

**AMENDMENT**

**OFFERED BY M**     .

Strike titles I through V and insert the following  
(and update the table of contents accordingly):

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-  
18                                   fice” and “surgical center”; and

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

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

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

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

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

16 “(2) PHYSICIAN PAYMENT.—Beginning in  
17 2021, the Secretary may expand the information in-  
18 cluded on the Internet website described in para-  
19 graph (1) to include—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 “(3) REFUND AMOUNT.—

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

21 “(i) the product of—

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

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

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

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

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

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

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

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

1                   “(II) if applicable, in the case of  
2                   a refundable single-dose container or  
3                   single-use package drug described in  
4                   clause (ii), a percentage specified by  
5                   the Secretary pursuant to such clause.

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

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

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

25                  “(6) ENFORCEMENT.—

1 “(A) AUDITS.—

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

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

17 “(B) CIVIL MONEY PENALTY.—

18 “(i) IN GENERAL.—The Secretary  
19 shall impose a civil money penalty on a  
20 manufacturer of a refundable single-dose  
21 container or single-use package drug who  
22 has failed to comply with the requirement  
23 under paragraph (2) for such drug for a  
24 calendar quarter in an amount equal to the  
25 sum of—

1                   “(I) the amount that the manu-  
2                   facturer would have paid under such  
3                   paragraph with respect to such drug  
4                   for such quarter; and

5                   “(II) 25 percent of such amount.

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

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

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

18                  “(A) IN GENERAL.—Except as provided in  
19                  subparagraph (B), in this subsection, the term  
20                  ‘refundable single-dose container or single-use  
21                  package drug’ means a single source drug or bi-  
22                  ological (as defined in section 1847A(c)(6)(D))  
23                  or a biosimilar biological product (as defined in  
24                  section 1847A(c)(6)(H)) for which payment is  
25                  established under this part and that is fur-

1 nished from a single-dose container or single-  
2 use package.

3 “(B) EXCLUSIONS.—The term ‘refundable  
4 single-dose container or single-use package  
5 drug’ does not include—

6 “(i) a drug or biological that is either  
7 a radiopharmaceutical or an imaging  
8 agent;

9 “(ii) a drug or biological for which  
10 dosage and administration instructions ap-  
11 proved by the Commissioner of Food and  
12 Drugs require filtration during the drug  
13 preparation process, prior to dilution and  
14 administration, and require that any un-  
15 used portion of such drug after the filtra-  
16 tion process be discarded after the comple-  
17 tion of such filtration process; or

18 “(iii) a drug or biological approved by  
19 the Food and Drug Administration on or  
20 after the date of enactment of this sub-  
21 section and with respect to which payment  
22 has been made under this part for less  
23 than 18 months.”.

1 **SEC. 103. PROVIDING FOR VARIATION IN PAYMENT FOR**  
2 **CERTAIN DRUGS COVERED UNDER PART B**  
3 **OF THE MEDICARE PROGRAM.**

4 (a) COMPUTING PAYMENT RATES BY APPLYING  
5 VARIABLE PERCENTAGES OF AVERAGE SALES PRICE  
6 (ASP) BASED ON RELATIVE DRUG COST.—

7 (1) IN GENERAL.—Section 1847A(b) of the So-  
8 cial Security Act (42 U.S.C. 1395w-3a(b)) is  
9 amended—

10 (A) in paragraph (1)—

11 (i) in subparagraph (A), by inserting  
12 after “or 106 percent” the following: “(or,  
13 for a multiple source drug furnished on or  
14 after January 1, 2021, the applicable per-  
15 cent specified in paragraph (9)(A) for the  
16 drug and quarter involved)”; and

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

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

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

4                   “(A) APPLICABLE PERCENT TO BE AP-  
5           PLIED.—

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

15                                   “(I) at least equal to the 85th  
16                                   percentile, the applicable percent for  
17                                   the drug for such quarter under this  
18                                   subparagraph is 102 percent;

19                                   “(II) at least equal to the 70th  
20                                   percentile, but less than the 85th per-  
21                                   centile, such applicable percent is 104  
22                                   percent;

23                                   “(III) at least equal to the 50th  
24                                   percentile, but less than the 70th per-

1 centile, such applicable percent is 106  
2 percent; or

3 “(IV) less than the 50th per-  
4 centile, such applicable percent is 108  
5 percent.

6 “(ii) CASES WHERE DATA NOT SUFFI-  
7 CIENTLY AVAILABLE TO COMPUTE PER  
8 BENEFICIARY ALLOWED CHARGES.—In the  
9 case of a drug or biological furnished for  
10 which the amount of payment is deter-  
11 mined under subparagraph (A) or (B) of  
12 paragraph (1) and not under subsection  
13 (c)(4), for calendar quarters during a pe-  
14 riod in which data are not sufficiently  
15 available to compute a per beneficiary al-  
16 lowed charges for the drug or biological,  
17 the applicable percent is 106 percent.

18 “(B) DETERMINATION OF PERCENTILE  
19 RANK OF PER BENEFICIARY ALLOWED CHARGES  
20 OF DRUGS.—

21 “(i) IN GENERAL.—With respect to a  
22 calendar quarter beginning on or after  
23 January 1, 2021, for drugs and biologicals  
24 for which the amount of payment is deter-  
25 mined under subparagraph (A) or (B) of

1 paragraph (1), except for drugs or  
2 biologicals for which data are not suffi-  
3 ciently available, the Secretary shall—

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

8 “(II) adjust such per beneficiary  
9 allowed charges for the quarter, to the  
10 extent provided under subparagraph  
11 (D); and

12 “(III) array such adjusted per  
13 beneficiary allowed charges for all  
14 such drugs or biologicals from high to  
15 low and rank such drugs or biologicals  
16 by percentile of such arrayed per ben-  
17 eficiary allowed charges.

18 “(ii) FREQUENCY.—The Secretary  
19 shall make the computations under clause  
20 (i)(I) every 6 months (or, if necessary, as  
21 determined by the Secretary, every 9 or 12  
22 months) and such computations shall apply  
23 to succeeding calendar quarters until a  
24 new computation has been made.

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

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

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

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

23                  “(D) ADJUSTMENT TO REFLECT CHANGES  
24                  IN AVERAGE SALES PRICE.—In applying this  
25                  paragraph for a particular calendar quarter, the

1 Secretary shall adjust the per beneficiary al-  
2 lowed charges for a drug or biological by multi-  
3 plying such per beneficiary allowed charges  
4 under subparagraph (C) for the applicable data  
5 period by the ratio of—

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

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

15 (2) APPLICATION OF JUDICIAL REVIEW PROVI-  
16 SIONS.—Section 1847A(g) of the Social Security Act  
17 (42 U.S.C. 1395w–3a(g)) is amended—

18 (A) by striking “and” at the end of para-  
19 graph (4);

20 (B) by striking the period at the end of  
21 paragraph (5) and inserting “; and”; and

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

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

4           (b) REQUIRING REGULATIONS ON ALLOCATION OF  
5 BUNDLED DISCOUNTS AMONG DRUG PRODUCTS.—

6           (1) IN GENERAL.—The Secretary of Health and  
7           Human Services shall promulgate final regulations,  
8           to be effective no later than July 1, 2021, that re-  
9           quire manufacturers, in implementing section 1847A  
10          of the Social Security Act (42 U.S.C. 1395w–3a)  
11          and in order that the average sales price for each  
12          drug accurately reflects the average transaction  
13          price for that drug, to allocate the total value of all  
14          bundled discounts proportionately according to the  
15          dollar value of the units of each drug sold under a  
16          bundled arrangement.

17          (2) ALTERNATIVE APPROACHES.—After pro-  
18          mulgating such regulations, the Secretary may revise  
19          such regulations to incorporate alternative ap-  
20          proaches, such as allocating discounts to reflect con-  
21          tingencies in the contracts between manufacturers  
22          and purchasers of drugs, in a way that more accu-  
23          rately represents the average transaction prices for  
24          drugs with bundled discounts.

1 **SEC. 104. 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 12 U.S.C. 1395l(t)(16)) is amended by adding at the end  
7 the 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 **Subtitle B—METRIC Act**

### 7 **SEC. 111. REPORTING ON EXPLANATION FOR DRUG PRICE** 8 **INCREASES.**

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

#### 12 **“PART W—DRUG PRICE REPORTING; DRUG** 13 **VALUE FUND**

#### 14 **“SEC. 3990O. REPORTING ON EXPLANATION FOR DRUG** 15 **PRICE INCREASES.**

16 “(a) DEFINITIONS.—In this section:

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

19 “(A) that holds the application for a drug  
20 approved under section 505 of the Federal  
21 Food, Drug, and Cosmetic Act or licensed  
22 under section 351 of this Act; or

23 “(B) who is responsible for setting the  
24 wholesale acquisition cost for the drug.

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

6           “(A) that has a wholesale acquisition cost  
7 of \$100 or more, adjusted for inflation occur-  
8 ring after the date of enactment of this section,  
9 for a month’s supply or a typical course of  
10 treatment that lasts less than a month, and  
11 is—

12           “(i) subject to section 503(b)(1) of  
13 the Federal Food, Drug, and Cosmetic  
14 Act;

15           “(ii) administered or otherwise dis-  
16 pensed to treat a disease or condition af-  
17 fecting more than 200,000 persons in the  
18 United States; and

19           “(iii) not a vaccine; and

20           “(B) for which, during the previous cal-  
21 endar year, at least 1 dollar of the total amount  
22 of sales were for individuals enrolled under the  
23 Medicare program under title XVIII of the So-  
24 cial Security Act (42 U.S.C. 1395 et seq.) or  
25 under a State Medicaid plan under title XIX of

1           such Act (42 U.S.C. 1396 et seq.) or under a  
2           waiver of such plan.

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

7           “(b) REPORT.—

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

13                 “(A) 10 percent or more within a single  
14                 calendar year beginning on or after January 1,  
15                 2019; or

16                 “(B) 25 percent or more within three con-  
17                 secutive calendar years for which the first such  
18                 calendar year begins on or after January 1,  
19                 2019.

20          “(2) REPORT DEADLINE.—Each report de-  
21          scribed in paragraph (1) shall be submitted to the  
22          Secretary—

23                 “(A) in the case of a report with respect  
24                 to an increase in the price of a qualifying drug  
25                 that occurs during the period beginning on Jan-

1            uary 1, 2019, and ending on the day that is 60  
2            days after the date of enactment of this section,  
3            not later than 90 days after such date of enact-  
4            ment; and

5                  “(B) in the case of a report with respect  
6            to an increase in the price of a qualifying drug  
7            that occurs after the period described in sub-  
8            paragraph (A), not later than 30 days prior to  
9            the planned effective date of such price increase  
10           for such qualifying drug.

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

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

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

23               “(B) an explanation for, and description  
24               of, each price increase for such drug that will  
25               occur during the calendar year period described

1 in subsection (b)(1)(A) or the three consecutive  
2 calendar year period described in subsection  
3 (b)(1)(B), as applicable;

4 “(C) if known and different from the man-  
5 ufacturer of the qualifying drug, the identity  
6 of—

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

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

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

18 “(ii) the sponsor of an application for  
19 the drug approved under such section 505  
20 of the Federal Food, Drug, and Cosmetic  
21 Act or licensed under section 351 of this  
22 Act;

23 “(D) a description of the history of the  
24 manufacturer’s price increases for the drug  
25 since the approval of the application for the

1 drug under section 505 of the Federal Food,  
2 Drug, and Cosmetic Act or the issuance of the  
3 license for the drug under section 351 of this  
4 Act, or since the manufacturer acquired such  
5 approved application or license, if applicable;

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

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

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

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

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

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

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

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

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

22          “(A) the total revenue and the net profit  
23          of the manufacturer for each of the 1-year pe-  
24          riod described in subsection (b)(1)(A) or the 3-

1 year period described in subsection (b)(1)(B),  
2 as applicable;

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

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

12 “(i) drug research and development;

13 or

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

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

20 “(d) INFORMATION PROVIDED.—The manufacturer  
21 of a qualifying drug that is required to submit a report  
22 under subsection (b), shall ensure that such report and  
23 any explanation for, and description of, each price increase  
24 described in subsection (c)(1)(B) shall be truthful, not  
25 misleading, and accurate.

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

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

13       “(g) PUBLIC POSTING.—

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

20           “(2) FORMAT.—In developing the format in  
21 which reports will be publicly posted under para-  
22 graph (1), the Secretary shall consult with stake-  
23 holders, including beneficiary groups, and shall seek  
24 feedback from consumer advocates and readability  
25 experts on the format and presentation of the con-

1 tent of such reports to ensure that such reports  
2 are—

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

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

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

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

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

20 “(1) summarizing the information reported pur-  
21 suant to section 39900;

22 “(2) including copies of the reports and sup-  
23 porting detailed economic analyses submitted pursu-  
24 ant to such section;

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

4           “(4) explaining how the Department of Health  
5           and Human Services is improving consumer and  
6           provider information about drug value and drug  
7           price transparency.

8           “(b) PROTECTED INFORMATION.—Nothing in this  
9           section shall be construed to authorize the public dislo-  
10          sure of information submitted by a manufacturer that is  
11          prohibited from disclosure by applicable laws concerning  
12          the protection of trade secrets, commercial information,  
13          and other information covered under such laws.”.

14          (b) EFFECTIVE DATE.—The amendment made by  
15          subsection (a) takes effect on the date of enactment of  
16          this Act.

17       **SEC. 112. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.**

18          Section 1150A of the Social Security Act (42 U.S.C.  
19          1320b–23) is amended—

20               (1) in subsection (e), in the matter preceding  
21               paragraph (1), by inserting “(other than as per-  
22               mitted under subsection (e))” after “disclosed by the  
23               Secretary”; and

24               (2) by adding at the end the following new sub-  
25               section:

1           “(e) PUBLIC AVAILABILITY OF CERTAIN INFORMA-  
2 TION.—

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

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

23           “(A) CONFIDENTIALITY.—The information  
24 described in such paragraph is displayed in a  
25 manner that prevents the disclosure of informa-

1           tion, with respect to an individual drug or an  
2           individual plan, on rebates, discounts, direct  
3           and indirect remuneration fees, administrative  
4           fees, and price concessions.

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

14 **SEC. 113. STUDY OF PHARMACEUTICAL SUPPLY CHAIN**  
15 **INTERMEDIARIES AND MERGER ACTIVITY.**

16          (a) INITIAL REPORT.—Not later than 1 year after  
17          the date of enactment of this Act, the Commission shall  
18          submit to the appropriate committees of Congress a report  
19          that—

20               (1) addresses at minimum—

21                       (A) whether pharmacy benefit managers—

22                               (i) charge payers a higher price than  
23                               the reimbursement rate at which the phar-  
24                               macy benefit managers reimburse com-  
25                               peting pharmacies;

1                   (ii) steer patients for anticompetitive  
2                   purposes to any pharmacies, including re-  
3                   tail, mail-order, or any other type of phar-  
4                   macy, in which the pharmacy benefit man-  
5                   ager has an ownership interest;

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

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

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

23                  (C) whether there are any specific legal or  
24                  regulatory obstacles the Commission currently  
25                  faces in ensuring a competitive and transparent

1 marketplace in the pharmaceutical supply  
2 chain, including the pharmacy benefit manager  
3 marketplace and pharmacy services administra-  
4 tive organizations; and

5 (2) provides—

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

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

18 (C) policy or legislative recommendations  
19 to—

20 (i) improve transparency and competi-  
21 tion in the pharmaceutical supply chain;

22 (ii) prevent and deter anticompetitive  
23 behavior in the pharmaceutical supply  
24 chain; and

1 (iii) best ensure that consumers ben-  
2 efit from any cost savings or efficiencies  
3 that may result from mergers and consoli-  
4 dations.

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

11 (c) DEFINITIONS.—In this section:

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

15 (A) the Committee on Energy and Com-  
16 merce of the House of Representatives;

17 (B) the Committee on the Judiciary of the  
18 Senate; and

19 (C) the Committee on the Judiciary of the  
20 House of Representatives.

21 (2) COMMISSION.—The term “Commission”  
22 means the Federal Trade Commission.

1 **SEC. 114. REQUIRING CERTAIN MANUFACTURERS TO RE-**  
2 **PORT DRUG PRICING INFORMATION WITH**  
3 **RESPECT TO DRUGS UNDER THE MEDICARE**  
4 **PROGRAM.**

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

7 (1) in subsection (b)—

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

11 (B) in paragraph (3), in the matter pre-  
12 ceding subparagraph (A), by inserting “or sub-  
13 section (f)(2), as applicable,” before “deter-  
14 mined by”; and

15 (C) in paragraph (6)(A), in the matter  
16 preceding clause (i), by inserting “or subsection  
17 (f)(2), as applicable,” before “determined by”;  
18 and

19 (2) in subsection (f)—

20 (A) by striking “For requirements” and  
21 inserting the following:

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

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

25 “(2) MANUFACTURERS WITHOUT A REBATE  
26 AGREEMENT UNDER TITLE XIX.—

1           “(A) IN GENERAL.—If the manufacturer  
2 of a drug or biological described in subpara-  
3 graph (C), (E), or (G) of section 1842(o)(1) or  
4 in section 1881(b)(14)(B) that is payable under  
5 this part has not entered into and does not  
6 have in effect a rebate agreement described in  
7 subsection (b) of section 1927, for calendar  
8 quarters beginning on or after January 1,  
9 2020, such manufacturer shall report to the  
10 Secretary the information described in sub-  
11 section (b)(3)(A)(iii) of such section 1927 with  
12 respect to such drug or biological in a time and  
13 manner specified by the Secretary. For pur-  
14 poses of applying this paragraph, a drug or bio-  
15 logical described in the previous sentence in-  
16 cludes items, services, supplies, and products  
17 that are payable under this part as a drug or  
18 biological.

19           “(B) AUDIT.—Information reported under  
20 subparagraph (A) is subject to audit by the In-  
21 spector General of the Department of Health  
22 and Human Services.

23           “(C) VERIFICATION.—The Secretary may  
24 survey wholesalers and manufacturers that di-  
25 rectly distribute drugs described in subpara-

1 graph (A), when necessary, to verify manufac-  
2 turer prices and manufacturer's average sales  
3 prices (including wholesale acquisition cost) if  
4 required to make payment reported under sub-  
5 paragraph (A). The Secretary may impose a  
6 civil monetary penalty in an amount not to ex-  
7 ceed \$100,000 on a wholesaler, manufacturer,  
8 or direct seller, if the wholesaler, manufacturer,  
9 or direct seller of such a drug refuses a request  
10 for information about charges or prices by the  
11 Secretary in connection with a survey under  
12 this subparagraph or knowingly provides false  
13 information. The provisions of section 1128A  
14 (other than subsections (a) (with respect to  
15 amounts of penalties or additional assessments)  
16 and (b)) shall apply to a civil money penalty  
17 under this subparagraph in the same manner as  
18 such provisions apply to a penalty or proceeding  
19 under section 1128A(a).

20 “(D) CONFIDENTIALITY.—Notwith-  
21 standing any other provision of law, information  
22 disclosed by manufacturers or wholesalers  
23 under this paragraph (other than the wholesale  
24 acquisition cost for purposes of carrying out  
25 this section) is confidential and shall not be dis-

1 closed by the Secretary in a form which dis-  
2 closes the identity of a specific manufacturer or  
3 wholesaler or prices charged for drugs by such  
4 manufacturer or wholesaler, except—

5 “(i) as the Secretary determines to be  
6 necessary to carry out this section (includ-  
7 ing the determination and implementation  
8 of the payment amount), or to carry out  
9 section 1847B;

10 “(ii) to permit the Comptroller Gen-  
11 eral of the United States to review the in-  
12 formation provided; and

13 “(iii) to permit the Director of the  
14 Congressional Budget Office to review the  
15 information provided.”.

16 (b) ENFORCEMENT.—Section 1847A of such Act (42  
17 U.S.C. 1395w-3a) is further amended—

18 (1) in subsection (d)(4)—

19 (A) in subparagraph (A), by striking “IN  
20 GENERAL” and inserting “MISREPRESENTA-  
21 TION”;

22 (B) in subparagraph (B), by striking “sub-  
23 paragraph (B)” and inserting “subparagraph  
24 (A), (B), or (C)”;

1 (C) by redesignating subparagraph (B) as  
2 subparagraph (D); and

3 (D) by inserting after subparagraph (A)  
4 the following new subparagraphs:

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

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

23 (2) in subsection (c)(6)(A), by striking the pe-  
24 riod at the end and inserting “, except that, for pur-  
25 poses of subsection (f)(2), the Secretary may, if the

1 Secretary determines appropriate, exclude repack-  
2 agers of a drug or biological from such term.”.

3 (c) MANUFACTURERS WITH A REBATE AGREE-  
4 MENT.—

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

13 (2) TECHNICAL AMENDMENT.—Section  
14 1927(b)(3)(A)(iii) of the Social Security Act (42  
15 U.S.C. 1396r–8(b)(3)(A)(iii)) is amended by striking  
16 “section 1881(b)(13)(A)(ii)” and inserting “section  
17 1881(b)(14)(B)”.

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

1 **SEC. 115. 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. 116. REQUIRING PRESCRIPTION DRUG PLAN SPON-**  
12 **SORS TO INCLUDE REAL-TIME BENEFIT IN-**  
13 **FORMATION AS PART OF SUCH SPONSOR’S**  
14 **ELECTRONIC PRESCRIPTION PROGRAM**  
15 **UNDER THE MEDICARE PROGRAM.**

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

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

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

23           “(F) REAL-TIME BENEFIT INFORMA-  
24           TION.—

1           “(i) IN GENERAL.—Not later than  
2           January 1, 2021, the program shall imple-  
3           ment real-time benefit tools that are capa-  
4           ble of integrating with a prescribing health  
5           care professional’s electronic prescribing or  
6           electronic health record system for the  
7           transmission of formulary and benefit in-  
8           formation in real time to prescribing health  
9           care professionals. With respect to a cov-  
10          ered part D drug, such tools shall be capa-  
11          ble of transmitting such information spe-  
12          cific to an individual enrolled in a prescrip-  
13          tion drug plan. Such information shall in-  
14          clude the following:

15                   “(I) A list of any clinically-appro-  
16                   priate alternatives to such drug in-  
17                   cluded in the formulary of such plan.

18                   “(II) Cost-sharing information  
19                   for such drug and such alternatives,  
20                   including a description of any vari-  
21                   ance in cost-sharing based on the  
22                   pharmacy dispensing such drug or  
23                   such alternatives.

24                   “(III) Information relating to  
25                   whether such drug is included in the

1           formulary of such plan and any prior  
2           authorization or other utilization man-  
3           agement requirements applicable to  
4           such drug and such alternatives so in-  
5           cluded.

6           “(ii) ELECTRONIC TRANSMISSION.—  
7           The provisions of subclauses (I) and (II) of  
8           clause (ii) of subparagraph (E) shall apply  
9           to an electronic transmission described in  
10          clause (i) in the same manner as such pro-  
11          visions apply with respect to an electronic  
12          transmission described in clause (i) of such  
13          subparagraph.

14          “(iii) SPECIAL RULE FOR 2021.—The  
15          program shall be deemed to be in compli-  
16          ance with clause (i) for 2021 if the pro-  
17          gram complies with the provisions of sec-  
18          tion 423.160(b)(7) of title 42, Code of  
19          Federal Regulations (or a successor regula-  
20          tion), for such year.

21          “(iv) RULE OF CONSTRUCTION.—  
22          Nothing in this subparagraph shall be con-  
23          strued as to allow a real-time benefits tool  
24          to steer an individual, without the consent  
25          of the individual, to a particular pharmacy

1 or pharmacy setting over their preferred  
2 pharmacy setting nor prohibit the designa-  
3 tion of a preferred pharmacy under such  
4 tool.”.

5 **SEC. 117. SENSE OF CONGRESS REGARDING THE NEED TO**  
6 **EXPAND COMMERCIALY AVAILABLE DRUG**  
7 **PRICING COMPARISON PLATFORMS.**

8 It is the sense of Congress that—

9 (1) commercially available drug pricing com-  
10 parison platforms can, at no cost, help patients find  
11 the lowest price for their medications at their local  
12 pharmacy;

13 (2) such platforms should be integrated, to the  
14 maximum extent possible, in the health care delivery  
15 ecosystem; and

16 (3) pharmacy benefit managers should work to  
17 disclose generic and brand name drug prices to such  
18 platforms to ensure that—

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

21 (B) overall drug prices can be reduced as  
22 more educated purchasing decisions are made  
23 based on price transparency.

1 **SEC. 118. TECHNICAL CORRECTIONS.**

2 (a) IN GENERAL.—Section 3022(b) of the Public  
3 Health Service Act (42 U.S.C. 300jj–52(b)) is amended  
4 by adding at the end the following new paragraph:

5 “(4) APPLICATION OF AUTHORITIES UNDER IN-  
6 SPECTOR GENERAL ACT OF 1978.—In carrying out  
7 this subsection, the Inspector General shall have the  
8 same authorities as provided under section 6 of the  
9 Inspector General Act of 1978 (5 U.S.C. App.).”.

10 (b) EFFECTIVE DATE.—The amendment made by  
11 subsection (a) shall take effect as if included in the enact-  
12 ment of the 21st Century Cures Act (Public Law 114–  
13 255).

