

116TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

To amend titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices in the Medicare and Medicaid programs, to improve transparency related to pharmaceutical prices and transactions, to lower patients' out-of-pocket costs, and to ensure accountability to taxpayers, to address current and future expiring provisions, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

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\_\_\_\_\_ introduced the following bill; which was read twice  
and referred to the Committee on \_\_\_\_\_

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## **A BILL**

To amend titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices in the Medicare and Medicaid programs, to improve transparency related to pharmaceutical prices and transactions, to lower patients' out-of-pocket costs, and to ensure accountability to taxpayers, to address current and future expiring provisions, and for other purposes.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Prescription Drug  
3 Pricing Reduction and Health and Human Services Im-  
4 provements Act”.

5 **DIVISION A—PRESCRIPTION**  
6 **DRUG PRICING REDUCTION ACT**

7 **SEC. 10100. SHORT TITLE; TABLE OF CONTENTS.**

8 (a) **SHORT TITLE.**—This division may be cited as the  
9 “Prescription Drug Pricing Reduction Act of 2019”.

10 (b) **TABLE OF CONTENTS.**—The table of contents of  
11 this division is as follows:

Sec. 1. Short title.

**DIVISION A—PRESCRIPTION DRUG PRICING REDUCTION ACT**

Sec. 10100. Short title; table of contents.

**TITLE I—MEDICARE**

**Subtitle A—Part B**

Sec. 10101. Improving manufacturers’ reporting of average sales prices to set accurate payment rates.

Sec. 10102. Inclusion of value of coupons in determination of average sales price for drugs and biologicals under Medicare part B.

Sec. 10103. Payment for biosimilar biological products during initial period.

Sec. 10104. Temporary increase in Medicare part B payment for biosimilar biological products.

Sec. 10105. Improvements to Medicare site-of-service transparency.

Sec. 10106. Medicare part B rebate by manufacturers for drugs or biologicals with prices increasing faster than inflation.

Sec. 10107. Requiring manufacturers of certain single-dose container or single-use package drugs payable under part B of the Medicare program to provide refunds with respect to discarded amounts of such drugs.

Sec. 10108. HHS Inspector General study and report on bona fide service fees.

Sec. 10109. Establishment of maximum add-on payment for drugs and biologicals.

Sec. 10110. Treatment of drug administration services furnished by certain excepted off-campus outpatient departments of a provider.

Sec. 10111. GAO study and report on average sales price.

Sec. 10112. Authority to use alternative payment for drugs and biologicals to prevent potential drug shortages.

## 3

## Subtitle B—Part D

- Sec. 10121. Medicare part D modernization redesign.
- Sec. 10121A. Maximum monthly cap on cost-sharing payments under prescription drug plans and MA–PD plans.
- Sec. 10121B. Requiring pharmacy-negotiated price concessions, payment, and fees to be included in negotiated prices at the point-of-sale under part D of the medicare program.
- Sec. 10122. Providing the Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission with access to certain drug payment information, including certain rebate information.
- Sec. 10123. Public disclosure of drug discounts and other pharmacy benefit manager (PBM) provisions.
- Sec. 10124. Public disclosure of direct and indirect remuneration review and audit results.
- Sec. 10125. Increasing the use of real-time benefit tools to lower beneficiary costs.
- Sec. 10126. Improvements to provision of parts A and B claims data to prescription drug plans.
- Sec. 10127. Permanently authorize a successful pilot on retroactive Medicare part D coverage for low-income beneficiaries.
- Sec. 10128. Medicare part D rebate by manufacturers for certain drugs with prices increasing faster than inflation.
- Sec. 10129. Prohibiting branding on part D benefit cards.
- Sec. 10130. Requiring prescription drug plans and MA–PD plans to report potential fraud, waste, and abuse to the Secretary of HHS.
- Sec. 10131. Establishment of pharmacy quality measures under Medicare part D.
- Sec. 10132. Addition of new measures based on access to biosimilar biological products to the 5-star rating system under Medicare Advantage.
- Sec. 10133. HHS study and report on the influence of pharmaceutical manufacturer third-party reimbursement hubs on health care providers who prescribe their drugs and biologicals.

## Subtitle C—Miscellaneous

- Sec. 10141. Drug manufacturer price transparency.
- Sec. 10142. Strengthening and expanding pharmacy benefit managers transparency requirements.
- Sec. 10143. Prescription drug pricing dashboards.
- Sec. 10144. Improving coordination between the Food and Drug Administration and the Centers for Medicare & Medicaid Services.
- Sec. 10145. Patient consultation in Medicare national and local coverage determinations in order to mitigate barriers to inclusion of such perspectives.
- Sec. 10146. GAO study on increases to Medicare and Medicaid spending due to copayment coupons and other patient assistance programs.
- Sec. 10147. MedPAC report on shifting coverage of certain Medicare part B drugs to Medicare part D.
- Sec. 10148. Taking steps to fulfill treaty obligations to tribal communities.

## TITLE II—MEDICAID

- Sec. 10201. Medicaid pharmacy and therapeutics committee improvements.

- Sec. 10202. Improving reporting requirements and developing standards for the use of drug use review boards in State Medicaid programs.
- Sec. 10203. GAO report on conflicts of interest in State Medicaid program drug use review boards and pharmacy and therapeutics (P&T) committees.
- Sec. 10204. Ensuring the accuracy of manufacturer price and drug product information under the Medicaid drug rebate program.
- Sec. 10205. Excluding authorized generic drugs from calculation of average manufacturer price under the Medicaid drug rebate program.
- Sec. 10206. Improving transparency and preventing the use of abusive spread pricing and related practices in Medicaid.
- Sec. 10207. T-MSIS drug data analytics reports.
- Sec. 10208. Risk-sharing value-based payment agreements for covered outpatient drugs under Medicaid.
- Sec. 10209. Modification of maximum rebate amount under Medicaid drug rebate program.
- Sec. 10210. Applying Medicaid drug rebate requirement to drugs provided as part of outpatient hospital services.

## **TITLE I—MEDICARE**

### **Subtitle A—Part B**

#### **SEC. 10101. IMPROVING MANUFACTURERS' REPORTING OF AVERAGE SALES PRICES TO SET ACCURATE PAYMENT RATES.**

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

(1) by striking “PRICE.—For requirements” and inserting “PRICE.—

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

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

“(2) MANUFACTURERS THAT DO NOT HAVE A REBATE AGREEMENT.—

“(A) IN GENERAL.—For calendar quarters beginning with the first calendar quarter after the date of the enactment of this paragraph,

1 the following provisions shall apply with respect  
2 to a manufacturer of an applicable drug or bio-  
3 logical (as defined in subparagraph (B)) that  
4 has not entered into and does not have in effect  
5 a rebate agreement described in subsection (b)  
6 of section 1927 in the same manner and to the  
7 same extent as such provisions apply with re-  
8 spect to a manufacturer that has entered into  
9 and has in effect such a rebate agreement:

10 “(i) Section 1927(b)(3)(A)(iii).

11 “(ii) Subparagraphs (B) and (C)  
12 (other than the rebate agreement suspen-  
13 sion described in such subparagraph (C))  
14 of section 1927(b)(3).

15 “(B) APPLICABLE DRUG OR BIOLOGICAL  
16 DEFINED.—For purposes of subparagraph (A),  
17 the term ‘applicable drug or biological’ means a  
18 drug or biological described in subparagraph  
19 (C), (E), or (G) of section 1842(o)(1) or in sec-  
20 tion 1881(b)(14)(B) that is payable under this  
21 part. For purposes of applying this paragraph,  
22 a drug or biological described in the previous  
23 sentence includes an item, service, supply, or  
24 product that is payable under this part as a  
25 drug or biological.”.

1 (b) CONFORMING AMENDMENTS.—

2 (1) TITLE XVIII.—Section 1847A(b) of the So-  
3 cial Security Act (42 U.S.C. 1395w-3a(b)) is  
4 amended—

5 (A) in paragraph (2)(A), by inserting “or  
6 subsection (f)(2), as applicable” after “under  
7 section 1927(b)(3)(A)(iii)”; and

8 (B) in each of paragraphs (3) and (6)(A),  
9 in the matter preceding subparagraph (A) and  
10 clause (i), respectively, by inserting “or sub-  
11 section (f)(2), as applicable,” after “under sec-  
12 tion 1927(b)(3)(A)(iii)”.

13 (2) TITLE XIX.—Section 1927(b)(3) of the So-  
14 cial Security Act (42 U.S.C. 1396r-8(b)(3)) is  
15 amended—

16 (A) in subparagraph (A), in the flush mat-  
17 ter following clause (iv), by inserting “or sec-  
18 tion 1847A(f)(2)” after “Information reported  
19 under this subparagraph”; and

20 (B) in subparagraph (D), in the matter  
21 preceding clause (i), by striking “or wholesalers  
22 under this paragraph or under” and inserting  
23 “or wholesalers under this paragraph, under  
24 section 1847A(f)(2), or under”.

1           (3)       TECHNICAL       CORRECTION.—Section  
 2       1927(b)(3)(A)(iii) of such Act (42 U.S.C. 1396r–  
 3       8(b)(3)(A)(iii)) is amended by striking “section  
 4       1881(b)(13)(A)(ii)” and inserting “section  
 5       1881(b)(14)(B)”.

6   **SEC. 10102. INCLUSION OF VALUE OF COUPONS IN DETER-**  
 7                           **MINATION OF AVERAGE SALES PRICE FOR**  
 8                           **DRUGS AND BIOLOGICALS UNDER MEDICARE**  
 9                           **PART B.**

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

12           (1) in paragraph (3)—

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

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

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

21                   “(B) COUPONS PROVIDED TO REDUCE  
 22       COST-SHARING.—For calendar quarters begin-  
 23       ning on or after July 1, 2021, in calculating the  
 24       manufacturer’s average sales price under this  
 25       subsection, such price shall include the value

1 (as defined in paragraph (6)(J)) of any coupons  
2 provided under a drug coupon program of a  
3 manufacturer (as those terms are defined in  
4 subparagraphs (K) and (L), respectively, of  
5 paragraph (6)).”; and

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

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

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

17 “(ii) any charge to the patient for the  
18 use of such coupon.

19 “(K) COUPON.—The term ‘coupon’ means  
20 any financial support that is provided to a pa-  
21 tient, either directly to the patient or indirectly  
22 to the patient through a physician, prescriber,  
23 pharmacy, or other provider, under a drug cou-  
24 pon program of a manufacturer (as defined in  
25 subparagraph (L)) that is used to reduce or



1 eliminate cost-sharing or other out-of-pocket  
2 costs of the patient, including costs related to  
3 a deductible, coinsurance, or copayment, with  
4 respect to a drug or biological, including a bio-  
5 similar biological product, of the manufacturer.

6 “(L) DRUG COUPON PROGRAM.—

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

13 “(ii) EXCLUSIONS.—Such term does  
14 not include—

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

21 “(II) a contribution by a manu-  
22 facturer to a nonprofit or Foundation  
23 that provides free or discounted drugs  
24 or biologicals, including biosimilar bio-

1                   logical products, (through in-kind do-  
2                   nations) to patients of low income.”.

