Requiring prescription drug plans and MA–PD plans to report potential fraud, waste, and abuse to the Secretary of HHS.
- Sec. 119. Establishment of pharmacy quality measures under Medicare part D.

## TITLE II—DRUG PRICE TRANSPARENCY

- Sec. 201. Reporting on explanation for drug price increases.
- Sec. 202. Public disclosure of drug discounts.
- Sec. 203. Requiring certain manufacturers to report drug pricing information with respect to drugs under the Medicare program.
- Sec. 204. Making prescription drug marketing sample information reported by manufacturers available to certain individuals and entities.
- Sec. 205. Providing the Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission with access to certain drug payment information, including certain rebate information.
- Sec. 206. Sense of the Senate regarding the need to expand commercially available drug pricing comparison platforms.

## TITLE III—REVENUE PROVISIONS

- Sec. 301. Permanent extension of reduction in medical expense deduction floor.

- Sec. 302. Safe harbor for high deductible health plans without deductible for insulin.
- Sec. 303. Inclusion of certain over-the-counter medical products as qualified medical expenses.

TITLE IV—MISCELLANEOUS

- Sec. 401. Improving coordination between the Food and Drug Administration and the Centers for Medicare & Medicaid Services.
- Sec. 402. Patient consultation in Medicare national and local coverage determinations in order to mitigate barriers to inclusion of such perspectives.
- Sec. 403. MedPAC report on shifting coverage of certain Medicare part B drugs to Medicare part D.
- Sec. 404. Requirement that direct-to-consumer advertisements for prescription drugs and biological products include truthful and non-misleading pricing information.
- Sec. 405. Chief Pharmaceutical Negotiator at the Office of the United States Trade Representative.

1       **TITLE I—MEDICARE PARTS B**  
 2                                   **AND D**  
 3                   **Subtitle A—Medicare Part B**  
 4                                   **Provisions**

5       **SEC. 101. IMPROVEMENTS TO MEDICARE SITE-OF-SERVICE**  
 6                                   **TRANSPARENCY.**

7           Section 1834(t) of the Social Security Act (42 U.S.C.  
 8       1395m(t)) is amended—

9                   (1) in paragraph (1)—

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

12                           (B) in the matter preceding subparagraph

13                           (A)—

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

16                                   (ii) by inserting “, or to a physician  
 17                                   for services furnished in a physician’s of-

1            fice” after “surgical center under this  
2            title”; and

3            (iii) by inserting “(or 2021 with re-  
4            spect to a physician for services furnished  
5            in a physician’s office)” after “2018”; and  
6            (C) in subparagraph (A)—

7            (i) by striking “and the” and insert-  
8            ing “, the”; and

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

14           (2) by redesignating paragraphs (2) through  
15           (4) as paragraphs (3) through (5), respectively; and

16           (3) by inserting after paragraph (1) the fol-  
17           lowing new paragraph:

18           “(2) PHYSICIAN PAYMENT.—Beginning in  
19           2021, the Secretary shall expand the information in-  
20           cluded on the Internet website described in para-  
21           graph (1) to include—

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

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

3 **SEC. 102. REQUIRING MANUFACTURERS OF CERTAIN SIN-**  
4 **GLE-DOSE CONTAINER OR SINGLE-USE PACK-**  
5 **AGE DRUGS PAYABLE UNDER PART B OF THE**  
6 **MEDICARE PROGRAM TO PROVIDE REFUNDS**  
7 **WITH RESPECT TO DISCARDED AMOUNTS OF**  
8 **SUCH DRUGS.**

9           Section 1847A of the Social Security Act (42 U.S.C.  
10 1395–3a) is amended by adding at the end the following  
11 new subsection:

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

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

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

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

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

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

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

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

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

16 “(3) REFUND AMOUNT.—

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

25 “(i) the product of—

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

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

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

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

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

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

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

6                   “(II) 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), the Secretary, through notice and  
18           comment rulemaking, may increase the ap-  
19           plicable percentage otherwise applicable  
20           under clause (i)(I) as determined appro-  
21           priate 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 established under this part and that is fur-  
6 nished from a single-dose container or single-  
7 use package.

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 for which  
15 dosage and administration instructions ap-  
16 proved by the Commissioner of Food and  
17 Drugs require filtration during the drug  
18 preparation process, prior to dilution and  
19 administration, and require that any un-  
20 used portion of such drug after the filtra-  
21 tion process be discarded after the comple-  
22 tion of such filtration process; or

23 “(iii) a drug or biological approved by  
24 the Food and Drug Administration on or  
25 after the date of enactment of this sub-

1 section and with respect to which payment  
2 has been made under this part for less  
3 than 18 months.”.

4 **SEC. 103. PROVIDING FOR VARIATION IN PAYMENT FOR**  
5 **CERTAIN DRUGS COVERED UNDER PART B**  
6 **OF THE MEDICARE PROGRAM.**

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

9 (1) in paragraph (1)—

10 (A) in subparagraph (A), by inserting after  
11 “or 106 percent” the following: “(or, for a mul-  
12 tiple source drug (other than autologous cellular  
13 immunotherapy) furnished on or after January  
14 1, 2021, the applicable percent specified in  
15 paragraph (9)(A) for the drug and quarter in-  
16 volved)”; and

17 (B) in subparagraph (B) of paragraph (1),  
18 by inserting after “106 percent” the following:  
19 “(or, for a single source drug or biological  
20 (other than autologous cellular immunotherapy)  
21 furnished on or after January 1, 2021, the ap-  
22 plicable percent specified in paragraph (9)(A)  
23 for the drug or biological and quarter in-  
24 volved)”; and

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

3           “(9) APPLICATION OF VARIABLE PERCENTAGES  
4 BASED ON PERCENTILE RANKING OF PER BENE-  
5 FICIARY ALLOWED CHARGES.—

6           “(A) APPLICABLE PERCENT TO BE AP-  
7 PLIED.—

8           “(i) IN GENERAL.—Subject to clause  
9 (ii), with respect to a drug or biological  
10 furnished in a calendar quarter beginning  
11 on or after January 1, 2021, if the Sec-  
12 retary determines that the percentile rank  
13 of a drug or biological under subparagraph  
14 (B)(i)(III), with respect to per beneficiary  
15 allowed charges for all such drugs or  
16 biologicals, is—

17           “(I) at least equal to the 85th  
18 percentile, the applicable percent for  
19 the drug for such quarter under this  
20 subparagraph is 104 percent;

21           “(II) at least equal to the 70th  
22 percentile, but less than the 85th per-  
23 centile, such applicable percent is 106  
24 percent;

1                   “(III) at least equal to the 50th  
2                   percentile, but less than the 70th per-  
3                   centile, such applicable percent is 108  
4                   percent; or

5                   “(IV) less than the 50th per-  
6                   centile, such applicable percent is 110  
7                   percent.

8                   “(ii) CASES WHERE DATA NOT SUFFI-  
9                   CIENTLY AVAILABLE TO COMPUTE PER  
10                  BENEFICIARY ALLOWED CHARGES.—Sub-  
11                  ject to clause (iii), in the case of a drug or  
12                  biological furnished for which the amount  
13                  of payment is determined under subpara-  
14                  graph (A) or (B) of paragraph (1) and not  
15                  under subsection (c)(4), for calendar quar-  
16                  ters during a period in which data are not  
17                  sufficiently available to compute a per ben-  
18                  eficiary allowed charges for the drug or bi-  
19                  ological, the applicable percent is 106 per-  
20                  cent.

21                  “(B) DETERMINATION OF PERCENTILE  
22                  RANK OF PER BENEFICIARY ALLOWED CHARGES  
23                  OF DRUGS.—

24                  “(i) IN GENERAL.—With respect to a  
25                  calendar quarter beginning on or after

1 January 1, 2021, for drugs and biologicals  
2 for which the amount of payment is deter-  
3 mined under subparagraph (A) or (B) of  
4 paragraph (1), except for drugs or  
5 biologicals for which data are not suffi-  
6 ciently available, the Secretary shall—

7 “(I) compute the per beneficiary  
8 allowed charges (as defined in sub-  
9 paragraph (C)) for each such drug or  
10 biological;

11 “(II) adjust such per beneficiary  
12 allowed charges for the quarter, to the  
13 extent provided under subparagraph  
14 (D); and

15 “(III) arrange such adjusted per  
16 beneficiary allowed charges for all  
17 such drugs or biologicals from high to  
18 low and rank such drugs or biologicals  
19 by percentile of such per beneficiary  
20 allowed charges.

21 “(ii) FREQUENCY.—The Secretary  
22 shall make the computations under clause  
23 (i)(I) every 6 months (or, if necessary, as  
24 determined by the Secretary, every 9 or 12  
25 months) and such computations shall apply

1 to succeeding calendar quarters until a  
2 new computation has been made.