14 **Subtitle C—Medicare Part D**  
15 **Benefit Redesign**

16 **SEC. 121. MEDICARE PART D BENEFIT REDESIGN.**

17 (a) BENEFIT STRUCTURE REDESIGN.—Section  
18 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–  
19 102(b)) is amended—

20 (1) in paragraph (2)—

21 (A) in subparagraph (A)—

22 (i) in the matter preceding clause (i),  
23 by inserting “for a year preceding 2022  
24 and for costs above the annual deductible  
25 specified in paragraph (1) and up to the  
26 annual out-of-pocket threshold specified in

1 paragraph (4)(B) for 2022 and each subse-  
2 quent year” after “paragraph (3)”; and

3 (ii) in clause (i), by inserting after  
4 “25 percent” the following: “(or, for 2022  
5 and each subsequent year, 15 percent)”;  
6

(B) in subparagraph (C)—

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

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

(C) in subparagraph (D)—

14 (i) in clause (i)—

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

19 (II) in subclause (I)(bb), by  
20 striking “a year after 2018” and in-  
21 sserting “each of years 2018 through  
22 2021”; and

23 (ii) in clause (ii)(V), by striking  
24 “2019 and each subsequent year” and in-  
25

1                   serting “each of years 2019 through  
2                   2021”;

3                   (2) in paragraph (3)(A)—

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

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

10                  (3) in paragraph (4)—

11                  (A) in subparagraph (A)—

12                  (i) in clause (i)—

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

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

21                   “(I) for a year preceding 2022,  
22                   the greater of—”.

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

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

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

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

6 “(VII) for 2022, is equal to  
7 \$3,100; or

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

14 (ii) in clause (ii), by striking “clause  
15 (i)(II)” and inserting “clause (i)”;

16 (C) in subparagraph (C)(i), by striking  
17 “and for amounts” and inserting “and for a  
18 year preceding 2022 for amounts”; and

19 (D) in subparagraph (E), by striking “In  
20 applying” and inserting “For each of 2011  
21 through 2021, in applying”.

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

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

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

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

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

10                   “(B) for 2022 and each subsequent year,  
11                   the sum of—

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

23                           “(ii) an amount equal to 30 percent of  
24                           the allowable reinsurance costs (as speci-  
25                           fied in paragraph (2)) attributable to that

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

9 (c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

15 “(a) ESTABLISHMENT.—The Secretary shall estab-  
16 lish a manufacturer discount program (in this section re-  
17 ferred to as the ‘program’). Under the program, the Sec-  
18 retary shall enter into agreements described in subsection  
19 (b) with manufacturers and provide for the performance  
20 of the duties described in subsection (c). The Secretary  
21 shall establish a model agreement for use under the pro-  
22 gram by not later than January 1, 2021, in consultation  
23 with manufacturers, and allow for comment on such model  
24 agreement.

25 “(b) TERMS OF AGREEMENT.—

1           “(1) IN GENERAL.—

2                   “(A) AGREEMENT.—An agreement under  
3 this section shall require the manufacturer to  
4 provide applicable beneficiaries access to—

5                           “(i) discounted prices for applicable  
6 drugs of the manufacturer that are dis-  
7 pensed on or after January 1, 2022; and

8                           “(ii) discounted prices for generic  
9 drugs of the manufacturer that are dis-  
10 pensed on or after January 1, 2022.

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

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

24                   “(3) COMPLIANCE WITH REQUIREMENTS FOR  
25 ADMINISTRATION OF PROGRAM.—Each manufac-

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

8 “(4) LENGTH OF AGREEMENT.—

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

15 “(B) TERMINATION.—

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

1           such a termination, and such hearing shall  
2           take place prior to the effective date of the  
3           termination with sufficient time for such  
4           effective date to be repealed if the Sec-  
5           retary determines appropriate.

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

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

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

19           “(iii) EFFECTIVENESS OF TERMI-  
20           NATION.—Any termination under this sub-  
21           paragraph shall not affect discounts for  
22           applicable drugs of the manufacturer that  
23           are due under the agreement before the ef-  
24           fective date of its termination.

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

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

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

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

15                         “(A) the determination of the amount of  
16                         the discounted price of an applicable drug of a  
17                         manufacturer and of the discounted price of a  
18                         generic drug of a manufacturer;

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

1           “(C) the establishment of procedures to  
2           ensure that, not later than the applicable num-  
3           ber of calendar days after the dispensing of an  
4           applicable drug or a generic drug, as the case  
5           may be, by a pharmacy or mail order service,  
6           the pharmacy or mail order service is reim-  
7           bursed for an amount equal to the difference  
8           between—

9                   “(i) the negotiated price of the appli-  
10                  cable drug or generic drug, respectively;  
11                  and

12                   “(ii) the discounted price of the appli-  
13                  cable drug or generic drug, respectively;

14           “(D) the establishment of procedures to  
15           ensure that the discounted price for an applica-  
16           ble drug or a generic drug under this section is  
17           applied before any coverage or financial assist-  
18           ance under other health benefit plans or pro-  
19           grams that provide coverage or financial assist-  
20           ance for the purchase or provision of prescrip-  
21           tion drug coverage on behalf of applicable bene-  
22           ficiaries as the Secretary may specify; and

23           “(E) providing a reasonable dispute resolu-  
24           tion mechanism to resolve disagreements be-  
25           tween manufacturers, applicable beneficiaries,

1 and the third party with a contract under sub-  
2 section (d)(3).

3 “(2) MONITORING COMPLIANCE.—

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

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

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

20 “(d) ADMINISTRATION.—

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

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

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

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

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

21                 “(C) provide adequate and timely informa-  
22                 tion to manufacturers, consistent with the  
23                 agreement with the manufacturer under this  
24                 section, as necessary for the manufacturer to  
25                 fulfill its obligations under this section; and

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

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

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

16          “(e) ENFORCEMENT.—

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

20                 “(2) CIVIL MONEY PENALTY.—

21                         “(A) IN GENERAL.—The Secretary shall  
22                         impose a civil money penalty on a manufacturer  
23                         that fails to provide applicable beneficiaries dis-  
24                         counts for applicable drugs of the manufacturer  
25                         or generic drugs of the manufacturer in accord-

1           ance with such agreement for each such failure  
2           in an amount the Secretary determines is com-  
3           mensurate with the sum of—

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

10                   “(ii) 25 percent of such amount.

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

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

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

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

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

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

8                   “(C) has incurred costs for covered part D  
9                   drugs in the year that are equal to or exceed  
10                  the annual deductible specified in section  
11                  1860D–2(b)(1) for such year.

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

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

22                   “(B)(i) if the PDP sponsor of the prescrip-  
23                   tion drug plan or the MA organization offering  
24                   the MA–PD plan uses a formulary, which is on  
25                   the formulary of the prescription drug plan or

1 MA–PD plan that the applicable beneficiary is  
2 enrolled in;

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

9 “(iii) is provided through an exception or  
10 appeal.

11 “(3) APPLICABLE NUMBER OF CALENDAR  
12 DAYS.—The term ‘applicable number of calendar  
13 days’ means—

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

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

18 “(4) DISCOUNTED PRICE.—

19 “(A) IN GENERAL.—The term ‘discounted  
20 price’ means—

21 “(i) with respect to an applicable drug  
22 of a manufacturer furnished during a year  
23 to an applicable beneficiary—

24 “(I) who has not incurred costs  
25 for covered part D drugs in the year

1 that are equal to or exceed the annual  
2 out-of-pocket threshold specified in  
3 section 1860D–2(b)(4)(B)(i) for the  
4 year, 90 percent of the negotiated  
5 price of such drug; and

6 “(II) who has incurred such costs  
7 in the year that are equal to or exceed  
8 such threshold for the year, 90 per-  
9 cent of the negotiated price of such  
10 drug; and

11 “(ii) with respect to a generic drug of  
12 a manufacturer furnished during a year to  
13 an applicable beneficiary who has not in-  
14 curred costs for covered part D drugs in  
15 the year that are equal to or exceed the  
16 annual out-of-pocket threshold specified in  
17 section 1860D–2(b)(4)(B)(i) for the year,  
18 90 percent of the negotiated price of such  
19 drug.

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

1           “(C) SPECIAL CASE FOR CLAIMS SPANNING  
2           DEDUCTIBLE.—In the case where the entire  
3           amount of the negotiated price of an individual  
4           claim for an applicable drug or a generic drug  
5           with respect to an applicable beneficiary does  
6           not fall at or above the annual deductible speci-  
7           fied in section 1860D–2(b)(1) for the year, the  
8           manufacturer of the applicable drug shall pro-  
9           vide the discounted price under this section on  
10          only the portion of the negotiated price of the  
11          applicable drug or generic drug, respectively,  
12          that falls at or above such annual deductible.

13          “(5) GENERIC DRUG.—The term ‘generic drug’  
14          means, with respect to an applicable beneficiary, a  
15          covered part D drug that is not an applicable drug.

16          “(6) MANUFACTURER.—The term ‘manufac-  
17          turer’ means any entity which is engaged in the pro-  
18          duction, preparation, propagation, compounding,  
19          conversion, or processing of prescription drug prod-  
20          ucts, either directly or indirectly by extraction from  
21          substances of natural origin, or independently by  
22          means of chemical synthesis, or by a combination of  
23          extraction and chemical synthesis. Such term does  
24          not include a wholesale distributor of drugs or a re-  
25          tail pharmacy licensed under State law.

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

6           “(8) QUALIFIED RETIREE PRESCRIPTION DRUG  
7           PLAN.—The term ‘qualified retiree prescription drug  
8           plan’ has the meaning given such term in section  
9           11860D–22(a)(2).”.

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

14                   (A) in subsection (a), in the first sentence,  
15                   by striking “The Secretary” and inserting  
16                   “Subject to subsection (h), the Secretary”; and

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

19           “(h) SUNSET OF PROGRAM.—

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

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

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

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

12                           (i) by striking “assumptions regarding  
13                           the reinsurance” and inserting “assump-  
14                           tions regarding—

15                                   “(I) the reinsurance”; and

16                           (ii) by adding at the end the fol-  
17                           lowing:

18                                   “(II) for 2022 and each subse-  
19                           quent year, the manufacturer dis-  
20                           counts provided under section 1860D–  
21                           14B subtracted from the actuarial  
22                           value to produce such bid; and”; and

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

1 (i) by striking “an actuarial valuation  
2 of the reinsurance” and inserting “an ac-  
3 tuarial valuation of—

4 “(i) the reinsurance”;

5 (ii) in clause (i), as added by clause  
6 (i) of this subparagraph, by adding “and”  
7 at the end; and

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

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

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

16 (1) in paragraph (2)—

17 (A) by striking “COSTS.—For purposes”  
18 and inserting “COSTS.—

19 “(A) IN GENERAL.—Subject to subpara-  
20 graph (B), for purposes”.

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

23 “(B) INCLUSION OF MANUFACTURER DIS-  
24 COUNTS ON APPLICABLE DRUGS AND GENERIC  
25 DRUGS.—For purposes of applying subpara-

1 graph (A), the term ‘allowable reinsurance  
2 costs’ shall include the portion of the negotiated  
3 price (as defined in section 1860D–14B(g)(7))  
4 of an applicable drug (as defined in section  
5 1860D–14(g)(2)) that was paid by a manufac-  
6 turer under the manufacturer discount program  
7 under section 1860D–14B and the portion of  
8 the negotiated price (as so defined) of a generic  
9 drug (as defined in section 1860D–14(g)(5))  
10 that was paid by a manufacturer under such  
11 program.”; and

12 (2) in paragraph (3)—

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

16 (B) in the second sentence, by inserting  
17 “or, in the case of an applicable drug or a ge-  
18 neric drug, by a manufacturer” after “by the  
19 individual or under the plan”.

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

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

1           “(3) UPDATING RISK ADJUSTMENT METH-  
2           ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA-  
3           TION REDESIGN.—The Secretary shall update the  
4           risk adjustment model used to adjust bid amounts  
5           pursuant to this subsection as appropriate to take  
6           into account changes in benefits under this part pur-  
7           suant to the amendments made by section 121 of  
8           the Lower Drug Costs Now Act of 2019.”.

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

12                 (1) in subsection (a)—

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

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

17                         (C) by adding at the end the following new  
18                         paragraphs:

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

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

24                         “(6) have entered into and have in effect, under  
25                         terms and conditions specified by the Secretary, a

1 contract with a third party that the Secretary has  
2 entered into a contract with under subsection (d)(3)  
3 of such section 1860D–14B.”;

4 (2) by striking subsection (b) and inserting the  
5 following:

6 “(b) EFFECTIVE DATE.—Paragraphs (1) through (3)  
7 of subsection (a) shall apply to covered part D drugs dis-  
8 pensed under this part on or after January 1, 2011, and  
9 before January 1, 2022, and paragraphs (4) through (6)  
10 of such subsection shall apply to covered part D drugs  
11 dispensed on or after January 1, 2022.”; and

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

14 “(2) the Secretary determines that in the period  
15 beginning on January 1, 2011, and ending on De-  
16 cember 31, 2011 (with respect to paragraphs (1)  
17 through (3) of subsection (a)) or the period begin-  
18 ning on January 1, 2022, and ending December 31,  
19 2022 (with respect to paragraphs (4) through (6) of  
20 such subsection), there were extenuating cir-  
21 cumstances.”.

22 (g) CONFORMING AMENDMENTS.—

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

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

5 (B) in subsection (c)(1)(C)—

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

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

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

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

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

24 (A) in paragraph (1)—

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

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

7 (iii) in subparagraph (E), by striking  
8 “The elimination” and inserting “For a  
9 year preceding 2022, the elimination”; and  
10 (B) in paragraph (2)—

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

15 (ii) in subparagraph (E)—  
16 (I) by inserting “for a year pre-  
17 ceding 2022,” after “subsection (e)”;  
18 and

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

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

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

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

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

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

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

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

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

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

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

22      (h) EFFECTIVE DATE.—The amendments made by  
23      this section shall apply to plan year 2022 and subsequent  
24      plan years.

1 **Subtitle D—Other Medicare Part D**  
2 **Provisions**

3 **SEC. 131. TRANSITIONAL COVERAGE AND RETROACTIVE**  
4 **MEDICARE PART D COVERAGE FOR CERTAIN**  
5 **LOW-INCOME BENEFICIARIES.**

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

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

10 (2) by adding after subsection (d) the following  
11 new subsection:

12 “(e) LIMITED INCOME NEWLY ELIGIBLE TRANSI-  
13 TION PROGRAM.—

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

19 “(2) LI NET ELIGIBLE INDIVIDUAL DEFINED.—  
20 For purposes of this subsection, the term ‘LI NET  
21 eligible individual’ means a part D eligible individual  
22 who—

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

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

5           “(3) TRANSITIONAL COVERAGE.—For purposes  
6 of this subsection, the term ‘transitional coverage’  
7 means, with respect to an LI NET eligible indi-  
8 vidual—

9           “(A) immediate access to covered part D  
10 drugs at the point-of-sale during the period that  
11 begins on the first day of the month such indi-  
12 vidual is determined to meet the requirements  
13 of clauses (ii) and (iii) of subsection (a)(3)(A)  
14 and ends on the date that coverage under a pre-  
15 scription drug plan or MA–PD plan takes effect  
16 with respect to such individual; and

17           “(B) in the case of an LI NET eligible in-  
18 dividual who is a full-benefit dual eligible indi-  
19 vidual (as defined in section 1935(c)(6)) or a  
20 recipient of supplemental security income bene-  
21 fits under title XVI, retroactive coverage (in the  
22 form of reimbursement of the amounts that  
23 would have been paid under this part had such  
24 individual been enrolled in a prescription drug  
25 plan or MA–PD plan) of covered part D drugs

1 purchased by such individual during the period  
2 that begins on the date that is the later of—

3 “(i) the date that such individual was  
4 first eligible for a low-income subsidy  
5 under this part; or

6 “(ii) the date that is 36 months prior  
7 to the date such individual enrolls in a pre-  
8 scription drug plan or MA–PD plan, and  
9 ends on the date that coverage under such  
10 plan takes effect.

11 “(4) PROGRAM ADMINISTRATION.—

12 “(A) SINGLE POINT OF CONTACT.—The  
13 Secretary shall, to the extent feasible, admin-  
14 ister the program under this subsection through  
15 a contract with a single program administrator.

16 “(B) BENEFIT DESIGN.—The Secretary  
17 shall ensure that the transitional coverage pro-  
18 vided to LI NET eligible individuals under this  
19 subsection—

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

22 “(ii) permits all pharmacies deter-  
23 mined by the Secretary to be in good  
24 standing to process claims under the pro-  
25 gram;

1           “(iii) is consistent with such require-  
2           ments as the Secretary considers necessary  
3           to improve patient safety and ensure ap-  
4           propriate dispensing of medication; and

5           “(iv) meets such other requirements  
6           as the Secretary may establish.

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

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

12           “(i) Paragraphs (1) and (3)(B) of sec-  
13          tion 1860D–4(a) (relating to dissemination  
14          of general information; availability of infor-  
15          mation on changes in formulary through  
16          the internet).

17           “(ii) Subparagraphs (A) and (B) of  
18          section 1860D–4(b)(3) (relating to require-  
19          ments on development and application of  
20          formularies; formulary development).

21           “(iii) Paragraphs (1)(C) and (2) of  
22          section 1860D–4(c) (relating to medication  
23          therapy management program).

24           “(B) WAIVER AUTHORITY.—The Secretary  
25          may waive such other requirements of title XI

1           and this title as may be necessary to carry out  
2           the purposes of the program established under  
3           this subsection.”.

4 **SEC. 132. DRUG DISCOUNTS REQUIRED TO BE PASSED**  
5 **THROUGH TO THE PLAN SPONSOR.**

6           (a) IN GENERAL.—Section 1150A of the Social Secu-  
7 rity Act (42 U.S.C. 1320b–23), as amended by section  
8 112, is further amended—

9           (1) in the heading, by inserting “**;** **DRUG DIS-**  
10 **COUNTS REQUIRED TO BE PASSED THROUGH**  
11 **TO THE PLAN SPONSOR**” before the period at the  
12 end; and

13           (2) by adding at the end the following new sub-  
14 sections:

15           “(f) **DRUG DISCOUNTS REQUIRED TO BE PASSED**  
16 **THROUGH TO THE PLAN SPONSOR.**—

17           “(1) **REQUIREMENT.**—Beginning January 1,  
18 2022, a PBM that manages prescription drug cov-  
19 erage under a contract with a PDP sponsor or MA  
20 organization described in subsection (b)(1) or a  
21 qualified health benefits plan described in subsection  
22 (b)(2), shall, with respect to the plan sponsor of a  
23 health benefits plan, pass through to the plan spon-  
24 sor 100 percent of the aggregate amount of the re-  
25 bates, discounts, or price concessions (other than

1        bona fide service fees (as defined in subsection (g)))  
2        that the PBM negotiates that are attributable to pa-  
3        tient utilization under the plan (including any re-  
4        bates, discounts, or other price concessions (other  
5        than bona fide service fees (as so defined)) that are  
6        received by an agent or affiliate of the PBM acting  
7        on the PBM’s behalf). Such a PBM may retain bona  
8        fide service fees (as so defined), to the extent that  
9        such fees are not based on a percentage of the sales  
10       for a drug or otherwise linked in any way to the  
11       price or formulary position or placement of a drug.

12            “(2) ENFORCEMENT.—A PDP sponsor of a  
13       prescription drug plan or an MA organization offer-  
14       ing an MA–PD plan under part D of title XVIII  
15       may not contract with a PBM that is not in compli-  
16       ance with the requirement under paragraph (1).

17            “(g) BONA FIDE SERVICE FEES DEFINED.—The  
18       term ‘bona fide service fees’ means, with respect to a  
19       PBM, fees paid to such PBM (or an agent or affiliate of  
20       such PBM acting on the PBM’s behalf) by a manufac-  
21       turer, customer, or client of the PBM that represent the  
22       fair market value for a bona fide, itemized service actually  
23       performed on behalf of the manufacturer, customer, or cli-  
24       ent, that the manufacturer, customer, or client would oth-  
25       erwise perform (or contract for) in the absence of the serv-

1 ice arrangement, and that the PBM does not pass on to  
2 another party.”.

3 (b) EFFECTIVE DATE.—The amendments made by  
4 subsection (a) shall take effect on January 1, 2022.

5 **SEC. 133. PART D NEGOTIATED PRICES REQUIRED TO TAKE**  
6 **INTO ACCOUNT CERTAIN PRICE CONCES-**  
7 **SIONS AT THE POINT-OF-SALE.**

8 (a) IN GENERAL.—Section 1860D–2(d)(1)(B) of the  
9 Social Security Act (42 U.S.C. 1395w–102(d)(1)(B)) is  
10 amended—

11 (1) by striking “PRICES.—For purposes” and  
12 inserting “PRICES.—

13 “(i) IN GENERAL.—For purposes”;

14 and

15 (2) by adding at the end the following new  
16 clause:

17 “(ii) NEGOTIATED PRICES AT POINT-  
18 OF-SALE.—

19 “(I) IN GENERAL.—Negotiated  
20 prices for covered part D drugs de-  
21 scribed in clause (i) shall be provided  
22 at the point-of-sale of the covered part  
23 D drug. If the negotiated price is not  
24 possible to calculate at the point-of-  
25 sale, an approximate negotiated price

1 (as established by the Secretary) shall  
2 be used under the prescription drug  
3 plan or MA–PD plan.

4 “(II) INCLUSION OF CERTAIN  
5 PRICE CONCESSIONS.—Negotiated  
6 prices described in subclause (I) shall  
7 include the value of at least 80 per-  
8 cent of all rebates, discounts, or other  
9 price concessions received by a PDP  
10 sponsor offering a prescription drug  
11 plan or an MA organization offering  
12 an MA–PD plan from a drug manu-  
13 facturer, either directly or indirectly  
14 from a PBM to such PDP sponsor or  
15 MA organization.

16 “(III) APPROXIMATE NEGO-  
17 TIATED PRICE.—In determining an  
18 approximate negotiated price for a  
19 covered part D drug under subclause  
20 (I), the Secretary shall ensure that—

21 “(aa) such price reflects the  
22 estimated negotiated price that is  
23 based on the previous year’s ne-  
24 gotiated price concessions nego-  
25 tiated under the plan for all or

1 similar covered part D drugs or  
2 is based on such other factors as  
3 the Secretary may determine ap-  
4 propriate; and

5 “(bb) the use of such price  
6 does not prevent the use of value-  
7 based contracts between drug  
8 manufacturers, PDP sponsors,  
9 MA organizations, and phar-  
10 macies.”.

11 (b) EFFECTIVE DATE.—The amendments made by  
12 subsection (a) shall apply to plan years beginning on or  
13 after January 1, 2021.

14 **SEC. 134. ALLOWING CERTAIN ENROLLEES OF PRESCRIP-**  
15 **TION DRUGS PLANS AND MA-PD PLANS**  
16 **UNDER MEDICARE PROGRAM TO SPREAD**  
17 **OUT COST-SHARING UNDER CERTAIN CIR-**  
18 **CUMSTANCES.**

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

23 (1) in subparagraph (A), by striking “Subject  
24 to subparagraphs (C) and (D)” and inserting “Sub-  
25 ject to subparagraphs (C), (D), and (E)”; and

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

3                   “(E) ENROLLEE OPTION REGARDING  
4 SPREADING COST-SHARING.—

5                           “(i) IN GENERAL.—The Secretary  
6 shall establish by regulation a process  
7 under which, with respect to plan year  
8 2022 and subsequent plan years, a pre-  
9 scription drug plan or an MA–PD plan  
10 shall, in the case of a part D eligible indi-  
11 vidual enrolled with such plan for such  
12 plan year with respect to whom the plan  
13 projects that the dispensing of a covered  
14 part D drug to such individual will result  
15 in the individual incurring costs within a  
16 30-day period that are equal to a signifi-  
17 cant percentage (as specified by the Sec-  
18 retary pursuant to such regulation) of the  
19 annual out-of-pocket threshold specified in  
20 paragraph (4)(B) for such plan year, pro-  
21 vide such individual with the option to  
22 make the coinsurance payment required  
23 under subparagraph (A) for such costs in  
24 the form of equal monthly installments  
25 over the remainder of such plan year.

1                   “(ii) SIGNIFICANT PERCENTAGE LIM-  
2                   TATIONS.—In specifying a significant per-  
3                   centage pursuant to the regulation estab-  
4                   lished by the Secretary under clause (i),  
5                   the Secretary may not specify a percentage  
6                   that is less than 30 percent or greater  
7                   than 100 percent.”.