3 **SEC. 10103. PAYMENT FOR BIOSIMILAR BIOLOGICAL PROD-**  
4 **UCTS DURING INITIAL PERIOD.**

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

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

11          (2) by redesignating subparagraphs (A) and  
12          (B) as clauses (i) and (ii) and moving such clauses  
13          2 ems to the right;

14          (3) by striking “UNAVAILABLE.—In the case”  
15          and inserting “UNAVAILABLE.—

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

18          (4) by adding at the end the following new sub-  
19          paragraph:

20                 “(B) LIMITATION ON PAYMENT AMOUNT  
21                 FOR BIOSIMILAR BIOLOGICAL PRODUCTS DUR-  
22                 ING INITIAL PERIOD.—In the case of a bio-  
23                 similar biological product furnished on or after  
24                 July 1, 2020, in lieu of applying subparagraph  
25                 (A) during the initial period described in such

1           subparagraph with respect to the biosimilar bio-  
2           logical product, the amount payable under this  
3           section for the biosimilar biological product is  
4           the lesser of the following:

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

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

11 **SEC. 10104. TEMPORARY INCREASE IN MEDICARE PART B**  
12                   **PAYMENT FOR BIOSIMILAR BIOLOGICAL**  
13                   **PRODUCTS.**

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

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

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

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

23                   (3) by adding at the end the following new sub-  
24                   paragraph:

1                   “(B) TEMPORARY PAYMENT INCREASE FOR  
2                   BIOSIMILAR BIOLOGICAL PRODUCTS.—

3                   “(i) IN GENERAL.—Beginning Janu-  
4                   ary 1, 2020, in the case of a biosimilar bio-  
5                   logical product described in paragraph  
6                   (1)(C) that is furnished during the applica-  
7                   ble 5-year period for such product, the  
8                   amount specified in this paragraph for  
9                   such product is an amount equal to the  
10                  lesser of the following:

11                  “(I) The amount specified in sub-  
12                  paragraph (A) for such product if  
13                  clause (ii) of such subparagraph was  
14                  applied by substituting ‘8 percent’ for  
15                  ‘6 percent’.

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

19                  “(ii) APPLICABLE 5-YEAR PERIOD.—  
20                  For purposes of clause (i), the applicable  
21                  5-year period for a biosimilar biological  
22                  product is—

23                  “(I) in the case of such a product  
24                  for which payment was made under  
25                  this paragraph as of December 31,

1                   2019, the 5-year period beginning on  
2                   January 1, 2020; and

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

9   **SEC. 10105. IMPROVEMENTS TO MEDICARE SITE-OF-SERV-**  
10                   **ICE TRANSPARENCY.**

11           Section 1834(t) of the Social Security Act (42 U.S.C.  
12 1395m(t)) is amended—

13                   (1) in paragraph (1)—

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

16                           (B) in the matter preceding subparagraph  
17                           (A)—

18                                   (i) by striking “or to” and inserting “,  
19                                   to”;

20                                   (ii) by inserting “, or to a physician  
21                                   for services furnished in a physician’s of-  
22                                   fice” after “surgical center”; and

23                                   (iii) by inserting “(or 2021 with re-  
24                                   spect to a physician for services furnished  
25                                   in a physician’s office)” after “2018”; and

1 (C) in subparagraph (A)—

2 (i) by striking “and the” and insert-  
3 ing “, the”; and

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

9 (2) by redesignating paragraphs (2) through  
10 (4) and paragraphs (3) through (5), respectively;  
11 and

12 (3) by inserting after paragraph (1) the fol-  
13 lowing new paragraph:

14 “(2) PHYSICIAN PAYMENT.—Beginning in  
15 2021, the Secretary may expand the information in-  
16 cluded on the Internet website described in para-  
17 graph (1) to include—

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

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

1 **SEC. 10106. MEDICARE PART B REBATE BY MANUFACTUR-**  
2 **ERS FOR DRUGS OR BIOLOGICALS WITH**  
3 **PRICES INCREASING FASTER THAN INFLA-**  
4 **TION.**

5 (a) IN GENERAL.—Section 1847A of the Social Secu-  
6 rity Act (42 U.S.C. 1395w–3a) is amended by adding at  
7 the end the following new subsection:

8 “(h) REBATE BY MANUFACTURERS FOR DRUGS OR  
9 BIOLOGICALS WITH PRICES INCREASING FASTER THAN  
10 INFLATION.—

11 “(1) REQUIREMENTS.—

12 “(A) SECRETARIAL PROVISION OF INFOR-  
13 MATION.—Not later than 6 months after the  
14 end of each rebate period (as defined in para-  
15 graph (2)(A)) beginning on or after January 1,  
16 2021, the Secretary shall, for each rebatable  
17 drug (as defined in paragraph (2)(B)), report  
18 to each manufacturer of such rebatable drug  
19 the following for such rebate period:

20 “(i) Information on the total number  
21 of units of the billing and payment code  
22 described in subparagraph (A)(i) of para-  
23 graph (3) with respect to such rebatable  
24 drug and rebate period.

25 “(ii) Information on the amount (if  
26 any) of the excess average sales price in-

1           crease described in subparagraph (A)(ii) of  
2           such paragraph for such rebatable drug  
3           and rebate period.

4           “(iii) The rebate amount specified  
5           under such paragraph for such rebatable  
6           drug and rebate period.

7           “(B) MANUFACTURER REBATE.—

8           “(i) IN GENERAL.—Subject to clause  
9           (ii), for each rebate period beginning on or  
10          after January 1, 2021, the manufacturer  
11          of a rebatable drug shall, for such drug,  
12          not later than 30 days after the date of re-  
13          ceipt from the Secretary of the information  
14          and rebate amount pursuant to subpara-  
15          graph (A) for such rebate period, provide  
16          to the Secretary a rebate that is equal to  
17          the amount specified in paragraph (3) for  
18          such drug for such rebate period.

19          “(ii) EXEMPTION FOR SHORTAGES.—  
20          The Secretary may reduce or waive the re-  
21          bate under this subparagraph with respect  
22          to a rebatable drug that is listed on the  
23          drug shortage list maintained by the Food  
24          and Drug Administration pursuant to sec-



1                   tion 506E of the Federal Food, Drug, and  
2                   Cosmetic Act .

3                   “(C) REQUEST FOR RECONSIDERATION.—  
4                   The Secretary shall establish procedures under  
5                   which a manufacturer of a rebatable drug may  
6                   request a reconsideration by the Secretary of  
7                   the rebate amount specified under paragraph  
8                   (3) for such rebatable drug and rebate period,  
9                   as reported to the manufacturer pursuant to  
10                  subparagraph (A)(iii).

11                  “(2) REBATE PERIOD AND REBATABLE DRUG  
12                  DEFINED.—In this subsection:

13                         “(A) REBATE PERIOD.—The term ‘rebate  
14                         period’ means a calendar quarter beginning on  
15                         or after January 1, 2021.

16                         “(B) REBATABLE DRUG.—The term  
17                         ‘rebatable drug’ means a single source drug or  
18                         biological (other than a biosimilar biological  
19                         product)—

20                                 “(i)       described       in       section  
21                                 1842(o)(1)(C) for which the payment  
22                                 amount is provided under this section; or

23                                 “(ii) for which payment is made sepa-  
24                                 rately under section 1833(i) or section  
25                                 1833(t) and for which the payment

1 amount is calculated based on the payment  
2 amount under this section.

3 “(3) REBATE AMOUNT.—

4 “(A) IN GENERAL.—For purposes of para-  
5 graph (1)(B), the amount specified in this para-  
6 graph for a rebatable drug assigned to a billing  
7 and payment code for a rebate period is, subject  
8 to paragraph (4), the amount equal to the prod-  
9 uct of—

10 “(i) subject to subparagraph (B), the  
11 total number of units of the billing and  
12 payment code for such rebatable drug fur-  
13 nished during the rebate period; and

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

15 “(I) the amount determined  
16 under subsection (b)(4) for such  
17 rebatable drug during the rebate pe-  
18 riod; exceeds

19 “(II) the inflation-adjusted base  
20 payment amount determined under  
21 subparagraph (C) of this paragraph  
22 for such rebatable drug during the re-  
23 bate period.

24 “(B) EXCLUDED UNITS.—For purposes of  
25 subparagraph (A)(i), the total number of units

1 of the billing and payment code for rebatable  
2 drugs furnished during a rebate period shall not  
3 include units with respect to which the manu-  
4 facturer provides a discount under the program  
5 under section 340B of the Public Health Serv-  
6 ice Act or a rebate under section 1927.

7 “(C) DETERMINATION OF INFLATION-AD-  
8 JUSTED PAYMENT AMOUNT.—The inflation-ad-  
9 justed payment amount determined under this  
10 subparagraph for a rebatable drug for a rebate  
11 period is—

12 “(i) the amount determined under  
13 subsection (b)(4) for such rebatable drug  
14 in the payment amount benchmark quarter  
15 (as defined in subparagraph (D)); in-  
16 creased by

17 “(ii) the percentage by which the re-  
18 bate period CPI-U (as defined in subpara-  
19 graph (F)) for the rebate period exceeds  
20 the benchmark period CPI-U (as defined  
21 in subparagraph (E)).

22 “(D) PAYMENT AMOUNT BENCHMARK  
23 QUARTER.—The term ‘payment amount bench-  
24 mark quarter’ means the calendar quarter be-  
25 ginning July 1, 2019.

1           “(E) BENCHMARK PERIOD CPI-U.—The  
2 term ‘benchmark period CPI-U’ means the con-  
3 sumer price index for all urban consumers  
4 (United States city average) for July 2019.

5           “(F) REBATE PERIOD CPI-U.—The term  
6 ‘rebate period CPI-U’ means, with respect to a  
7 rebate period, the consumer price index for all  
8 urban consumers (United States city average)  
9 for the last month of the calendar quarter that  
10 is two calendar quarters prior to the rebate pe-  
11 riod.

12           “(4) APPLICATION TO NEW DRUGS.—In the  
13 case of a rebatable drug first approved or licensed  
14 by the Food and Drug Administration after July 1,  
15 2019, the following shall apply:

16           “(A) DURING INITIAL PERIOD.—For quar-  
17 ters during the initial period in which the pay-  
18 ment amount for such drug is determined using  
19 the methodology described in subsection  
20 (c)(4)—

21           “(i) clause (ii)(I) of paragraph (3)(A)  
22 shall be applied as if the reference to ‘the  
23 amount determined under subsection  
24 (b)(4),’ were a reference to ‘the wholesale

1 acquisition cost applicable under subsection  
2 (c)(4)';

3 “(ii) clause (i) of paragraph (3)(C)  
4 shall be applied—

5 “(I) as if the reference to ‘the  
6 amount determined under subsection  
7 (b)(4),’ were a reference to ‘the whole-  
8 sale acquisition cost applicable under  
9 subsection (c)(4)’; and

10 “(II) as if the term ‘payment  
11 amount benchmark quarter’ were de-  
12 fined under paragraph (3)(D) as the  
13 first full calendar quarter after the  
14 day on which the drug was first mar-  
15 keted; and

16 “(iii) clause (ii) of paragraph (3)(C)  
17 shall be applied as if the term ‘benchmark  
18 period CPI-U’ were defined under para-  
19 graph (4)(E) as if the reference to ‘July  
20 2019’ under such paragraph were a ref-  
21 erence to ‘the first month of the first full  
22 calendar quarter after the day on which  
23 the drug was first marketed’.