3 “(iii) APPLICABLE DATA PERIOD.—  
4 For purposes of this paragraph, the term  
5 ‘applicable data period’ means the most re-  
6 cent period for which the data necessary  
7 for making the computations under clause  
8 (i) are available, as determined by the Sec-  
9 retary.

10 “(C) PER BENEFICIARY ALLOWED  
11 CHARGES DEFINED.—In this paragraph, the  
12 term ‘per beneficiary allowed charges’ means,  
13 with respect to a drug or biological for which  
14 the amount of payment is determined under  
15 subparagraph (A) or (B) of paragraph (1)—

16 “(i) the allowed charges for the drug  
17 or biological for which payment is so made  
18 for the applicable data period, as estimated  
19 by the Secretary; divided by

20 “(ii) the number of individuals for  
21 whom any payment for the drug or biologi-  
22 cal was made under paragraph (1) for the  
23 applicable data period, as estimated by the  
24 Secretary.

1           “(D) ADJUSTMENT TO REFLECT CHANGES  
2           IN AVERAGE SALES PRICE.—In applying this  
3           paragraph for a particular calendar quarter, the  
4           Secretary shall adjust the per beneficiary al-  
5           lowed charges for a drug or biological by multi-  
6           plying such per beneficiary allowed charges  
7           under subparagraph (C) for the applicable data  
8           period by the ratio of—

9                   “(i) the average sales price for the  
10                   drug or biological for the most recent cal-  
11                   endar quarter used under subsection  
12                   (c)(5)(B); to

13                   “(ii) the average sales price for the  
14                   drug or biological for the calendar quarter  
15                   (or the weighted average for the quarters  
16                   involved) included in the applicable data  
17                   period.”.

18           (b) APPLICATION OF JUDICIAL REVIEW PROVI-  
19           SIONS.—Section 1847A(g) of the Social Security Act is  
20           amended—

21                   (1) by striking “and” at the end of paragraph

22                   (4);

23                   (2) by striking the period at the end of para-

24                   graph (5) and inserting “; and”; and

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

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

6 **SEC. 104. ESTABLISHMENT OF MAXIMUM ADD-ON PAYMENT**  
7 **FOR DRUGS AND BIOLOGICALS.**

8           (a) IN GENERAL.—Section 1847A of the Social Secu-  
9 rity Act (42 U.S.C. 1395w-3a), as amended by section  
10 103, is amended—

11           (1) in subsection (b)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 “(i) with respect to a drug or biological  
2 cal (other than autologous or allogenic  
3 cellular immunotherapy)—

4 “(I) for each of 2021 through  
5 2028, \$1,000; and

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

14 “(ii) with respect to a drug or biological  
15 cal consisting of autologous or allogenic  
16 cellular immunotherapy—

17 “(I) for each of 2021 through  
18 2028, \$2,000; and

19 “(II) for a subsequent year, the  
20 amount specified in this subparagraph  
21 for the preceding year increased by  
22 the percentage increase in the con-  
23 sumer price index for all urban con-  
24 sumers (all items; United States city

1 average) for the 12-month period end-  
2 ing with June of the previous year.

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

6 (2) in subsection (c)(4)(A)(ii), by striking “in  
7 the case” and inserting “subject to subsection  
8 (b)(10), in the case”.

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

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

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

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

18 “(I) APPLICATION OF MAXIMUM ADD-ON  
19 PAYMENT FOR SEPARATELY PAYABLE DRUGS  
20 AND BIOLOGICALS.—In establishing the amount  
21 of payment under subparagraph (A) for a speci-  
22 fied covered outpatient drug that is furnished  
23 as part of a covered OPD service (or group of  
24 services) on or after January 1, 2021, if such  
25 payment is determined based on the average

1 price for the year established under section  
2 1847A pursuant to clause (iii)(II) of such sub-  
3 paragraph, the provisions of subsection (b)(10)  
4 of section 1847A shall apply to the amount of  
5 payment so established in the same manner as  
6 such provisions apply to the amount of payment  
7 under section 1847A.”.

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

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

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

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

16 “(vi) If there is a separate payment  
17 under the system described in clause (i) for  
18 a drug or biological furnished on or after  
19 January 1, 2021, the provisions of sub-  
20 section (t)(14)(I) shall apply to the estab-  
21 lishment of the amount of payment for the  
22 drug or biological under such system in the  
23 same manner in which such provisions  
24 apply to the establishment of the amount  
25 of payment under subsection (t)(14)(A).”.

1 **SEC. 105. TREATMENT OF DRUG ADMINISTRATION SERV-**  
2 **ICES FURNISHED BY CERTAIN EXCEPTED**  
3 **OFF-CAMPUS OUTPATIENT DEPARTMENTS OF**  
4 **A PROVIDER.**

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

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

11 “(i) IN GENERAL.—In the case of a  
12 covered OPD service that is a drug admin-  
13 istration service (as defined by the Sec-  
14 retary) furnished by a department of a  
15 provider described in clause (ii) or (iv) of  
16 paragraph (21)(B), the payment amount  
17 for such service furnished on or after Jan-  
18 uary 1, 2021, shall be the same payment  
19 amount (as determined in paragraph  
20 (21)(C)) that would apply if the drug ad-  
21 ministration service was furnished by an  
22 off-campus outpatient department of a pro-  
23 vider (as defined in paragraph (21)(B)).

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

1 “(I) shall not be considered an  
2 adjustment under paragraph (2)(E);  
3 and

4 “(II) shall not be implemented in  
5 a budget neutral manner.”.

6 **SEC. 106. PAYMENT FOR BIOSIMILAR BIOLOGICAL PROD-**  
7 **UCTS DURING INITIAL PERIOD.**

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

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

14 (2) by redesignating subparagraphs (A) and  
15 (B) as clauses (i) and (ii) and moving such clauses  
16 2 ems to the right;

17 (3) by striking “UNAVAILABLE.—In the case”  
18 and inserting “UNAVAILABLE.—

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

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

23 “(B) LIMITATION ON PAYMENT AMOUNT  
24 FOR BIOSIMILAR BIOLOGICAL PRODUCTS DUR-  
25 ING INITIAL PERIOD.—In the case of a bio-

1 similar biological product furnished on or after  
2 July 1, 2020, in lieu of applying subparagraph  
3 (A) during the initial period described in such  
4 subparagraph with respect to the biosimilar bio-  
5 logical product, the amount payable under this  
6 section for the biosimilar biological product is  
7 the lesser of the following:

8 “(i) The amount determined under  
9 clause (ii) of such subparagraph for the  
10 biosimilar biological product.

11 “(ii) The amount determined under  
12 subsection (b)(1)(B) for the reference bio-  
13 logical product.”.

14 **SEC. 107. EDUCATION ON BIOLOGICAL AND BIOSIMILAR**  
15 **PRODUCTS.**

16 (a) IN GENERAL.—The Secretary of Health and  
17 Human Services shall advance education and awareness  
18 among health care providers regarding biological products,  
19 including biosimilar biological products and interchange-  
20 able biosimilar biological products, as appropriate, includ-  
21 ing by developing or improving continuing education pro-  
22 grams that advance the education of such providers on the  
23 prescribing of, and relevant clinical considerations with re-  
24 spect to, biological products, including biosimilar biological

1 products and interchangeable biosimilar biological prod-  
2 ucts.

3 (b) APPLICATION UNDER THE MEDICARE MERIT-  
4 BASED INCENTIVE PAYMENT SYSTEM.—Section  
5 1848(q)(5)(C) of the Social Security Act (42 U.S.C.  
6 1395w-4(q)(5)(C)) is amended by adding at the end the  
7 following new clause:

8 (iv) CLINICAL MEDICAL EDUCATION  
9 PROGRAM ON BIOSIMILAR BIOLOGICAL  
10 PRODUCTS.—Completion of a clinical med-  
11 ical education program developed or im-  
12 proved under section 107(a) of the Lower  
13 Costs, More Cures Act of 2019 by a MIPS  
14 eligible professional during a performance  
15 period shall earn such eligible professional  
16 one-half of the highest potential score for  
17 the performance category described in  
18 paragraph (2)(A)(iii) for such performance  
19 period. A MIPS eligible professional may  
20 only count the completion of such a pro-  
21 gram for purposes of such category one  
22 time during the eligible professional’s life-  
23 time.”.

1 **SEC. 108. GAO STUDY AND REPORT ON AVERAGE SALES**

2 **PRICE.**

3 (a) STUDY.—

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

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

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

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

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

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

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

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

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

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

14 (i) formulary placement;

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

17 (iii) other purposes.