8           (b) ALTERNATIVE PRESCRIPTION DRUG COV-  
9           ERAGE.—Section 1860D–2(c) of the Social Security Act  
10           (42 U.S.C. 1395w–102(c)) is amended by adding at the  
11           end the following new paragraph:

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

1                                   **Subtitle E—MedPAC**  
2   **SEC. 141. PROVIDING THE MEDICARE PAYMENT ADVISORY**  
3                                   **COMMISSION AND MEDICAID AND CHIP PAY-**  
4                                   **MENT AND ACCESS COMMISSION WITH AC-**  
5                                   **CESS TO CERTAIN DRUG PAYMENT INFORMA-**  
6                                   **TION, INCLUDING CERTAIN REBATE INFOR-**  
7                                   **MATION.**

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

- 11                   (1) in paragraph (2)—
- 12                           (A) in subparagraph (A)(ii), by striking  
13                           “and” at the end;
- 14                           (B) in subparagraph (B), by striking the  
15                           period at the end and inserting “; and”; and
- 16                           (C) by inserting at the end the following  
17                           new subparagraph:
- 18                                   “(C) by the Executive Director of the  
19                                   Medicare Payment Advisory Commission for  
20                                   purposes of monitoring, making recommenda-  
21                                   tions, and analysis of the program under this  
22                                   title and by the Executive Director of the Med-  
23                                   icaid and CHIP Payment and Access Commis-  
24                                   sion for purposes of monitoring, making rec-  
25                                   ommendations, and analysis of the Medicaid

1 program established under title XIX and the  
2 Children’s Health Insurance Program under  
3 title XXI.”; and

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

6 “(3) ADDITIONAL RESTRICTIONS ON DISCLO-  
7 SURE OF INFORMATION.—The Executive Directors  
8 described in paragraph (2)(C) shall not disclose any  
9 of the following information disclosed to such Execu-  
10 tive Directors or obtained by such Executive Direc-  
11 tors pursuant to such paragraph, with respect to a  
12 prescription drug plan offered by a PDP sponsor:

13 “(A) The specific amounts or the identity  
14 of the source of any rebates, price concessions,  
15 or other forms of direct or indirect remunera-  
16 tion under such prescription drug plan.

17 “(B) Information submitted with the bid  
18 submitted under section 1860D–11 by such  
19 PDP sponsor.

20 “(C) In the case of such information from  
21 prescription drug event records, in a form that  
22 would not be permitted under section  
23 423.505(m) of title 42, Code of Federal Regula-  
24 tions, or any successor regulation, if made by  
25 the Centers for Medicare & Medicaid Services.”.

1 (b) ACCESS TO CERTAIN REBATE AND PAYMENT  
2 DATA UNDER MEDICARE AND MEDICAID.—Section  
3 1927(b)(3)(D) of the Social Security Act (42 U.S.C.  
4 1396r–8(b)(3)(D)) is amended—

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

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

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

11 (4) by inserting after clause (vi) the following  
12 new clause:

13 “(vii) to permit the Executive Direc-  
14 tor of the Medicare Payment Advisory  
15 Commission and the Executive Director of  
16 the Medicaid and CHIP Payment and Ac-  
17 cess Commission to review the information  
18 provided.”;

19 (5) in the matter at the end, by striking  
20 “1860D–4(c)(2)(E)” and inserting “1860D–  
21 4(c)(2)(G)”;

22 (6) by adding at the end the following new sen-  
23 tence: “Any information disclosed to the Executive  
24 Director of the Medicare Payment Advisory Commis-  
25 sion or the Executive Director of the Medicaid and

1 CHIP Payment and Access Commission pursuant to  
2 this subparagraph shall not be disclosed by either  
3 such Executive Director in a form which discloses  
4 the identity of a specific manufacturer or wholesaler  
5 or prices charged for drugs by such manufacturer or  
6 wholesaler.”.

## 7 **TITLE II—MEDICAID**

### 8 **SEC. 201. REQUIREMENT FOR CERTAIN COVERED ENTITIES**

#### 9 **PASS THROUGH SAVINGS FROM 340B DRUG** 10 **DISCOUNT PROGRAM TO PATIENTS.**

11 (a) IN GENERAL.—Section 340B(a)(5) of the Public  
12 Health Service Act (42 U.S.C. 256b(a)(5)) is amended by  
13 adding at the end the following new subparagraph:

14 “(E) PASS-THROUGH OF SAVINGS.—

15 “(i) IN GENERAL.—A hospital that is  
16 a covered entity described in subparagraph  
17 (L), (M), (N), or (O) of paragraph (4)  
18 shall, with respect to a covered outpatient  
19 drug subject to an agreement under this  
20 section that is purchased on or after the  
21 date that is 180 days after the date of the  
22 enactment of this subparagraph, pass  
23 through the savings amount determined  
24 under clause (ii) with respect to such drug  
25 to the patient receiving such drug.

1                   “(ii) SAVINGS AMOUNT.—The savings  
2                   amount determined under this clause, with  
3                   respect to a covered outpatient drug sub-  
4                   ject to an agreement under this section, is  
5                   the amount equal to 75 percent of the re-  
6                   duction in the price of the drug provided  
7                   under such agreement.”.

8                   (b) REQUIREMENT FOR COST-SHARING FOR 340B  
9                   DRUGS TO BE BASED ON 340B PRICE.—

10                   (1) IN GENERAL.—Subpart II of part A of title  
11                   XXVII of the Public Health Service Act (42 U.S.C.  
12                   300gg–11 et seq.) is amended by adding at the end  
13                   the following new section:

14                   **“SEC. 2729A. COST-SHARING FOR DRUGS PURCHASED**  
15                   **UNDER 340B DRUG DISCOUNT PROGRAM.**

16                   “‘If a group health plan or a health insurance issuer  
17                   offering group or individual health insurance coverage pro-  
18                   vides or covers any benefits for a covered outpatient drug  
19                   (as defined in section 1927(k) of the Social Security Act)  
20                   subject to an agreement under section 340B and an en-  
21                   rollee of such plan or coverage is furnished such drug,  
22                   then such plan or issuer shall calculate the cost-sharing  
23                   requirement for an enrollee of such plan or coverage for  
24                   such drug as if the total amount charged for such drug

1 was the amount paid for such drug under an agreement  
2 under the drug discount program under section 340B.”.

3 (2) EFFECTIVE DATE.—The amendment made  
4 by paragraph (1) shall apply with respect to plan  
5 years beginning on or after the date that is 180 days  
6 after the date of the enactment of this Act.

7 **SEC. 202. SENSE OF CONGRESS RELATING TO 340B DRUG**  
8 **DISCOUNT PROGRAM.**

9 It is the sense of Congress that the purpose of the  
10 drug discount program under section 340B of the Public  
11 Health Service Act (42 U.S.C. 256b) is to lower out-of-  
12 pocket drugs costs for low-income and uninsured individ-  
13 uals.

14 **SEC. 203. SUNSET OF LIMIT ON MAXIMUM REBATE AMOUNT**  
15 **FOR SINGLE SOURCE DRUGS AND INNO-**  
16 **VATOR MULTIPLE SOURCE DRUGS.**

17 Section 1927(c)(2)(D) of the Social Security Act (42  
18 U.S.C. 1396r–8(c)(2)(D)) is amended by inserting after  
19 “December 31, 2009,” the following: “and before January  
20 1, 2023,”.

21 **SEC. 204. MEDICAID PHARMACY AND THERAPEUTICS COM-**  
22 **MITTEE IMPROVEMENTS.**

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

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

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

10                   “(I) is publicly accessible;

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

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

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

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

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

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

15                             “(II) is made publicly available.

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

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

1           “(vi) If the Secretary determines it appro-  
2           priate or necessary based on the findings and  
3           recommendations of the Comptroller General of  
4           the United States in the report submitted to  
5           Congress under section 205 of the Lower Drug  
6           Costs Now Act of 2019, the Secretary shall  
7           issue guidance that States must follow for es-  
8           tablishing conflict of interest policies for the  
9           pharmacy and therapeutics committee in ac-  
10          cordance with the requirements of clause (ii),  
11          including appropriate standards and require-  
12          ments for identifying, addressing, and reporting  
13          on conflicts of interest.”.

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

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

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

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

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

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

7 **SEC. 205. GAO REPORT ON CONFLICTS OF INTEREST IN**  
8                           **STATE MEDICAID PROGRAM DRUG USE RE-**  
9                           **VIEW BOARDS AND PHARMACY AND THERA-**  
10                           **PEUTICS (P&T) COMMITTEES.**

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

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

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

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

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

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

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

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

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

1 other entities or individuals in the pharmaceutical  
2 industry.

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

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

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

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

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

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

3 **SEC. 206. ENSURING THE ACCURACY OF MANUFACTURER**  
4 **PRICE AND DRUG PRODUCT INFORMATION**  
5 **UNDER THE MEDICAID DRUG REBATE PRO-**  
6 **GRAM.**

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

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

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

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

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

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

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

11                   “(iv) REPORTS.—

12                           “(I) REPORT TO CONGRESS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

11                  “(v) APPROPRIATIONS.—Out of any  
12                  funds in the Treasury not otherwise appro-  
13                  priated, there is appropriated to the Sec-  
14                  retary \$2,000,000 for fiscal year 2020 and  
15                  each fiscal year thereafter to carry out this  
16                  subparagraph.”.

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

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

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

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

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

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

19 **SEC. 207. IMPROVING TRANSPARENCY AND PREVENTING**  
20 **THE USE OF ABUSIVE SPREAD PRICING AND**  
21 **RELATED PRACTICES IN MEDICAID.**

22 (a) PASS-THROUGH PRICING REQUIRED.—

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

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

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

16                               “(i) is limited to—

17                                       “(I) ingredient cost; and

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

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

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

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

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

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

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

14 (2) CONFORMING AMENDMENT.—Clause (xiii)  
15 of section 1903(m)(2)(A) of such Act (42 U.S.C.  
16 1396b(m)(2)(A)), as amended by section 204, is fur-  
17 ther amended—

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

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

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

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

9           (b) SURVEY OF RETAIL PRICES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 “(H) PENALTIES.—

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

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

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

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

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

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

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

3 (C) in paragraph (2)—

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

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

11 (D) in paragraph (4), by inserting “, and  
12 \$5,000,000 for fiscal year 2020 and each fiscal  
13 year thereafter,” after “2010”.

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

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

22 (1) in subparagraph (A)(i)—

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

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

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

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

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

17 (2) in subparagraph (D)—

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

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

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

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

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

13 **SEC. 208. T-MSIS DRUG DATA ANALYTICS REPORTS.**

14 (a) IN GENERAL.—Not later than May 1 of each cal-  
15 endar year beginning with calendar year 2021, the Sec-  
16 retary of Health and Human Services (in this section re-  
17 ferred to as the “Secretary”) shall publish on a website  
18 of the Centers for Medicare & Medicaid Services that is  
19 accessible to the public a report of the most recently avail-  
20 able data on provider prescribing patterns under the Med-  
21 icaid program.

22 (b) CONTENT OF REPORT.—

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

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

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

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

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

17 (iii) by episodes of care for—

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

25 (II) procedural groupings; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 (e) APPROPRIATION.—For fiscal year 2020 and each  
6 fiscal year thereafter, there is appropriated to the Sec-  
7 retary \$2,000,000 to carry out this section.

8 **SEC. 209. RISK-SHARING VALUE-BASED PAYMENT AGREE-**  
9 **MENTS FOR COVERED OUTPATIENT DRUGS**  
10 **UNDER MEDICAID.**

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

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

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

1           “(2) SECRETARIAL APPROVAL.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 “(i) TIMING OF FIRST PAYMENT.—

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

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

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

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

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

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

15 “(4) NOTICE OF INTENT.—

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

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

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

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

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

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

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

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

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

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

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

23 “(5) SPECIAL PAYMENT RULES.—

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

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

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

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

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

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

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

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

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

19                 “(A) ASSESSMENTS.—

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

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

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

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

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

6                   “(B) RESULTS OF ASSESSMENTS.—

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

23                  “(ii) REPAYMENT REQUIRED.—

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

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

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

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

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

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

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

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

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

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

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

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

9           “(8) GUIDANCE AND REGULATIONS.—

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

19           “(B) MODEL AGREEMENTS.—

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

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

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

21 “(C) OIG CONSULTATION.—

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

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

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

15          “(9) RULES OF CONSTRUCTION.—

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

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

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

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

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

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

4 “(10) APPROPRIATIONS.—For fiscal year 2020  
5 and each fiscal year thereafter, there are appro-  
6 priated to the Secretary \$5,000,000 for the purpose  
7 of carrying out this subsection.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20                  “(iv) which provides that—

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

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

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

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

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

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

18                  (b) CONFORMING AMENDMENTS.—

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

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

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

8                   (B) in paragraph (3)—

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

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

16 **SEC. 210. APPLYING MEDICAID DRUG REBATE REQUIRE-**  
17 **MENT TO DRUGS PROVIDED AS PART OF OUT-**  
18 **PATIENT HOSPITAL SERVICES.**

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

22                   “(3) LIMITING DEFINITION.—

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

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

6 “(i) Inpatient hospital services.

7 “(ii) Hospice services.

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

12 “(iv) Physicians’ services.

13 “(v) Outpatient hospital services.

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

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

19 “(viii) Renal dialysis.

20 “(B) OTHER EXCLUSIONS.—Such term  
21 also does not include any such drug or product  
22 for which a National Drug Code number is not  
23 required by the Food and Drug Administration  
24 or a drug or biological used for a medical indi-

1 cation which is not a medically accepted indica-  
2 tion.

3 “(C) STATE OPTION.—At the option of a  
4 State, such term may include any drug, biologi-  
5 cal product, or insulin for which the State is  
6 the primary payer under this title or a dem-  
7 onstration project concerning this title, and that  
8 is provided on an outpatient basis as part of, or  
9 as incident to and in the same setting as, de-  
10 scribed in clause (iv) or (v) of subparagraph (A)  
11 and for which payment is made as part of pay-  
12 ment for such services.

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

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

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

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

11 **SEC. 211. PROHIBITION ON ADDITIONAL REBATE UNDER**  
12 **MEDICAID FOR CERTAIN NONINNOVATOR**  
13 **MULTIPLE SOURCE DRUGS.**

14 Section 1927(c)(3)(C) of the Social Security Act (42  
15 U.S.C. 1396r–8(c)(3)(C)) is amended—

16           (1) in clause (i), by striking “The amount” and  
17 inserting “Subject to clause (v), the amount”; and

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

20                           “(v) PROHIBITION ON ADDITIONAL  
21 REBATE FOR CERTAIN NONINNOVATOR  
22 MULTIPLE SOURCE DRUGS.—With respect  
23 to a rebate period beginning on or after  
24 January 1, 2020, and a dosage form and  
25 strength of a covered outpatient drug de-

1           scribed in clause (i), the amount of the re-  
2           bate specified in subparagraph (A) for  
3           such dosage form and strength for such re-  
4           bate period may not be increased if the av-  
5           erage manufacturer price for a unit of  
6           such dosage form and strength for such re-  
7           bate period is less than \$1.”.

8 **SEC. 212. EXEMPTING EXCHANGE PLANS AND CHILD**  
9 **HEALTH PLANS FROM DETERMINATION OF**  
10 **BEST PRICE UNDER MEDICAID OUTPATIENT**  
11 **DRUG PROGRAM.**

12       (a) IN GENERAL.—Section 1927(c)(1)(C)(i) of the  
13 Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(i)) is  
14 amended—

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

17           (2) in subclause (VI), by striking the period at  
18 the end and inserting a semicolon; and

19           (3) by adding at the end of the following new  
20 subclauses:

21                           “(VII) any prices charged which  
22                           are negotiated by a qualified health  
23                           plan offered in the individual market  
24                           (as defined in section 2791 of the  
25                           Public Health Service Act), whether

1 or not through an exchange estab-  
2 lished under title I of the Patient Pro-  
3 tection and Affordable Care Act, with  
4 respect to drugs on behalf of individ-  
5 uals enrolled in such plan; and

6 “(VIII) any prices charged under  
7 a State child health plan under title  
8 XXI (or a waiver of such plan).”.

9 (b) EFFECTIVE DATE.—The amendments made by  
10 subsection (a) shall apply with respect to rebate periods  
11 beginning on or after January 1, 2021.

12 **TITLE III—FOOD AND DRUG**  
13 **ADMINISTRATION**  
14 **Subtitle A—CREATES Act**

15 **SEC. 301. ACTIONS FOR DELAYS OF GENERIC DRUGS AND**  
16 **BIOSIMILAR BIOLOGICAL PRODUCTS.**

17 (a) DEFINITIONS.—In this section—

18 (1) the term “commercially reasonable, market-  
19 based terms” means—

20 (A) a nondiscriminatory price for the sale  
21 of the covered product at or below, but not  
22 greater than, the most recent wholesale acquisi-  
23 tion cost for the drug, as defined in section  
24 1847A(c)(6)(B) of the Social Security Act (42  
25 U.S.C. 1395w–3a(c)(6)(B));

1 (B) a schedule for delivery that results in  
2 the transfer of the covered product to the eligi-  
3 ble product developer consistent with the timing  
4 under subsection (b)(2)(A)(iv); and

5 (C) no additional conditions are imposed  
6 on the sale of the covered product;

7 (2) the term “covered product”—

8 (A) means—

9 (i) any drug approved under sub-  
10 section (c) or (j) of section 505 of the Fed-  
11 eral Food, Drug, and Cosmetic Act (21  
12 U.S.C. 355) or biological product licensed  
13 under subsection (a) or (k) of section 351  
14 of the Public Health Service Act (42  
15 U.S.C. 262);

16 (ii) any combination of a drug or bio-  
17 logical product described in clause (i); or

18 (iii) when reasonably necessary to  
19 support approval of an application under  
20 section 505 of the Federal Food, Drug,  
21 and Cosmetic Act (21 U.S.C. 355), or sec-  
22 tion 351 of the Public Health Service Act  
23 (42 U.S.C. 262), as applicable, or other-  
24 wise meet the requirements for approval  
25 under either such section, any product, in-

1 including any device, that is marketed or in-  
2 tended for use with such a drug or biologi-  
3 cal product; and

4 (B) does not include any drug or biological  
5 product that appears on the drug shortage list  
6 in effect under section 506E of the Federal  
7 Food, Drug, and Cosmetic Act (21 U.S.C.  
8 356e), unless—

9 (i) the drug or biological product has  
10 been on the drug shortage list in effect  
11 under such section 506E continuously for  
12 more than 6 months; or

13 (ii) the Secretary determines that in-  
14 clusion of the drug or biological product as  
15 a covered product is likely to contribute to  
16 alleviating or preventing a shortage;

17 (3) the term “device” has the meaning given  
18 the term in section 201 of the Federal Food, Drug,  
19 and Cosmetic Act (21 U.S.C. 321);

20 (4) the term “eligible product developer” means  
21 a person that seeks to develop a product for ap-  
22 proval pursuant to an application for approval under  
23 subsection (b)(2) or (j) of section 505 of the Federal  
24 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or  
25 for licensing pursuant to an application under sec-

1       tion 351(k) of the Public Health Service Act (42  
2       U.S.C. 262(k));

3           (5) the term “license holder” means the holder  
4       of an application approved under subsection (c) or  
5       (j) of section 505 of the Federal Food, Drug, and  
6       Cosmetic Act (21 U.S.C. 355) or the holder of a li-  
7       cense under subsection (a) or (k) of section 351 of  
8       the Public Health Service Act (42 U.S.C. 262) for  
9       a covered product;

10          (6) the term “REMS” means a risk evaluation  
11       and mitigation strategy under section 505–1 of the  
12       Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13       355–1);

14          (7) the term “REMS with ETASU” means a  
15       REMS that contains elements to assure safe use  
16       under section 505–1(f) of the Federal Food, Drug,  
17       and Cosmetic Act (21 U.S.C. 355–1(f));

18          (8) the term “Secretary” means the Secretary  
19       of Health and Human Services;

20          (9) the term “single, shared system of elements  
21       to assure safe use” means a single, shared system  
22       of elements to assure safe use under section 505–  
23       1(f) of the Federal Food, Drug, and Cosmetic Act  
24       (21 U.S.C. 355–1(f)); and

1           (10) the term “sufficient quantities” means an  
2 amount of a covered product that the eligible prod-  
3 uct developer determines allows it to—

4           (A) conduct testing to support an applica-  
5 tion under—

6           (i) subsection (b)(2) or (j) of section  
7 505 of the Federal Food, Drug, and Cos-  
8 metic Act (21 U.S.C. 355); or

9           (ii) section 351(k) of the Public  
10 Health Service Act (42 U.S.C. 262(k));  
11 and

12           (B) fulfill any regulatory requirements re-  
13 lating to approval of such an application.

14           (b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFI-  
15 CIENT QUANTITIES OF A COVERED PRODUCT.—

16           (1) IN GENERAL.—An eligible product developer  
17 may bring a civil action against the license holder  
18 for a covered product seeking relief under this sub-  
19 section in an appropriate district court of the United  
20 States alleging that the license holder has declined  
21 to provide sufficient quantities of the covered prod-  
22 uct to the eligible product developer on commercially  
23 reasonable, market-based terms.

24           (2) ELEMENTS.—

1 (A) IN GENERAL.—To prevail in a civil ac-  
2 tion brought under paragraph (1), an eligible  
3 product developer shall prove, by a preponder-  
4 ance of the evidence—

5 (i) that—

6 (I) the covered product is not  
7 subject to a REMS with ETASU; or

8 (II) if the covered product is sub-  
9 ject to a REMS with ETASU—

10 (aa) the eligible product de-  
11 veloper has obtained a covered  
12 product authorization from the  
13 Secretary in accordance with sub-  
14 paragraph (B); and

15 (bb) the eligible product de-  
16 veloper has provided a copy of  
17 the covered product authorization  
18 to the license holder;

19 (ii) that, as of the date on which the  
20 civil action is filed, the product developer  
21 has not obtained sufficient quantities of  
22 the covered product on commercially rea-  
23 sonable, market-based terms;

24 (iii) that the eligible product developer  
25 has submitted a written request to pur-

1 chase sufficient quantities of the covered  
2 product to the license holder and such re-  
3 quest—

4 (I) was sent to a named cor-  
5 porate officer of the license holder;

6 (II) was made by certified or reg-  
7 istered mail with return receipt re-  
8 quested;

9 (III) specified an individual as  
10 the point of contact for the license  
11 holder to direct communications re-  
12 lated to the sale of the covered prod-  
13 uct to the eligible product developer  
14 and a means for electronic and writ-  
15 ten communications with that indi-  
16 vidual; and

17 (IV) specified an address to  
18 which the covered product was to be  
19 shipped upon reaching an agreement  
20 to transfer the covered product; and

21 (iv) that the license holder has not de-  
22 livered to the eligible product developer  
23 sufficient quantities of the covered product  
24 on commercially reasonable, market-based  
25 terms—

1 (I) for a covered product that is  
2 not subject to a REMS with ETASU,  
3 by the date that is 31 days after the  
4 date on which the license holder re-  
5 ceived the request for the covered  
6 product; and

7 (II) for a covered product that is  
8 subject to a REMS with ETASU, by  
9 31 days after the later of—

10 (aa) the date on which the  
11 license holder received the re-  
12 quest for the covered product; or

13 (bb) the date on which the  
14 license holder received a copy of  
15 the covered product authorization  
16 issued by the Secretary in ac-  
17 cordance with subparagraph (B).

18 (B) AUTHORIZATION FOR COVERED PROD-  
19 UCT SUBJECT TO A REMS WITH ETASU.—

20 (i) REQUEST.—An eligible product de-  
21 veloper may submit to the Secretary a  
22 written request for the eligible product de-  
23 veloper to be authorized to obtain suffi-  
24 cient quantities of an individual covered  
25 product subject to a REMS with ETASU.

1 (ii) AUTHORIZATION.—Not later than  
2 120 days after the date on which a request  
3 under clause (i) is received, the Secretary  
4 shall, by written notice, authorize the eligi-  
5 ble product developer to obtain sufficient  
6 quantities of an individual covered product  
7 subject to a REMS with ETASU for pur-  
8 poses of—

9 (I) development and testing that  
10 does not involve human clinical trials,  
11 if the eligible product developer has  
12 agreed to comply with any conditions  
13 the Secretary determines necessary; or

14 (II) development and testing that  
15 involves human clinical trials, if the  
16 eligible product developer has—

17 (aa)(AA) submitted proto-  
18 cols, informed consent docu-  
19 ments, and informational mate-  
20 rials for testing that include pro-  
21 tections that provide safety pro-  
22 tections comparable to those pro-  
23 vided by the REMS for the cov-  
24 ered product; or

1 (BB) otherwise satisfied the  
2 Secretary that such protections  
3 will be provided; and

4 (bb) met any other require-  
5 ments the Secretary may estab-  
6 lish.

7 (iii) NOTICE.—A covered product au-  
8 thorization issued under this subparagraph  
9 shall state that the provision of the covered  
10 product by the license holder under the  
11 terms of the authorization will not be a  
12 violation of the REMS for the covered  
13 product.