24 “(B) AFTER INITIAL PERIOD.—For quar-  
25 ters beginning after such initial period—

1                   “(i) clause (i) of paragraph (3)(C)  
2                   shall be applied as if the term ‘payment  
3                   amount benchmark quarter’ were defined  
4                   under paragraph (3)(D) as the first full  
5                   calendar quarter for which the Secretary is  
6                   able to compute an average sales price for  
7                   the rebatable drug; and

8                   “(ii) clause (ii) of paragraph (3)(C)  
9                   shall be applied as if the term ‘benchmark  
10                  period CPI–U’ were defined under para-  
11                  graph (4)(E) as if the reference to ‘July  
12                  2019’ under such paragraph were a ref-  
13                  erence to ‘the first month of the first full  
14                  calendar quarter for which the Secretary is  
15                  able to compute an average sales price for  
16                  the rebatable drug’.

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

21                  “(6) ENFORCEMENT.—

22                         “(A) CIVIL MONEY PENALTY.—

23                                 “(i) IN GENERAL.—The Secretary  
24                                 shall impose a civil money penalty on a  
25                                 manufacturer that fails to comply with the

1 requirements under paragraph (1)(B) with  
2 respect to providing a rebate for a  
3 rebatable drug for a rebate period for each  
4 such failure in an amount equal to the sum  
5 of—

6 “(I) the rebate amount specified  
7 pursuant to paragraph (3) for such  
8 drug for such rebate period; and

9 “(II) 25 percent of such amount.

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

18 “(B) NO PAYMENT FOR MANUFACTURERS  
19 WHO FAIL TO PAY PENALTY.—If the manufac-  
20 turer of a rebatable drug fails to pay a civil  
21 money penalty under subparagraph (A) with re-  
22 spect to the failure to provide a rebate for a  
23 rebatable drug for a rebate period by a date  
24 specified by the Secretary after the imposition  
25 of such penalty, no payment shall be available

1 under this part for such rebatable drug for cal-  
2 endar quarters beginning on or after such date  
3 until the Secretary determines the manufac-  
4 turer has paid the penalty due under such sub-  
5 paragraph.”.

6 (b) IMPLEMENTATION.—Section 1847A(g) of the So-  
7 cial Security Act (42 U.S.C. 1395w-3(g)) is amended—

8 (1) in paragraph (4), by striking “and” at the  
9 end;

10 (2) in paragraph (5), by striking the period at  
11 the end and inserting “; and”; and

12 (3) by adding at the end the following new  
13 paragraph:

14 “(6) determination of the rebate amount for a  
15 rebatable drug under paragraph (3) of subsection  
16 (h), including with respect to a new drug pursuant  
17 to paragraph (4) of such subsection, including—

18 “(A) a decision by the Secretary with re-  
19 spect to a request for reconsideration under  
20 paragraph (1)(C); and

21 “(B) the determination of—

22 “(i) the total number of units of the  
23 billing and payment code under paragraph  
24 (3)(A)(i); and



1                   “(ii) the inflation-adjusted payment  
2                   amount under paragraph (3)(C).”.

3           (c) CONFORMING AMENDMENT TO PART B ASP CAL-  
4 CULATION.—Section 1847A(c)(3) of the Social Security  
5 Act (42 U.S.C. 1395w–3a(c)(3)) is amended by inserting  
6 “or subsection (h)” after “section 1927”.

7 **SEC. 10107. REQUIRING MANUFACTURERS OF CERTAIN SIN-**  
8 **GLE-DOSE CONTAINER OR SINGLE-USE PACK-**  
9 **AGE DRUGS PAYABLE UNDER PART B OF THE**  
10 **MEDICARE PROGRAM TO PROVIDE REFUNDS**  
11 **WITH RESPECT TO DISCARDED AMOUNTS OF**  
12 **SUCH DRUGS.**

13           Section 1847A of the Social Security Act (42 U.S.C.  
14 1395–3a), as amended by section 10106, is amended by  
15 adding at the end the following new subsection:

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

18                   “(1) SECRETARIAL PROVISION OF INFORMA-  
19 TION.—

20                           “(A) IN GENERAL.—For each calendar  
21 quarter beginning on or after July 1, 2021, the  
22 Secretary shall, with respect to a refundable  
23 single-dose container or single-use package drug  
24 (as defined in paragraph (8)), report to each  
25 manufacturer (as defined in subsection

1 (c)(6)(A)) of such refundable single-dose con-  
2 tainer or single-use package drug the following  
3 for the calendar quarter:

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

14 “(ii) The refund amount that the  
15 manufacturer is liable for pursuant to  
16 paragraph (3).

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

1                   “(C) EXCLUSION OF UNITS OF PACKAGED  
2                   DRUGS.—The total number of units of the bill-  
3                   ing and payment code of a refundable single-  
4                   dose container or single-use package drug of a  
5                   manufacturer furnished during a calendar quar-  
6                   ter for purposes of subparagraph (A)(i), and  
7                   the determination of the estimated total allowed  
8                   charges for the drug in the quarter for purposes  
9                   of paragraph (3)(A)(ii), shall not include such  
10                  units that are packaged into the payment  
11                  amount for an item or service and are not sepa-  
12                  rately payable.

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

20                  “(3) REFUND AMOUNT.—

21                         “(A) IN GENERAL.—The amount of the re-  
22                         fund specified in this paragraph is, with respect  
23                         to a refundable single-dose container or single-  
24                         use package drug of a manufacturer assigned to  
25                         a billing and payment code for a calendar quar-

1           ter beginning on or after July 1, 2021, an  
2           amount equal to the estimated amount (if any)  
3           by which—

4                   “(i) the product of—

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

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

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

22                           “(ii) an amount equal to the applica-  
23                           ble percentage (as defined in subparagraph  
24                           (B)) of the estimated total allowed charges  
25                           for such drug during the quarter.

1                   “(B) APPLICABLE PERCENTAGE DE-  
2 FINED.—

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

6                   “(I) subject to subclause (II), 10  
7 percent; and

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

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

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

1 cable under clause (i)(I) as deter-  
2 mined appropriate by the Secretary;  
3 and

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

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

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

1                   carded after the completion of such  
2                   filtration process.

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

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

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

16                  “(6) ENFORCEMENT.—

17                          “(A) AUDITS.—

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

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

9                   “(B) CIVIL MONEY PENALTY.—

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

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

22                   “(II) 25 percent of such amount.

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



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

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

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

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

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

1 **SEC. 10108. HHS INSPECTOR GENERAL STUDY AND REPORT**  
2 **ON BONA FIDE SERVICE FEES.**

3 (a) STUDY.—The Inspector General of the Depart-  
4 ment of Health and Human Services (in this section re-  
5 ferred to as the “Inspector General”) shall conduct a  
6 study on the effect of the use of bona fide service fee con-  
7 tracting arrangements by drug manufacturers and other  
8 entities on Medicare payments for drugs and biologicals  
9 furnished under part B of title XVIII of the Social Secu-  
10 rity Act (42 U.S.C. 1395j et seq.). Such study shall in-  
11 clude an analysis of—

12 (1) the various types of entities that enter into  
13 contracting arrangements that use bona fide service  
14 fees, such as group purchasing organizations, whole-  
15 salers, providers, and pharmacies;

16 (2) the various types of bona fide service fee  
17 contracting arrangements used by such entities;

18 (3) the types of services that are paid for  
19 through such arrangements;

20 (4) whether manufacturers define bona fide  
21 service fees differently across different entities;

22 (5) how such arrangements are structured;

23 (6) whether the structure or use of such ar-  
24 rangements has changed over time;

25 (7) the extent, if any, to which there is consist-  
26 ency across manufacturers in what they consider to

1 be a bona fide service fee as opposed to a discount  
2 or rebate that should be excluded from the deter-  
3 mination of average sales price pursuant to the  
4 methodology under section 1847A of the Social Se-  
5 curity Act (42 U.S.C. 1395w-3a);

6 (8) the overall magnitude of bona fide service  
7 fees;

8 (9) what share of bona fide service fees are paid  
9 to various entities;

10 (10) how the magnitude of bona fide service  
11 fees compares to other fees and rebates that are in-  
12 cluded in the determination of average sales price;

13 (11) whether and, if so, how much, the mag-  
14 nitude of bona fide service fees has grown over time  
15 and how such growth compares to growth in the  
16 magnitude of other fees and rebates; and

17 (12) what share of bona fide service fees are  
18 based on a percentage of sales.

19 (b) REPORT.—Not later than 18 months after the  
20 date of enactment of this Act, the Inspector General shall  
21 submit to Congress a report containing the results of the  
22 study conducted under subsection (a), together with rec-  
23 ommendations for such legislation and administrative ac-  
24 tion as the Inspector General determines appropriate.

1 **SEC. 10109. ESTABLISHMENT OF MAXIMUM ADD-ON PAY-**  
2 **MENT FOR DRUGS AND BIOLOGICALS.**

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

5 (1) in subsection (b)—

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

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

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

13 “(A) IN GENERAL.—In determining the  
14 payment amount under the provisions of sub-  
15 paragraph (A), (B), or (C) of paragraph (1) of  
16 this subsection, subsection (c)(4)(A)(ii), or sub-  
17 section (d)(3)(C) for a drug or biological fur-  
18 nished on or after January 1, 2021, if the ap-  
19 plicable add-on payment (as defined in subpara-  
20 graph (B)) for each drug or biological on a  
21 claim for a date of service exceeds the max-  
22 imum add-on payment amount specified under  
23 subparagraph (C) for the drug or biological,  
24 then the payment amount otherwise determined  
25 for the drug or biological under those provi-

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

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

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

11 “(I) the amount that would oth-  
12 erwise be applied under paragraph  
13 (1)(A); and

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

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

21 “(I) the amount that would oth-  
22 erwise be applied under paragraph  
23 (1)(B); and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17                               “(i) for each of 2021 through 2028,  
18                               \$1,000; and

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

1 **SEC. 10110. TREATMENT OF DRUG ADMINISTRATION SERV-**  
2 **ICES FURNISHED BY CERTAIN EXCEPTED**  
3 **OFF-CAMPUS OUTPATIENT DEPARTMENTS OF**  
4 **A PROVIDER.**

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

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

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

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

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

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

6 **SEC. 10111. GAO STUDY AND REPORT ON AVERAGE SALES**  
7                   **PRICE.**

8                   (a) STUDY.—

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

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

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

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

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

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

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

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

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

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

20                 (i) formulary placement;

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

23                 (iii) other purposes.