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

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

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

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

## 4           **Subtitle B—Medicare Part D** 5                           **Provisions**

### 6 **SEC. 111. MEDICARE PART D BENEFIT REDESIGN.**

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

10                       (1) in paragraph (2)—

11                               (A) in subparagraph (A)—

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

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

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

1 (B) in subparagraph (C)—

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

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

9 (C) in subparagraph (D)—

10 (i) in clause (i)—

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

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

19 (ii) in clause (ii)(V), by striking  
20 “2019 and each subsequent year” and in-  
21 serting “each of years 2019 through  
22 2021”;

23 (2) in paragraph (3)(A)—

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

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

7 (3) in paragraph (4)—

8 (A) in subparagraph (A)—

9 (i) in clause (i)—

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

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

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

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

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

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

1                   “(VII) for 2022, is equal to  
2                   \$3,100; or

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

9                   (ii) in clause (ii), by striking “clause  
10                   (i)(II)” and inserting “clause (i)”;

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

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

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

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

22                   “(A) for a year preceding 2022, 80 per-  
23                   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, 2021, 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, 2022.

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 (c).

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 one or  
18          more third parties to administer the requirements  
19          established by the Secretary in order to carry out  
20          this section. At a minimum, the contract with a  
21          third party under the preceding sentence shall re-  
22          quire 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, 2022, 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, 2022, 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 2022 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”;

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 2022 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 REDE-  
 16 SIGN.—Section 1860D–15(c) of the Social Security Act  
 17 (42 U.S.C. 1395w–115(c)) is amended by adding at the  
 18 end the following new paragraph:

19 “(3) UPDATING RISK ADJUSTMENT METH-  
 20 ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA-  
 21 TION REDESIGN.—The Secretary shall update the  
 22 risk adjustment 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 2019.”.

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, 2022, and paragraphs (4) through (6)  
5 of such subsection shall apply to covered part D drugs  
6 dispensed on or after January 1, 2022.”; 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, 2022, and ending December 31,  
14 2022 (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 2022 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 2022 or the annual out-of-pocket threshold  
6 specified in subsection (b)(4)(B) for the  
7 year for 2022 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 2022, 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 2022, 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 2022, 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 2022, 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 2022, the continuation”;  
8 and

9 (ii) in subparagraph (E)—  
10 (I) by inserting “for a year pre-  
11 ceding 2022,” 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 2022, 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 2022 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 2022”  
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 2022 and subsequent  
19 plan years.

20 **SEC. 112. TRANSITIONAL COVERAGE AND RETROACTIVE**  
21 **MEDICARE PART D COVERAGE FOR CERTAIN**  
22 **LOW-INCOME BENEFICIARIES.**

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

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

3           (2) by adding after subsection (d) the following  
4           new subsection:

5           “(e) LIMITED INCOME NEWLY ELIGIBLE TRANSI-  
6           TION PROGRAM.—

7           “(1) IN GENERAL.—Beginning not later than  
8           January 1, 2021, the Secretary shall carry out a  
9           program to provide transitional coverage for covered  
10          part D drugs for LI NET eligible individuals in ac-  
11          cordance with this subsection.

12          “(2) LI NET ELIGIBLE INDIVIDUAL DEFINED.—  
13          For purposes of this subsection, the term ‘LI NET  
14          eligible individual’ means a part D eligible individual  
15          who—

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

18                  “(B) has not yet enrolled in a prescription  
19                  drug plan or an MA–PD plan, or, who has so  
20                  enrolled, but with respect to whom coverage  
21                  under such plan has not yet taken effect.

22          “(3) TRANSITIONAL COVERAGE.—For purposes  
23          of this subsection, the term ‘transitional coverage’  
24          means, with respect to an LI NET eligible indi-  
25          vidual—

1           “(A) immediate access to covered part D  
2 drugs at the point-of-sale during the period that  
3 begins on the first day of the month such indi-  
4 vidual is determined to meet the requirements  
5 of clauses (ii) and (iii) of subsection (a)(3)(A)  
6 and ends on the date that coverage under a pre-  
7 scription drug plan or MA–PD plan takes effect  
8 with respect to such individual; and

9           “(B) in the case of an LI NET eligible in-  
10 dividual who is a full-benefit dual eligible indi-  
11 vidual (as defined in section 1935(c)(6)) or a  
12 recipient of supplemental security income bene-  
13 fits under title XVI, retroactive coverage (in the  
14 form of reimbursement of the amounts that  
15 would have been paid under this part had such  
16 individual been enrolled in a prescription drug  
17 plan or MA–PD plan) of covered part D drugs  
18 purchased by such individual during the period  
19 that—

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

22                           “(I) the date that such individual  
23 was first eligible for a low-income sub-  
24 sidy under this part; or

1                   “(II) the date that is 36 months  
2                   prior to the date such individual en-  
3                   rolls in a prescription drug plan or  
4                   MA–PD plan; and

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

7                   “(4) PROGRAM ADMINISTRATION.—

8                   “(A) SINGLE POINT OF CONTACT.—The  
9                   Secretary shall, to the extent feasible, admin-  
10                  ister the program under this subsection through  
11                  a contract with a single program administrator.

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

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

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

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

1                   “(iv) meets such other requirements  
2                   as the Secretary may establish.

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

5                   “(A) IN GENERAL.—The following provi-  
6 sions shall not apply with respect to the pro-  
7 gram under this subsection:

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

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

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

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

1 **SEC. 113. ALLOWING THE OFFERING OF ADDITIONAL PRE-**  
2 **SCRIPTION DRUG PLANS UNDER MEDICARE**  
3 **PART D.**

4 (a) **RESCINDING AND ISSUANCE OF NEW GUID-**  
5 **ANCE.**—Not later than one year after the date of the en-  
6 actment of this Act, the Secretary of Health and Human  
7 Services (in this section referred to as the “Secretary”)  
8 shall—

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

15 (2) issue new guidance specifying that a PDP  
16 sponsor may offer up to 4 (or a greater number if  
17 determined appropriate by the Secretary) prescrip-  
18 tion drug plans in each PDP region, except in cases  
19 where the PDP sponsor may offer up to 2 additional  
20 plans in a PDP region pursuant to section 1860D–  
21 11(d)(4) of the Social Security Act (42 U.S.C.  
22 1395w–111(d)(4)), as added by subsection (b).

23 (b) **OFFERING OF ADDITIONAL PLANS.**—Section  
24 1860D–11(d) of the Social Security Act (42 U.S.C.  
25 1395w–111(d)) is amended by adding at the end the fol-  
26 lowing new paragraph:

1 “(4) OFFERING OF ADDITIONAL PLANS.—

2 “(A) IN GENERAL.—For plan year 2022  
3 and each subsequent plan year, a PDP sponsor  
4 may offer up to 2 additional prescription drug  
5 plans in a PDP region (in addition to any limit  
6 established by the Secretary under this part)  
7 provided that the PDP sponsor complies with  
8 subparagraph (B) with respect to at least one  
9 such prescription drug plan.

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

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

3                   “(ii) are used to reduce total bene-  
4                   ficiary cost-sharing estimated by the PDP  
5                   sponsor for prescription drug coverage  
6                   under the plan in the annual bid submitted  
7                   by the PDP sponsor under section 1860D-  
8                   11(b).

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

19                  (c) RULE OF CONSTRUCTION.—Nothing in the provi-  
20                  sions of, or amendments made by, this section shall be  
21                  construed as limiting the ability of the Secretary to in-  
22                  crease any limit otherwise applicable on the number of  
23                  prescription drug plans that a PDP sponsor may offer,  
24                  at the discretion of the PDP sponsor, in a PDP region

1 under part D of title XVIII of the Social Security Act (42  
2 U.S.C. 1395w–101 et seq.).

3 **SEC. 114. ALLOWING CERTAIN ENROLLEES OF PRESCRIP-**  
4 **TION DRUG PLANS AND MA-PD PLANS UNDER**  
5 **THE MEDICARE PROGRAM TO SPREAD OUT**  
6 **COST-SHARING UNDER CERTAIN CIR-**  
7 **CUMSTANCES.**

8 (a) STANDARD PRESCRIPTION DRUG COVERAGE.—  
9 Section 1860D–2(b)(2) of the Social Security Act (42  
10 U.S.C. 1395w–102(b)(2)), as amended by section 111, is  
11 amended—

12 (1) in subparagraph (A), by striking “Subject  
13 to subparagraphs (C) and (D)” and inserting “Sub-  
14 ject to subparagraphs (C), (D), and (E)”; and

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

17 “(E) ENROLLEE OPTION REGARDING  
18 SPREADING COST-SHARING.—

19 “(i) IN GENERAL.—The Secretary  
20 shall establish by regulation a process  
21 under which, with respect to plan year  
22 2022 and subsequent plan years, a pre-  
23 scription drug plan or an MA–PD plan  
24 shall, in the case of a part D eligible indi-  
25 vidual enrolled with such plan for such

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

15 “(ii) SIGNIFICANT PERCENTAGE LIM-  
16 TATIONS.—In specifying a significant per-  
17 centage pursuant to the regulation estab-  
18 lished by the Secretary under clause (i),  
19 the Secretary shall not specify a percent-  
20 age that is less than 30 percent or greater  
21 than 100 percent.”.