14 (3) AFFIRMATIVE DEFENSE.—In a civil action  
15 brought under paragraph (1), it shall be an affirma-  
16 tive defense, on which the defendant has the burden  
17 of persuasion by a preponderance of the evidence—

18 (A) that, on the date on which the eligible  
19 product developer requested to purchase suffi-  
20 cient quantities of the covered product from the  
21 license holder—

22 (i) neither the license holder nor any  
23 of its agents, wholesalers, or distributors  
24 was engaged in the manufacturing or com-

1           merchial marketing of the covered product;  
2           and

3                   (ii) neither the license holder nor any  
4           of its agents, wholesalers, or distributors  
5           otherwise had access to inventory of the  
6           covered product to supply to the eligible  
7           product developer on commercially reason-  
8           able, market-based terms;

9           (B) that—

10                   (i) the license holder sells the covered  
11           product through agents, distributors, or  
12           wholesalers;

13                   (ii) the license holder has placed no  
14           restrictions, explicit or implicit, on its  
15           agents, distributors, or wholesalers to sell  
16           covered products to eligible product devel-  
17           opers; and

18                   (iii) the covered product can be pur-  
19           chased by the eligible product developer in  
20           sufficient quantities on commercially rea-  
21           sonable, market-based terms from the  
22           agents, distributors, or wholesalers of the  
23           license holder; or

24           (C) that the license holder made an offer  
25           to the individual specified pursuant to para-

1 graph (2)(A)(iii)(III), by a means of commu-  
2 nication (electronic, written, or both) specified  
3 pursuant to such paragraph, to sell sufficient  
4 quantities of the covered product to the eligible  
5 product developer at commercially reasonable  
6 market-based terms—

7 (i) for a covered product that is not  
8 subject to a REMS with ETASU, by the  
9 date that is 14 days after the date on  
10 which the license holder received the re-  
11 quest for the covered product, and the eli-  
12 gible product developer did not accept such  
13 offer by the date that is 7 days after the  
14 date on which the eligible product devel-  
15 oper received such offer from the license  
16 holder; or

17 (ii) for a covered product that is sub-  
18 ject to a REMS with ETASU, by the date  
19 that is 20 days after the date on which the  
20 license holder received the request for the  
21 covered product, and the eligible product  
22 developer did not accept such offer by the  
23 date that is 10 days after the date on  
24 which the eligible product developer re-  
25 ceived such offer from the license holder.

1 (4) REMEDIES.—

2 (A) IN GENERAL.—If an eligible product  
3 developer prevails in a civil action brought  
4 under paragraph (1), the court shall—

5 (i) order the license holder to provide  
6 to the eligible product developer without  
7 delay sufficient quantities of the covered  
8 product on commercially reasonable, mar-  
9 ket-based terms;

10 (ii) award to the eligible product de-  
11 veloper reasonable attorney's fees and costs  
12 of the civil action; and

13 (iii) award to the eligible product de-  
14 veloper a monetary amount sufficient to  
15 deter the license holder from failing to pro-  
16 vide eligible product developers with suffi-  
17 cient quantities of a covered product on  
18 commercially reasonable, market-based  
19 terms, if the court finds, by a preponder-  
20 ance of the evidence—

21 (I) that the license holder delayed  
22 providing sufficient quantities of the  
23 covered product to the eligible product  
24 developer without a legitimate busi-  
25 ness justification; or

1 (II) that the license holder failed  
2 to comply with an order issued under  
3 clause (i).

4 (B) MAXIMUM MONETARY AMOUNT.—A  
5 monetary amount awarded under subparagraph  
6 (A)(iii) shall not be greater than the revenue  
7 that the license holder earned on the covered  
8 product during the period—

9 (i) beginning on—

10 (I) for a covered product that is  
11 not subject to a REMS with ETASU,  
12 the date that is 31 days after the date  
13 on which the license holder received  
14 the request; or

15 (II) for a covered product that is  
16 subject to a REMS with ETASU, the  
17 date that is 31 days after the later  
18 of—

19 (aa) the date on which the  
20 license holder received the re-  
21 quest; or

22 (bb) the date on which the  
23 license holder received a copy of  
24 the covered product authorization  
25 issued by the Secretary in ac-

1 cordance with paragraph (2)(B);

2 and

3 (ii) ending on the date on which the  
4 eligible product developer received suffi-  
5 cient quantities of the covered product.

6 (C) AVOIDANCE OF DELAY.—The court  
7 may issue an order under subparagraph (A)(i)  
8 before conducting further proceedings that may  
9 be necessary to determine whether the eligible  
10 product developer is entitled to an award under  
11 clause (ii) or (iii) of subparagraph (A), or the  
12 amount of any such award.

13 (c) LIMITATION OF LIABILITY.—A license holder for  
14 a covered product shall not be liable for any claim under  
15 Federal, State, or local law arising out of the failure of  
16 an eligible product developer to follow adequate safeguards  
17 to assure safe use of the covered product during develop-  
18 ment or testing activities described in this section, includ-  
19 ing transportation, handling, use, or disposal of the cov-  
20 ered product by the eligible product developer.

21 (d) NO VIOLATION OF REMS.—Section 505–1 of the  
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–  
23 1) is amended by adding at the end the following new sub-  
24 section:

1           “(l) PROVISION OF SAMPLES NOT A VIOLATION OF  
2 STRATEGY.—The provision of samples of a covered prod-  
3 uct to an eligible product developer (as those terms are  
4 defined in section 301(a) of the Lower Drug Costs Now  
5 Act of 2019) shall not be considered a violation of the  
6 requirements of any risk evaluation and mitigation strat-  
7 egy that may be in place under this section for such  
8 drug.”.

9           (e) RULE OF CONSTRUCTION.—

10           (1) DEFINITION.—In this subsection, the term  
11 “antitrust laws”—

12           (A) has the meaning given the term in  
13 subsection (a) of the first section of the Clayton  
14 Act (15 U.S.C. 12); and

15           (B) includes section 5 of the Federal  
16 Trade Commission Act (15 U.S.C. 45) to the  
17 extent that such section applies to unfair meth-  
18 ods of competition.

19           (2) ANTITRUST LAWS.—Nothing in this section  
20 shall be construed to limit the operation of any pro-  
21 vision of the antitrust laws.

1 **SEC. 302. REMS APPROVAL PROCESS FOR SUBSEQUENT**  
2 **FILERS.**

3 Section 505–1 of the Federal Food, Drug, and Cos-  
4 metic Act (21 U.S.C. 355–1), as amended by section 301,  
5 is further amended—

6 (1) in subsection (g)(4)(B)—

7 (A) in clause (i) by striking “or” after the  
8 semicolon;

9 (B) in clause (ii) by striking the period at  
10 the end and inserting “; or”; and

11 (C) by adding at the end the following:

12 “(iii) accommodate different, com-  
13 parable aspects of the elements to assure  
14 safe use for a drug that is the subject of  
15 an application under section 505(j), and  
16 the applicable listed drug.”;

17 (2) in subsection (i)(1), by striking subpara-  
18 graph (C) and inserting the following:

19 “(C)(i) Elements to assure safe use, if re-  
20 quired under subsection (f) for the listed drug,  
21 which, subject to clause (ii), for a drug that is  
22 the subject of an application under section  
23 505(j) may use—

24 “(I) a single, shared system with  
25 the listed drug under subsection (f);

26 or

1                   “(II) a different, comparable as-  
2                   pect of the elements to assure safe use  
3                   under subsection (f).

4                   “(ii) The Secretary may require a  
5                   drug that is the subject of an application  
6                   under section 505(j) and the listed drug to  
7                   use a single, shared system under sub-  
8                   section (f), if the Secretary determines  
9                   that no different, comparable aspect of the  
10                  elements to assure safe use could satisfy  
11                  the requirements of subsection (f).”;

12                  (3) in subsection (i), by adding at the end the  
13                  following:

14                  “(3) SHARED REMS.—If the Secretary ap-  
15                  proves, in accordance with paragraph (1)(C)(i)(II), a  
16                  different, comparable aspect of the elements to as-  
17                  sure safe use under subsection (f) for a drug that  
18                  is the subject of an abbreviated new drug application  
19                  under section 505(j), the Secretary may require that  
20                  such different comparable aspect of the elements to  
21                  assure safe use can be used with respect to any  
22                  other drug that is the subject of an application  
23                  under section 505(j) or 505(b) that references the  
24                  same listed drug.”; and

25                  (4) by adding at the end the following:

1           “(m) SEPARATE REMS.—When used in this section,  
2 the terms ‘different, comparable aspect of the elements to  
3 assure safe use’ or ‘different, comparable approved risk  
4 evaluation and mitigation strategies’ means a risk evalua-  
5 tion and mitigation strategy for a drug that is the subject  
6 of an application under section 505(j) that uses different  
7 methods or operational means than the strategy required  
8 under subsection (a) for the applicable listed drug, or  
9 other application under section 505(j) with the same such  
10 listed drug, but achieves the same level of safety as such  
11 strategy.”.

12 **SEC. 303. RULE OF CONSTRUCTION.**

13           (a) IN GENERAL.—Nothing in this subtitle, the  
14 amendments made by this subtitle, or in section 505–1  
15 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
16 355–1), shall be construed as—

17           (1) prohibiting a license holder from providing  
18 an eligible product developer access to a covered  
19 product in the absence of an authorization under  
20 this subtitle; or

21           (2) in any way negating the applicability of a  
22 REMS with ETASU, as otherwise required under  
23 such section 505–1, with respect to such covered  
24 product.

1 (b) DEFINITIONS.—In this section, the terms “cov-  
2 ered product”, “eligible product developer”, “license hold-  
3 er”, and “REMS with ETASU” have the meanings given  
4 such terms in section 301(a).

## 5 **Subtitle B—Pay-for-Delay**

### 6 **SEC. 311. UNLAWFUL AGREEMENTS.**

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

13 (1) a subsequent filer directly or indirectly re-  
14 ceives from such holder (or in the case of such an  
15 agreement between two subsequent filers, the other  
16 subsequent filer) anything of value, including a li-  
17 cense; and

18 (2) the subsequent filer agrees to limit or fore-  
19 go research on, or development, manufacturing,  
20 marketing, or sales, for any period of time, of the  
21 covered product that is the subject of the application  
22 described in subparagraph (A) or (B) of subsection  
23 (g)(8).

24 (b) EXCLUSION.—It shall not be unlawful under sub-  
25 section (a) if a party to an agreement described in such

1 subsection demonstrates by clear and convincing evidence  
2 that the value described in subsection (a)(1) is compensa-  
3 tion solely for other goods or services that the subsequent  
4 filer has promised to provide.

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

11 (1) The right to market the covered product  
12 that is the subject of the application described in  
13 subparagraph (A) or (B) of subsection (g)(8) in the  
14 United States before the expiration of—

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

17 (B) any patent right or other statutory ex-  
18 clusivity that would prevent the marketing of  
19 such covered product.

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

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

24 (d) ENFORCEMENT BY FEDERAL TRADE COMMIS-  
25 SION.—

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

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

8           (B) a person, partnership, or corporation  
9 over which the Commission would have author-  
10 ity pursuant to such section but for the fact  
11 that such person, partnership, or corporation is  
12 not organized to carry on business for its own  
13 profit or that of its members.

14           (2) UNFAIR OR DECEPTIVE ACTS OR PRACTICES  
15 ENFORCEMENT AUTHORITY.—

16           (A) IN GENERAL.—A violation of this sec-  
17 tion shall be treated as an unfair or deceptive  
18 act or practice in violation of section 5(a)(1) of  
19 the Federal Trade Commission Act (15 U.S.C.  
20 45(a)(1)).

21           (B) POWERS OF COMMISSION.—Except as  
22 provided in subparagraph (C) and paragraphs  
23 (1)(B) and (3)—

24           (i) the Commission shall enforce this  
25 section in the same manner, by the same

1 means, and with the same jurisdiction,  
2 powers, and duties as though all applicable  
3 terms and provisions of the Federal Trade  
4 Commission Act (15 U.S.C. 41 et seq.)  
5 were incorporated into and made a part of  
6 this section; and

7 (ii) any NDA or BLA holder or subse-  
8 quent filer that violates this section shall  
9 be subject to the penalties and entitled to  
10 the privileges and immunities provided in  
11 the Federal Trade Commission Act.

12 (C) JUDICIAL REVIEW.—In the case of a  
13 cease and desist order issued by the Commis-  
14 sion under section 5 of the Federal Trade Com-  
15 mission Act (15 U.S.C. 45) for violation of this  
16 section, a party to such order may obtain judi-  
17 cial review of such order as provided in such  
18 section 5, except that—

19 (i) such review may only be obtained  
20 in—

21 (I) the United States Court of  
22 Appeals for the District of Columbia  
23 Circuit;

24 (II) the United States Court of  
25 Appeals for the circuit in which the

1 ultimate parent entity, as defined in  
2 section 801.1(a)(3) of title 16, Code  
3 of Federal Regulations, or any suc-  
4 cessor thereto, of the NDA or BLA  
5 holder (if any such holder is a party  
6 to such order) is incorporated as of  
7 the date that the application described  
8 in subparagraph (A) or (B) of sub-  
9 section (g)(8) or an approved applica-  
10 tion that is deemed to be a license for  
11 a biological product under section  
12 351(k) of the Public Health Service  
13 Act (42 U.S.C. 262(k)) pursuant to  
14 section 7002(e)(4) of the Biologics  
15 Price Competition and Innovation Act  
16 of 2009 (Public Law 111–148; 124  
17 Stat. 817) is submitted to the Com-  
18 missioner of Food and Drugs; or

19 (III) the United States Court of  
20 Appeals for the circuit in which the  
21 ultimate parent entity, as so defined,  
22 of any subsequent filer that is a party  
23 to such order is incorporated as of the  
24 date that the application described in  
25 subparagraph (A) or (B) of subsection

1 (g)(8) is submitted to the Commis-  
2 sioner of Food and Drugs; and

3 (ii) the petition for review shall be  
4 filed in the court not later than 30 days  
5 after such order is served on the party  
6 seeking review.

7 (3) ADDITIONAL ENFORCEMENT AUTHORITY.—

8 (A) CIVIL PENALTY.—The Commission  
9 may commence a civil action to recover a civil  
10 penalty in a district court of the United States  
11 against any NDA or BLA holder or subsequent  
12 filer that violates this section.

13 (B) SPECIAL RULE FOR RECOVERY OF  
14 PENALTY IF CEASE AND DESIST ORDER  
15 ISSUED.—

16 (i) IN GENERAL.—If the Commission  
17 has issued a cease and desist order in a  
18 proceeding under section 5 of the Federal  
19 Trade Commission Act (15 U.S.C. 45) for  
20 violation of this section—

21 (I) the Commission may com-  
22 mence a civil action under subpara-  
23 graph (A) to recover a civil penalty  
24 against any party to such order at  
25 any time before the expiration of the

1 1-year period beginning on the date  
2 on which such order becomes final  
3 under section 5(g) of such Act (15  
4 U.S.C. 45(g)); and

5 (II) in such civil action, the find-  
6 ings of the Commission as to the ma-  
7 terial facts in such proceeding shall be  
8 conclusive, unless—

9 (aa) the terms of such order  
10 expressly provide that the Com-  
11 mission's findings shall not be  
12 conclusive; or

13 (bb) such order became final  
14 by reason of section 5(g)(1) of  
15 such Act (15 U.S.C. 45(g)(1)), in  
16 which case such findings shall be  
17 conclusive if supported by evi-  
18 dence.

19 (ii) RELATIONSHIP TO PENALTY FOR  
20 VIOLATION OF AN ORDER.—The penalty  
21 provided in clause (i) for violation of this  
22 section is separate from and in addition to  
23 any penalty that may be incurred for viola-  
24 tion of an order of the Commission under

1 section 5(l) of the Federal Trade Commis-  
2 sion Act (15 U.S.C. 45(l)).

3 (C) AMOUNT OF PENALTY.—

4 (i) IN GENERAL.—The amount of a  
5 civil penalty imposed in a civil action under  
6 subparagraph (A) on a party to an agree-  
7 ment described in subsection (a) shall be  
8 sufficient to deter violations of this section,  
9 but in no event greater than—

10 (I) if such party is the NDA or  
11 BLA holder (or, in the case of an  
12 agreement between two subsequent fil-  
13 ers, the subsequent filer who gave the  
14 value described in subsection (a)(1)),  
15 the greater of—

16 (aa) 3 times the value re-  
17 ceived by such NDA or BLA  
18 holder (or by such subsequent  
19 filer) that is reasonably attrib-  
20 utable to the violation of this sec-  
21 tion; or

22 (bb) 3 times the value given  
23 to the subsequent filer (or to the  
24 other subsequent filer) reason-

1 ably attributable to the violation  
2 of this section; and

3 (II) if such party is the subse-  
4 quent filer (or, in the case of an  
5 agreement between two subsequent fil-  
6 ers, the subsequent filer who received  
7 the value described in subsection  
8 (a)(1)), 3 times the value received by  
9 such subsequent filer that is reason-  
10 ably attributable to the violation of  
11 this section.

12 (ii) FACTORS FOR CONSIDERATION.—  
13 In determining such amount, the court  
14 shall take into account—

15 (I) the nature, circumstances, ex-  
16 tent, and gravity of the violation;

17 (II) with respect to the violator,  
18 the degree of culpability, any history  
19 of violations, the ability to pay, any  
20 effect on the ability to continue doing  
21 business, profits earned by the NDA  
22 or BLA holder (or, in the case of an  
23 agreement between two subsequent fil-  
24 ers, the subsequent filer who gave the  
25 value described in subsection (a)(1)),

1 compensation received by the subse-  
2 quent filer (or, in the case of an  
3 agreement between two subsequent fil-  
4 ers, the subsequent filer who received  
5 the value described in subsection  
6 (a)(1)), and the amount of commerce  
7 affected; and

8 (III) other matters that justice  
9 requires.

10 (D) INJUNCTIONS AND OTHER EQUITABLE  
11 RELIEF.—In a civil action under subparagraph  
12 (A), the United States district courts are em-  
13 powered to grant mandatory injunctions and  
14 such other and further equitable relief as they  
15 deem appropriate.

16 (4) REMEDIES IN ADDITION.—Remedies pro-  
17 vided in this subsection are in addition to, and not  
18 in lieu of, any other remedy provided by Federal  
19 law.

20 (5) PRESERVATION OF AUTHORITY OF COMMIS-  
21 SION.—Nothing in this section shall be construed to  
22 affect any authority of the Commission under any  
23 other provision of law.

24 (e) FEDERAL TRADE COMMISSION RULEMAKING.—  
25 The Commission may, in its discretion, by rule promul-

1 gated under section 553 of title 5, United States Code,  
2 exempt from this section certain agreements described in  
3 subsection (a) if the Commission finds such agreements  
4 to be in furtherance of market competition and for the  
5 benefit of consumers.

6 (f) ANTITRUST LAWS.—Nothing in this section shall  
7 modify, impair, limit, or supersede the applicability of the  
8 antitrust laws as defined in subsection (a) of the first sec-  
9 tion of the Clayton Act (15 U.S.C. 12(a)), and of section  
10 5 of the Federal Trade Commission Act (15 U.S.C. 45)  
11 to the extent that such section 5 applies to unfair methods  
12 of competition. Nothing in this section shall modify, im-  
13 pair, limit, or supersede the right of a subsequent filer  
14 to assert claims or counterclaims against any person,  
15 under the antitrust laws or other laws relating to unfair  
16 competition.

17 (g) DEFINITIONS.—In this section:

18 (1) AGREEMENT RESOLVING OR SETTLING A  
19 COVERED PATENT INFRINGEMENT CLAIM.—The  
20 term “agreement resolving or settling a covered pat-  
21 ent infringement claim” means any agreement  
22 that—

23 (A) resolves or settles a covered patent in-  
24 fringement claim; or

1 (B) is contingent upon, provides for a con-  
2 tingent condition for, or is otherwise related to  
3 the resolution or settlement of a covered patent  
4 infringement claim.

5 (2) COMMISSION.—The term “Commission”  
6 means the Federal Trade Commission.

7 (3) COVERED PATENT INFRINGEMENT CLAIM.—  
8 The term “covered patent infringement claim”  
9 means an allegation made by the NDA or BLA hold-  
10 er to a subsequent filer (or, in the case of an agree-  
11 ment between two subsequent filers, by one subse-  
12 quent filer to another), whether or not included in  
13 a complaint filed with a court of law, that—

14 (A) the submission of the application de-  
15 scribed in subparagraph (A) or (B) of para-  
16 graph (9), or the manufacture, use, offering for  
17 sale, sale, or importation into the United States  
18 of a covered product that is the subject of such  
19 an application—

20 (i) in the case of an agreement be-  
21 tween an NDA or BLA holder and a sub-  
22 sequent filer, infringes any patent owned  
23 by, or exclusively licensed to, the NDA or  
24 BLA holder of the covered product; or

1 (ii) in the case of an agreement be-  
2 tween two subsequent filers, infringes any  
3 patent owned by the subsequent filer; or

4 (B) in the case of an agreement between  
5 an NDA or BLA holder and a subsequent filer,  
6 the covered product to be manufactured under  
7 such application uses a covered product as  
8 claimed in a published patent application.

9 (4) COVERED PRODUCT.—The term “covered  
10 product” means a drug (as defined in section 201(g)  
11 of the Federal Food, Drug, and Cosmetic Act (21  
12 U.S.C. 321(g))), including a biological product (as  
13 defined in section 351(i) of the Public Health Serv-  
14 ice Act (42 U.S.C. 262(i)).

15 (5) NDA OR BLA HOLDER.—The term “NDA  
16 or BLA holder” means—

17 (A) the holder of—

18 (i) an approved new drug application  
19 filed under section 505(b)(1) of the Fed-  
20 eral Food, Drug, and Cosmetic Act (21  
21 U.S.C. 355(b)(1)) for a covered product;  
22 or

23 (ii) a biologics license application filed  
24 under section 351(a) of the Public Health

1 Service Act (42 U.S.C. 262(a)) with re-  
2 spect to a biological product;

3 (B) a person owning or controlling enforce-  
4 ment of the patent on—

5 (i) the list published under section  
6 505(j)(7) of the Federal Food, Drug, and  
7 Cosmetic Act (21 U.S.C. 355(j)(7)) in con-  
8 nection with the application described in  
9 subparagraph (A)(i); or

10 (ii) any list published under section  
11 351 of the Public Health Service Act (42  
12 U.S.C. 262) comprised of patents associ-  
13 ated with biologics license applications filed  
14 under section 351(a) of such Act (42  
15 U.S.C. 262(a)); or

16 (C) the predecessors, subsidiaries, divi-  
17 sions, groups, and affiliates controlled by, con-  
18 trolling, or under common control with any en-  
19 tity described in subparagraph (A) or (B) (such  
20 control to be presumed by direct or indirect  
21 share ownership of 50 percent or greater), as  
22 well as the licensees, licensors, successors, and  
23 assigns of each of the entities.

1           (6) PATENT.—The term “patent” means a pat-  
2           ent issued by the United States Patent and Trade-  
3           mark Office.

4           (7) STATUTORY EXCLUSIVITY.—The term  
5           “statutory exclusivity” means those prohibitions on  
6           the submission or approval of drug applications  
7           under clauses (ii) through (iv) of section  
8           505(c)(3)(E) (5- and 3-year exclusivity), clauses (ii)  
9           through (iv) of section 505(j)(5)(F) (5-year and 3-  
10          year exclusivity), section 505(j)(5)(B)(iv) (180-day  
11          exclusivity), section 527 (orphan drug exclusivity),  
12          section 505A (pediatric exclusivity), or section 505E  
13          (qualified infectious disease product exclusivity) of  
14          the Federal Food, Drug, and Cosmetic Act (21  
15          U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 355(j)(5)(F),  
16          360cc, 355a, 355f), or prohibitions on the submis-  
17          sion or licensing of biologics license applications  
18          under section 351(k)(6) (interchangeable biological  
19          product exclusivity) or section 351(k)(7) (biological  
20          product reference product exclusivity) of the Public  
21          Health Service Act (42 U.S.C. 262(k)(6), (7)).

22          (8) SUBSEQUENT FILER.—The term “subse-  
23          quent filer” means—

24                 (A) in the case of a drug, a party that  
25                 owns or controls an abbreviated new drug appli-

1 cation submitted pursuant to section 505(j) of  
2 the Federal Food, Drug, and Cosmetic Act (21  
3 U.S.C. 355(j)) or a new drug application sub-  
4 mitted pursuant to section 505(b)(2) of the  
5 Federal Food, Drug, and Cosmetic Act  
6 (21U.S.C. 355(b)(2)) and filed under section  
7 505(b)(1) of such Act (21 U.S.C. 355(b)(1)) or  
8 has the exclusive rights to distribute the cov-  
9 ered product that is the subject of such applica-  
10 tion; or

11 (B) in the case of a biological product, a  
12 party that owns or controls an application filed  
13 with the Food and Drug Administration under  
14 section 351(k) of the Public Health Service Act  
15 (42 U.S.C. 262(k)) or has the exclusive rights  
16 to distribute the biological product that is the  
17 subject of such application.

18 (h) EFFECTIVE DATE.—This section applies with re-  
19 spect to agreements described in subsection (a) entered  
20 into on or after the date of the enactment of this Act.

21 **SEC. 312. NOTICE AND CERTIFICATION OF AGREEMENTS.**

22 (a) NOTICE OF ALL AGREEMENTS.—Section 1111(7)  
23 of the Medicare Prescription Drug, Improvement, and  
24 Modernization Act of 2003 (21 U.S.C. 355 note) is  
25 amended by inserting “or the owner of a patent for which

1 a claim of infringement could reasonably be asserted  
2 against any person for making, using, offering to sell, sell-  
3 ing, or importing into the United States a biological prod-  
4 uct that is the subject of a biosimilar biological product  
5 application” before the period at the end.