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

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

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

12 **SEC. 10112. AUTHORITY TO USE ALTERNATIVE PAYMENT**  
13 **FOR DRUGS AND BIOLOGICALS TO PREVENT**  
14 **POTENTIAL DRUG SHORTAGES.**

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

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

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

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

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

1           “(A) IN GENERAL.—In the case of a drug  
2 or biological that the Secretary determines is  
3 described in subparagraph (B) for one or more  
4 quarters beginning on or after January 1,  
5 2021, the Secretary may use wholesale acquisi-  
6 tion cost (or other reasonable measure of a  
7 drug or biological price) instead of the manu-  
8 facturer’s average sales price for such quarters  
9 and for subsequent quarters until the end of  
10 the quarter in which such drug or biological is  
11 removed from the drug shortage list under sec-  
12 tion 506E of the Federal Food, Drug, and Cos-  
13 metic Act, or in the case of a drug or biological  
14 described in subparagraph (B)(ii), the date on  
15 which the Secretary determines that the total  
16 manufacturing capacity or the total number of  
17 manufacturers of such drug or biological is suf-  
18 ficient to mitigate a potential shortage of the  
19 drug or biological.

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

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

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

10           “(ii) that—

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

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

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

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

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

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

23                  (c) HHS REPORT AND RECOMMENDATIONS.—

24                         (1) IN GENERAL.—Not later than July 1, 2021,  
25                         the Secretary shall submit to Congress a report on



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

4 (A) an analysis of—

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

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

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

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

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

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

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

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

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

## 13 **Subtitle B—Part D**

### 14 **SEC. 10121. MEDICARE PART D MODERNIZATION REDESIGN.**

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

18 (1) in paragraph (2)—

19 (A) in subparagraph (A), in the matter  
20 preceding clause (i), by inserting “for a year  
21 preceding 2022 and for costs above the annual  
22 deductible specified in paragraph (1) and up to  
23 the annual out-of-pocket threshold specified in  
24 paragraph (4)(B) for 2022 and each subsequent  
25 year” after “paragraph (3)”;

1 (B) in subparagraph (C)—

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

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

9 (C) in subparagraph (D)—

10 (i) in clause (i)—

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

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

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

23 (2) in paragraph (3)(A)—

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

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

7 (3) in paragraph (4)—

8 (A) in subparagraph (A)—

9 (i) in clause (i)—

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

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

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

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

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

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

3 (ii) in clause (ii)—

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

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

13 (B) in subparagraph (B)—

14 (i) in clause (i)—

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

17 (II) in subclause (VI)—

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

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

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

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

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

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

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

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

17 (b) REDUCTION IN BENEFICIARY COINSURANCE.—

18 (1) IN GENERAL.—Section 1860D–2(b)(2)(A)  
19 of the Social Security Act (42 U.S.C. 1395w–  
20 102(b)(2)(A)), as amended by subsection (a), is  
21 amended—

22 (A) by redesignating clauses (i) and (ii) as  
23 subclauses (I) and (II) and moving such sub-  
24 clauses 2 ems to the right;

1 (B) by striking “25 PERCENT COINSUR-  
2 ANCE.—Subject to” and inserting “COINSUR-  
3 ANCE.—

4 “(i) IN GENERAL.—Subject to”;

5 (C) in each of subclauses (I) and (II), as  
6 redesignated by subparagraph (A), by striking  
7 “25 percent” and inserting “the applicable per-  
8 centage (as defined in clause (ii))”; and

9 (D) by adding at the end the following new  
10 clause:

11 “(ii) APPLICABLE PERCENTAGE DE-  
12 FINED.—For purposes of clause (i), the  
13 term ‘applicable percentage’ means—

14 “(I) for a year preceding 2022,  
15 25 percent; and

16 “(II) for 2022 and each subse-  
17 quent year, 20 percent.”.

18 (2) CONFORMING AMENDMENT.—Section  
19 1860D–14(a)(2)(D) of the Social Security Act (42  
20 U.S.C. 1395w–114(a)(2)(D)) is amended by striking  
21 “25 percent” and inserting “the applicable percent-  
22 age”.

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

1 (1) in paragraph (1)—

2 (A) by striking “equal to 80 percent” and  
3 inserting “equal to—

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

6 (B) in subparagraph (A), as added by  
7 paragraph (1), by striking the period at the end  
8 and inserting “; and”; and

9 (C) by adding at the end the following new  
10 subparagraph:

11 “(B) for a subsequent year, the sum of—

12 “(i) an amount equal to the applicable  
13 percentage specified in paragraph (5)(A) of  
14 such allowable reinsurance costs attrib-  
15 utable to that portion of gross prescription  
16 drug 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 the applica-  
24 ble percentage specified in paragraph  
25 (5)(B) of allowable reinsurance costs at-



1           tributable to that portion of gross prescrip-  
2           tion drug costs as specified in paragraph  
3           (3) incurred in the coverage year after  
4           such individual has incurred costs that ex-  
5           ceed the annual out-of-pocket threshold  
6           specified in section 1860D–2(b)(4)(B) with  
7           respect to covered part D drugs that are  
8           not applicable drugs (as so defined).”;

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

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

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

16                           “(i) for 2022, 60 percent;

17                           “(ii) for 2023, 40 percent; and

18                           “(iii) for 2024 and each subsequent  
19                   year, 20 percent; and

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

22                           “(i) for 2022, 80 percent;

23                           “(ii) for 2023, 60 percent; and

24                           “(iii) for 2024 and each subsequent  
25           year, 40 percent.”.

1 (d) MANUFACTURER DISCOUNT PROGRAM DURING  
2 INITIAL AND CATASTROPHIC PHASES OF COVERAGE.—

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

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

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

18 “(b) TERMS OF AGREEMENT.—

19 “(1) IN GENERAL.—

20 “(A) AGREEMENT.—An agreement under  
21 this section shall require the manufacturer to  
22 provide applicable beneficiaries access to dis-  
23 counted prices for applicable drugs of the man-  
24 ufacturer that are dispensed on or after Janu-  
25 ary 1, 2022.

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

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

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

22          “(4) LENGTH OF AGREEMENT.—

23                 “(A) IN GENERAL.—An agreement under  
24                 this section shall be effective for an initial pe-  
25                 riod of not less than 12 months and shall be

1 automatically renewed for a period of not less  
2 than 1 year unless terminated under subpara-  
3 graph (B).

4 “(B) TERMINATION.—

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

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

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

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

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

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

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

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

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

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

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

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

20                               “(i) the negotiated price of the appli-  
21 cable drug; and

22                               “(ii) the discounted price of the appli-  
23 cable drug;

24                      “(D) the establishment of procedures to  
25 ensure that the discounted price for an applica-

1 ble drug under this section is applied before any  
2 coverage or financial assistance under other  
3 health benefit plans or programs that provide  
4 coverage or financial assistance for the pur-  
5 chase or provision of prescription drug coverage  
6 on behalf of applicable beneficiaries as the Sec-  
7 retary may specify; and

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

13 “(2) MONITORING COMPLIANCE.—

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

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

23 “(3) COLLECTION OF DATA FROM PRESCRIP-  
24 TION DRUG PLANS AND MA-PD PLANS.—The Sec-  
25 retary may collect appropriate data from prescrip-

1       tion drug plans and MA–PD plans in a timeframe  
2       that allows for discounted prices to be provided for  
3       applicable drugs under this section.

4       “(d) ADMINISTRATION.—

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

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

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

20               “(A) receive and transmit information be-  
21       tween the Secretary, manufacturers, and other  
22       individuals or entities the Secretary determines  
23       appropriate;

24               “(B) receive, distribute, or facilitate the  
25       distribution of funds of manufacturers to ap-



1           appropriate individuals or entities in order to  
2           meet the obligations of manufacturers under  
3           agreements under this section;

4           “(C) provide adequate and timely informa-  
5           tion to manufacturers, consistent with the  
6           agreement with the manufacturer under this  
7           section, as necessary for the manufacturer to  
8           fulfill its obligations under this section; and

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

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

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

23          “(6) FUNDING.—For purposes of carrying out  
24          this section, the Secretary shall provide for the  
25          transfer, from the Federal Supplementary Medical

1 Insurance Trust Fund under section 1841 to the  
2 Centers for Medicare & Medicaid Services Program  
3 Management Account, of \$4,000,000 for each of fis-  
4 cal years 2020 through 2023, to remain available  
5 until expended.”.

6 “(e) ENFORCEMENT.—

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

10 “(2) CIVIL MONEY PENALTY.—

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

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

24 “(ii) 25 percent of such amount.

1           “(B) APPLICATION.—The provisions of  
2           section 1128A (other than subsections (a) and  
3           (b)) shall apply to a civil money penalty under  
4           this paragraph in the same manner as such  
5           provisions apply to a penalty or proceeding  
6           under section 1128A(a).

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

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

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

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

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

22                         “(C) has incurred costs for covered part D  
23                         drugs in the year that are above the annual de-  
24                         ductible specified in section 1860D–2(b)(1).

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

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

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

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

23           “(iii) is provided through an exception or  
24 appeal.

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

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

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

8           “(4) DISCOUNTED PRICE.—

9                   “(A) IN GENERAL.—The term ‘discounted  
10                  price’ means—

11                          “(i) with respect to an applicable drug  
12                          dispensed for an applicable beneficiary who  
13                          has incurred costs that are below the an-  
14                          nual out-of-pocket threshold specified in  
15                          section 1860D–2(b)(4)(B), 93 percent of  
16                          the negotiated price of the applicable drug  
17                          of a manufacturer; and

18                          “(ii) with respect to an applicable  
19                          drug dispensed for an applicable bene-  
20                          ficiary who has incurred costs for covered  
21                          part D drugs in the year that are equal to  
22                          or exceed the annual out-of-pocket thresh-  
23                          old specified in section 1860D–2(b)(4)(B),  
24                          86 percent of the negotiated price of the  
25                          applicable drug of a manufacturer.

1           “(B) CLARIFICATION.—Nothing in this  
2 section shall be construed as affecting the re-  
3 sponsibility of an applicable beneficiary for pay-  
4 ment of a dispensing fee for an applicable drug.

5           “(C) CLARIFICATION FOR CERTAIN  
6 CLAIMS.—With respect to the amount of the ne-  
7 gotiated price of an individual claim for an ap-  
8 plicable drug with respect to an applicable bene-  
9 ficiary, the manufacturer of the applicable drug  
10 shall provide—

11                   “(i) the discounted price under clause  
12 (i) of subparagraph (A) only on the portion  
13 of the negotiated price of the applicable  
14 drug that falls above the deductible speci-  
15 fied in section 1860D–2(b)(1) and below  
16 the annual out-of-pocket threshold speci-  
17 fied in section 1860D–2(b)(4)(B); and

18                   “(ii) the discounted price under clause  
19 (ii) of subparagraph (A) only on the por-  
20 tion of the negotiated price of the applica-  
21 ble drug that falls at or above such annual  
22 out-of-pocket threshold.