22 (b) ALTERNATIVE PRESCRIPTION DRUG COV-  
23 ERAGE.—Section 1860D–2(c) of the Social Security Act  
24 (42 U.S.C. 1395w–102(c)) is amended by adding at the  
25 end the following new paragraph:

1           “(4) SAME ENROLLEE OPTION REGARDING  
2           SPREADING COST-SHARING.—For plan year 2022  
3           and subsequent plan years, the coverage provides the  
4           enrollee option regarding spreading cost-sharing de-  
5           scribed in and required under subsection  
6           (b)(2)(E).”.

7   **SEC. 115. ESTABLISHING A MONTHLY CAP ON BENEFICIARY**  
8                   **INCURRED COSTS FOR INSULIN PRODUCTS**  
9                   **AND SUPPLIES UNDER A PRESCRIPTION**  
10                  **DRUG PLAN OR MA-PD PLAN.**

11           (a) IN GENERAL.—Section 1860D–2 of the Social  
12           Security Act (42 U.S.C. 1395w–102), as amended by sec-  
13           tions 111 and 114, is amended—

14                   (1) in subsection (b)(2)—

15                           (A) in subparagraph (A), by striking “and  
16                           (E)” and inserting “(E), and (F)”;

17                           (B) in subparagraph (B), by striking “and  
18                           (D)” and inserting “(D), and (F)”;

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

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

23   “(i) IN GENERAL.—The coverage pro-  
24   vides benefits, for costs above the annual  
25   deductible specified in paragraph (1) and

1 up to the annual out-of-pocket threshold  
2 described in paragraph (4)(B) and with re-  
3 spect to a month (beginning with January  
4 of 2022), with cost sharing that is equal to  
5 \$0 for a specified covered part D drug (as  
6 defined in clause (iii)) furnished to an indi-  
7 vidual who has incurred costs during such  
8 month with respect to specified covered  
9 part D drugs equal to—

10 “(I) for months occurring in  
11 2022, \$50; or

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

21 “(ii) APPLICATION.—The provisions  
22 of clauses (i) through (iii) of paragraph  
23 (4)(C) shall apply with respect to the de-  
24 termination of the incurred costs for speci-  
25 fied covered part D drugs for purposes of

1 clause (i) in the same manner as such pro-  
 2 visions apply with respect to the deter-  
 3 mination of incurred costs for covered part  
 4 D drugs for purposes of paragraph (4)(A).

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

10 “(I) insulin; or

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

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

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

22 (b) CONFORMING AMENDMENTS.—

23 (1) IN GENERAL.—Section 1860D–14(a)(1)(D)  
 24 of the Social Security Act (42 U.S.C. 1395w–

1 114(a)(1)(D)), as amended by section 111, is  
2 amended—

3 (A) in clause (ii), by striking “section  
4 1860D–2(b)(2)” and inserting “section 1860D–  
5 2(b)(2)(A)”; and

6 (B) in clause (iii), by striking “section  
7 1860D–2(b)(2)” and inserting “section 1860D–  
8 2(b)(2)(A)”.

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

12 **SEC. 116. GROWTH RATE OF MEDICARE PART D OUT-OF-**  
13 **POCKET COST THRESHOLD.**

14 (a) PROVIDING MEDICARE PART D BENEFICIARIES  
15 WITH CERTAIN 2020 OFFSET PAYMENTS.—Section  
16 1860D–2(b)(4) of the Social Security Act (42 U.S.C.  
17 1395w–102(b)(4)) is amended by adding at the end the  
18 following new subparagraph:

19 “(F) 2020 OFFSET PAYMENTS.—

20 “(i) IN GENERAL.—Subject to clause  
21 (iv), the Secretary shall provide for pay-  
22 ment from the Medicare Prescription Drug  
23 Account as follows:

24 “(I) In the case of a specified in-  
25 dividual (as defined in clause (ii)(I))

1           who as of the last day of a calendar  
2           quarter in 2020 has incurred costs for  
3           covered part D drugs so that the indi-  
4           vidual has exceeded the annual out-of-  
5           pocket threshold applied under sub-  
6           paragraph (B)(i)(V) for 2020, pay-  
7           ment to the individual by not later  
8           than 15th day of the third month fol-  
9           lowing the end of such quarter of the  
10          amount by which such threshold so  
11          applied exceeded the target threshold  
12          for 2020.

13                 “(II) In the case of a specified  
14           individual who is not described in sub-  
15           clause (I) and who as of the last day  
16           of 2020 has incurred costs for covered  
17           part D drugs so that the individual  
18           has exceeded the target threshold for  
19           2020, payment to the individual by  
20           not later than December 31, 2021, of  
21           the amount by which such incurred  
22           costs exceeded the target threshold for  
23           2020.

24                 “(ii) DEFINITIONS.—For purposes of  
25           this subparagraph:

1                   “(I) SPECIFIED INDIVIDUAL.—

2                   The term ‘specified individual’ means  
3                   an individual who—

4                   “(aa) is enrolled in a pre-  
5                   scription drug plan or an MA-  
6                   PD plan;

7                   “(bb) is not enrolled in a  
8                   qualified retiree prescription drug  
9                   plan; and

10                   “(cc) is not entitled to an in-  
11                   come-related subsidy under sec-  
12                   tion 1860D–14(a).

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

22                   “(iii) NOTIFICATION.—In the case of  
23                   any specified individual who during 2020  
24                   has incurred costs for covered part D  
25                   drugs so that the individual has exceeded

1 the target threshold for 2020, the Sec-  
2 retary shall, not later than September 30,  
3 2021, provide to such individual a notifica-  
4 tion informing such individual of such indi-  
5 vidual’s right to a payment described in  
6 clause (i) and the estimated timing of such  
7 payment.

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

12 “(v) IMPLEMENTATION.—The Sec-  
13 retary may implement this subparagraph  
14 by program instruction or otherwise.”.

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

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

21 (2) by redesignating subclause (VI) as sub-  
22 clause (VIII); and

23 (3) by inserting after subclause (V) the fol-  
24 lowing new subclauses:

1           “(VI) for 2021, is equal to the  
2           amount that would have been applied  
3           under this subparagraph for 2020 if  
4           such amount had been determined in  
5           accordance with subclause (IV) in-  
6           stead of subclause (V), increased by  
7           the lesser of—

8                   “(aa) the annual percentage  
9                   increase described in paragraph  
10                  (7) for 2021, plus 2 percentage  
11                  points; or

12                   “(bb) the annual percentage  
13                   increase described in paragraph  
14                  (6) for 2021;

15           “(VII) for 2022, is equal to the  
16           amount that would have been applied  
17           under this subparagraph for 2022 if  
18           the amendments made by section  
19           1101(d)(1) of the Health Care and  
20           Education Reconciliation Act of 2010  
21           and by section 135 of the Lower  
22           Costs, More Cures Act of 2019 had  
23           not been enacted; or”.

1 **SEC. 117. REQUIRING PRESCRIPTION DRUG PLAN SPON-**  
 2 **SORS TO INCLUDE REAL-TIME BENEFIT IN-**  
 3 **FORMATION AS PART OF SUCH SPONSOR'S**  
 4 **ELECTRONIC PRESCRIPTION PROGRAM**  
 5 **UNDER THE MEDICARE PROGRAM.**

6 Section 1860D-4(e)(2) of the Social Security Act (42  
 7 U.S.C. 1395w-104(e)(2)) is amended—

8 (1) in subparagraph (D), by striking “To the  
 9 extent” and inserting “Except as provided in sub-  
 10 paragraph (F), to the extent”; and

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

13 “(F) REAL-TIME BENEFIT INFORMA-  
 14 TION.—

15 “(i) IN GENERAL.—Not later than  
 16 January 1, 2021, the program shall imple-  
 17 ment real-time benefit tools that are capa-  
 18 ble of integrating with a prescribing health  
 19 care professional’s electronic prescribing or  
 20 electronic health record system for the  
 21 transmission of formulary and benefit in-  
 22 formation in real time to prescribing health  
 23 care professionals. With respect to a cov-  
 24 ered part D drug, such tools shall be capa-  
 25 ble of transmitting such information spe-  
 26 cific to an individual enrolled in a prescrip-

1 tion drug plan. Such information shall in-  
2 clude the following:

3 “(I) A list of any clinically appro-  
4 priate alternatives to such drug in-  
5 cluded in the formulary of such plan.