6 (b) CERTIFICATION OF AGREEMENTS.—Section 1112  
7 of such Act (21 U.S.C. 355 note) is amended by adding  
8 at the end the following:

9 “(d) CERTIFICATION.—The Chief Executive Officer  
10 or the company official responsible for negotiating any  
11 agreement under subsection (a) or (b) that is required to  
12 be filed under subsection (c) shall, within 30 days of such  
13 filing, execute and file with the Assistant Attorney General  
14 and the Commission a certification as follows: ‘I declare  
15 that the following is true, correct, and complete to the best  
16 of my knowledge: The materials filed with the Federal  
17 Trade Commission and the Department of Justice under  
18 section 1112 of the Medicare Prescription Drug, Improve-  
19 ment, and Modernization Act of 2003, with respect to the  
20 agreement referenced in this certification—

21 “(1) represent the complete, final, and exclu-  
22 sive agreement between the parties;

23 “(2) include any ancillary agreements that are  
24 contingent upon, provide a contingent condition for,

1       were entered into within 30 days of, or are otherwise  
2       related to, the referenced agreement; and

3               “(3) include written descriptions of any oral  
4       agreements, representations, commitments, or prom-  
5       ises between the parties that are responsive to sub-  
6       section (a) or (b) of such section 1112 and have not  
7       been reduced to writing.’”.

8       **SEC. 313. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

9       Section 505(j)(5)(D)(i)(V) of the Federal Food,  
10      Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))  
11      is amended by inserting “section 311 of the Lower Drug  
12      Costs Now Act of 2019 or” after “that the agreement has  
13      violated”.

14      **SEC. 314. COMMISSION LITIGATION AUTHORITY.**

15      Section 16(a)(2) of the Federal Trade Commission  
16      Act (15 U.S.C. 56(a)(2)) is amended—

17              (1) in subparagraph (D), by striking “or” after  
18      the semicolon;

19              (2) in subparagraph (E), by inserting “or”  
20      after the semicolon; and

21              (3) by inserting after subparagraph (E) the fol-  
22      lowing:

23                      “(F) under section 311(d)(3)(A) of the  
24      Lower Drug Costs Now Act of 2019;”.

1 **SEC. 315. STATUTE OF LIMITATIONS.**

2 (a) IN GENERAL.—Except as provided in subsection  
3 (b), the Commission shall commence any administrative  
4 proceeding or civil action to enforce section 311 of this  
5 Act not later than 6 years after the date on which the  
6 parties to the agreement file the Notice of Agreement as  
7 provided by section 1112(c)(2) and (d) of the Medicare  
8 Prescription Drug, Improvement, and Modernization Act  
9 of 2003 (21 U.S.C. 355 note).

10 (b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND  
11 DESIST ORDER.—If the Commission has issued a cease  
12 and desist order under section 5 of the Federal Trade  
13 Commission Act (15 U.S.C. 45) for violation of section  
14 311 of this Act and the proceeding for the issuance of  
15 such order was commenced within the period required by  
16 subsection (a) of this section, such subsection does not  
17 prohibit the commencement, after such period, of a civil  
18 action under section 311(d)(3)(A) against a party to such  
19 order or a civil action under subsection (l) of such section  
20 5 for violation of such order.

21 **Subtitle C—BLOCKING Act**

22 **SEC. 321. CHANGE CONDITIONS OF FIRST GENERIC EXCLU-**  
23 **SIVITY TO SPUR ACCESS AND COMPETITION.**

24 Section 505(j)(5)(B)(iv) of the Federal Food, Drug,  
25 and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amend-  
26 ed—

1           (1) in subclause (I), by striking “180 days  
2 after” and all that follows through the period at the  
3 end and inserting the following: “180 days after the  
4 earlier of—

5                           “(aa) the date of the first com-  
6                           mercial marketing of the drug (includ-  
7                           ing the commercial marketing of the  
8                           listed drug) by any first applicant; or

9                           “(bb) the applicable date speci-  
10                           fied in subclause (III).”; and

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

13                           “(III) APPLICABLE DATE.—The appli-  
14                           cable date specified in this subclause, with  
15                           respect to an application for a drug de-  
16                           scribed in subclause (I), is the date on  
17                           which each of the following conditions is  
18                           first met:

19                                   “(aa) The approval of such an  
20                                   application could be made effective,  
21                                   but for the eligibility of a first appli-  
22                                   cant for 180-day exclusivity under  
23                                   this clause.

24                                   “(bb) At least 30 months have  
25                                   passed since the date of submission of

1 an application for the drug by at least  
2 one first applicant.

3 “(cc) Approval of an application  
4 for the drug submitted by at least one  
5 first applicant is not precluded under  
6 clause (iii).

7 “(dd) No application for the drug  
8 submitted by any first applicant is ap-  
9 proved at the time the conditions  
10 under items (aa), (bb), and (cc) are  
11 all met, regardless of whether such an  
12 application is subsequently ap-  
13 proved.”.

## 14 **Subtitle D—Purple Book**

### 15 **SEC. 331. PUBLIC LISTING.**

16 Section 351(k) of the Public Health Service Act (42  
17 U.S.C. 262(k)) is amended by adding at the end the fol-  
18 lowing:

19 “(9) PUBLIC LISTING.—

20 “(A) IN GENERAL.—

21 “(i) INITIAL PUBLICATION.—Not later  
22 than 180 days after the date of enactment  
23 of the Lower Drug Costs Now Act 2019,  
24 the Secretary shall publish and make avail-

1           able to the public in a searchable, elec-  
2           tronic format—

3                   “(I) a list in alphabetical order of  
4                   the nonproprietary or proper name of  
5                   each biological product for which a  
6                   biologics license under subsection (a)  
7                   or this subsection is in effect, or that  
8                   has been deemed to be licensed under  
9                   this section pursuant to section  
10                  7002(e)(4) of the Biologics Price  
11                  Competition and Innovation Act of  
12                  2009, as of such date of enactment;

13                   “(II) the date of approval of the  
14                   marketing application and the applica-  
15                   tion number; and

16                   “(III) the marketing or licensure  
17                   status of the biological product for  
18                   which a biologics license under sub-  
19                   section (a) or this subsection is in ef-  
20                   fect or that has been deemed to be li-  
21                   censed under this section pursuant to  
22                   section 7002(e)(4) of the Biologics  
23                   Price Competition and Innovation Act  
24                   of 2009.

1           “(ii) REVISIONS.—Every 30 days  
2 after the publication of the first list under  
3 clause (i), the Secretary shall revise the list  
4 to include each biological product which  
5 has been licensed under subsection (a) or  
6 this subsection during the 30-day period.

7           “(iii) PATENT INFORMATION.—Not  
8 later than 30 days after a list of patents  
9 under subsection (l)(3)(A), or a supple-  
10 ment to such list under subsection (l)(7),  
11 has been provided by the reference product  
12 sponsor to the subsection (k) applicant re-  
13 specting a biological product included on  
14 the list published under this subparagraph,  
15 the reference product sponsor shall provide  
16 such list of patents (or supplement there-  
17 to) and their corresponding expiry dates to  
18 the Secretary, and the Secretary shall, in  
19 revisions made under clause (ii), include  
20 such information for such biological prod-  
21 uct. Within 30 days of providing any sub-  
22 sequent or supplemental list of patents to  
23 any subsequent subsection (k) applicant  
24 under subsection (l)(3)(A) or (l)(7), the  
25 reference product sponsor shall update the

1 information provided to the Secretary  
2 under this clause with any additional pat-  
3 ents from such subsequent or supplemental  
4 list and their corresponding expiry dates.

5 “(iv) LISTING OF EXCLUSIVITIES.—  
6 For each biological product included on the  
7 list published under this subparagraph, the  
8 Secretary shall specify each exclusivity pe-  
9 riod that is applicable and has not con-  
10 cluded under paragraph (6) or paragraph  
11 (7).

12 “(B) WITHDRAWAL OR SUSPENSION OF LI-  
13 CENSURE.—If the licensing of a biological prod-  
14 uct was withdrawn or suspended for safety, pu-  
15 rity, or potency reasons, it may not be pub-  
16 lished in the list under subparagraph (A). If the  
17 withdrawal or suspension occurred after its  
18 publication in such list, the reference product  
19 sponsor shall notify the Secretary that—

20 “(i) the biological product shall be im-  
21 mediately removed from such list—

22 “(I) for the same period as the  
23 withdrawal or suspension; or

24 “(II) if the biological product has  
25 been withdrawn from sale, for the pe-

1                   riod of withdrawal from sale or, if ear-  
2                   lier, the period ending on the date the  
3                   Secretary determines that the with-  
4                   drawal from sale is not for safety, pu-  
5                   rity, or potency reasons; and

6                   “(ii) a notice of the removal shall be  
7                   published in the Federal Register.”.

8   **SEC. 332. REVIEW AND REPORT ON TYPES OF INFORMA-**  
9                   **TION TO BE LISTED.**

10           Not later than 3 years after the date of enactment  
11 of this Act, the Secretary of Health and Human Services  
12 shall—

13                   (1) solicit public comment regarding the type of  
14                   information, if any, that should be added to or re-  
15                   moved from the list required by paragraph (9) of  
16                   section 351(k) of the Public Health Service Act (42  
17                   U.S.C. 262(k)), as added by section 331; and

18                   (2) transmit to Congress an evaluation of such  
19                   comments, including any recommendations about the  
20                   types of information that should be added to or re-  
21                   moved from the list.

22                   **Subtitle E—Orange Book**

23   **SEC. 341. ORANGE BOOK.**

24           (a) SUBMISSION OF PATENT INFORMATION FOR  
25 BRAND NAME DRUGS.—Paragraph (1) of section 505(b)

1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
2 355(b)) is amended to read as follows:

3 “(b)(1) Any person may file with the Secretary an  
4 application with respect to any drug subject to the provi-  
5 sions of subsection (a). Such persons shall submit to the  
6 Secretary as part of the application—

7 “(A) full reports of investigations which have  
8 been made to show whether or not such drug is safe  
9 for use and whether such drug is effective in use;

10 “(B) a full list of the articles used as compo-  
11 nents of such drug;

12 “(C) a full statement of the composition of such  
13 drug;

14 “(D) a full description of the methods used in,  
15 and the facilities and controls used for, the manufac-  
16 ture, processing, and packing of such drug;

17 “(E) such samples of such drug and of the arti-  
18 cles used as components thereof as the Secretary  
19 may require;

20 “(F) specimens of the labeling proposed to be  
21 used for such drug;

22 “(G) any assessments required under section  
23 505B; and

24 “(H) patent information, with respect to each  
25 patent for which a claim of patent infringement

1       could reasonably be asserted if a person not licensed  
2       by the owner engaged in the manufacture, use, or  
3       sale of the drug, and consistent with the following  
4       requirements:

5               “(i) The applicant shall file with the appli-  
6               cation the patent number and the expiration  
7               date of—

8                       “(I) any patent which claims the drug  
9                       for which the applicant submitted the ap-  
10                      plication and is a drug substance (includ-  
11                      ing active ingredient) patent or a drug  
12                      product (including formulation and com-  
13                      position) patent; and

14                     “(II) any patent which claims the  
15                     method of using such drug.

16               “(ii) If an application is filed under this  
17               subsection for a drug and a patent of the type  
18               described in clause (i) which claims such drug  
19               or a method of using such drug is issued after  
20               the filing date but before approval of the appli-  
21               cation, the applicant shall amend the applica-  
22               tion to include such patent information.

23    Upon approval of the application, the Secretary shall pub-  
24    lish the information submitted under subparagraph (H).

25    The Secretary shall, in consultation with the Director of

1 the National Institutes of Health and with representatives  
2 of the drug manufacturing industry, review and develop  
3 guidance, as appropriate, on the inclusion of women and  
4 minorities in clinical trials required by subparagraph  
5 (A).”.

6 (b) CONFORMING CHANGES TO REQUIREMENTS FOR  
7 SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—  
8 Section 505(c)(2) of the Federal Food, Drug, and Cos-  
9 metic Act (21 U.S.C. 355(j)(7)) is amended—

10 (1) by inserting after “the patent number and  
11 the expiration date of any patent which” the fol-  
12 lowing: “fulfills the criteria in subsection (b) and”;

13 (2) by inserting after the first sentence the fol-  
14 lowing: “Patent information that is not the type of  
15 patent information required by subsection (b) shall  
16 not be submitted.”; and

17 (3) by inserting after “could not file patent in-  
18 formation under subsection (b) because no patent”  
19 the following: “of the type required to be submitted  
20 in subsection (b)”.

21 (c) LISTING OF EXCLUSIVITIES.—Subparagraph (A)  
22 of section 505(j)(7) of the Federal Food, Drug, and Cos-  
23 metic Act (21 U.S.C. 355(j)(7)) is amended by adding at  
24 the end the following:

1           “(iv) For each drug included on the list, the Sec-  
2   retary shall specify each exclusivity period that is applica-  
3   ble and has not concluded under—

4           “(I) clause (ii), (iii), or (iv) of subsection  
5   (c)(3)(E) of this section;

6           “(II) clause (iv) or (v) of paragraph (5)(B) of  
7   this subsection;

8           “(III) clause (ii), (iii), or (iv) of paragraph  
9   (5)(F) of this subsection;

10          “(IV) section 505A;

11          “(V) section 505E; or

12          “(VI) section 527(a).”.

13          (d) REMOVAL OF INVALID PATENTS.—

14           (1) IN GENERAL.—Section 505(j)(7) of the  
15   Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
16   355(j)(7)) is amended by adding at the end the fol-  
17   lowing:

18          “(D)(i) The holder of an application approved under  
19   subsection (c) for a drug on the list shall notify within  
20   14 days the Secretary in writing if either of the following  
21   occurs:

22           “(I) The Patent Trial and Appeals Board issues  
23   a decision from which no appeal has been or can be  
24   taken that a patent for such drug is invalid.

1           “(II) A court issues a decision from which no  
2           appeal has been or can be taken that a patent for  
3           such drug is invalid.

4           “(ii) The holder of an approved application shall in-  
5           clude in any notification under clause (i) a copy of the  
6           decision described in subclause (I) or (II) of clause (i).

7           “(iii) The Secretary shall remove from the list any  
8           patent that is determined to be invalid in a decision de-  
9           scribed in subclause (I) or (II) of clause (i)—

10           “(I) promptly; but

11           “(II) not before the expiration of any 180-day  
12           exclusivity period under paragraph (5)(B)(iv) that  
13           relies on a certification described in paragraph  
14           (2)(A)(vii)(IV) that such patent was invalid.”.

15           (2) APPLICABILITY.—Subparagraph (D) of sec-  
16           tion 505(j)(7) of the Federal Food, Drug, and Cos-  
17           metic Act (21 U.S.C. 355(j)(7)), as added by para-  
18           graph (1), applies only with respect to a decision de-  
19           scribed in such subparagraph that is issued on or  
20           after the date of enactment of this Act.

21           (e) REVIEW AND REPORT.—Not later than one year  
22           after the date of enactment of this Act, the Secretary of  
23           Health and Human Services, acting through the Commis-  
24           sioner of Food and Drugs, shall—

1           (1) solicit public comment regarding the types  
2           of patent information that should be included on the  
3           list under section 507(j)(7) of the Federal Food,  
4           Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)); and

5           (2) transmit to the Congress an evaluation of  
6           such comments, including any recommendations  
7           about the types of patent information that should be  
8           included on or removed from such list.

9   **SEC. 342. GAO REPORT TO CONGRESS.**

10          (a) IN GENERAL.—Not later than one year after the  
11          date of enactment of this Act, the Comptroller General  
12          of the United States (referred to in this section as the  
13          “Comptroller General”) shall submit to the Committee on  
14          Energy and Commerce of the House of Representatives  
15          a report on the patents included in the list published under  
16          section 505(j)(7) of the Federal Food, Drug and Cosmetic  
17          Act (21 U.S.C. 355(j)(7)), including an analysis and eval-  
18          uation of the types of patents included in such list and  
19          the claims such patents make about the products they  
20          claim.

21          (b) CONTENTS.—The Comptroller General shall in-  
22          clude in the report under subsection (a)—

23                  (1) data on the number of—

24                          (A) patents included in the list published  
25                          under paragraph (7) of section 505(j) of the

1 Federal Food, Drug and Cosmetic Act (21  
2 U.S.C. 355(j)), that claim the active ingredient  
3 or formulation of a drug in combination with a  
4 device that is used for delivery of the drug, to-  
5 gether comprising the finished dosage form of  
6 the drug; and

7 (B) claims in each patent that claim a de-  
8 vice that is used for the delivery of the drug,  
9 but do not claim such device in combination  
10 with an active ingredient or formulation of a  
11 drug;

12 (2) data on the date of inclusion in the list  
13 under paragraph (7) of such section 505(j) for all  
14 patents under such list, as compared to patents that  
15 claim a method of using the drug in combination  
16 with a device;

17 (3) an analysis regarding the impact of includ-  
18 ing on the list under paragraph (7) of such section  
19 505(j) certain types of patent information for drug  
20 product applicants and approved application holders,  
21 including an analysis of whether—

22 (A) the listing of the patents described in  
23 paragraph (1)(A) delayed the market entry of  
24 one or more drugs approved under such section  
25 505(j); and

1 (B) not listing the patents described in  
2 paragraph (1)(A) would delay the market entry  
3 of one or more such drugs; and

4 (4) recommendations about which kinds of pat-  
5 ents relating to devices described in paragraph  
6 (1)(A) should be submitted to the Secretary of  
7 Health and Human Services for inclusion on the list  
8 under paragraph (7) of such section 505(j) and  
9 which patents should not be required to be so sub-  
10 mitted.

## 11 **Subtitle F—Advancing Education** 12 **on Biosimilars**

### 13 **SEC. 351. EDUCATION ON BIOLOGICAL PRODUCTS.**

14 (a) WEBSITE; CONTINUING EDUCATION.—Subpart 1  
15 of part F of title III of the Public Health Service Act (42  
16 U.S.C. 262 et seq.) is amended by adding at the end the  
17 following:

#### 18 **“SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.**

19 “(a) INTERNET WEBSITE.—

20 “(1) IN GENERAL.—The Secretary shall main-  
21 tain and operate an internet website to provide edu-  
22 cational materials for health care providers, patients,  
23 and caregivers, regarding the meaning of the terms,  
24 and the standards for review and licensing of, bio-  
25 logical products, including biosimilar biological prod-

1       ucts and interchangeable biosimilar biological prod-  
2       ucts.

3           “(2) CONTENT.—Educational materials pro-  
4       vided under paragraph (1) may include—

5           “(A) explanations of key statutory and  
6       regulatory terms, including ‘biosimilar’ and  
7       ‘interchangeable’, and clarification regarding  
8       the use of interchangeable biosimilar biological  
9       products;

10          “(B) information related to development  
11       programs for biological products, including bio-  
12       similar biological products and interchangeable  
13       biosimilar biological products and relevant clin-  
14       ical considerations for prescribers, which may  
15       include, as appropriate and applicable, informa-  
16       tion related to the comparability of such biologi-  
17       cal products;

18          “(C) an explanation of the process for re-  
19       porting adverse events for biological products,  
20       including biosimilar biological products and  
21       interchangeable biosimilar biological products;  
22       and

23          “(D) an explanation of the relationship be-  
24       tween biosimilar biological products and inter-  
25       changeable biosimilar biological products li-

1 censed under section 351(k) and reference  
2 products (as defined in section 351(i)), includ-  
3 ing the standards for review and licensing of  
4 each such type of biological product.

5 “(3) FORMAT.—The educational materials pro-  
6 vided under paragraph (1) may be—

7 “(A) in formats such as webinars, con-  
8 tinuing medical education modules, videos, fact  
9 sheets, infographics, stakeholder toolkits, or  
10 other formats as appropriate and applicable;  
11 and

12 “(B) tailored for the unique needs of  
13 health care providers, patients, caregivers, and  
14 other audiences, as the Secretary determines  
15 appropriate.

16 “(4) OTHER INFORMATION.—In addition to the  
17 information described in paragraph (2), the Sec-  
18 retary shall continue to publish the following infor-  
19 mation:

20 “(A) The action package of each biological  
21 product licensed under subsection (a) or (k).

22 “(B) The summary review of each biologi-  
23 cal product licensed under subsection (a) or (k).

24 “(5) CONFIDENTIAL AND TRADE SECRET IN-  
25 FORMATION.—This subsection does not authorize

1 the disclosure of any trade secret, confidential com-  
2 mercial or financial information, or other matter de-  
3 scribed in section 552(b) of title 5.

4 “(b) CONTINUING EDUCATION.—The Secretary shall  
5 advance education and awareness among health care pro-  
6 viders regarding biological products, including biosimilar  
7 biological products and interchangeable biosimilar biologi-  
8 cal products, as appropriate, including by developing or  
9 improving continuing education programs that advance  
10 the education of such providers on the prescribing of, and  
11 relevant clinical considerations with respect to, biological  
12 products, including biosimilar biological products and  
13 interchangeable biosimilar biological products.”.

14 (b) APPLICATION UNDER THE MEDICARE MERIT-  
15 BASED INCENTIVE PAYMENT SYSTEM.—Section  
16 1848(q)(5)(C) of the Social Security Act (42 U.S.C.  
17 1395w–4(q)(5)(C)) is amended by adding at the end the  
18 following new clause:

19 “(iv) CLINICAL MEDICAL EDUCATION  
20 PROGRAM ON BIOSIMILAR BIOLOGICAL  
21 PRODUCTS.—Completion of a clinical med-  
22 ical education program developed or im-  
23 proved under section 352A(b) of the Public  
24 Health Service Act by a MIPS eligible pro-  
25 fessional during a performance period shall

1           earn such eligible professional one-half of  
2           the highest potential score for the perform-  
3           ance category described in paragraph  
4           (2)(A)(iii) for such performance period. A  
5           MIPS eligible professional may only count  
6           the completion of such a program for pur-  
7           poses of such category one time during the  
8           eligible professional’s lifetime.”.

## 9           **TITLE IV—NO SURPRISES ACT**

### 10       **SEC. 401. SHORT TITLE.**

11           This title may be cited as the “No Surprises Act”.

### 12       **SEC. 402. PREVENTING SURPRISE MEDICAL BILLS.**

13           (a) **COVERAGE OF EMERGENCY SERVICES.**—Section  
14       2719A(b) of the Public Health Service Act (42 U.S.C.  
15       300gg–19a(b)) is amended—

16                   (1) in paragraph (1)—

17                           (A) in the matter preceding subparagraph

18                           (A)—

19                                   (i) by striking “a group health plan,  
20                                   or a health insurance issuer offering group  
21                                   or individual health insurance issuer,” and  
22                                   inserting “a health plan (as defined in sub-  
23                                   section (e)(2)(A))”;

24                                   (ii) by inserting “or, for plan year  
25                                   2021 or a subsequent plan year, with re-

1           spect to emergency services in an inde-  
2           pendent freestanding emergency depart-  
3           ment (as defined in paragraph (3)(D))”  
4           after “emergency department of a hos-  
5           pital”;

6                     (iii) by striking “the plan or issuer”  
7                     and inserting “the plan”; and

8                     (iv) by striking “paragraph (2)(B)”  
9                     and inserting “paragraph (3)(C)”;

10                    (B) in subparagraph (B), by inserting “or  
11                    a participating emergency facility, as applica-  
12                    ble,” after “participating provider”; and

13                    (C) in subparagraph (C)—

14                             (i) in the matter preceding clause (i),  
15                             by inserting “by a nonparticipating pro-  
16                             vider or a nonparticipating emergency fa-  
17                             cility” after “enrollee”;

18                             (ii) by striking clause (i);

19                             (iii) by striking “(ii)(I) such services”  
20                             and inserting “(i) such services”;

21                             (iv) by striking “where the provider of  
22                             services does not have a contractual rela-  
23                             tionship with the plan for the providing of  
24                             services”;

1 (v) by striking “emergency depart-  
2 ment services received from providers who  
3 do have such a contractual relationship  
4 with the plan; and” and inserting “emer-  
5 gency services received from participating  
6 providers and participating emergency fa-  
7 cilities with respect to such plan;”;

8 (vi) by striking “(II) if such services”  
9 and all that follows through “were pro-  
10 vided in-network;” and inserting the fol-  
11 lowing:

12 “(ii) the cost-sharing requirement (ex-  
13 pressed as a copayment amount or coinsur-  
14 ance rate) is not greater than the require-  
15 ment that would apply if such services  
16 were provided by a participating provider  
17 or a participating emergency facility;”;

18 (vii) by adding at the end the fol-  
19 lowing new clauses:

20 “(iii) such requirement is calculated  
21 as if the total amount that would have  
22 been charged for such services by such  
23 participating provider or participating  
24 emergency facility were equal to—

1                   “(I) in the case of such services  
2                   furnished in a State described in  
3                   paragraph (3)(H)(ii), the median con-  
4                   tracted rate (as defined in paragraph  
5                   (3)(E)(i)) for such services; and

6                   “(II) in the case of such services  
7                   furnished in a State described in  
8                   paragraph (3)(H)(i), the lesser of—

9                   “(aa) the amount deter-  
10                  mined by such State for such  
11                  services in accordance with the  
12                  method described in such para-  
13                  graph; and

14                  “(bb) the median contracted  
15                  rate (as so defined) for such  
16                  services;

17                  “(iv) the health plan pays to such pro-  
18                  vider or facility, respectively, the amount  
19                  by which the recognized amount (as de-  
20                  fined in paragraph (3)(H)) for such serv-  
21                  ices exceeds the cost-sharing amount for  
22                  such services (as determined in accordance  
23                  with clauses (ii) and (iii)); and

24                  “(v) any cost-sharing payments made  
25                  by the participant, beneficiary, or enrollee

1 with respect to such emergency services so  
2 furnished shall be counted toward any in-  
3 network deductible or out-of-pocket maxi-  
4 mums applied under the plan (and such in-  
5 network deductible shall be applied) in the  
6 same manner as if such cost-sharing pay-  
7 ments were with respect to emergency  
8 services furnished by a participating pro-  
9 vider and a participating emergency facil-  
10 ity; and”;

11 (2) by redesignating paragraph (2) as para-  
12 graph (3);

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

15 “(2) AUDIT PROCESS FOR MEDIAN CON-  
16 TRACTED RATES.—

17 “(A) IN GENERAL.—Not later than July 1,  
18 2020, the Secretary, in consultation with appro-  
19 priate State agencies, shall establish through  
20 rulemaking a process, in accordance with sub-  
21 paragraph (B), under which health plans are  
22 audited by such Secretaries to ensure that—

23 “(i) such plans are in compliance with  
24 the requirement of applying a median con-  
25 tracted rate under this section; and

1           “(ii) that such median contracted rate  
2           so applied satisfies the definition under  
3           paragraph (3)(E) with respect to the year  
4           involved, including with respect to a health  
5           plan described in clause (ii) of such para-  
6           graph.