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

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

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

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

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

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

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

1 “(h) SUNSET OF PROGRAM.—

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

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

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

17 (A) in subsection (b)(2)(C)(iii)—

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

21 “(I) the reinsurance”; and

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

24 “(II) for 2022 and each subse-  
25 quent year, the manufacturer dis-



1 counts provided under section 1860D–  
 2 14B subtracted from the actuarial  
 3 value to produce such bid; and”; and

4 (B) in subsection (c)(1)(C)—

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

8 “(i) the reinsurance”;

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

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

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

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

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

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

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

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

9                   (1) in paragraph (2)—

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

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

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

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

1 (2) in paragraph (3)—

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

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

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

14 “(3) UPDATING RISK ADJUSTMENT METH-  
15 ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA-  
16 TION REDESIGN.—The Secretary shall update the  
17 risk adjustment methodologies used to adjust bid  
18 amounts pursuant to this subsection as appropriate  
19 to take into account changes in benefits under this  
20 part pursuant to the amendments made by section  
21 121 of the Prescription Drug Pricing Reduction Act  
22 of 2019.”.

23 (g) CONFORMING AMENDMENTS.—

24 (1) Section 1860D–2 of the Social Security Act  
25 (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;

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)) 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 (E), by striking  
5 “The elimination” and inserting “For a  
6 year preceding 2022, the elimination”; and

7 (iii) in subparagraph (D)(iii), by strik-  
8 ing “1860D–2(b)(4)(A)(i)(I)” and insert-  
9 ing “1860D–2(b)(4)(A)(i)(I)(aa)”; 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)(B)(4)(B)(i)” and  
25 inserting “section 1860D–2(b)(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           (7) Section 1860D–43(a)(1) of the Social Secu-  
23 rity Act (42 U.S.C. 1395w–153(a)(1)) is amended to  
24 read as follows:

25           “(1) participate in—

1           “(A) for 2011 through 2021, the Medicare  
2 coverage gap discount program under section  
3 1860D–14A; and

4           “(B) for 2022 and each subsequent year,  
5 the manufacturer discount program under sec-  
6 tion 1860D–14B;”.

7           (h) EFFECTIVE DATE.—The amendments made by  
8 this section shall apply to plan year 2022 and subsequent  
9 plan years.

10 **SEC. 10121A. MAXIMUM MONTHLY CAP ON COST-SHARING**  
11 **PAYMENTS UNDER PRESCRIPTION DRUG**  
12 **PLANS AND MA-PD PLANS.**

13           (a) IN GENERAL.—Section 1860D–2(b) of the Social  
14 Security Act (42 U.S.C. 1395w–102(b)), as amended by  
15 section 10121, is amended—

16           (1) in paragraph (2)—

17           (A) in subparagraph (A), by striking “and  
18 (D)” and inserting “, (D), and (E)”; and

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

21           “(E) MAXIMUM MONTHLY CAP ON COST-  
22 SHARING PAYMENTS.—

23           “(i) IN GENERAL.—For plan years be-  
24 ginning on or after January 1, 2022, the  
25 Secretary shall, through notice and com-

1           ment rulemaking, establish a process under  
2           which each PDP sponsor offering a pre-  
3           scription drug plan and each MA organiza-  
4           tion offering an MA–PD plan shall provide  
5           to any enrollee, including an enrollee who  
6           is a subsidy eligible individual (as defined  
7           in paragraph (3) of section 1860D–14(a)),  
8           the option to elect with respect to a plan  
9           year to have their monthly cost-sharing  
10          payments under the plan capped in accord-  
11          ance with this subparagraph.

12           “(ii) DETERMINATION OF MAXIMUM  
13          MONTHLY CAP.—For each month in the  
14          plan year after an enrollee in a prescrip-  
15          tion drug plan or an MA–PD plan has  
16          made an election pursuant to clause (i),  
17          the PDP sponsor or MA organization shall  
18          determine a maximum monthly cap (as de-  
19          fined in clause (iv)) for such enrollee.

20           “(iii) BENEFICIARY MONTHLY PAY-  
21          MENTS.—With respect to an enrollee who  
22          has made an election pursuant to clause  
23          (i), for each month described in clause (ii),  
24          the PDP sponsor or MA organization shall  
25          bill such enrollee an amount (not to exceed



1 the maximum monthly cap) for the out-of-  
2 pocket costs of such enrollee in such  
3 month.

4 “(iv) MAXIMUM MONTHLY CAP DE-  
5 FINED.—In this subparagraph, the term  
6 ‘maximum monthly cap’ means, with re-  
7 spect to an enrollee—

8 “(I) for the first month in which  
9 this subparagraph applies, an amount  
10 determined by calculating—

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

17 “(bb) the number of months  
18 remaining in the plan year; and

19 “(II) for a subsequent month, an  
20 amount determined by calculating—

21 “(aa) the sum of any re-  
22 maining out-of-pocket costs owed  
23 by the enrollee from a previous  
24 month that have not yet been  
25 billed to the enrollee and any ad-

1                   ditional costs incurred by the en-  
2                   rollee; divided by

3                   “ (bb) the number of months  
4                   remaining in the plan year.

5                   “(v) ADDITIONAL REQUIREMENTS.—  
6                   The following requirements shall apply  
7                   with respect to the option to make an elec-  
8                   tion pursuant to clause (i) under this sub-  
9                   paragraph:

10                   “(I) SECRETARIAL RESPONSIBIL-  
11                   ITIES.—The Secretary shall provide  
12                   information to part D eligible individ-  
13                   uals on the option to make such elec-  
14                   tion through educational materials, in-  
15                   cluding through the notices provided  
16                   under section 1804(a).

17                   “(II) TIMING OF ELECTION.—An  
18                   enrollee in a prescription drug plan or  
19                   an MA–PD plan may make such an  
20                   election—

21                   “(aa) prior to the beginning  
22                   of the plan year; or

23                   “(bb) in any month during  
24                   the plan year.

1                   “(III) PDP SPONSOR AND MA  
2 ORGANIZATION RESPONSIBILITIES.—  
3 Each PDP sponsor offering a pre-  
4 scription drug plan or MA organiza-  
5 tion offering an MA–PD plan—

6                   “(aa) may not limit the op-  
7 tion for an enrollee to make such  
8 an election to certain covered  
9 part D drugs;

10                   “(bb) shall, prior to the plan  
11 year, notify prospective enrollees  
12 of the option to make such an  
13 election in promotional materials;

14                   “(cc) shall include informa-  
15 tion on such option in enrollee  
16 educational materials;

17                   “(dd) shall have in place a  
18 mechanism to notify a pharmacy  
19 during the plan year when an en-  
20 rollee incurs out-of-pocket costs  
21 with respect to covered part D  
22 drugs that make it likely the en-  
23 rollee may benefit from making  
24 such an election;

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

7           “(ff) shall ensure that such  
8 an election by an enrollee has no  
9 effect on the amount paid to  
10 pharmacies (or the timing of  
11 such payments) with respect to  
12 covered part D drugs dispensed  
13 to the enrollee; and

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

21           “(IV) FAILURE TO PAY AMOUNT  
22 BILLED.—If an enrollee fails to pay  
23 the amount billed for a month as re-  
24 quired under this subparagraph, the  
25 election of the enrollee pursuant to

1 clause (i) shall be terminated and en-  
2 rollee shall pay the cost-sharing other-  
3 wise applicable for any covered part D  
4 drugs subsequently dispensed to the  
5 enrollee up to the annual out-of-pock-  
6 et threshold specified in paragraph  
7 (4)(B).

8 “(V) CLARIFICATION REGARDING  
9 PAST DUE AMOUNTS.—Nothing in this  
10 subparagraph shall be construed as  
11 prohibiting a PDP sponsor or an MA  
12 organization from billing an enrollee  
13 for an amount owed under this sub-  
14 paragraph.

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

23 (2) in paragraph (4)—

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

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

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

5 “(G) INCLUSION OF COSTS PAID UNDER  
6 MAXIMUM MONTHLY CAP OPTION.—In applying  
7 subparagraph (A), with respect to an enrollee  
8 who has made an election pursuant to clause (i)  
9 of paragraph (2)(E), costs shall be treated as  
10 incurred if such costs are paid by a PDP spon-  
11 sor or an MA organization under the process  
12 provided under such paragraph.”.

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

17 “(4) SAME MAXIMUM MONTHLY CAP ON COST-  
18 SHARING.—For plan years beginning on or after  
19 January 1, 2022, the maximum monthly cap on  
20 cost-sharing payments under the process provided  
21 under subsection (b)(2)(E) shall apply to such cov-  
22 erage.”.

1 **SEC. 10121B. REQUIRING PHARMACY-NEGOTIATED PRICE**  
2 **CONCESSIONS, PAYMENT, AND FEES TO BE**  
3 **INCLUDED IN NEGOTIATED PRICES AT THE**  
4 **POINT-OF-SALE UNDER PART D OF THE MEDI-**  
5 **CARE PROGRAM.**

6 Section 1860D–2(d)(1)(B) of the Social Security Act  
7 (42 U.S.C. 1395w–102(d)(1)(B)) is amended—

8 (1) by striking “PRICES.—For purposes” and  
9 inserting “PRICES.—

10 “(i) IN GENERAL.—For purposes”;

11 and

12 (2) by adding at the end the following new  
13 clause:

14 “(ii) PRICES NEGOTIATED WITH  
15 PHARMACY AT POINT-OF-SALE.—For plan  
16 years beginning on or after January 1,  
17 2022, a negotiated price for a covered part  
18 D drug described in clause (i) shall be the  
19 approximate lowest possible reimbursement  
20 for such drug negotiated with the phar-  
21 macy dispensing such drug, and shall in-  
22 clude all contingent and noncontingent  
23 price concessions, payments, and fees nego-  
24 tiated with such pharmacy, but shall not  
25 include positive incentive payments paid or  
26 to be paid to such pharmacy. Such nego-

1                   tiated price shall be provided at the point-  
2                   of-sale of such drug.”.

3 **SEC. 10122. PROVIDING THE MEDICARE PAYMENT ADVI-**  
4 **SORY COMMISSION AND MEDICAID AND CHIP**  
5 **PAYMENT AND ACCESS COMMISSION WITH**  
6 **ACCESS TO CERTAIN DRUG PAYMENT INFOR-**  
7 **MATION, INCLUDING CERTAIN REBATE IN-**  
8 **FORMATION.**

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

12                   (1) in paragraph (2)—

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

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

17                           (C) by inserting at the end the following  
18                           new subparagraph:

19                                   “(C) by the Executive Director of the  
20                                   Medicare Payment Advisory Commission for  
21                                   purposes of monitoring, making recommenda-  
22                                   tions, and analysis of the program under this  
23                                   title and by the Executive Director of the Med-  
24                                   icaid and CHIP Payment and Access Commis-  
25                                   sion for purposes of monitoring, making rec-



1           ommendations, and analysis of the Medicaid  
2           program established under title XIX and the  
3           Children’s Health Insurance Program estab-  
4           lished under title XXI.”; and

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

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

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

20                 “(B) Information submitted with the bid  
21                 submitted under section 1860D–11 by such  
22                 PDP sponsor or section 1854 by such MA orga-  
23                 nization.