6 “(II) Cost-sharing information  
7 for such drug and such alternatives,  
8 including a description of any vari-  
9 ance in cost-sharing based on the  
10 pharmacy dispensing of such drug or  
11 such alternatives.

12 “(III) Information relating to  
13 whether such drug is included in the  
14 formulary of such plan and any prior  
15 authorization or other utilization man-  
16 agement requirements applicable to  
17 such drug and such alternatives so in-  
18 cluded.

19 “(ii) ELECTRONIC TRANSMISSION.—  
20 The provisions of subclauses (I) and (II) of  
21 clause (ii) of subparagraph (E) shall apply  
22 to an electronic transmission described in  
23 clause (i) in the same manner as such pro-  
24 visions apply with respect to an electronic

1 transmission described in clause (i) of such  
 2 subparagraph.

3 “(iii) SPECIAL RULE FOR 2021.—The  
 4 program shall be deemed to be in compli-  
 5 ance with clause (i) for 2021 if the pro-  
 6 gram complies with the provisions of sec-  
 7 tion 423.160(b)(7) of title 42, Code of  
 8 Federal Regulations (or a successor regula-  
 9 tion), for such year.

10 “(iv) RULE OF CONSTRUCTION.—  
 11 Nothing in this subparagraph shall be con-  
 12 strued as to allow a real-time benefits tool  
 13 to steer an individual, without the consent  
 14 of the individual, to a particular pharmacy  
 15 or pharmacy setting over their preferred  
 16 pharmacy setting nor prohibit the designa-  
 17 tion of a preferred pharmacy under such  
 18 tool.”.

19 **SEC. 118. REQUIRING PRESCRIPTION DRUG PLANS AND**  
 20 **MA-PD PLANS TO REPORT POTENTIAL**  
 21 **FRAUD, WASTE, AND ABUSE TO THE SEC-**  
 22 **RETARY OF HHS.**

23 Section 1860D–4 of the Social Security Act (42  
 24 U.S.C. 1395w–104) is amended by adding at the end the  
 25 following new subsection:

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

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

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

12 **SEC. 119. ESTABLISHMENT OF PHARMACY QUALITY MEAS-**  
 13 **URES UNDER MEDICARE PART D.**

14       Section 1860D–4(c) of the Social Security Act (42  
 15 U.S.C. 1395w–104(c)) is amended by adding at the end  
 16 the following new paragraph:

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

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

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

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

## 17           **TITLE II—DRUG PRICE** 18           **TRANSPARENCY**

### 19           **SEC. 201. REPORTING ON EXPLANATION FOR DRUG PRICE** 20           **INCREASES.**

21           (a) IN GENERAL.—Title XI of the Social Security Act  
 22 (42 U.S.C. 1301 et seq.) is amended by inserting after  
 23 section 1128K the following new section:

#### 24           **“SEC. 1128L. DRUG PRICE REPORTING.**

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

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

3           “(A) that holds the application for a drug  
4 approved under section 505 of the Federal  
5 Food, Drug, and Cosmetic Act or licensed  
6 under section 351 of the Public Health Service  
7 Act; or

8           “(B) who is responsible for setting the  
9 wholesale acquisition cost for the drug.

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

15          “(A) that has a wholesale acquisition cost  
16 of \$100 or more, adjusted for inflation occur-  
17 ring after the date of enactment of this section,  
18 for a month’s supply or a typical course of  
19 treatment that lasts less than a month, and  
20 is—

21           “(i) subject to section 503(b)(1) of  
22 the Federal Food, Drug, and Cosmetic  
23 Act;

24           “(ii) administered or otherwise dis-  
25 pensed to treat a disease or condition af-

1                   fecting more than 200,000 persons in the  
2                   United States; and

3                   “(iii) not a vaccine; and

4                   “(B) for which, during the previous cal-  
5                   endar year, at least 1 dollar of the total amount  
6                   of sales were for individuals enrolled under the  
7                   Medicare program under title XVIII or under a  
8                   State Medicaid plan under title XIX or under  
9                   a waiver of such plan.

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

13                  “(b) REPORT.—

14                   “(1) REPORT REQUIRED.—The manufacturer of  
15                   a qualifying drug shall submit a report to the Sec-  
16                   retary—

17                   “(A) for each increase in the price of a  
18                   qualifying drug that results in an increase in  
19                   the wholesale acquisition cost of that drug that  
20                   is equal to—

21                   “(i) 10 percent or more within a sin-  
22                   gle calendar year beginning on or after  
23                   January 1, 2019; or

24                   “(ii) 25 percent or more within three  
25                   consecutive calendar years for which the

1 first such calendar year begins on or after  
2 January 1, 2019; and

3 “(B) in the case that the qualifying drug  
4 is first covered under title XVIII with respect  
5 to an applicable year, if the estimated cost or  
6 spending under such title per individual or per  
7 user of such drug (as estimated by the Sec-  
8 retary) for such applicable year (or per course  
9 of treatment in such applicable year, as defined  
10 by the Secretary) is at least \$26,000.

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

14 “(A) in the case of a report with respect  
15 to an increase in the price of a qualifying drug  
16 that occurs during the period beginning on Jan-  
17 uary 1, 2019, and ending on the day that is 60  
18 days after the date of enactment of this section,  
19 not later than 90 days after such date of enact-  
20 ment;

21 “(B) in the case of a report with respect  
22 to an increase in the price of a qualifying drug  
23 that occurs after the period described in sub-  
24 paragraph (A), not later than 30 days prior to

1 the planned effective date of such price increase  
2 for such qualifying drug; and

3 “(C) in the case of a report with respect  
4 to a qualifying drug that meets the criteria de-  
5 scribed in paragraph (1)(B), not later than 30  
6 days after such drug meets such criteria.

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

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

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

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

1           “(C) if known and different from the man-  
2           ufacturer of the qualifying drug, the identity  
3           of—

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

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

13                           “(II) for licensure of the drug  
14                           under section 351 of the Public  
15                           Health Service Act; and

16                   “(ii) the sponsor of an application for  
17                   the drug approved under such section 505  
18                   of the Federal Food, Drug, and Cosmetic  
19                   Act or licensed under section 351 of the  
20                   Public Health Service Act;

21           “(D) a description of the history of the  
22           manufacturer’s price increases for the drug  
23           since the approval of the application for the  
24           drug under section 505 of the Federal Food,  
25           Drug, and Cosmetic Act or the issuance of the

1 license for the drug under section 351 of the  
2 Public Health Service Act, or since the manu-  
3 facturer acquired such approved application or  
4 license, if applicable;

5 “(E) the current wholesale acquisition cost  
6 of the drug;

7 “(F) the total expenditures of the manu-  
8 facturer on—

9 “(i) materials and manufacturing for  
10 such drug; and

11 “(ii) acquiring patents and licensing  
12 for such drug;

13 “(G) the percentage of total expenditures  
14 of the manufacturer on research and develop-  
15 ment for such drug that was derived from Fed-  
16 eral funds;

17 “(H) the total expenditures of the manu-  
18 facturer on research and development for such  
19 drug that is necessary to demonstrate that it  
20 meets applicable statutory standards for ap-  
21 proval under section 505 of the Federal Food,  
22 Drug, and Cosmetic Act or licensure under sec-  
23 tion 351 of the Public Health Service Act, as  
24 applicable;

1           “(I) the total expenditures of the manufac-  
2           turer on pursuing new or expanded indications  
3           or dosage changes for such drug under section  
4           505 of the Federal Food, Drug, and Cosmetic  
5           Act or section 351 of the Public Health Service  
6           Act;

7           “(J) the total expenditures of the manufac-  
8           turer on carrying out postmarket requirements  
9           related to such drug, including under section  
10          505(o)(3) of the Federal Food, Drug, and Cos-  
11          metic Act;

12          “(K) the total revenue and the net profit  
13          generated from the qualifying drug for each cal-  
14          endar year since the approval of the application  
15          for the drug under section 505 of the Federal  
16          Food, Drug, and Cosmetic Act or the issuance  
17          of the license for the drug under section 351 of  
18          the Public Health Service Act, or since the  
19          manufacturer acquired such approved applica-  
20          tion or license; and

21          “(L) the total costs associated with mar-  
22          keting and advertising for the qualifying drug;  
23          “(2) with respect to the manufacturer—

24          “(A) the total revenue and the net profit  
25          of the manufacturer for each of the 1-year pe-

1           riod described in subsection (b)(1)(A) or the 3-  
2           year period described in subsection (b)(1)(B),  
3           as applicable;

4           “(B) all stock-based performance metrics  
5           used by the manufacturer to determine execu-  
6           tive compensation for each of the 1-year period  
7           described in subsection (b)(1)(A) or the 3-year  
8           period described in subsection (b)(1)(B), as ap-  
9           plicable; and

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

13                   “(i) drug research and development;

14                   or

15                   “(ii) clinical trials, including on drugs  
16                   that failed to receive approval by the Food  
17                   and Drug Administration; and

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

21           “(d) INFORMATION PROVIDED.—The manufacturer  
22           of a qualifying drug that is required to submit a report  
23           under subsection (b), shall ensure that such report and  
24           any explanation for, and description of, each price increase

1 described in subsection (c)(1)(B) shall be truthful, not  
2 misleading, and accurate.