7           “(B) AUDIT SAMPLES.—Under the process  
8           established pursuant to subparagraph (A), the  
9           Secretary—

10           “(i) shall conduct audits described in  
11           such subparagraph, with respect to a year  
12           (beginning with 2021), of a sample with  
13           respect to such year of claims data from  
14           not more than 25 health plans; and

15           “(ii) may audit any health plan if the  
16           Secretary has received any complaint about  
17           such plan that involves the compliance of  
18           the plan with either of the requirements  
19           described in clauses (i) and (ii) of such  
20           subparagraph.”; and

21           (4) in paragraph (3), as redesignated by para-  
22           graph (2) of this subsection—

23           (A) in the matter preceding subparagraph  
24           (A), by inserting “and subsection (e)” after  
25           “this subsection”;

1 (B) by redesignating subparagraphs (A)  
2 through (C) as subparagraphs (B) through (D),  
3 respectively;

4 (C) by inserting before subparagraph (B),  
5 as redesignated by subparagraph (B) of this  
6 paragraph, the following new subparagraph:

7 “(A) EMERGENCY DEPARTMENT OF A HOS-  
8 PITAL.—The term ‘emergency department of a  
9 hospital’ includes a hospital outpatient depart-  
10 ment that provides emergency services.”;

11 (D) by amending subparagraph (C), as re-  
12 designated by subparagraph (B) of this para-  
13 graph, to read as follows:

14 “(C) EMERGENCY SERVICES.—

15 “(i) IN GENERAL.—The term ‘emer-  
16 gency services’, with respect to an emer-  
17 gency medical condition, means—

18 “(I) a medical screening exam-  
19 ination (as required under section  
20 1867 of the Social Security Act, or as  
21 would be required under such section  
22 if such section applied to an inde-  
23 pendent freestanding emergency de-  
24 partment) that is within the capability  
25 of the emergency department of a hos-

1           pital or of an independent free-  
2           standing emergency department, as  
3           applicable, including ancillary services  
4           routinely available to the emergency  
5           department to evaluate such emer-  
6           gency medical condition; and

7                   “(II) within the capabilities of  
8           the staff and facilities available at the  
9           hospital or the independent free-  
10          standing emergency department, as  
11          applicable, such further medical exam-  
12          ination and treatment as are required  
13          under section 1867 of such Act, or as  
14          would be required under such section  
15          if such section applied to an inde-  
16          pendent freestanding emergency de-  
17          partment, to stabilize the patient.

18                   “(ii)           INCLUSION           OF  
19          POSTSTABILIZATION SERVICES.—For pur-  
20          poses of this subsection and section 2799,  
21          in the case of an individual enrolled in a  
22          health plan who is furnished services de-  
23          scribed in clause (i) by a provider or facil-  
24          ity to stabilize such individual with respect  
25          to an emergency medical condition, the

1 term ‘emergency services’ shall include  
2 such items and services in addition to  
3 those described in clause (i) that such a  
4 provider or facility determines are needed  
5 to be furnished (after such stabilization  
6 but during such visit in which such indi-  
7 vidual is so stabilized) to such individual,  
8 unless each of the following conditions are  
9 met:

10 “(I) Such a provider or facility  
11 determines such individual is able to  
12 travel using nonmedical transpor-  
13 tation or nonemergency medical trans-  
14 portation.

15 “(II) Such provider furnishing  
16 such additional items and services is  
17 in compliance with section 2799A(d)  
18 with respect to such items and serv-  
19 ices.”;

20 (E) by redesignating subparagraph (D), as  
21 redesignated by subparagraph (B) of this para-  
22 graph, as subparagraph (I); and

23 (F) by inserting after subparagraph (C),  
24 as redesignated by subparagraph (B) of this  
25 paragraph, the following new subparagraphs:

1           “(D) INDEPENDENT FREESTANDING  
2 EMERGENCY DEPARTMENT.—The term ‘inde-  
3 pendent freestanding emergency department’  
4 means a facility that—

5           “(i) is geographically separate and  
6 distinct and licensed separately from a hos-  
7 pital under applicable State law; and

8           “(ii) provides emergency services.

9           “(E) MEDIAN CONTRACTED RATE.—

10           “(i) IN GENERAL.—The term ‘median  
11 contracted rate’ means, with respect to an  
12 item or service and a health plan (as de-  
13 fined in subsection (e)(2)(A))—

14           “(I) for 2021, the median of the  
15 negotiated rates recognized by the  
16 sponsor or issuer of such plan (deter-  
17 mined with respect to all such plans  
18 of such sponsor or such issuer that  
19 are within the same line of business)  
20 as the total maximum payment (in-  
21 cluding the cost-sharing amount im-  
22 posed for such services (as determined  
23 in accordance with clauses (ii) and  
24 (iii) of paragraph (1)(C) or subpara-  
25 graphs (A) and (B) of subsection

1 (e)(1), as applicable) and the amount  
2 to be paid by the plan or issuer)  
3 under such plans in 2019 for the  
4 same or a similar item or service that  
5 is provided by a provider in the same  
6 or similar specialty and provided in  
7 the geographic region in which the  
8 item or service is furnished, consistent  
9 with the methodology established by  
10 the Secretary under section 402(e) of  
11 the No Surprises Act, increased by  
12 the percentage increase in the con-  
13 sumer price index for all urban con-  
14 sumers (United States city average)  
15 over 2019 and 2020; and

16 “(II) for 2022 and each subse-  
17 quent year, the median contracted  
18 rate determined under this clause for  
19 the previous year, increased by the  
20 percentage increase in the consumer  
21 price index for all urban consumers  
22 (United States city average) over such  
23 previous year.

24 “(ii) SPECIAL RULE.—The Secretary  
25 shall provide pursuant to rulemaking de-

1                   scribed in section 402(e) of the No Sur-  
2                   prises Act that—

3                   “ (I) if the sponsor or issuer of a  
4                   health plan does not have sufficient  
5                   information to calculate a median con-  
6                   tracted rate for an item or service or  
7                   provider type, or amount of, claims  
8                   for items or services (as determined  
9                   by the Secretary) provided in a par-  
10                  ticular geographic area (other than in  
11                  a case described in item (bb)), such  
12                  sponsor or issuer shall demonstrate  
13                  that such sponsor or issuer will use  
14                  any database free of conflicts of inter-  
15                  est that has sufficient information re-  
16                  flecting allowed amounts paid to a  
17                  health care provider for relevant serv-  
18                  ices provided in the applicable geo-  
19                  graphic region (such as State All  
20                  Payer Claims Databases (as defined  
21                  in section 404(d) of such Act)), and  
22                  that such sponsor or issuer will use  
23                  any such database to determine a me-  
24                  dian contracted rate and cover the

1 cost of accessing any such database;  
2 and

3 “(II) in the case of a sponsor or  
4 issuer offering a health plan in a geo-  
5 graphic region that did not offer any  
6 health plan in such region during  
7 2019, such sponsor or issuer shall use  
8 a methodology established by the Sec-  
9 retary for determining the median  
10 contracted rate for items and services  
11 covered by such plan for the first year  
12 in which such plan is offered in such  
13 region, and that, for each succeeding  
14 year, the median contracted rate for  
15 such items and services under such  
16 plan shall be the median contracted  
17 rate for such items and services under  
18 such plan for the previous year, in-  
19 creased by the percentage increase in  
20 the consumer price index for all urban  
21 consumers (United States city aver-  
22 age) over such previous year.

23 “(F) NONPARTICIPATING EMERGENCY FA-  
24 CILITY; PARTICIPATING EMERGENCY FACIL-  
25 ITY.—

1           “(i) NONPARTICIPATING EMERGENCY  
2 FACILITY.—The term ‘nonparticipating  
3 emergency facility’ means, with respect to  
4 an item or service and a health plan, an  
5 emergency department of a hospital, or an  
6 independent freestanding emergency de-  
7 partment, that does not have a contractual  
8 relationship with the plan (or, if applicable,  
9 issuer offering the plan) for furnishing  
10 such item or service under the plan.

11           “(ii) PARTICIPATING EMERGENCY FA-  
12 CILITY.—The term ‘participating emer-  
13 gency facility’ means, with respect to an  
14 item or service and a health plan, an emer-  
15 gency department of a hospital, or an inde-  
16 pendent freestanding emergency depart-  
17 ment, that has a contractual relationship  
18 with the plan (or, if applicable, issuer of-  
19 fering the plan) for furnishing such item  
20 or service under the plan.

21           “(G) NONPARTICIPATING PROVIDERS; PAR-  
22 TICIPATING PROVIDERS.—

23           “(i) NONPARTICIPATING PROVIDER.—  
24 The term ‘nonparticipating provider’  
25 means, with respect to an item or service

1 and a health plan, a physician or other  
2 health care provider who is acting within  
3 the scope of practice of that provider’s li-  
4 cense or certification under applicable  
5 State law and who does not have a con-  
6 tractual relationship with the plan (or, if  
7 applicable, issuer offering the plan) for  
8 furnishing such item or service under the  
9 plan.

10 “(ii) PARTICIPATING PROVIDER.—The  
11 term ‘participating provider’ means, with  
12 respect to an item or service and a health  
13 plan, a physician or other health care pro-  
14 vider who is acting within the scope of  
15 practice of that provider’s license or certifi-  
16 cation under applicable State law and who  
17 has a contractual relationship with the  
18 plan (or, if applicable, issuer offering the  
19 plan) for furnishing such item or service  
20 under the plan.

21 “(H) RECOGNIZED AMOUNT.—The term  
22 ‘recognized amount’ means, with respect to an  
23 item or service—

24 “(i) in the case of such item or service  
25 furnished in a State that has in effect a

1 State law that provides for a method for  
2 determining the amount of payment that is  
3 required to be covered by a health plan  
4 regulated by such State in the case of a  
5 participant, beneficiary, or enrollee covered  
6 under such plan and receiving such item or  
7 service from a nonparticipating provider or  
8 facility, not more than the amount deter-  
9 mined in accordance with such law plus  
10 the cost-sharing amount imposed under the  
11 plan for such item or service (as deter-  
12 mined in accordance with clauses (ii) and  
13 (iii) of paragraph (1)(C) or subparagraphs  
14 (A) and (B) of subsection (e)(1), as appli-  
15 cable); or

16 “(ii) in the case of such item or serv-  
17 ice furnished in a State that does not have  
18 in effect such a law, an amount that is at  
19 least the median contracted rate (as de-  
20 fined in subparagraph (E)(i) and deter-  
21 mined in accordance with rulemaking de-  
22 scribed in section 402(e) of the No Sur-  
23 prises Act) for such item or service.”.

24 (b) COVERAGE OF NON-EMERGENCY SERVICES PER-  
25 FORMED BY NONPARTICIPATING PROVIDERS AT CERTAIN

1 PARTICIPATING FACILITIES; INDEPENDENT DISPUTE  
2 RESOLUTION PROCESS.—Section 2719A of the Public  
3 Health Service Act (42 U.S.C. 300gg–19a) is amended by  
4 adding at the end the following new subsections:

5 “(e) COVERAGE OF NON-EMERGENCY SERVICES PER-  
6 FORMED BY NONPARTICIPATING PROVIDERS AT CERTAIN  
7 PARTICIPATING FACILITIES.—

8 “(1) IN GENERAL.—Subject to paragraph (3),  
9 in the case of items or services (other than emer-  
10 gency services to which subsection (b) applies) fur-  
11 nished to a participant, beneficiary, or enrollee of a  
12 health plan (as defined in paragraph (2)(A)) by a  
13 nonparticipating provider (as defined in subsection  
14 (b)(3)(G)(i)) during a visit (as defined by the Sec-  
15 retary in accordance with paragraph (2)(C)) at a  
16 participating health care facility (as defined in para-  
17 graph (2)(B)), with respect to such plan, the plan—

18 “(A) shall not impose on such participant,  
19 beneficiary, or enrollee a cost-sharing amount  
20 (expressed as a copayment amount or coinsur-  
21 ance rate) for such items and services so fur-  
22 nished that is greater than the cost-sharing  
23 amount that would apply under such plan had  
24 such items or services been furnished by a par-

1            participating provider (as defined in subsection  
2            (b)(3)(G)(ii));

3            “(B) shall calculate such cost-sharing  
4            amount as if the amount that would have been  
5            charged for such items and services by such  
6            participating provider were equal to—

7            “(i) in the case of such items and  
8            services furnished in a State described in  
9            subsection (b)(3)(H)(ii), the median con-  
10            tracted rate (as defined in subsection  
11            (b)(3)(E)(i)) for such items and services;  
12            and

13            “(ii) in the case of such items and  
14            services furnished in a State described in  
15            subsection (b)(3)(H)(i), the lesser of—

16            “(I) the amount determined by  
17            such State for such items and services  
18            in accordance with the method de-  
19            scribed in such subsection; and

20            “(II) the median contracted rate  
21            (as so defined) for such items and  
22            services;

23            “(C) shall pay to such provider furnishing  
24            such items and services to such participant,  
25            beneficiary, or enrollee the amount by which the

1 recognized amount (as defined in subsection  
2 (b)(3)(H)) for such items and services exceeds  
3 the cost-sharing amount imposed under the  
4 plan for such items and services (as determined  
5 in accordance with subparagraphs (A) and (B));  
6 and

7 “(D) shall count toward any in-network  
8 deductible or out-of-pocket maximums applied  
9 under the plan any cost-sharing payments made  
10 by the participant, beneficiary, or enrollee (and  
11 such in-network deductible shall be applied)  
12 with respect to such items and services so fur-  
13 nished in the same manner as if such cost-shar-  
14 ing payments were with respect to items and  
15 services furnished by a participating provider.

16 “(2) DEFINITIONS.—In this subsection and  
17 subsection (b):

18 “(A) HEALTH PLAN.—The term ‘health  
19 plan’ means a group health plan and health in-  
20 surance coverage offered by a health insurance  
21 issuer in the group or individual market and in-  
22 cludes a grandfathered health plan (as defined  
23 in section 1251(e) of the Patient Protection and  
24 Affordable Care Act).

1                   “(B) PARTICIPATING HEALTH CARE FACIL-  
2                   ITY.—

3                   “(i) IN GENERAL.—The term ‘partici-  
4                   pating health care facility’ means, with re-  
5                   spect to an item or service and a health  
6                   plan, a health care facility described in  
7                   clause (ii) that has a contractual relation-  
8                   ship with the plan (or, if applicable, issuer  
9                   offering the plan) for furnishing such item  
10                  or service.

11                  “(ii) HEALTH CARE FACILITY DE-  
12                  SCRIBED.—A health care facility described  
13                  in this clause is each of the following:

14                         “(I) A hospital (as defined in  
15                         1861(e) of the Social Security Act).

16                         “(II) A critical access hospital  
17                         (as defined in section 1861(mm) of  
18                         such Act).

19                         “(III) An ambulatory surgical  
20                         center (as defined in section  
21                         1833(i)(1)(A) of such Act).

22                         “(IV) A laboratory.

23                         “(V) A radiology facility or imag-  
24                         ing center.

1           “(C) DURING A VISIT.—The term ‘during  
2           a visit’ shall, with respect to items and services  
3           furnished to an individual at a participating  
4           health care facility, include equipment and de-  
5           vices, telemedicine services, imaging services,  
6           laboratory services, and such other items and  
7           services as the Secretary may specify, regard-  
8           less of whether or not the provider furnishing  
9           such items or services is at the facility.

10           “(3) EXCEPTION.—Paragraph (1) shall not  
11           apply to a health plan in the case of items or serv-  
12           ices (other than emergency services to which sub-  
13           section (b) applies) furnished to a participant, bene-  
14           ficiary, or enrollee of a health plan (as defined in  
15           paragraph (2)(A)) by a nonparticipating provider (as  
16           defined in subsection (b)(3)(G)(i)) during a visit (as  
17           defined by the Secretary in accordance with para-  
18           graph (2)(C)) at a participating health care facility  
19           (as defined in paragraph (2)(B)) if such provider is  
20           in compliance with section 2799A(d) with respect to  
21           such items and services.

22           “(f) INDEPENDENT DISPUTE RESOLUTION PROC-  
23           ESS.—

24           “(1) ESTABLISHMENT.—

1           “(A) IN GENERAL.—Not later than 1 year  
2 after the date of the enactment of this sub-  
3 section, the Secretary, in consultation with the  
4 Secretary of Labor, shall establish by regulation  
5 an independent dispute resolution process (re-  
6 ferred to in this subsection as the ‘IDR proc-  
7 ess’) under which—

8           “(i) a nonparticipating provider (as  
9 defined in subparagraph (G) of subsection  
10 (b)(3)), nonparticipating emergency facility  
11 (as defined in subparagraph (F) of such  
12 subsection), or health plan (as defined in  
13 subsection (e)(2)(A)) may submit a request  
14 for resolution by an entity certified under  
15 paragraph (2) (in this subsection referred  
16 to as a ‘certified IDR entity’) of a specified  
17 claim; and

18           “(ii) in the case a settlement de-  
19 scribed in subparagraph (B) of paragraph  
20 (4) is not reached with respect to such  
21 claim, such entity so resolves such claim in  
22 accordance with such paragraph.

23           “(B) DEFINITIONS.—In this subsection:

24           “(i) SPECIFIED CLAIM.—

1                   “(I) IN GENERAL.—Subject to  
2                   subclause (II), the term ‘specified  
3                   claim’ means a claim by a nonpartici-  
4                   pating provider, a nonparticipating  
5                   emergency facility, or a health plan  
6                   with respect to qualifying items and  
7                   services (as defined in clause (ii)) fur-  
8                   nished by such provider or facility in  
9                   a State described in subparagraph  
10                  (H)(ii) of subsection (b)(3) for which  
11                  a health plan is required to make pay-  
12                  ment pursuant to subsection (b)(1) or  
13                  subsection (e)(1)—

14                               “(aa) that such payment  
15                               should be increased or decreased;  
16                               and

17                               “(bb) that is made not later  
18                               than—

19                                       “(AA) in the case of  
20                                       such a claim filed by such a  
21                                       provider or facility, the date  
22                                       on which the appeal with re-  
23                                       spect to such items and  
24                                       services described in clause  
25                                       (ii)(I)(aa)(AA) has been re-

1                   solved (or the date that is  
2                   30 days after such appeal is  
3                   filed, whichever is earlier);  
4                   or

5                   “(BB) in the case of  
6                   such a claim filed by such  
7                   plan, the date on which the  
8                   period described in clause  
9                   (ii)(I)(bb)(BB) with respect  
10                  to such items and services  
11                  elapses.

12                  “(II) LIMITATION ON PACKAGING  
13                  OF ITEMS AND SERVICES IN A SPECI-  
14                  FIED CLAIM.—The term ‘specified  
15                  claim’ shall not include, in the case  
16                  such claim is made by such provider,  
17                  facility, or plan with respect to mul-  
18                  tiple items and services, any claim  
19                  with respect to items and services fur-  
20                  nished by such provider or facility if—

21                  “(aa) such items and serv-  
22                  ices were not furnished by the  
23                  same provider or facility;

24                  “(bb) payment for such  
25                  items and services made pursu-

1 ant to subsection (b)(1) or sub-  
2 section (e)(1) was made by mul-  
3 tiple health plans;

4 “(cc) such items and serv-  
5 ices are not related to the treat-  
6 ment of the same condition; or

7 “(dd) such items and serv-  
8 ices were not furnished within 30  
9 days of the date of the earliest  
10 item or service furnished that is  
11 included in such claim.

12 “(ii) QUALIFYING ITEMS AND SERV-  
13 ICES.—

14 “(I) IN GENERAL.—Subject to  
15 subclause (II), the term ‘qualifying  
16 items and services’ means—

17 “(aa) with respect to a spec-  
18 ified claim made by a nonpartici-  
19 pating provider or nonpartici-  
20 pating emergency facility, items  
21 and services furnished by such  
22 provider or facility for which a  
23 health plan is required to make  
24 payment pursuant to subsection

1 (b)(1) or subsection (e)(1), but  
2 only if—

3 “(AA) such items and  
4 services are included in an  
5 appeal filed under such  
6 plan’s internal appeals proc-  
7 ess not later than 30 days  
8 after such payment is re-  
9 ceived; and

10 “(BB) such appeal  
11 under such plan’s internal  
12 appeals process has been re-  
13 solved, or a 30-day period  
14 has elapsed since such ap-  
15 peal was so filed; and

16 “(bb) with respect to a spec-  
17 ified claim made by a health  
18 plan, items and services fur-  
19 nished by such a provider or fa-  
20 cility for which such health plan  
21 is required to make payment pur-  
22 suant to subsection (b)(1) or sub-  
23 section (e)(1), but only if—

24 “(AA) such plan sub-  
25 mits a notice to such pro-

1                   vider or facility not later  
2                   than 30 days after such pro-  
3                   vider or facility receives such  
4                   payment that such plan dis-  
5                   putes the amount of such  
6                   payment with respect to  
7                   such items and services; and  
8                   “(BB) a 30-day period  
9                   has elapsed since the sub-  
10                  mission of such notice.

11                  “(II) LIMITATION.—The term  
12                  ‘qualifying items and services’ shall  
13                  not include an item or service fur-  
14                  nished in a geographic area during a  
15                  year by such provider or facility for  
16                  which a health plan is required to  
17                  make payment pursuant to subsection  
18                  (b)(1) or subsection (e)(1) if the me-  
19                  dian contracted rate (as defined in  
20                  subsection (b)(3)(E)) under such plan  
21                  for such year with respect to such  
22                  item or service furnished by such a  
23                  provider or such a facility in such  
24                  area does not exceed—

1                   “(aa) with respect to an  
2                   item or service furnished during  
3                   2021, \$1,250; and

4                   “(bb) with respect to an  
5                   item or service furnished during  
6                   a subsequent year, the amount  
7                   specified under this subclause for  
8                   the previous year, increased by  
9                   the percentage increase in the  
10                  consumer price index for all  
11                  urban consumers (United States  
12                  city average) over such previous  
13                  year.

14                  “(2) CERTIFICATION OF ENTITIES.—

15                  “(A) PROCESS OF CERTIFICATION.—The  
16                  process described in paragraph (1) shall include  
17                  a certification process under which eligible enti-  
18                  ties may be certified to carry out the IDR proc-  
19                  ess.

20                  “(B) ELIGIBILITY.—

21                  “(i) IN GENERAL.—For purposes of  
22                  subparagraph (A), an eligible entity is an  
23                  entity that is a nongovernmental entity  
24                  that agrees to comply with the fee limita-  
25                  tions described in clause (ii).

1                   “(ii) FEE LIMITATION.—For purposes  
2                   of clause (i), the fee limitations described  
3                   in this clause are limitations established by  
4                   the Secretary on the amount a certified  
5                   IDR entity may charge a nonparticipating  
6                   provider, nonparticipating emergency facil-  
7                   ity, or health plan for services furnished by  
8                   such entity with respect to the resolution  
9                   of a specified claim of such provider, facil-  
10                  ity, or plan under the process described in  
11                  paragraph (1).

12                  “(3) SELECTION OF CERTIFIED IDR ENTITY  
13                  FOR A SPECIFIED CLAIM.—With respect to the reso-  
14                  lution of a specified claim under the IDR process,  
15                  the health plan and the nonparticipating provider or  
16                  the nonparticipating emergency facility (as applica-  
17                  ble) involved shall agree on a certified IDR entity to  
18                  resolve such claim. In the case that such plan and  
19                  such provider or facility (as applicable) cannot so  
20                  agree, such an entity shall be selected by the Sec-  
21                  retary at random.