24                 “(C) In the case of such information from  
25                 prescription drug event records, in a form that

1 would not be permitted under section  
2 423.505(m) of title 42, Code of Federal Regula-  
3 tions, or any successor regulation, if made by  
4 the Centers for Medicare & Medicaid Services.”.

5 (b) ACCESS TO CERTAIN REBATE AND PAYMENT  
6 DATA UNDER MEDICARE AND MEDICAID.—Section  
7 1927(b)(3)(D) of the Social Security Act (42 U.S.C.  
8 1396r–8(b)(3)(D)) is amended—

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

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

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

15 (4) by inserting after clause (vi) the following  
16 new clause:

17 “(vii) to permit the Executive Direc-  
18 tor of the Medicare Payment Advisory  
19 Commission and the Executive Director of  
20 the Medicaid and CHIP Payment and Ac-  
21 cess Commission to review the information  
22 provided.”;

23 (5) in the matter at the end, by striking  
24 “1860D–4(c)(2)(E)” and inserting “1860D–  
25 4(c)(2)(G)”;

1           (6) by adding at the end the following new sen-  
 2           tence: “Any information disclosed to the Executive  
 3           Director of the Medicare Payment Advisory Commis-  
 4           sion or the Executive Director of the Medicaid and  
 5           CHIP Payment and Access Commission pursuant to  
 6           this subparagraph shall not be disclosed by either  
 7           such Executive Director in a form which discloses  
 8           the identity of a specific manufacturer or wholesaler  
 9           or prices charged for drugs by such manufacturer or  
 10          wholesaler.”.

11 **SEC. 10123. PUBLIC DISCLOSURE OF DRUG DISCOUNTS AND**  
 12                           **OTHER PHARMACY BENEFIT MANAGER (PBM)**  
 13                           **PROVISIONS.**

14           (a) PUBLIC DISCLOSURE OF DRUG DISCOUNTS.—

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

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

20                           (B) by adding at the end the following new  
 21                           subsection:

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

24                           “(1) IN GENERAL.—Subject to paragraphs (2)  
 25                           and (3), in order to allow patients and employers to

1 compare PBMs' ability to negotiate rebates, dis-  
2 counts, and price concessions and the amount of  
3 such rebates, discounts, and price concessions that  
4 are passed through to plan sponsors, not later than  
5 July 1, 2022, the Secretary shall make available on  
6 the Internet website of the Department of Health  
7 and Human Services the information provided to the  
8 Secretary and described in paragraphs (2) and (3)  
9 of subsection (b) with respect to each PBM.

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

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

21 (2) EFFECTIVE DATE.—The amendment made  
22 by paragraph (1)(A) shall take effect on January 1,  
23 2022.

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

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

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

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

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

13 “(i) IN GENERAL.—Beginning Janu-  
14 ary 1, 2022, in order to ensure that—

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

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

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

3 “(ii) INDEPENDENT THIRD PARTY.—

4 An audit described in clause (i) shall—

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

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

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

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

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

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

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

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

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

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

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

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

20 “(ix) CIVIL MONETARY PENALTIES.—

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



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

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

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

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

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

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

23 “(B) TO PHARMACIES.—

24 “(i) IN GENERAL.—For plan year  
25 2022 and subsequent plan years, a PDP

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

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

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

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

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

5                   “(iii) DISCLOSURE OF CONFLICTS OF  
6 INTEREST.—With respect to plan year  
7 2022 and subsequent plan years, a PDP  
8 sponsor of a prescription drug plan and an  
9 MA organization offering an MA–PD plan  
10 shall, as part of its bid submission under  
11 section 1860D–11(b), provide the Sec-  
12 retary with a completed statement of fi-  
13 nancial conflicts of interest, including with  
14 manufacturers, from each member of any  
15 pharmacy and therapeutic committee used  
16 by the sponsor or organization pursuant to  
17 this paragraph.”.

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

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

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

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

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

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

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

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

17                          (B) in clause (iv), by striking the period at  
18                          the end and inserting the following: “, and, with  
19                          respect to plan year 2022 and subsequent plan  
20                          years, actual and projected administrative ex-  
21                          penses assumed in the bid, categorized by the  
22                          type of such expense, including actual and pro-  
23                          jected price concessions retained by a pharmacy  
24                          benefit manager; and”; and

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

3 “(v) with respect to plan year 2022  
4 and subsequent plan years, actual and pro-  
5 jected direct and indirect remuneration,  
6 categorized as received from each of the  
7 following:

8 “(I) A pharmacy.

9 “(II) A manufacturer.

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

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

14 **SEC. 10124. PUBLIC DISCLOSURE OF DIRECT AND INDIRECT**  
15 **REMUNERATION REVIEW AND AUDIT RE-**  
16 **SULTS.**

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

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

23 “(1) DIRECT AND INDIRECT REMUNERATION  
24 REVIEW RESULTS.—

1           “(A) IN GENERAL.—Except as provided in  
2           subparagraph (B), in 2021 and each subse-  
3           quent year, the Secretary shall make available  
4           to the public on the Internet website of the  
5           Centers for Medicare & Medicaid Services infor-  
6           mation on discrepancies related to summary  
7           and detailed direct and indirect remuneration  
8           reports submitted by PDP sponsors pursuant to  
9           section 1860D–15 across all prescription drug  
10          plans based on the most recent data available.  
11          Information made available under this subpara-  
12          graph shall include the following:

13                   “(i) The number of potential discrep-  
14                   ancies in summary and detailed direct and  
15                   indirect remuneration identified by the  
16                   Secretary for PDP sponsors to review.

17                   “(ii) The extent to which PDP spon-  
18                   sors resubmitted summary direct and indi-  
19                   rect remuneration reports to make changes  
20                   for previous contract years.

21                   “(iii) The extent to which resubmitted  
22                   summary direct and indirect remuneration  
23                   reports resulted in an increase or decrease  
24                   in direct and indirect remuneration in a  
25                   previous contract year.

1           “(B) EXCLUSION OF CERTAIN SUBMIS-  
2           SIONS IN CALCULATION.—The Secretary shall  
3           exclude any information in direct and indirect  
4           remuneration reports submitted with respect to  
5           PACE programs under section 1894 (pursuant  
6           to section 1860D–21(f)) and qualified retiree  
7           prescription drug plans (as defined in section  
8           1860D–22(a)(2)) from the information that is  
9           made available to the public under subpara-  
10          graph (A).

11          “(2) FINANCIAL AUDIT RESULTS.—In 2021 and  
12          each subsequent year, the Secretary shall make  
13          available to the public on the Internet website of the  
14          Centers for Medicare & Medicaid Services data on  
15          the results of financial audits required under section  
16          1860D–12(b)(3)(C). Information made available  
17          under this paragraph shall include the following:

18                 “(A) With respect to a year, the number of  
19                 PDP sponsors that received each of the fol-  
20                 lowing (or successor categories), with an indica-  
21                 tion of the number that pertain to direct and  
22                 indirect remuneration:

23                         “(i) A notice of observations or find-  
24                         ings.

1                   “(ii) An unqualified audit opinion that  
2 renders the audit closed.

3                   “(iii) A qualified audit opinion that  
4 requires the sponsor to submit a corrective  
5 action plan to the Secretary.

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

10                   “(v) A disclaimed opinion.

11                   “(B) With respect to a year, the number of  
12 PDP sponsors—

13                   “(i) that reopened a previously closed  
14 reconciliation as a result of an audit, indi-  
15 cating those that pertain to direct and in-  
16 direct remuneration changes; and

17                   “(ii) for which the Secretary recouped  
18 a payment or made a payment as a result  
19 of a reopening of a previously closed rec-  
20 onciliation, indicating when such  
21 recoupment or payment pertains to direct  
22 and indirect remuneration.

23                   “(3) NO IDENTIFICATION OF SPECIFIC PDP  
24 SPONSORS.—The information to be made available  
25 on the Internet website of the Centers for Medicare



1 & Medicaid Services described in paragraph (1) and  
 2 paragraph (2) shall not identify the specific PDP  
 3 sponsor to which any determination or action per-  
 4 tains.

5 “(4) DEFINITION OF DIRECT AND INDIRECT  
 6 REMUNERATION.—For purposes of this subsection,  
 7 the term ‘direct and indirect remuneration’ means  
 8 direct and indirect remuneration as described in sec-  
 9 tion 423.308 of title 42, Code of Federal Regula-  
 10 tions, or any successor regulation.”.

11 **SEC. 10125. INCREASING THE USE OF REAL-TIME BENEFIT**  
 12 **TOOLS TO LOWER BENEFICIARY COSTS.**

13 (a) REQUIRING PRESCRIPTION DRUG PLAN SPON-  
 14 SORS AND MEDICARE ADVANTAGE ORGANIZATIONS TO IN-  
 15 CLUDE REAL-TIME BENEFIT INFORMATION UNDER  
 16 MEDICARE PART D.—Section 1860D–4 of the Social Se-  
 17 curity Act (42 U.S.C. 1395w–104) is amended—

18 (1) by redesignating subsection (m) (relating to  
 19 program integrity transparency measures), as added  
 20 by section 6063(c) of the Substance Use-Disorder  
 21 Prevention that Promotes Opioid Recovery and  
 22 Treatment for Patients and Communities Act (Pub-  
 23 lic Law 115–271), as subsection (n); and

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

1 “(o) REAL-TIME BENEFIT INFORMATION.—

2 “(1) IN GENERAL.—After the Secretary has  
3 adopted a standard under paragraph (3) for elec-  
4 tronic real-time benefit tools, and at a time deter-  
5 mined appropriate by the Secretary, a PDP sponsor  
6 of a prescription drug plan shall implement one or  
7 more of such tools that meet the requirements de-  
8 scribed in paragraph (2).

9 “(2) REQUIREMENTS.—For purposes of para-  
10 graph (1), the requirements described in this para-  
11 graph, with respect to an electronic real-time benefit  
12 tool, are that the tool is capable of—

13 “(A) integrating with electronic prescribing  
14 and electronic health record systems of pre-  
15 scribing health care professionals for the trans-  
16 mission of eligibility and formulary and benefit  
17 information in real time to such professionals;  
18 and

19 “(B) with respect to a covered part D  
20 drug, transmitting such information specific to  
21 an individual enrolled in a prescription drug  
22 plan, including the following:

23 “(i) A list of any clinically-appropriate  
24 alternatives to such drug included in the  
25 formulary of such plan.

1                   “(ii) Cost-sharing information and the  
2                   negotiated price for such drug and such al-  
3                   ternatives at—

4                                 “(I) multiple pharmacy options,  
5                                 including the individual’s preferred  
6                                 pharmacy and, as applicable, other re-  
7                                 tail pharmacies and a mail order  
8                                 pharmacy; and

9                                 “(II) the formulary status of  
10                                 such drug and such alternatives and  
11                                 any prior authorization or other utili-  
12                                 zation management requirements ap-  
13                                 plicable to such drug and such alter-  
14                                 natives included in the formulary of  
15                                 such plan.