3 “(e) CIVIL MONETARY PENALTY.—Any manufac-  
4 turer of a qualifying drug that fails to submit a report  
5 for the drug as required by this section, following notifica-  
6 tion by the Secretary to the manufacturer that the manu-  
7 facturer is not in compliance with this section, shall be  
8 subject to a civil monetary penalty of \$75,000 for each  
9 day on which the violation continues.

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

15 “(g) PUBLIC POSTING.—

16 “(1) IN GENERAL.—Subject to paragraph (3),  
17 the Secretary shall post each report submitted under  
18 subsection (b) on the public website of the Depart-  
19 ment of Health and Human Services the day the  
20 price increase of a qualifying drug is scheduled to go  
21 into effect.

22 “(2) FORMAT.—In developing the format in  
23 which reports will be publicly posted under para-  
24 graph (1), the Secretary shall consult with stake-  
25 holders, including beneficiary groups, and shall seek

1 feedback from consumer advocates and readability  
2 experts on the format and presentation of the con-  
3 tent of such reports to ensure that such reports  
4 are—

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

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

8 “(3) PROTECTED INFORMATION.—Nothing in  
9 this section shall be construed to authorize the pub-  
10 lic disclosure of information submitted by a manu-  
11 facturer that is prohibited from disclosure by appli-  
12 cable laws concerning the protection of trade secrets,  
13 commercial information, and other information cov-  
14 ered under such laws.

15 “(h) ANNUAL REPORT TO CONGRESS.—

16 “(1) IN GENERAL.—Subject to paragraph (2),  
17 the Secretary shall submit to Congress, and post on  
18 the public website of the Department of Health and  
19 Human Services in a way that is user-friendly to the  
20 public and written in plain language that consumers  
21 can readily understand, an annual report—

22 “(A) summarizing the information re-  
23 ported pursuant to this section;

1           “(B) including copies of the reports and  
2           supporting detailed economic analyses sub-  
3           mitted pursuant to this section;

4           “(C) detailing the costs and expenditures  
5           incurred by the Department of Health and  
6           Human Services in carrying out this section;  
7           and

8           “(D) explaining how the Department of  
9           Health and Human Services is improving con-  
10          sumer and provider information about drug  
11          value and drug price transparency.

12          “(2) PROTECTED INFORMATION.—Nothing in  
13          this subsection shall be construed to authorize the  
14          public disclosure of information submitted by a man-  
15          ufacturer that is prohibited from disclosure by appli-  
16          cable laws concerning the protection of trade secrets,  
17          commercial information, and other information cov-  
18          ered under such laws.”.

19          (b) EFFECTIVE DATE.—The amendment made by  
20          subsection (a) shall take effect on the date of enactment  
21          of this Act.

22          **SEC. 202. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.**

23          Section 1150A of the Social Security Act (42 U.S.C.  
24          1320b–23) is amended—

1           (1) in subsection (e), in the matter preceding  
2 paragraph (1), by inserting “(other than as per-  
3 mitted under subsection (e))” after “disclosed by the  
4 Secretary”; and

5           (2) by adding at the end the following new sub-  
6 section:

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

9           “(1) IN GENERAL.—In order to allow the com-  
10 parison of PBMs’ ability to negotiate rebates, dis-  
11 counts, direct and indirect remuneration fees, ad-  
12 ministrative fees, and price concessions and the  
13 amount of such rebates, discounts, direct and indi-  
14 rect remuneration fees, administrative fees, and  
15 price concessions that are passed through to plan  
16 sponsors, beginning January 1, 2020, the Secretary  
17 shall make available on the Internet website of the  
18 Department of Health and Human Services the in-  
19 formation with respect to the second preceding cal-  
20 endar year provided to the Secretary on generic dis-  
21 pensing rates (as described in paragraph (1) of sub-  
22 section (b)) and information provided to the Sec-  
23 retary under paragraphs (2) and (3) of such sub-  
24 section that, as determined by the Secretary, is with  
25 respect to each PBM.

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

4           “(A) CONFIDENTIALITY.—The information  
5 described in such paragraph is displayed in a  
6 manner that prevents the disclosure of informa-  
7 tion, with respect to an individual drug or an  
8 individual plan, on rebates, discounts, direct  
9 and indirect remuneration fees, administrative  
10 fees, and price concessions.

11           “(B) CLASS OF DRUG.—The information  
12 described in such paragraph is made available  
13 by class of drug, using an existing classification  
14 system, but only if the class contains such num-  
15 ber of drugs, as specified by the Secretary (but  
16 not fewer than three drugs), to ensure confiden-  
17 tiality of proprietary information or other infor-  
18 mation that is prevented to be disclosed under  
19 subparagraph (A).”.

20 **SEC. 203. REQUIRING CERTAIN MANUFACTURERS TO RE-**  
21 **PORT DRUG PRICING INFORMATION WITH**  
22 **RESPECT TO DRUGS UNDER THE MEDICARE**  
23 **PROGRAM.**

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

1 (1) in subsection (b)—

2 (A) in paragraph (2)(A), by inserting “or  
3 subsection (f)(2), as applicable” before the pe-  
4 riod at the end;

5 (B) in paragraph (3), in the matter pre-  
6 ceding subparagraph (A), by inserting “or sub-  
7 section (f)(2), as applicable,” before “deter-  
8 mined by”; and

9 (C) in paragraph (6)(A), in the matter  
10 preceding clause (i), by inserting “or subsection  
11 (f)(2), as applicable,” before “determined by”;  
12 and

13 (2) in subsection (f)—

14 (A) by striking “For requirements” and  
15 inserting the following:

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

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

19 “(2) MANUFACTURERS WITHOUT A REBATE  
20 AGREEMENT UNDER TITLE XIX.—

21 “(A) IN GENERAL.—If the manufacturer  
22 of a drug or biological described in subpara-  
23 graph (C), (E), or (G) of section 1842(o)(1) or  
24 in section 1881(b)(14)(B) that is payable under  
25 this part has not entered into and does not

1 have in effect a rebate agreement described in  
2 subsection (b) of section 1927, for calendar  
3 quarters beginning on or after January 1,  
4 2020, such manufacturer shall report to the  
5 Secretary the information described in sub-  
6 section (b)(3)(A)(iii) of such section 1927 with  
7 respect to such drug or biological in a time and  
8 manner specified by the Secretary. For pur-  
9 poses of applying this paragraph, a drug or bio-  
10 logical described in the previous sentence in-  
11 cludes items, services, supplies, and products  
12 that are payable under this part as a drug or  
13 biological.

14 “(B) AUDIT.—Information reported under  
15 subparagraph (A) is subject to audit by the In-  
16 spector General of the Department of Health  
17 and Human Services.

18 “(C) VERIFICATION.—The Secretary may  
19 survey wholesalers and manufacturers that di-  
20 rectly distribute drugs described in subpara-  
21 graph (A), when necessary, to verify manufac-  
22 turer prices and manufacturer’s average sales  
23 prices (including wholesale acquisition cost) if  
24 required to make payment reported under sub-  
25 paragraph (A). The Secretary may impose a

1 civil monetary penalty in an amount not to ex-  
2 ceed \$100,000 on a wholesaler, manufacturer,  
3 or direct seller, if the wholesaler, manufacturer,  
4 or direct seller of such a drug refuses a request  
5 for information about charges or prices by the  
6 Secretary in connection with a survey under  
7 this subparagraph or knowingly provides false  
8 information. The provisions of section 1128A  
9 (other than subsections (a) (with respect to  
10 amounts of penalties or additional assessments)  
11 and (b)) shall apply to a civil money penalty  
12 under this subparagraph in the same manner as  
13 such provisions apply to a penalty or proceeding  
14 under section 1128A(a).

15 “(D) CONFIDENTIALITY.—Notwith-  
16 standing any other provision of law, information  
17 disclosed by manufacturers or wholesalers  
18 under this paragraph (other than the wholesale  
19 acquisition cost for purposes of carrying out  
20 this section) is confidential and shall not be dis-  
21 closed by the Secretary in a form which dis-  
22 closes the identity of a specific manufacturer or  
23 wholesaler or prices charged for drugs by such  
24 manufacturer or wholesaler, except—

1           “(i) as the Secretary determines to be  
2           necessary to carry out this section (includ-  
3           ing the determination and implementation  
4           of the payment amount), or to carry out  
5           section 1847B;

6           “(ii) to permit the Comptroller Gen-  
7           eral of the United States to review the in-  
8           formation provided; and

9           “(iii) to permit the Director of the  
10          Congressional Budget Office to review the  
11          information provided.”.