22                  “(4) PAYMENT DETERMINATION.—

23                         “(A) TIMING.—A certified IDR entity se-  
24                         lected under paragraph (3) by a health plan  
25                         and a nonparticipating provider or a nonparticipating

1           pating emergency facility (as applicable) with  
2           respect to a specified claim shall, subject to  
3           subparagraph (B), not later than 30 days after  
4           being so selected, determine the total reim-  
5           bursement that should have been made for  
6           items and services included in such claim in ac-  
7           cordance with subparagraph (C).

8           “(B) SETTLEMENT.—

9                   “(i) IN GENERAL.—If such entity de-  
10                   termines that a settlement between the  
11                   health plan and the provider or facility is  
12                   likely with respect to a specified claim, the  
13                   entity may direct the parties to attempt,  
14                   for a period not to exceed 10 days, a good  
15                   faith negotiation for a settlement of such  
16                   claim.

17                   “(ii) TIMING.—The period for a set-  
18                   tlement described in clause (i) shall accrue  
19                   towards the 30-day period described in  
20                   subparagraph (A).

21           “(C) DETERMINATION OF AMOUNT.—

22                   “(i) IN GENERAL.—The health plan  
23                   and the nonparticipating provider or non-  
24                   participating emergency facility (as appli-  
25                   cable) shall, with respect to a specified

1 claim, each submit to the certified IDR en-  
2 tity a final offer of payment or reimburse-  
3 ment (as applicable) with respect to items  
4 and services which are the subject of the  
5 specified claim. Such entity shall determine  
6 which such offer is the most reasonable in  
7 accordance with clause (ii).

8 “(ii) CONSIDERATIONS IN DETER-  
9 MINATION.—

10 “(I) IN GENERAL.—In deter-  
11 mining which final offer is the most  
12 reasonable under clause (i), the cer-  
13 tified IDR entity shall consider—

14 “(aa) the median contracted  
15 rates (as defined in subsection  
16 (b)(3)(E)) for items or services  
17 that are comparable to the items  
18 and services included in the spec-  
19 ified claim and that are furnished  
20 in the same geographic area (as  
21 defined by the Secretary for pur-  
22 poses of such subsection) as such  
23 items and services (not including  
24 any facility fees with respect to  
25 such rates); and

1           “(bb) the circumstances de-  
2           scribed in subclause (II), if any  
3           information with respect to such  
4           circumstances is submitted by ei-  
5           ther party.

6           “(II)        ADDITIONAL        CIR-  
7           CUMSTANCES.—For purposes of sub-  
8           clause (I)(bb), the circumstances de-  
9           scribed in this subclause are, with re-  
10          spect to items and services included in  
11          the specified claim of a nonpartici-  
12          pating provider, nonparticipating  
13          emergency facility, or health plan, the  
14          following:

15               “(aa) The level of training,  
16               education, experience, and quality  
17               and outcomes measurements of  
18               the provider or facility that fur-  
19               nished such items and services.

20               “(bb) Any other extenuating  
21               circumstances with respect to the  
22               furnishing of such items and  
23               services that relate to the acuity  
24               of the individual receiving such  
25               items and services or the com-

1                   plexity of furnishing such items  
2                   and services to such individual.

3                   “(III) PROHIBITION ON CONSID-  
4                   ERATION OF BILLED CHARGES.—In  
5                   determining which final offer is the  
6                   most reasonable under clause (i) with  
7                   respect to items and services fur-  
8                   nished by a provider or facility and in-  
9                   cluded in a specified claim, the cer-  
10                  tified IDR entity may not consider the  
11                  amount that would have been billed by  
12                  such provider or facility with respect  
13                  to such items and services had the  
14                  provisions of section 2799 or 2799A  
15                  (as applicable) not applied.

16                  “(iii) EFFECT OF DETERMINATION.—  
17                  A determination of a certified IDR entity  
18                  under clause (i)—

19                         “(I) shall be binding; and

20                         “(II) shall not be subject to judi-  
21                         cial review, except in a case described  
22                         in any of paragraphs (1) through (4)  
23                         of section 10(a) of title 9, United  
24                         States Code.

1                   “(iv) COSTS OF INDEPENDENT DIS-  
2                   PUTE RESOLUTION PROCESS.—In the case  
3                   of a specified claim made by a nonpartici-  
4                   pating provider, nonparticipating emer-  
5                   gency facility, or health plan and sub-  
6                   mitted to a certified IDR entity—

7                   “(I) if such entity makes a deter-  
8                   mination with respect to such claim  
9                   under clause (i), the party whose offer  
10                  is not chosen under such clause shall  
11                  be responsible for paying all fees  
12                  charged by such entity; and

13                  “(II) if the parties reach a settle-  
14                  ment with respect to such claim prior  
15                  to such a determination, such fees  
16                  shall be divided equally between the  
17                  parties, unless the parties otherwise  
18                  agree.

19                  “(v) PAYMENT.—Not later than 30  
20                  days after a determination described in  
21                  clause (i) is made with respect to a speci-  
22                  fied claim of a nonparticipating provider,  
23                  nonparticipating emergency facility, or  
24                  health plan—

1           “(I) in the case that such deter-  
2           mination finds that the amount paid  
3           with respect to such specified claim by  
4           the health plan should have been  
5           greater than the amount so paid, such  
6           plan shall pay directly to the provider  
7           or facility (as applicable) the dif-  
8           ference between the amount so paid  
9           and the amount so determined; and

10           “(II) in the case that such deter-  
11           mination finds that the amount paid  
12           with respect to such specified claim by  
13           the health plan should have been less  
14           than the amount so paid, the provider  
15           or facility (as applicable) shall pay di-  
16           rectly to the plan the difference be-  
17           tween the amount so paid and the  
18           amount so determined.

19           “(5) PUBLICATION OF INFORMATION RELATING  
20           TO DISPUTES.—

21           “(A) IN GENERAL.—For 2021 and each  
22           subsequent year, the Secretary and the Sec-  
23           retary of Labor shall publish on the public  
24           website of the Department of Health and

1 Human Services and the Department of Labor,  
2 respectively—

3 “(i) the number of specified claims  
4 filed during such year;

5 “(ii) the number of such claims with  
6 respect to which a final determination was  
7 made under paragraph (4)(C)(i); and

8 “(iii) the information described in  
9 subparagraph (B) with respect to each  
10 specified claim with respect to which such  
11 a decision was so made.

12 “(B) INFORMATION WITH RESPECT TO  
13 SPECIFIED CLAIMS.—For purposes of subpara-  
14 graph (A), the information described in this  
15 subparagraph is, with respect to a specified  
16 claim of a nonparticipating provider, nonpartici-  
17 pating emergency facility, or health plan—

18 “(i) a description of each item and  
19 service included in such claim;

20 “(ii) the amount of the offer sub-  
21 mitted under paragraph (4)(C)(i) by the  
22 health plan and by the nonparticipating  
23 provider or nonparticipating emergency fa-  
24 cility (as applicable);

1           “(iii) whether the offer selected by the  
2           certified IDR entity under such paragraph  
3           was the offer submitted by such plan or by  
4           such provider or facility (as applicable) and  
5           the amount of such offer so selected; and

6           “(iv) the category and practice spe-  
7           cialty of each such provider or facility in-  
8           volved in furnishing such items and serv-  
9           ices.

10          “(C) CONFIDENTIALITY OF PARTIES.—  
11          None of the information published under this  
12          paragraph may specify the identity of a health  
13          plan, provider, facility, or individual with re-  
14          spect to a specified claim.”.

15          (c) PROVIDER DIRECTORY REQUIREMENTS; DISCLO-  
16          SURE ON PATIENT PROTECTIONS.—Section 2719A of the  
17          Public Health Service Act, as amended by subsection (b),  
18          is further amended by adding at the end the following new  
19          subsections:

20          “(g) PROVIDER DIRECTORY INFORMATION REQUIRE-  
21          MENTS.—

22          “(1) IN GENERAL.—Not later than 1 year after  
23          the date of the enactment of this subsection, each  
24          group health plan and health insurance issuer offer-

1       ing group or individual health insurance coverage  
2       shall—

3               “(A) establish the verification process de-  
4               scribed in paragraph (2);

5               “(B) establish the response protocol de-  
6               scribed in paragraph (3);

7               “(C) establish the database described in  
8               paragraph (4); and

9               “(D) include in any print directory con-  
10              taining provider directory information with re-  
11              spect to such plan or such coverage the infor-  
12              mation described in paragraph (5).

13             “(2) VERIFICATION PROCESS.—The verification  
14             process described in this paragraph is, with respect  
15             to a group health plan or a health insurance issuer  
16             offering group or individual health insurance cov-  
17             erage, a process—

18               “(A) under which not less frequently than  
19               once every 90 days, such plan or such issuer (as  
20               applicable) verifies and updates the provider di-  
21               rectory information included on the database  
22               described in paragraph (4) of such plan or  
23               issuer of each health care provider and health  
24               care facility included in such database; and

1           “(B) that establishes a procedure for the  
2           removal of such a provider or facility with re-  
3           spect to which such plan or issuer has been un-  
4           able to verify such information during a period  
5           specified by the plan or issuer.

6           “(3) RESPONSE PROTOCOL.—The response pro-  
7           tocol described in this paragraph is, in the case of  
8           an individual enrolled under a group health plan or  
9           group or individual health insurance coverage of-  
10          fered by a health insurance issuer who requests in-  
11          formation on whether a health care provider or  
12          health care facility has a contractual relationship to  
13          furnish items and services under such plan or such  
14          coverage, a protocol under which such plan or such  
15          issuer (as applicable), in the case such request is  
16          made through a telephone call—

17                 “(A) responds to such individual as soon  
18                 as practicable and in no case later than 1 busi-  
19                 ness day after such call is received through a  
20                 written electronic communication; and

21                 “(B) retains such communication in such  
22                 individual’s file for at least 2 years following  
23                 such response.

24           “(4) DATABASE.—The database described in  
25           this paragraph is, with respect to a group health

1 plan or health insurance issuer offering group or in-  
2 dividual health insurance coverage, a database on  
3 the public website of such plan or issuer that con-  
4 tains—

5 “(A) a list of each health care provider and  
6 health care facility with which such plan or  
7 such issuer has a contractual relationship for  
8 furnishing items and services under such plan  
9 or such coverage; and

10 “(B) provider directory information with  
11 respect to each such provider and facility.

12 “(5) INFORMATION.—The information de-  
13 scribed in this paragraph is, with respect to a print  
14 directory containing provider directory information  
15 with respect to a group health plan or individual or  
16 group health insurance coverage offered by a health  
17 insurance issuer, a notification that such informa-  
18 tion contained in such directory was accurate as of  
19 the date of publication of such directory and that an  
20 individual enrolled under such plan or such coverage  
21 should consult the database described in paragraph  
22 (4) with respect to such plan or such coverage or  
23 contact such plan or the issuer of such coverage to  
24 obtain the most current provider directory informa-  
25 tion with respect to such plan or such coverage.

1           “(6) DEFINITION.—For purposes of this sub-  
2           section, the term ‘provider directory information’ in-  
3           cludes, with respect to a group health plan and a  
4           health insurance issuer offering group or individual  
5           health insurance coverage, the name, address, spe-  
6           cialty, and telephone number of each health care  
7           provider or health care facility with which such plan  
8           or such issuer has a contractual relationship for fur-  
9           nishing items and services under such plan or such  
10          coverage.

11          “(h) DISCLOSURE ON PATIENT PROTECTIONS.—  
12          Each group health plan and health insurance issuer offer-  
13          ing group or individual health insurance coverage shall  
14          make publicly available, and (if applicable) post on a pub-  
15          lic website of such plan or issuer—

16               “(1) information in plain language on—

17                   “(A) the requirements and prohibitions ap-  
18                   plied under sections 2799 and 2799A (relating  
19                   to prohibitions on balance billing in certain cir-  
20                   cumstances);

21                   “(B) if provided for under applicable State  
22                   law, any other requirements on providers and  
23                   facilities regarding the amounts such providers  
24                   and facilities may, with respect to an item or  
25                   service, charge a participant, beneficiary, or en-

1           rollee of such plan or coverage with respect to  
2           which such a provider or facility does not have  
3           a contractual relationship for furnishing such  
4           item or service under the plan or coverage after  
5           receiving payment from the plan or coverage for  
6           such item or service and any applicable cost-  
7           sharing payment from such participant, bene-  
8           ficiary, or enrollee; and

9                   “(C) the requirements applied under sub-  
10                   sections (b) and (e); and

11                   “(2) information on contacting appropriate  
12           State and Federal agencies in the case that an indi-  
13           vidual believes that such a provider or facility has  
14           violated any requirement described in paragraph (1)  
15           with respect to such individual.”.

16           (d) PREVENTING CERTAIN CASES OF BALANCE  
17   BILLING.—Title XXVII of the Public Health Service Act  
18   is amended by adding at the end the following new part:

19           **“PART D—PREVENTING CERTAIN CASES OF**  
20   **BALANCE BILLING**

21           **“SEC. 2799. BALANCE BILLING IN CASES OF EMERGENCY**  
22   **SERVICES.**

23                   “(a) IN GENERAL.—In the case of a participant, ben-  
24           eficiary, or enrollee with benefits under a health plan who  
25           is furnished on or after January 1, 2021, emergency serv-

1 ices with respect to an emergency medical condition during  
2 a visit at an emergency department of a hospital or an  
3 independent freestanding emergency department—

4           “(1) the emergency department of a hospital or  
5 independent freestanding emergency department  
6 shall not hold the participant, beneficiary, or enrollee  
7 liable for a payment amount for such emergency  
8 services so furnished that is more than the cost-  
9 sharing amount for such services (as determined in  
10 accordance with clauses (ii) and (iii) of section  
11 2719A(b)(1)(C)); and

12           “(2) a health care provider shall not hold such  
13 participant, beneficiary, or enrollee liable for a pay-  
14 ment amount for an emergency service furnished to  
15 such individual by such provider with respect to such  
16 emergency medical condition and visit for which the  
17 individual receives emergency services at the hospital  
18 or emergency department that is more than the cost-  
19 sharing amount for such services furnished by the  
20 provider (as determined in accordance with clauses  
21 (ii) and (iii) of section 2719A(b)(1)(C)).

22           “(b) DEFINITIONS.—In this section:

23           “(1) The terms ‘emergency department of a  
24 hospital’, ‘emergency medical condition’, ‘emergency  
25 services’, and ‘independent freestanding emergency

1 department' have the meanings given such terms, re-  
2 spectively, in section 2719A(b)(3).

3 “(2) The term ‘health plan’ has the meaning  
4 given such term in section 2719A(e).

5 “(3) The term ‘during a visit’ shall have such  
6 meaning as applied to such term for purposes of sec-  
7 tion 2719A(e).

8 **“SEC. 2799A. BALANCE BILLING IN CASES OF NON-EMER-**  
9 **GENCY SERVICES PERFORMED BY NON-**  
10 **PARTICIPATING PROVIDERS AT CERTAIN**  
11 **PARTICIPATING FACILITIES.**

12 “(a) IN GENERAL.—Subject to subsection (b), in the  
13 case of a participant, beneficiary, or enrollee with benefits  
14 under a health plan (as defined in section 2799(b)) who  
15 is furnished on or after January 1, 2021, items or services  
16 (other than emergency services to which section 2799 ap-  
17 plies) at a participating health care facility by a non-  
18 participating provider, such provider shall not hold such  
19 participant, beneficiary, or enrollee liable for a payment  
20 amount for such an item or service furnished by such pro-  
21 vider during a visit at such facility that is more than the  
22 cost-sharing amount for such item or service (as deter-  
23 mined in accordance with subparagraphs (A) and (B) of  
24 section 2719A(e)(1)).

25 “(b) EXCEPTION.—

1           “(1) IN GENERAL.—Subsection (a) shall not  
2           apply to a nonparticipating provider (other than a  
3           specified provider at a participating health care fa-  
4           cility), with respect to items or services furnished by  
5           the provider to a participant, beneficiary, or enrollee  
6           of a health plan, if the provider is in compliance  
7           with the notice and consent requirements of sub-  
8           section (d).

9           “(2) SPECIFIED PROVIDER DEFINED.—For pur-  
10          poses of paragraph (1), the term ‘specified provider’,  
11          with respect to a participating health care facility—

12                 “(A) means a facility-based provider, in-  
13                 cluding emergency medicine providers, anesthe-  
14                 siologists,           pathologists,           radiologists,  
15                 neonatologists, assistant surgeons, hospitalists,  
16                 intensivists, or other providers as determined by  
17                 the Secretary; and

18                 “(B) includes, with respect to an item or  
19                 service, a nonparticipating provider if there is  
20                 no participating provider at such facility who  
21                 can furnish such item or service.

22          “(c) CLARIFICATION.—In the case of a nonpartici-  
23          pating provider (other than a specified provider at a par-  
24          ticipating health care facility) that complies with the no-  
25          tice and consent requirements of subsection (d) with re-

1 spect to an item or service (referred to in this subsection  
2 as a ‘covered item or service’), such notice and consent  
3 requirements may not be construed as applying with re-  
4 spect to any item or service that is furnished as a result  
5 of unforeseen medical needs that arise at the time such  
6 covered item or service is furnished.

7 “(d) COMPLIANCE WITH NOTICE AND CONSENT RE-  
8 QUIREMENTS.—

9 “(1) IN GENERAL.—A nonparticipating provider  
10 or nonparticipating facility is in compliance with this  
11 subsection, with respect to items or services fur-  
12 nished by the provider or facility to a participant,  
13 beneficiary, or enrollee of a health plan, if the pro-  
14 vider (or, if applicable, the participating health care  
15 facility on behalf of such provider) or nonpartici-  
16 pating facility—

17 “(A) provides to the participant, bene-  
18 ficiary, or enrollee (or to an authorized rep-  
19 resentative of the participant, beneficiary, or  
20 enrollee) on the date on which the individual is  
21 furnished such items or services and, in the  
22 case that the participant, beneficiary, or en-  
23 rollee makes an appointment to be furnished  
24 such items or services, on such date the ap-  
25 pointment is made—

1 “(i) an oral explanation of the written  
2 notice described in clause (ii); and

3 “(ii) a written notice specified by the  
4 Secretary, not later than July 1, 2020,  
5 through guidance (which shall be updated  
6 as determined necessary by the Secretary)  
7 that—

8 “(I) contains the information re-  
9 quired under paragraph (2); and

10 “(II) is signed and dated by the  
11 participant, beneficiary, or enrollee (or  
12 by an authorized representative of the  
13 participant, beneficiary, or enrollee)  
14 and, with respect to items or services  
15 to be furnished by such a provider  
16 that are not poststabilization services  
17 described in section  
18 2719A(b)(3)(C)(ii), is so signed and  
19 dated not less than 72 hours prior to  
20 the participant, beneficiary, or en-  
21 rollee being furnished such items or  
22 services by such provider; and

23 “(B) obtains from the participant, bene-  
24 fiary, or enrollee (or from such an authorized

1 representative) the consent described in para-  
2 graph (3).

3 “(2) INFORMATION REQUIRED UNDER WRITTEN  
4 NOTICE.—For purposes of paragraph (1)(A)(ii)(I),  
5 the information described in this paragraph, with re-  
6 spect to a nonparticipating provider or nonpartici-  
7 pating facility and a participant, beneficiary, or en-  
8 rollee of a health plan, is each of the following:

9 “(A) Notification, as applicable, that the  
10 health care provider is a nonparticipating pro-  
11 vider with respect to the health plan or the  
12 health care facility is a nonparticipating facility  
13 with respect to the health plan.

14 “(B) Notification of the estimated amount  
15 that such provider or facility may charge the  
16 participant, beneficiary, or enrollee for such  
17 items and services involved.

18 “(C) In the case of a nonparticipating fa-  
19 cility, a list of any participating providers at the  
20 facility who are able to furnish such items and  
21 services involved and notification that the par-  
22 ticipant, beneficiary, or enrollee may be re-  
23 ferred, at their option, to such a participating  
24 provider.

1           “(3) CONSENT DESCRIBED.—For purposes of  
2 paragraph (1)(B), the consent described in this  
3 paragraph, with respect to a participant, beneficiary,  
4 or enrollee of a health plan who is to be furnished  
5 items or services by a nonparticipating provider or  
6 nonparticipating facility, is a document specified by  
7 the Secretary through rulemaking that—

8           “(A) is signed by the participant, bene-  
9 ficiary, or enrollee (or by an authorized rep-  
10 resentative of the participant, beneficiary, or  
11 enrollee) and, with respect to items or services  
12 to be furnished by such a provider or facility  
13 that are not poststabilization services described  
14 in section 2719A(b)(3)(C)(ii), is so signed not  
15 less than 72 hours prior to the participant, ben-  
16 eficiary, or enrollee being furnished such items  
17 or services by such provider or facility;

18           “(B) acknowledges that the participant,  
19 beneficiary, or enrollee has been—

20           “(i) provided with a written estimate  
21 and an oral explanation of the charge that  
22 the participant, beneficiary, or enrollee will  
23 be assessed for the items or services antici-  
24 pated to be furnished to the participant,

1 beneficiary, or enrollee by such provider or  
2 facility; and

3 “(ii) informed that the payment of  
4 such charge by the participant, beneficiary,  
5 or enrollee may not accrue toward meeting  
6 any limitation that the health plan places  
7 on cost-sharing; and

8 “(C) documents the consent of the partici-  
9 pant, beneficiary, or enrollee to—

10 “(i) be furnished with such items or  
11 services by such provider or facility; and

12 “(ii) in the case that the individual is  
13 so furnished such items or services, be  
14 charged an amount that may be greater  
15 than the amount that would otherwise be  
16 charged the individual if furnished by a  
17 participating provider or participating fa-  
18 cility with respect to such items or services  
19 and plan.

20 “(e) RETENTION OF CERTAIN DOCUMENTS.—A non-  
21 participating provider (or, in the case of a nonpartici-  
22 pating provider at a participating health care facility, such  
23 facility) or nonparticipating facility that obtains from a  
24 participant, beneficiary, or enrollee of a health plan (or  
25 an authorized representative of such participant, bene-

1 ficiary, or enrollee) a written notice in accordance with  
2 subsection (c)(1)(ii), with respect to furnishing an item  
3 or service to such participant, beneficiary, or enrollee,  
4 shall retain such notice for at least a 2-year period after  
5 the date on which such item or service is so furnished.

6 “(f) DEFINITIONS.—In this section:

7 “(1) The terms ‘nonparticipating provider’ and  
8 ‘participating provider’ have the meanings given  
9 such terms, respectively, in subsection (b)(3) of sec-  
10 tion 2719A.

11 “(2) The terms ‘participating health care facil-  
12 ity’ and ‘health plan’ have the meanings given such  
13 terms, respectively, in subsection (e)(2) of section  
14 2719A.

15 “(3) The term ‘nonparticipating facility’  
16 means—

17 “(A) with respect to emergency services (as  
18 defined in section 2719A(b)(3)(C)(i)) and a  
19 health plan, an emergency department of a hos-  
20 pital, or an independent freestanding emergency  
21 department, that does not have a contractual  
22 relationship with the plan (or, if applicable,  
23 issuer offering the plan) for furnishing such  
24 services under the plan; and

1           “(B) with respect to poststabilization serv-  
2           ices described in section 2719A(b)(3)(C)(ii) and  
3           a health plan, an emergency department of a  
4           hospital (or other department of such hospital),  
5           or an independent freestanding emergency de-  
6           partment, that does not have a contractual rela-  
7           tionship with the plan (or, if applicable, issuer  
8           offering the plan) for furnishing such services  
9           under the plan.

10          “(4) The term ‘participating facility’ means—

11           “(A) with respect to emergency services (as  
12           defined in section 2719A(b)(3)(C)(i)) and a  
13           health plan, an emergency department of a hos-  
14           pital, or an independent freestanding emergency  
15           department, that has a contractual relationship  
16           with the plan (or, if applicable, issuer offering  
17           the plan) for furnishing such services under the  
18           plan; and

19           “(B) with respect to poststabilization serv-  
20           ices described in section 2719A(b)(3)(C)(ii) and  
21           a health plan, an emergency department of a  
22           hospital (or other department of such hospital),  
23           or an independent freestanding emergency de-  
24           partment, that has a contractual relationship  
25           with the plan (or, if applicable, issuer offering

1 the plan) for furnishing such services under the  
2 plan.

3 **“SEC. 2799B. PROVIDER REQUIREMENTS WITH RESPECT TO**  
4 **PROVIDER DIRECTORY INFORMATION.**

5 “Not later than 1 year after the date of the enact-  
6 ment of this section, each health care provider and health  
7 care facility shall establish a process under which such  
8 provider or facility transmits, to each health insurance  
9 issuer offering group or individual health insurance cov-  
10 erage and group health plan with which such provider or  
11 facility has in effect a contractual relationship for fur-  
12 nishing items and services under such coverage or such  
13 plan, provider directory information (as defined in section  
14 2719A(g)(6)) with respect to such provider or facility, as  
15 applicable. Such provider or facility shall so transmit such  
16 information to such issuer offering such coverage or such  
17 group health plan—

18 “(1) when the provider or facility enters into  
19 such a relationship with respect to such coverage of-  
20 fered by such issuer or with respect to such plan;

21 “(2) when the provider or facility terminates  
22 such relationship with respect to such coverage of-  
23 fered by such issuer or with respect to such plan;

24 “(3) when there are any other material changes  
25 to such provider directory information of the pro-

1       vider or facility with respect to such coverage offered  
2       by such issuer or with respect to such plan; and

3               “(4) at any other time (including upon the re-  
4       quest of such issuer or plan) determined appropriate  
5       by the provider, facility, or the Secretary.