16                   “(3) STANDARDS.—In order to be treated (for  
17                   purposes of this subsection) as an electronic real-  
18                   time benefit tool described in paragraph (1), such  
19                   tool shall comply with technical standards adopted  
20                   by the Secretary in consultation with the National  
21                   Coordinator for Health Information Technology, the  
22                   National Council for Prescription Drug Programs,  
23                   other standard setting organizations determined ap-  
24                   propriate by the Secretary, and stakeholders includ-  
25                   ing PDP sponsors, Medicare Advantage organiza-

1 tions, health care professionals, and health informa-  
2 tion technology software vendors.

3 “(4) RULE OF CONSTRUCTION.—Nothing in  
4 this subsection shall be construed to prohibit the ap-  
5 plication of paragraph (b)(7) of section 423.160 of  
6 title 42, Code of Federal Regulations, as is to be  
7 added to such section pursuant to the final rule pub-  
8 lished in the Federal Register on May 23, 2019, and  
9 titled ‘Modernizing Part D and Medicare Advantage  
10 To Lower Drug Prices and Reduce Out-of-Pocket  
11 Expenses’ (84 Fed. Reg. 23832 through 23884).”.

12 (b) REQUIRING QUALIFIED ELECTRONIC HEALTH  
13 RECORDS TO INCLUDE REAL-TIME BENEFIT TOOLS.—  
14 Section 3000(13) of the Public Health Service Act (42  
15 U.S.C. 300jj(13)) is amended—

16 (1) in subparagraph (A), by striking “and” at  
17 the end;

18 (2) in subparagraph (B), by striking the period  
19 and inserting “; and”; and

20 (3) by adding at the end the following:

21 “(C) includes, or is capable of including, a  
22 real-time benefit tool that conveys patient-spe-  
23 cific real-time cost and coverage information  
24 with respect to prescription drugs that, with re-  
25 spect to any health information technology cer-



1 Law 115–123), relating to providing prescription  
2 drug plans with parts A and B claims data to pro-  
3 mote the appropriate use of medications and im-  
4 prove health outcomes, is amended—

5 (A) in subparagraph (B)—

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

10 (ii) by striking “PURPOSES.—A PDP  
11 sponsor” and inserting PURPOSES—

12 “(i) IN GENERAL.—A PDP sponsor.”;

13 and

14 (iii) by adding at the end the fol-  
15 lowing new clause:

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

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

1           (2) EFFECTIVE DATE.—The amendments made  
2           by this subsection shall apply to plan years begin-  
3           ning on or after January 1, 2022.

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

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

10           (2) by adding at the end the following new  
11           clause:

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

22                           “(II) IMPLEMENTATION.—Not-  
23                           withstanding any other provision of  
24                           law, the Secretary may implement this

1 clause by program instruction or oth-  
2 erwise.”.

3 (c) TECHNICAL CORRECTION.—Such paragraph (6)  
4 is redesignated as paragraph (7).

5 **SEC. 10127. PERMANENTLY AUTHORIZE A SUCCESSFUL**  
6 **PILOT ON RETROACTIVE MEDICARE PART D**  
7 **COVERAGE FOR LOW-INCOME BENE-**  
8 **FICIARIES.**

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

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

13 (2) by inserting after subsection (d) the fol-  
14 lowing new subsection:

15 “(e) LIMITED INCOME NEWLY ELIGIBLE TRANSI-  
16 TION (LI NET) PROGRAM.—

17 “(1) IN GENERAL.—By not later than 2022,  
18 the Secretary shall establish a program to provide  
19 transitional coverage for covered part D drugs for  
20 LI NET eligible individuals in accordance with this  
21 subsection.

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



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

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

7           “(3) TRANSITIONAL COVERAGE DEFINED.—For  
8           purposes of this subsection, the term ‘transitional  
9           coverage’ means the following with respect to a LI  
10          NET eligible individual:

11           “(A) ALL LI NET ELIGIBLE INDIVID-  
12          UALS.—Immediate access to covered part D  
13          drugs at the point of sale during the period  
14          that begins on the first day of the month such  
15          individual is determined to meet the require-  
16          ments of clauses (ii) and (iii) of subsection  
17          (a)(3)(A) and ends on the date that coverage  
18          under a prescription drug plan or an MA-PD  
19          plan takes effect with respect to such indi-  
20          vidual.

21           “(B) FULL-BENEFIT DUAL ELIGIBLES AND  
22          SSI RECIPIENTS.—In the case of a LI NET eli-  
23          gible individual who is a full-benefit dual eligi-  
24          ble individual (as defined in section 1935(c)(6))  
25          or recipient of supplemental security income

1 benefits under title XVI, retroactive coverage  
2 (in the form of reimbursement of the amounts  
3 that would have been paid under this part had  
4 such individual been enrolled in a prescription  
5 drug plan or an MA–PD plan) of covered part  
6 D drugs purchased by such individual during  
7 the period that—

8 “(i) begins on the date that is the  
9 later of the date that—

10 “(I) such individual was first eli-  
11 gible for a low income subsidy under  
12 this part; or

13 “(II) is 36 months prior to the  
14 date such individual enrolls in a pre-  
15 scription drug plan or an MA–PD  
16 plan; and

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

19 “(4) PROGRAM ADMINISTRATION.—

20 “(A) SINGLE POINT OF CONTACT.—The  
21 Secretary shall, to the extent feasible, admin-  
22 ister the program under this subsection through  
23 a contract with a single program administrator  
24 who will provide for a single point of contact for  
25 LI NET eligible individuals.

1           “(B) BENEFIT DESIGN.—The Secretary  
2 shall ensure that the transitional coverage pro-  
3 vided to LI NET eligible individuals under this  
4 subsection—

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

7           “(ii) permits all pharmacies deter-  
8 mined by the Secretary to be in good  
9 standing to process claims under the pro-  
10 gram;

11           “(iii) is consistent with such require-  
12 ments as the Secretary considers necessary  
13 to improve patient safety and ensure ap-  
14 propriate dispensing of medication; and

15           “(iv) meets such other requirements  
16 as the Secretary may establish.

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

19           “(A) IN GENERAL.—The following provi-  
20 sions shall not apply to the program under this  
21 subsection:

22           “(i) Paragraphs (1) and (3)(B) of sec-  
23 tion 1860D–4(a) (dissemination of general  
24 information; availability of information on

1 changes in formulary through the inter-  
2 net).

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

7 “(iii) Paragraphs (1)(C) and (2) of  
8 section 1860D–4(c) (medication therapy  
9 management program).

10 “(B) WAIVER AUTHORITY.—The Secretary  
11 may waive such other requirements of title XI  
12 and this title as may be necessary to carry out  
13 the purposes of the program established under  
14 this subsection.”.

15 **SEC. 10128. MEDICARE PART D REBATE BY MANUFACTUR-**  
16 **ERS FOR CERTAIN DRUGS WITH PRICES IN-**  
17 **CREASING FASTER THAN INFLATION.**

18 (a) IN GENERAL.—Subpart 2 of part D of title XVIII  
19 of the Social Security Act is amended by inserting after  
20 section 1860D–14B, as added by section 10121, the fol-  
21 lowing new section:

22 **“SEC. 1860D–14C. MANUFACTURER REBATE FOR CERTAIN**  
23 **DRUGS WITH PRICES INCREASING FASTER**  
24 **THAN INFLATION.**

25 “(a) REQUIREMENTS.—

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

3           “(A) IN GENERAL.—Subject to subpara-  
4           graph (B), not later than 6 months after the  
5           end of each rebate period (as defined in para-  
6           graph (4)(A)) beginning on or after January 1,  
7           2022, the Secretary shall, for each rebatable  
8           covered part D drug (as defined in paragraph  
9           (4)(B)), report to each manufacturer (as de-  
10          fined in paragraph (4)(C)) of such rebatable  
11          covered part D drug the following for the rebate  
12          period:

13                 “(i) Information on the total number  
14                 of units (as defined in paragraph (4)(D))  
15                 of each dosage form and strength de-  
16                 scribed in paragraph (1)(A) of subsection  
17                 (b) for such rebatable covered part D drug  
18                 and rebate period.

19                 “(ii) Information on the amount (if  
20                 any) of the excess price described in para-  
21                 graph (1)(B) of such subsection for such  
22                 rebatable covered part D drug and rebate  
23                 period.

1                   “(iii) The rebate amount specified  
2                   under such subsection for such rebatable  
3                   covered part D drug and rebate period.

4                   “(iv) Other information determined  
5                   appropriate by the Secretary.

6                   “(B) TRANSITION RULE FOR INFORMATION  
7                   IN 2022.—Notwithstanding subparagraph (A),  
8                   the Secretary may, for each rebatable covered  
9                   part D drug, delay the timeframe for reporting  
10                  the information and rebate amount described in  
11                  clauses (i), (ii), (iii), and (iv) of such subpara-  
12                  graph for rebate periods in 2022 until not later  
13                  than December 31, 2023.

14                  “(2) MANUFACTURER REBATE.—

15                  “(A) IN GENERAL.—Subject to subpara-  
16                  graph (B), for each rebate period beginning on  
17                  or after January 1, 2022, each manufacturer of  
18                  a rebatable covered part D drug shall, not later  
19                  than 30 days after the date of receipt from the  
20                  Secretary of the information and rebate amount  
21                  pursuant to paragraph (1), provide to the Sec-  
22                  retary a rebate that is equal to the amount  
23                  specified in subsection (b) for such drug for  
24                  such rebate period.

1           “(B) EXEMPTION FOR SHORTAGES.—The  
2           Secretary may reduce or waive the rebate under  
3           this paragraph with respect to a rebatable cov-  
4           ered part D drug that is listed on the drug  
5           shortage list maintained by the Food and Drug  
6           Administration pursuant to section 506E of the  
7           Federal Food, Drug, and Cosmetic Act.

8           “(3) REQUEST FOR RECONSIDERATION.—The  
9           Secretary shall establish procedures under which a  
10          manufacturer of a rebatable covered part D drug  
11          may request a reconsideration by the Secretary of  
12          the rebate amount specified under subsection (b) for  
13          such drug and rebate period, as reported to the  
14          manufacturer pursuant to paragraph (1). Timing for  
15          a reconsideration shall be coordinated with the tim-  
16          ing of reconciliation, as described in subsection  
17          (b)(6) and as determined appropriate by the Sec-  
18          retary.

19          “(4) DEFINITIONS.—In this section:

20                 “(A) REBATE PERIOD.—

21                         “(i) IN GENERAL.—Subject to clause  
22                         (ii), the term ‘rebate period’ means, with  
23                         respect to a year, each of the six month  
24                         periods that begin on January 1 and July  
25                         1 of the year.

1                   “(ii) INITIAL REBATE PERIOD FOR  
2                   SUBSEQUENTLY APPROVED DRUGS.—In  
3                   the case of a rebatable covered part D  
4                   drug described in subsection (c), the initial  
5                   rebate period for which a rebate amount is  
6                   determined for such rebatable covered part  
7                   D drug pursuant to such subsection shall  
8                   be the period beginning with the first  
9                   month after the last day of the six month  
10                  period that begins on the day on which the  
11                  drug was first marketed and ending on the  
12                  last day of the first full rebate period  
13                  under clause (i) that follows the last day of  
14                  such six month period.