12          (b) ENFORCEMENT.—Section 1847A of such Act (42  
13 U.S.C. 1395w–3a) is further amended—

14           (1) in subsection (d)(4)—

15           (A) in subparagraph (A), by striking “IN  
16           GENERAL” and inserting “MISREPRESENTA-  
17           TION”;

18           (B) in subparagraph (B), by striking “sub-  
19           paragraph (B)” and inserting “subparagraph  
20           (A), (B), or (C)”;

21           (C) by redesignating subparagraph (B) as  
22           subparagraph (D); and

23           (D) by inserting after subparagraph (A)  
24          the following new subparagraphs:

1           “(B) FAILURE TO PROVIDE TIMELY INFOR-  
2           MATION.—If the Secretary determines that a  
3           manufacturer described in subsection (f)(2) has  
4           failed to report on information described in sec-  
5           tion 1927(b)(3)(A)(iii) with respect to a drug or  
6           biological in accordance with such subsection,  
7           the Secretary shall apply a civil money penalty  
8           in an amount of \$10,000 for each day the man-  
9           ufacturer has failed to report such information  
10          and such amount shall be paid to the Treasury.

11          “(C) FALSE INFORMATION.—Any manu-  
12          facturer required to submit information under  
13          subsection (f)(2) that knowingly provides false  
14          information is subject to a civil money penalty  
15          in an amount not to exceed \$100,000 for each  
16          item of false information. Such civil money pen-  
17          alties are in addition to other penalties as may  
18          be prescribed by law.”; and

19          (2) in subsection (c)(6)(A), by striking the pe-  
20          riod at the end and inserting “, except that, for pur-  
21          poses of subsection (f)(2), the Secretary may, if the  
22          Secretary determines appropriate, exclude repack-  
23          agers of a drug or biological from such term.”.

24          (c) MANUFACTURERS WITH A REBATE AGREE-  
25          MENT.—

1           (1) IN GENERAL.—Section 1927(b)(3)(A) of the  
2           Social Security Act (42 U.S.C. 1396r–8(b)(3)(A)) is  
3           amended by adding at the end the following new  
4           sentence: “For purposes of applying clause (iii), a  
5           drug or biological described in the flush matter fol-  
6           lowing such clause includes items, services, supplies,  
7           and products that are payable under this part as a  
8           drug or biological.”.

9           (2)       TECHNICAL        AMENDMENT.—Section  
10          1927(b)(3)(A)(iii) of the Social Security Act (42  
11          U.S.C. 1396r–8(b)(3)(A)(iii)) is amended by striking  
12          “section 1881(b)(13)(A)(ii)” and inserting “section  
13          1881(b)(14)(B)”.

14          (d) REPORT.—Not later than January 1, 2021, the  
15          Inspector General of the Department of Health and  
16          Human Services shall assess and submit to Congress a  
17          report on the accuracy of average sales price information  
18          submitted by manufacturers under section 1847A of the  
19          Social Security Act (42 U.S.C. 1395w–3a). Such report  
20          shall include any recommendations on how to improve the  
21          accuracy of such information.

1 **SEC. 204. MAKING PRESCRIPTION DRUG MARKETING SAM-**  
2 **PLE INFORMATION REPORTED BY MANUFAC-**  
3 **TURERS AVAILABLE TO CERTAIN INDIVID-**  
4 **UALS 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 2021), 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. 205. PROVIDING THE MEDICARE PAYMENT ADVISORY**  
12                           **COMMISSION AND MEDICAID AND CHIP PAY-**  
13                           **MENT AND ACCESS COMMISSION WITH AC-**  
14                           **CESS TO CERTAIN DRUG PAYMENT INFORMA-**  
15                           **TION, INCLUDING CERTAIN REBATE INFOR-**  
16                           **MATION.**

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

20                 (1) in paragraph (2)—

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

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

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

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

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

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

24 “(A) The specific amounts or the identity  
25 of the source of any rebates, price concessions,

1 or other forms of direct or indirect remunera-  
2 tion under such prescription drug plan or such  
3 MA–PD plan.

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

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

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

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

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

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

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

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

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

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

20 **SEC. 206. SENSE OF THE SENATE REGARDING THE NEED TO**  
 21                   **EXPAND COMMERCIALLY AVAILABLE DRUG**  
 22                   **PRICING COMPARISON PLATFORMS.**

23          It is the sense of the Senate that—

24           (1) commercially available drug pricing com-  
 25          parison platforms can, at no cost, help patients find

1 the lowest price for their medications at their local  
2 pharmacy;

3 (2) such platforms should be integrated, to the  
4 maximum extent possible, in the health care delivery  
5 ecosystem; and

6 (3) pharmacy benefit managers should work to  
7 disclose generic and brand name drug prices to such  
8 platforms to ensure that—

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

11 (B) overall drug prices can be reduced as  
12 more educated purchasing decisions are made  
13 based on price transparency.

## 14 **TITLE III—REVENUE** 15 **PROVISIONS**

### 16 **SEC. 301. PERMANENT EXTENSION OF REDUCTION IN MED-** 17 **ICAL EXPENSE DEDUCTION FLOOR.**

18 (a) IN GENERAL.—Section 213(a) of the Internal  
19 Revenue Code of 1986 is amended by striking “10 per-  
20 cent” and inserting “7.5 percent”.

21 (b) CONFORMING AMENDMENTS.—

22 (1) Section 213 of such Code is amended by  
23 striking subsection (f).

24 (2) Section 56(b)(1) of such Code is amended  
25 by striking subparagraph (B) and by redesignating



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

3           “(D) MENSTRUAL CARE PRODUCT.—For  
4 purposes of this paragraph, the term ‘menstrual  
5 care product’ means a tampon, pad, liner, cup,  
6 sponge, or similar product used by individuals  
7 with respect to menstruation or other genital-  
8 tract secretions.”.

9           (b) ARCHER MSAS.—Section 220(d)(2)(A) of such  
10 Code is amended by striking the last sentence and insert-  
11 ing the following: “For purposes of this subparagraph,  
12 amounts paid for menstrual care products (as defined in  
13 section 223(d)(2)(D)) shall be treated as paid for medical  
14 care.”.

15           (c) HEALTH FLEXIBLE SPENDING ARRANGEMENTS  
16 AND HEALTH REIMBURSEMENT ARRANGEMENTS.—Sec-  
17 tion 106 of such Code is amended by striking subsection  
18 (f) and inserting the following new subsection:

19           “(f) REIMBURSEMENTS FOR MENSTRUAL CARE  
20 PRODUCTS.—For purposes of this section and section  
21 105, expenses incurred for menstrual care products (as  
22 defined in section 223(d)(2)(D)) shall be treated as in-  
23 curred for medical care.”.

24           (d) EFFECTIVE DATES.—

1           (1) DISTRIBUTIONS FROM SAVINGS AC-  
2           COUNTS.—The amendment made by subsections (a)  
3           and (b) shall apply to amounts paid after December  
4           31, 2019.

5           (2) REIMBURSEMENTS.—The amendment made  
6           by subsection (c) shall apply to expenses incurred  
7           after December 31, 2019.

## 8           **TITLE IV—MISCELLANEOUS**

### 9           **SEC. 401. IMPROVING COORDINATION BETWEEN THE FOOD** 10                                   **AND DRUG ADMINISTRATION AND THE CEN-** 11                                   **TERS FOR MEDICARE & MEDICAID SERVICES.**

12           (a) IN GENERAL.—

13                           (1) PUBLIC MEETING.—

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

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

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

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

14 (iii) representatives of commercial  
15 health insurance payers;

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

19 (v) stakeholders representing patients  
20 and with expertise in the utilization of pa-  
21 tient experience data in medical product  
22 development.

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

- 1 (i) the status of the drug and medical  
2 device development pipeline related to the  
3 availability of novel medical products;
- 4 (ii) the anticipated expertise necessary  
5 to review the safety and effectiveness of  
6 such products at the Food and Drug Ad-  
7 ministration and current gaps in such ex-  
8 pertise, if any;
- 9 (iii) the expertise necessary to make  
10 coding, coverage, and payment decisions  
11 with respect to such products within the  
12 Centers for Medicare & Medicaid Services,  
13 and current gaps in such expertise, if any;
- 14 (iv) trends in the differences in the  
15 data necessary to determine the safety and  
16 effectiveness of a novel medical product  
17 and the data necessary to determine  
18 whether a novel medical product meets the  
19 reasonable and necessary requirements for  
20 coverage and payment under title XVIII of  
21 the Social Security Act pursuant to section  
22 1862(a)(1)(A) of such Act (42 U.S.C.  
23 1395y(a)(1)(A));

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

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

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

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

19 (A) DRAFT GUIDANCE.—Not later than 18  
20 months after the public meeting under para-  
21 graph (1), the Secretary shall update the final  
22 guidance titled “National Coverage Determina-  
23 tions with Data Collection as a Condition of  
24 Coverage: Coverage with Evidence Develop-  
25 ment” to address any opportunities to improve

1 the availability and coordination of information  
2 as described in clauses (iv) through (vi) of para-  
3 graph (1)(C).