6       **“SEC. 2799C. PROVIDER REQUIREMENT WITH RESPECT TO**  
7                       **PUBLIC PROVISION OF INFORMATION.**

8       “Each health care provider and health care facility  
9       shall make publicly available, and (if applicable) post on  
10      a public website of such provider or facility—

11               “(1) information in plain language on—

12                       “(A) the requirements and prohibitions of  
13                       such provider or facility under sections 2799  
14                       and 2799A (relating to prohibitions on balance  
15                       billing in certain circumstances); and

16                       “(B) if provided for under applicable State  
17                       law, any other requirements on such provider or  
18                       facility regarding the amounts such provider or  
19                       facility may, with respect to an item or service,  
20                       charge a participant, beneficiary, or enrollee of  
21                       a health plan (as defined in section  
22                       2719A(e)(2)) with respect to which such pro-  
23                       vider or facility does not have a contractual re-  
24                       lationship for furnishing such item or service  
25                       under the plan after receiving payment from

1           the plan for such item or service and any appli-  
2           cable cost-sharing payment from such partici-  
3           pant, beneficiary, or enrollee; and

4           “(2) information on contacting appropriate  
5           State and Federal agencies in the case that an indi-  
6           vidual believes that such provider or facility has vio-  
7           lated any requirement described in paragraph (1)  
8           with respect to such individual.

9   **“SEC. 2799D. ENFORCEMENT.**

10          “(a) STATE ENFORCEMENT.—

11                 “(1) STATE AUTHORITY.—Each State may re-  
12                 quire a provider or health care facility subject to the  
13                 requirements of sections 2719A(f), 2799, 2799A,  
14                 2799B, or 2799C to satisfy such requirements appli-  
15                 cable to the provider or facility.

16                 “(2) FAILURE TO IMPLEMENT REQUIRE-  
17                 MENTS.—In the case of a determination by the Sec-  
18                 retary that a State has failed to substantially en-  
19                 force the requirements specified in paragraph (1)  
20                 with respect to applicable providers and facilities in  
21                 the State, the Secretary shall enforce such require-  
22                 ments under subsection (b) insofar as they relate to  
23                 violations of such requirements occurring in such  
24                 State.

25          “(b) SECRETARIAL ENFORCEMENT AUTHORITY.—

1           “(1) IN GENERAL.—If a provider or facility is  
2           found to be in violation specified in subsection (a)(1)  
3           by the Secretary, the Secretary may apply a civil  
4           monetary penalty with respect to such provider or  
5           facility in an amount not to exceed \$10,000 per vio-  
6           lation. The provisions of subsections (c), (d), (e),  
7           (g), (h), (k), and (l) of section 1128A of the Social  
8           Security Act shall apply to a civil monetary penalty  
9           or assessment under this subsection in the same  
10          manner as such provisions apply to a penalty, as-  
11          sessment, or proceeding under subsection (a) of such  
12          section.

13          “(2) LIMITATION.—The provisions of para-  
14          graph (1) shall apply to enforcement of a provision  
15          (or provisions) specified in subsection (a)(1) only as  
16          provided under subsection (a)(2).

17          “(3) COMPLAINT PROCESS.—The Secretary  
18          shall, through rulemaking, establish a process to re-  
19          ceive consumer complaints of violations of such pro-  
20          visions and resolve such complaints within 60 days  
21          of receipt of such complaints.

22          “(4) EXCEPTION.—The Secretary shall waive  
23          the penalties described under paragraph (1) with re-  
24          spect to a facility or provider who does not know-  
25          ingly violate, and should not have reasonably known

1       it violated, section 2799 or 2799A with respect to a  
2       participant, beneficiary, or enrollee, if such facility  
3       or practitioner, within 30 days of the violation, with-  
4       draws the bill that was in violation of such provision  
5       and reimburses the health plan or enrollee, as appli-  
6       cable, in an amount equal to the difference between  
7       the amount billed and the amount allowed to be  
8       billed under the provision, plus interest, at an inter-  
9       est rate determined by the Secretary.

10           “(5) HARDSHIP EXEMPTION.—The Secretary  
11       may establish a hardship exemption to the penalties  
12       under this subsection.

13           “(c) CONTINUED APPLICABILITY OF STATE LAW.—  
14       The sections specified in subsection (a)(1) shall not be  
15       construed to supersede any provision of State law which  
16       establishes, implements, or continues in effect any require-  
17       ment or prohibition except to the extent that such require-  
18       ment or prohibition prevents the application of a require-  
19       ment or prohibition of such a section.”.

20           “(e) RULEMAKING FOR MEDIAN CONTRACTED  
21       RATES.—Not later than July 1, 2020, the Secretary of  
22       Health and Human Services, jointly with the Secretary of  
23       Labor, shall establish through rulemaking—

24           (1) the methodology the sponsor or issuer of a  
25       health plan (as defined in subsection (e) of section

1 2719A of the Public Health Service Act (42 U.S.C.  
2 300gg-19a), as added by subsection (b) of this sec-  
3 tion) shall use to determine the median contracted  
4 rate (as defined in section 2719A(b) of such Act, as  
5 amended by subsection (a) of this section), differen-  
6 tiating by business line;

7 (2) the information such sponsor or issuer shall  
8 share with the nonparticipating provider (as defined  
9 in such section) involved when making such a deter-  
10 mination; and

11 (3) the geographic regions applied for purposes  
12 of subparagraph (E) of section 2719A(b)(3), as  
13 amended by subsection (a) of this section, taking  
14 into account the needs of rural and underserved  
15 areas, including health professional shortage areas.

16 Such rulemaking shall take into account payments that  
17 are made by such sponsor or issuer that are not on a fee-  
18 for-service basis. Such methodology may account for rel-  
19 evant payment adjustments that take into account facility  
20 type (including higher acuity settings and the case-mix of  
21 various facility types) that are otherwise taken into ac-  
22 count for purposes of determining payment amounts with  
23 respect to participating facilities.

1 (f) EFFECTIVE DATE.—The amendments made by  
2 subsections (a) and (b) shall apply with respect to plan  
3 years beginning on or after January 1, 2021.

4 **SEC. 403. GOVERNMENT ACCOUNTABILITY OFFICE STUDY**  
5 **ON PROFIT- AND REVENUE-SHARING IN**  
6 **HEALTH CARE.**

7 (a) STUDY.—The Comptroller General of the United  
8 States shall conduct a study to—

9 (1) describe what is known about profit- and  
10 revenue-sharing relationships in the commercial  
11 health care markets, including those relationships  
12 that—

13 (A) involve one or more—

14 (i) physician groups that practice  
15 within a hospital included in the profit- or  
16 revenue-sharing relationship, or refer pa-  
17 tients to such hospital;

18 (ii) laboratory, radiology, or pharmacy  
19 services that are delivered to privately in-  
20 sured patients of such hospital;

21 (iii) surgical services;

22 (iv) hospitals or group purchasing or-  
23 ganizations; or

24 (v) rehabilitation or physical therapy  
25 facilities or services; and

1 (B) include revenue- or profit-sharing  
2 whether through a joint venture, management  
3 or professional services agreement, or other  
4 form of gain-sharing contract;

5 (2) describe Federal oversight of such relation-  
6 ships, including authorities of the Department of  
7 Health and Human Services and the Federal Trade  
8 Commission to review such relationships and their  
9 potential to increase costs for patients, and identify  
10 limitations in such oversight; and

11 (3) as appropriate, make recommendations to  
12 improve Federal oversight of such relationships.

13 (b) REPORT.—Not later than 2 years after the date  
14 of the enactment of this Act, the Comptroller General of  
15 the United States shall prepare and submit a report on  
16 the study conducted under subsection (a) to the Com-  
17 mittee on Health, Education, Labor, and Pensions of the  
18 Senate and the Committee on Education and Labor and  
19 Committee on Energy and Commerce of the House of  
20 Representatives.

21 **SEC. 404. STATE ALL PAYER CLAIMS DATABASES.**

22 (a) IN GENERAL.—The Secretary of Health and  
23 Human Services shall make one-time grants to eligible  
24 States for the purposes described in subsection (b).

1 (b) USES.—A State may use a grant received under  
2 subsection (a) for one of the following purposes:

3 (1) To establish an All Payer Claims Database  
4 for the State.

5 (2) To maintain an existing All Payer Claims  
6 Databases for the State.

7 (c) ELIGIBILITY.—To be eligible to receive a grant  
8 under subsection (a), a State shall submit to the Secretary  
9 an application at such time, in such manner, and con-  
10 taining such information as the Secretary specifies. Such  
11 information shall include, with respect to an All Payer  
12 Claims Database for the State, at least specifics on how  
13 the State will ensure uniform data collection through the  
14 database and the security of such data submitted to and  
15 maintained in the database.

16 (d) ALL PAYER CLAIMS DATABASE.—For purposes  
17 of this section, the term “All Payer Claims Database”  
18 means, with respect to a State, a State database that may  
19 include medical claims, pharmacy claims, dental claims,  
20 and eligibility and provider files, which are collected from  
21 private and public payers.

22 (e) AUTHORIZATION OF APPROPRIATIONS.—To carry  
23 out this section, there are authorized to be appropriated  
24 \$50,000,000, to remain available until expended.

1 **SEC. 405. AIR AMBULANCE COST DATA REPORTING PRO-**  
2 **GRAM.**

3 (a) COST DATA REPORTING PROGRAM.—

4 (1) IN GENERAL.—Not later than 6 months  
5 after the date of the promulgation of the rule under  
6 subsection (c), and annually thereafter, a provider of  
7 emergency air medical services shall submit to the  
8 Secretary of Health and Human Services the infor-  
9 mation specified in subsection (b) with respect to the  
10 preceding 180-day period (in the case of the initial  
11 period) and the preceding 1-year period (in each  
12 subsequent period).

13 (2) PUBLICATION.—Not later than 180 days  
14 after the date the Secretary of Health and Human  
15 Services receives from a provider described in para-  
16 graph (1) the information specified in subsection (b),  
17 the Secretary shall make publicly available such in-  
18 formation.

19 (b) SPECIFIED INFORMATION.—Information de-  
20 scribed in subsection (a) is—

21 (1) information, with respect to a claim for an  
22 item or service—

23 (A) identified as paid by health insurance  
24 coverage offered in the group or individual mar-  
25 ket or a group health plan (including a self-in-  
26 sured plan);

1 (B) identified as paid for non-emergent  
2 transport requiring prior authorization and  
3 emergent transport;

4 (C) identified as paid for hospital-affiliated  
5 providers and independent providers;

6 (D) identified as paid for rural transport  
7 and urban transport;

8 (E) identified as provided using rotor  
9 transport and fixed wing transport; and

10 (F) identified as furnished by a provider of  
11 emergency air medical services that has a con-  
12 tractual relationship with the plan or coverage  
13 of an individual for which such item or service  
14 is provided and such a provider that does not  
15 have a contractual relationship with the plan or  
16 coverage or such an individual; and

17 (2) cost data for an air ambulance service fur-  
18 nished by such a provider of emergency air medical  
19 services that the Secretary of Health and Human  
20 Services, in consultation with suppliers and pro-  
21 viders of such services, determines appropriate, sepa-  
22 rated by the cost of air travel and the cost of emer-  
23 gency medical services and supplies.

24 (c) RULEMAKING.—Not later than 1 year after the  
25 date of the enactment of this Act, the Secretary of Health

1 and Human Services shall determine the form and manner  
2 for submitting the information described in subsection (b)  
3 through notice and comment rulemaking.

4 (d) CIVIL MONETARY PENALTIES.—

5 (1) IN GENERAL.—A provider of emergency air  
6 medical services who violates the requirements of  
7 subsection (a)(1) shall be subject to a civil monetary  
8 penalty of not more than \$10,000 for each act con-  
9 stituting such violation.

10 (2) PROCEDURE.—The provisions of section  
11 1128A of the Social Security Act (42 U.S.C. 1320a-  
12 7a), other than subsections (a) and (b) and the first  
13 sentence of subsection (c)(1) of such subsection,  
14 shall apply to civil monetary penalties under this  
15 subsection in the same manner as such provisions  
16 apply to a penalty or proceeding under such section.

17 (e) REPORTING.—

18 (1) SECRETARY OF HEALTH AND HUMAN SERV-  
19 ICES.—Not later than July 1, 2023, the Secretary of  
20 Health and Human Services shall submit to Con-  
21 gress a report summarizing the information and  
22 data specified in subsection (b).

23 (2) COMPTROLLER GENERAL.—Not later than  
24 July 1, 2023, the Comptroller General of the United

1 States shall submit to Congress a report that in-  
2 cludes—

3 (A) an analysis of the cost variation of  
4 providers of emergency air ambulance services  
5 by geography and status; and

6 (B) any other recommendations the Comp-  
7 troller General determines appropriate, which  
8 may include a recommendation of an adequate  
9 amount of reimbursement for such services that  
10 reflects operational costs of such providers in  
11 order to preserve access to emergency air ambu-  
12 lance services.

13 (f) LIMITATION.—The information publicly disclosed  
14 under subsection (a) and the reports under subsection (f)  
15 may not contain any proprietary information.

16 **SEC. 406. REPORT BY SECRETARY OF LABOR.**

17 Not later than one year after the date of the enact-  
18 ment of this Act, and annually thereafter for each of the  
19 following 5 years, the Secretary of Labor shall—

20 (1) conduct a study of—

21 (A) the effects of the provisions of, includ-  
22 ing amendments made by, this Act on pre-  
23 miums and out-of-pocket costs in group health  
24 plans, including out-of-pocket costs that are  
25 permitted by reason of compliance with section

1           2799A(d) of the Public Health Service Act, as  
2           added by section 2(d);

3           (B) the adequacy of provider networks in  
4           group health plans; and

5           (C) such other effects of such provisions,  
6           and amendments, as the Secretary deems rel-  
7           evant; and

8           (2) submit a report on such study to the Com-  
9           mittee on Health, Education, Labor, and Pensions  
10          of the Senate and the Committee on Education and  
11          Labor and the Committee on Energy and Commerce  
12          of the House of Representatives.

13 **SEC. 407. BILLING STATUTE OF LIMITATIONS.**

14          Notwithstanding any other provision of law, a health  
15          care provider or health care facility (or health insurance  
16          issuer offering health insurance coverage or group health  
17          plan) may not initiate a process to seek reimbursement  
18          from an individual for a service furnished by such provider  
19          or facility to such individual more than a year after such  
20          date of service. Any provider, facility, issuer, or plan that  
21          bills an individual in violation of the previous sentence  
22          shall be subject to a civil monetary penalty in such amount  
23          as specified by the Secretary of Health and Human Serv-  
24          ices.

1 **SEC. 408. GAO REPORT ON IMPACT OF SURPRISE BILLING**  
2 **PROVISIONS.**

3 Not later than 3 years after the date of the enact-  
4 ment of this Act, the Comptroller General of the United  
5 States shall submit to Congress a report containing the  
6 following:

7 (1) What is known about the impacts of the  
8 provisions of this Act, including the amendments  
9 made by this Act, on the incidence and prevalence  
10 of the furnishing of items and services to individuals  
11 enrolled under a group health plan or health insur-  
12 ance coverage by health care providers and health  
13 care facilities that do not have a contractual rela-  
14 tionship with such plan or such coverage (as applica-  
15 ble) for furnishing such items and services to such  
16 an individual.

17 (2) What is known about such impacts on pro-  
18 vider shortages and accessibility to such providers,  
19 focusing on rural and medically underserved commu-  
20 nities.

21 (3) The number of grants that have been  
22 awarded under section 404 (relating to State All  
23 Payer Claims Databases) and for what purposes  
24 States have used funds made available under such  
25 grants.

1           (4) An analysis of how data made available  
2           through State All Payer Claims Databases receiving  
3           funding under such grants has been used.

4   **SEC. 409. REPORT BY THE SECRETARY OF HEALTH AND**  
5                           **HUMAN SERVICES.**

6           Not later than one year after the date of the enact-  
7           ment of this Act, and annually thereafter for each of the  
8           following 5 years, the Secretary of Health and Human  
9           Services shall—

10           (1) conduct a study of—

11                   (A) the effects of the provisions of, includ-  
12                   ing amendments made by, this Act on pre-  
13                   miums and out-of-pocket costs with respect to  
14                   individual health insurance coverage and small  
15                   group health plans;

16                   (B) the adequacy of provider networks  
17                   with respect to individual health insurance cov-  
18                   erage and small group health plans, taking into  
19                   consideration maximum travel time and dis-  
20                   tance; and

21                   (C) such other effects of such provisions,  
22                   and amendments, as the Secretary deems rel-  
23                   evant; and

24           (2) submit a report on such study to the Com-  
25           mittee on Health, Education, Labor, and Pensions

1 of the Senate and the Committee on Education and  
2 Labor and the Committee on Energy and Commerce  
3 of the House of Representatives.

## 4 **TITLE V—MISCELLANEOUS**

### 5 **SEC. 501. PAYMENT FOR BIOSIMILAR BIOLOGICAL PROD-** 6 **UCTS DURING INITIAL PERIOD.**

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

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

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

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

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

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

22 “(B) LIMITATION ON PAYMENT AMOUNT  
23 FOR BIOSIMILAR BIOLOGICAL PRODUCTS DUR-  
24 ING INITIAL PERIOD.—In the case of a bio-  
25 similar biological product furnished on or after

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

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

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

13 **SEC. 502. GAO STUDY AND REPORT ON AVERAGE SALES**  
14 **PRICE.**

15 (a) STUDY.—

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

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

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

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

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

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

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

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

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

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

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

3                           (i) formulary placement;

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

6                           (iii) other purposes.

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

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

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

18 **SEC. 503. REQUIRING PRESCRIPTION DRUG PLANS AND**  
19 **MA-PD PLANS TO REPORT POTENTIAL**  
20 **FRAUD, WASTE, AND ABUSE TO THE SEC-**  
21 **RETARY OF HHS.**

22           Section 1860D–4 of the Social Security Act (42  
23 U.S.C. 1395w–104) is amended by adding at the end the  
24 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. 504. 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 **SEC. 505. IMPROVING COORDINATION BETWEEN THE FOOD**  
18 **AND DRUG ADMINISTRATION AND THE CEN-**  
19 **TERS FOR MEDICARE & MEDICAID SERVICES.**

20 (a) IN GENERAL.—

21 (1) PUBLIC MEETING.—

22 (A) IN GENERAL.—Not later than 12  
23 months after the date of the enactment of this  
24 Act, the Secretary of Health and Human Serv-  
25 ices (referred to in this section as the “Sec-

1           retary’) shall convene a public meeting for the  
2           purposes of discussing and providing input on  
3           improvements to coordination between the Food  
4           and Drug Administration and the Centers for  
5           Medicare & Medicaid Services in preparing for  
6           the availability of novel medical products de-  
7           scribed in subsection (c) on the market in the  
8           United States.

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

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

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

22                           (iii) representatives of commercial  
23                           health insurance payers;

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

4 (v) stakeholders representing patients  
5 and with expertise in the utilization of pa-  
6 tient experience data in medical product  
7 development.

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

10 (i) the status of the drug and medical  
11 device development pipeline related to the  
12 availability of novel medical products;

13 (ii) the anticipated expertise necessary  
14 to review the safety and effectiveness of  
15 such products at the Food and Drug Ad-  
16 ministration and current gaps in such ex-  
17 pertise, if any;

18 (iii) the expertise necessary to make  
19 coding, coverage, and payment decisions  
20 with respect to such products within the  
21 Centers for Medicare & Medicaid Services,  
22 and current gaps in such expertise, if any;

23 (iv) trends in the differences in the  
24 data necessary to determine the safety and  
25 effectiveness of a novel medical product

1 and the data necessary to determine  
2 whether a novel medical product meets the  
3 reasonable and necessary requirements for  
4 coverage and payment under title XVIII of  
5 the Social Security Act pursuant to section  
6 1862(a)(1)(A) of such Act (42 U.S.C.  
7 1395y(a)(1)(A));

8 (v) the availability of information for  
9 sponsors of such novel medical products to  
10 meet each of those requirements; and

11 (vi) the coordination of information  
12 related to significant clinical improvement  
13 over existing therapies for patients between  
14 the Food and Drug Administration and the  
15 Centers for Medicare & Medicaid Services  
16 with respect to novel medical products.

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

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

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

11 (B) FINAL GUIDANCE.—Not later than 12  
12 months after issuing draft guidance under sub-  
13 paragraph (A), the Secretary shall finalize the  
14 updated guidance to address any such opportu-  
15 nities.

16 (b) REPORT ON CODING, COVERAGE, AND PAYMENT  
17 PROCESSES UNDER MEDICARE FOR NOVEL MEDICAL  
18 PRODUCTS.—Not later than 12 months after the date of  
19 the enactment of this Act, the Secretary shall publish a  
20 report on the Internet website of the Department of  
21 Health and Human Services regarding processes under  
22 the Medicare program under title XVIII of the Social Se-  
23 curity Act (42 U.S.C. 1395 et seq.) with respect to the  
24 coding, coverage, and payment of novel medical products

1 described in subsection (c). Such report shall include the  
2 following:

3 (1) A description of challenges in the coding,  
4 coverage, and payment processes under the Medicare  
5 program for novel medical products.

6 (2) Recommendations to—

7 (A) incorporate patient experience data  
8 (such as the impact of a disease or condition on  
9 the lives of patients and patient treatment pref-  
10 erences) into the coverage and payment proc-  
11 esses within the Centers for Medicare & Med-  
12 icaid Services;

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

19 (C) streamline the coverage process under  
20 the Medicare program and incorporate input  
21 from relevant stakeholders into such coverage  
22 determinations; and

23 (D) identify potential mechanisms to incor-  
24 porate novel payment designs similar to those  
25 in development in commercial insurance plans

1 and State plans under title XIX of such Act  
2 (42 U.S.C. 1396 et seq.) into the Medicare pro-  
3 gram.

4 (c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For  
5 purposes of this section, a novel medical product described  
6 in this subsection is a medical product, including a drug,  
7 biological (including gene and cell therapy), or medical de-  
8 vice, that has been designated as a breakthrough therapy  
9 under section 506(a) of the Federal Food, Drug, and Cos-  
10 metic Act (21 U.S.C. 356(a)), a breakthrough device  
11 under section 515B of such Act (21 U.S.C. 360e–3), or  
12 a regenerative advanced therapy under section 506(g) of  
13 such Act (21 U.S.C. 356(g)).

14 **SEC. 506. PATIENT CONSULTATION IN MEDICARE NA-**  
15 **TIONAL AND LOCAL COVERAGE DETERMINA-**  
16 **TIONS IN ORDER TO MITIGATE BARRIERS TO**  
17 **INCLUSION OF SUCH PERSPECTIVES.**

18 Section 1862(l) of the Social Security Act (42 U.S.C.  
19 1395y(l)) is amended by adding at the end the following  
20 new paragraph:

21 “(7) PATIENT CONSULTATION IN NATIONAL  
22 AND LOCAL COVERAGE DETERMINATIONS.—The Sec-  
23 retary may consult with patients and organizations  
24 representing patients in making national and local  
25 coverage determinations.”.

1 **SEC. 507. MEDPAC REPORT ON SHIFTING COVERAGE OF**  
2 **CERTAIN MEDICARE PART B DRUGS TO MEDI-**  
3 **CARE PART D.**

4 (a) STUDY.—The Medicare Payment Advisory Com-  
5 mission (in this section referred to as the “Commission”)  
6 shall conduct a study on shifting coverage of certain drugs  
7 and biologicals for which payment is currently made under  
8 part B of title XVIII of the Social Security Act (42 U.S.C.  
9 1395j et seq.) to part D of such title (42 U.S.C. 1395w–  
10 21 et seq.). Such study shall include an analysis of—

11 (1) differences in program structures and pay-  
12 ment methods for drugs and biologicals covered  
13 under such parts B and D, including effects of such  
14 a shift on program spending, beneficiary cost-shar-  
15 ing liability, and utilization management techniques  
16 for such drugs and biologicals; and

17 (2) the feasibility and policy implications of  
18 shifting coverage of drugs and biologicals for which  
19 payment is currently made under such part B to  
20 such part D.

21 (b) REPORT.—

22 (1) IN GENERAL.—Not later than June 30,  
23 2021, the Commission shall submit to Congress a re-  
24 port containing the results of the study conducted  
25 under subsection (a).

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

4                   (A) formulary design under such part D;

5                   (B) the ability of the benefit structure  
6           under such part D to control total spending on  
7           drugs and biologicals for which payment is cur-  
8           rently made under such part B;

9                   (C) changes to the bid process under such  
10          part D, if any, that may be necessary to inte-  
11          grate coverage of such drugs and biologicals  
12          into such part D; and

13                  (D) any other changes to the program that  
14          Congress should consider in determining wheth-  
15          er to shift coverage of such drugs and  
16          biologicals from such part B to such part D.