4 (B) FINAL GUIDANCE.—Not later than 12  
5 months after issuing draft guidance under sub-  
6 paragraph (A), the Secretary shall finalize the  
7 updated guidance to address any such opportu-  
8 nities.

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

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

23 (2) Recommendations to—

24 (A) incorporate patient experience data  
25 (such as the impact of a disease or condition on

1 the lives of patients and patient treatment pref-  
2 erences) into the coverage and payment proc-  
3 esses within the Centers for Medicare & Med-  
4 icaid Services;

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

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

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

21 (c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For  
22 purposes of this section, a novel medical product described  
23 in this subsection is a medical product, including a drug,  
24 biological (including gene and cell therapy), or medical de-  
25 vice, that has been designated as a breakthrough therapy

1 under section 506(a) of the Federal Food, Drug, and Cos-  
 2 metic Act (21 U.S.C. 356(a)), a breakthrough device  
 3 under section 515B of such Act (21 U.S.C. 360e-3), or  
 4 a regenerative advanced therapy under section 506(g) of  
 5 such Act (21 U.S.C. 356(g)).

6 **SEC. 402. PATIENT CONSULTATION IN MEDICARE NA-**  
 7 **TIONAL AND LOCAL COVERAGE DETERMINA-**  
 8 **TIONS IN ORDER TO MITIGATE BARRIERS TO**  
 9 **INCLUSION OF SUCH PERSPECTIVES.**

10 Section 1862(l) of the Social Security Act (42 U.S.C.  
 11 1395y(l)) is amended by adding at the end the following  
 12 new paragraph:

13 “(7) PATIENT CONSULTATION IN NATIONAL  
 14 AND LOCAL COVERAGE DETERMINATIONS.—The Sec-  
 15 retary may consult with patients and organizations  
 16 representing patients in making national and local  
 17 coverage determinations.”.

18 **SEC. 403. MEDPAC REPORT ON SHIFTING COVERAGE OF**  
 19 **CERTAIN MEDICARE PART B DRUGS TO MEDI-**  
 20 **CARE PART D.**

21 (a) STUDY.—The Medicare Payment Advisory Com-  
 22 mission (in this section referred to as the “Commission”)  
 23 shall conduct a study on shifting coverage of certain drugs  
 24 and biologicals for which payment is currently made under  
 25 part B of title XVIII of the Social Security Act (42 U.S.C.

1 1395j et seq.) to part D of such title (42 U.S.C. 1395w–  
2 21 et seq.). Such study shall include an analysis of—

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

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

13 (b) REPORT.—

14 (1) IN GENERAL.—Not later than June 30,  
15 2021, the Commission shall submit to Congress a re-  
16 port containing the results of the study conducted  
17 under subsection (a).

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

21 (A) formulary design under such part D;

22 (B) the ability of the benefit structure  
23 under such part D to control total spending on  
24 drugs and biologicals for which payment is cur-  
25 rently made under such part B;

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

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

10 (E) the feasibility and policy implications  
11 of creating a methodology to preserve the  
12 healthcare provider's ability to take title of the  
13 drug, including a methodology under which—

14 (i) prescription drug plans negotiate  
15 reimbursement rates and other arrange-  
16 ments with drug manufacturers on behalf  
17 of a wholesaler;

18 (ii) wholesalers purchase the drugs  
19 from the manufacturers at the negotiated  
20 rate and ship them through distributors to  
21 physicians to administer to patients;

22 (iii) physicians and hospitals purchase  
23 the drug from the wholesaler via the dis-  
24 tributor;

1 (iv) after administering the drug, the  
 2 physician submits a claim to the MAC for  
 3 their drug administration fee;

4 (v) to be reimbursed for the purchase  
 5 of the drug from the distributor, the physi-  
 6 cian furnishes the claim for the drug itself  
 7 to the wholesaler and the wholesaler would  
 8 refund the cost of the drug to the physi-  
 9 cian; and

10 (vi) the wholesaler passes this claim to  
 11 the PDP to receive reimbursement.

12 **SEC. 404. REQUIREMENT THAT DIRECT-TO-CONSUMER AD-**  
 13 **VERTISEMENTS FOR PRESCRIPTION DRUGS**  
 14 **AND BIOLOGICAL PRODUCTS INCLUDE**  
 15 **TRUTHFUL AND NON-MISLEADING PRICING**  
 16 **INFORMATION.**

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

19 **“SEC. 1150C. REQUIREMENT THAT DIRECT-TO-CONSUMER**  
 20 **ADVERTISEMENTS FOR PRESCRIPTION**  
 21 **DRUGS AND BIOLOGICAL PRODUCTS IN-**  
 22 **CLUDE TRUTHFUL AND NON-MISLEADING**  
 23 **PRICING INFORMATION.**

24 “(a) IN GENERAL.—The Secretary shall require that  
 25 each direct-to-consumer advertisement for a prescription

1 drug or biological product for which payment is available  
 2 under title XVIII or XIX includes an appropriate disclo-  
 3 sure of truthful and non-misleading pricing information  
 4 with respect to the drug or product.

5 “(b) DETERMINATION BY CMS.—The Secretary, act-  
 6 ing through the Administrator of the Centers for Medicare  
 7 & Medicaid Services, shall determine the components of  
 8 the requirement under subsection (a), such as the forms  
 9 of advertising, the manner of disclosure, the price point  
 10 listing, and the price information for disclosure.”.

11 **SEC. 405. CHIEF PHARMACEUTICAL NEGOTIATOR AT THE**  
 12 **OFFICE OF THE UNITED STATES TRADE REP-**  
 13 **RESENTATIVE.**

14 (a) IN GENERAL.—Section 141 of the Trade Act of  
 15 1974 (19 U.S.C. 2171) is amended—

16 (1) in subsection (b)(2)—

17 (A) by striking “and one Chief Innovation  
 18 and Intellectual Property Negotiator” and in-  
 19 serting “one Chief Innovation and Intellectual  
 20 Property Negotiator, and one Chief Pharma-  
 21 ceutical Negotiator”;

22 (B) by striking “or the Chief Innovation  
 23 and Intellectual Property Negotiator” and in-  
 24 serting “the Chief Innovation and Intellectual

1 Property Negotiator, or the Chief Pharma-  
2 ceutical Negotiator”; and

3 (C) by striking “and the Chief Innovation  
4 and Intellectual Property Negotiator” and in-  
5 serting “the Chief Innovation and Intellectual  
6 Property Negotiator, and the Chief Pharma-  
7 ceutical Negotiator”; and

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

10 “(7) The principal function of the Chief Phar-  
11 maceutical Negotiator shall be to conduct trade ne-  
12 gotiations and to enforce trade agreements relating  
13 to United States pharmaceutical products and serv-  
14 ices. The Chief Pharmaceutical Negotiator shall be  
15 a vigorous advocate on behalf of United States phar-  
16 maceutical interests. The Chief Pharmaceutical Ne-  
17 gotiator shall perform such other functions as the  
18 United States Trade Representative may direct.”.

19 (b) COMPENSATION.—Section 5314 of title 5, United  
20 States Code, is amended by striking “Chief Innovation  
21 and Intellectual Property Negotiator, Office of the United  
22 States Trade Representative.” and inserting the following:

23 “Chief Innovation and Intellectual Property Ne-  
24 gotiator, Office of the United States Trade Rep-  
25 resentative.

1           “Chief Pharmaceutical Negotiator, Office of the  
2           United States Trade Representative.”.

3           (c) REPORT REQUIRED.—Not later than the date  
4 that is one year after the appointment of the first Chief  
5 Pharmaceutical Negotiator pursuant to paragraph (2) of  
6 section 141(b) of the Trade Act of 1974, as amended by  
7 subsection (a), and annually thereafter, the United States  
8 Trade Representative shall submit to the Committee on  
9 Finance of the Senate and the Committee on Ways and  
10 Means of the House of Representatives a report describing  
11 in detail—

12           (1) enforcement actions taken by the United  
13 States Trade Representative during the 1-year pe-  
14 riod preceding the submission of the report to en-  
15 sure the protection of United States pharmaceutical  
16 products and services; and

17           (2) other actions taken by the United States  
18 Trade Representative to advance United States  
19 pharmaceutical products and services.

○