15               “(B) REBATABLE COVERED PART D  
16               DRUG.—The term ‘rebatable covered part D  
17               drug’ means a covered part D drug approved  
18               under a new drug application under section  
19               505(c) of the Federal Food, Drug, and Cos-  
20               metic Act or, in the case of a biologic product,  
21               licensed under section 351(a) of the Public  
22               Health Service Act.

23               “(C) MANUFACTURER.—The term ‘manu-  
24               facturer’ has the meaning given such term in  
25               section 1860D—14A(g).



1           “(D) UNITS.—The term ‘units’ means,  
2           with respect to a rebatable covered part D  
3           drug, the lowest common quantity (such as the  
4           number of capsules or tablets, milligrams of  
5           molecules, or grams) of such drug dispensed to  
6           individuals under this part.

7           “(E) PRICE.—The term ‘price’ means,  
8           with respect to a rebatable covered part D  
9           drug, the wholesale acquisition cost (as defined  
10          in section 1847A(c)(6)(B)) for such drug.

11       “(b) REBATE AMOUNT.—

12           “(1) IN GENERAL.—Subject to subsection  
13          (e)(2), the amount of the rebate specified in this  
14          subsection for a rebate period, with respect to each  
15          dosage form and strength of a rebatable covered  
16          part D drug, is the amount equal to the product  
17          of—

18           “(A) the total number of units of such dos-  
19          age form and strength for each rebatable cov-  
20          ered part D drug during the rebate period; and

21           “(B) the amount (if any) by which—

22           “(i) the unit-weighted average price  
23          for such dosage form and strength of the  
24          drug determined under paragraph (2) for  
25          the rebate period; exceeds

1                   “(ii) the inflation-adjusted price for  
2                   such dosage form and strength determined  
3                   under paragraph (3) for the rebate period.

4                   “(2) DETERMINATION OF UNIT-WEIGHTED AV-  
5                   ERAGE PRICE.—

6                   “(A) IN GENERAL.—The unit-weighted av-  
7                   erage price determined under this paragraph  
8                   for a rebate period, with respect to each dosage  
9                   form and strength of a rebatable covered Part  
10                  D drug, is the sum of the products of—

11                  “(i) the weighted average price deter-  
12                  mined under subparagraph (B) with re-  
13                  spect to each package size of such dosage  
14                  form and strength dispensed during the re-  
15                  bate period; and

16                  “(ii) the ratio of—

17                          “(I) the total number of units of  
18                          such package size dispensed during  
19                          the rebate period; to

20                          “(II) the total number of units of  
21                          such dosage form and strength of  
22                          such drug dispensed during such re-  
23                          bate period.

24                  “(B) COMPUTATION OF WEIGHTED AVER-  
25                  AGE PRICE.—The weighted average price, with

1 respect to each package size of such dosage  
2 form and strength of a rebatable covered part  
3 D drug dispensed during a rebate period, is the  
4 sum of the products of—

5 “(i) each price, as calculated for a  
6 unit of such drug, applicable to each pack-  
7 age size of such dosage form and strength  
8 of such drug during the rebate period; and

9 “(ii) the ratio of—

10 “(I) the number of days for  
11 which each such price is applicable  
12 during the rebate period; to

13 “(II) the total number of days in  
14 such rebate period.

15 “(3) DETERMINATION OF INFLATION-ADJUSTED  
16 PRICE.—

17 “(A) IN GENERAL.—The inflation-adjusted  
18 price determined under this paragraph for a re-  
19 bate period, with respect to each dosage form  
20 and strength of a rebatable covered part D  
21 drug, is—

22 “(i) the benchmark unit-weighted  
23 price determined under subparagraph (B)  
24 for the rebate period; increased by

1                   “(ii) the percentage by which the re-  
2                   bate period CPI-U (as defined in para-  
3                   graph (4)) for the rebate period exceeds  
4                   the benchmark CPI-U (as defined in para-  
5                   graph (5)).

6                   “(B) DETERMINATION OF BENCHMARK  
7                   UNIT-WEIGHTED PRICE.—The benchmark unit-  
8                   weighted price determined under this subpara-  
9                   graph for a rebate period, with respect to each  
10                  dosage form and strength of a rebatable cov-  
11                  ered part D drug, is the sum of the products  
12                  of—

13                  “(i) each price, as calculated for a  
14                  unit of such drug, applicable to each pack-  
15                  age size of such dosage form and strength  
16                  of such drug on July 1, 2019; and

17                  “(ii) the ratio of—

18                          “(I) the total number of units of  
19                          such package size dispensed on July  
20                          1, 2019; to

21                          “(II) the total number of units of  
22                          such dosage form and strength dis-  
23                          pensed on July 1, 2019.

24                  “(4) BENCHMARK CPI-U.—The term ‘bench-  
25                  mark CPI-U’ means the consumer price index for

1 all urban consumers (United States city average) for  
2 July 2019.

3 “(5) REBATE PERIOD CPI–U.—The term ‘rebate  
4 period CPI–U’ means, with respect to a rebate pe-  
5 riod, the consumer price index for all urban con-  
6 sumers (United States city average) for the last  
7 month of the rebate period.

8 “(6) ANNUAL RECONCILIATION OF REBATE  
9 AMOUNT.—The Secretary shall, on an annual basis,  
10 conduct a one-time reconciliation of the rebate  
11 amounts owed by a manufacturer under this section  
12 based on any changes submitted by a PDP sponsor  
13 of a prescription drug plan or an MA organization  
14 offering an MA–PD plan to the number of units of  
15 a rebatable covered part D drug dispensed during  
16 the preceding year. Such reconciliation shall be com-  
17 pleted not later than 6 months after the date by  
18 which the Secretary reconciles payment for covered  
19 part D drugs with PDP sponsors of prescription  
20 drug plans or MA organizations offering MA–PD  
21 plans.

22 “(c) TREATMENT OF SUBSEQUENTLY APPROVED  
23 DRUGS.—Subject to subsection (e)(2), in the case of a  
24 rebatable covered part D drug first approved or licensed

1 by the Food and Drug Administration after July 1,  
2 2019—

3 “(1) subparagraph (A)(ii) of subsection (b)(3)  
4 shall be applied as if the term ‘benchmark CPI-U’  
5 were defined under subsection (b)(4) as if the ref-  
6 erence to ‘July 2019’ under such subsection were a  
7 reference to ‘the first month after the last day of the  
8 six month period that begins on the day on which  
9 the drug was first marketed’; and

10 “(2) subsection (b)(3) shall be applied by sub-  
11 stituting, for the benchmark unit-weighted price oth-  
12 erwise determined under subparagraph (B) of such  
13 subsection, the benchmark unit-weighted average  
14 price determined under paragraph (3) for the rebate  
15 period;

16 “(3) the benchmark unit-weighted average price  
17 determined under this paragraph for a rebate period,  
18 with respect to each dosage form and strength of a  
19 rebatable covered part D drug, is the sum of the  
20 products of—

21 “(A) the subsequently rebatable drug  
22 weighted average price determined under para-  
23 graph (4) with respect to each package size of  
24 such dosage form and strength of such drug  
25 dispensed during the six month period that be-

1 gins on the day on which the drug was first  
2 marketed; and

3 “(B) the ratio of—

4 “(i) the total number of units of such  
5 package size dispensed during the six  
6 month period that begins on the day on  
7 which the drug was first marketed; to

8 “(ii) the total number of units of such  
9 dosage form and strength of such drug dis-  
10 pensed during such six month period; and

11 “(4) the subsequently rebatable drug weighted  
12 average price, with respect to each package size of  
13 such dosage form and strength of such rebatable  
14 covered part D drug dispensed during the six month  
15 period that begins on the day on which the drug was  
16 first marketed, is the sum of the products of—

17 “(A) each price, as calculated for a unit of  
18 such drug, applicable to each package size of  
19 such dosage form and strength of such drug  
20 during the six month period that begins on the  
21 day on which the drug was first marketed; and

22 “(B) the ratio of—

23 “(i) the number of days for which  
24 each such price is applicable during such  
25 six month period; to

1                   “(ii) the total number of days in such  
2                   six month period.

3           “(d) REBATE DEPOSITS.—Amounts paid as rebates  
4 under subsection (b) shall be deposited into the Federal  
5 Supplementary Medical Insurance Trust Fund established  
6 under section 1841.

7           “(e) ADMINISTRATION.—

8               “(1) PERIODIC AUDITS.—The Secretary shall  
9 permit a manufacturer of a rebatable covered part  
10 D drug to conduct periodic audits, directly or  
11 through contracts, of the data and information used  
12 to determine the rebate amount for such drug under  
13 this section.

14               “(2) SPECIAL RULES FOR CALCULATION OF  
15 BENCHMARK UNIT-WEIGHTED PRICE AND BENCH-  
16 MARK-UNIT-WEIGHTED AVERAGE PRICE.—

17                   “(A) BENCHMARK UNIT-WEIGHTED  
18 PRICE.—In the case that the benchmark unit-  
19 weighted price of a dosage form and strength of  
20 a rebatable covered part D drug is determined  
21 under subsection (b)(3)(B) to be \$0 due to no  
22 units of such dosage form and strength of such  
23 drug being dispensed on July 1, 2019, the Sec-  
24 retary may use a calculation, as determined ap-  
25 propriate by the Secretary, to determine the



1 benchmark-unit weighted price for such dosage  
2 form and strength of such drug that is different  
3 than the calculation described in such sub-  
4 section.

5 “(B) BENCHMARK UNIT-WEIGHTED AVER-  
6 AGE PRICE.—In the case that the benchmark  
7 unit-weighted average price of a dosage form  
8 and strength of a rebatable covered part D  
9 drug described under subsection (c) is deter-  
10 mined under paragraph (3) of such subsection  
11 to be \$0 due to no units of such dosage form  
12 and strength of such drug being dispensed dur-  
13 ing the six month period that begins on the day  
14 on which the drug was first marketed, the Sec-  
15 retary may use a calculation, as determined ap-  
16 propriate by the Secretary, to determine the  
17 benchmark-unit weighted average price for such  
18 dosage form and strength of such drug that is  
19 different than the calculation described in such  
20 paragraph.

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

24 “(4) JUDICIAL REVIEW.—There shall be no ad-  
25 ministrative or judicial review under section 1869,

1 section 1878, or otherwise of the determination of  
2 the rebate amount under subsection (b), including  
3 with respect to a subsequently approved drug pursu-  
4 ant to subsection (c), including—

5 “(A) the determination of—

6 “(i) the total number of units of each  
7 rebatable covered part D drug under sub-  
8 section (b)(1)(A);

9 “(ii) the unit-weighted average price  
10 under subsection (b)(2);

11 “(iii) the inflation-adjusted price  
12 under subsection (b)(3);

13 “(iv) the benchmark unit-weighted av-  
14 erage price under subsection (c)(3); and

15 “(v) the subsequently rebatable drug  
16 weighted average price under subsection  
17 (c)(4); and

18 “(B) the application of special rules for  
19 calculation of benchmark unit-weighted price  
20 and benchmark unit-weighted average price  
21 under paragraph (2) of this subsection.

22 “(f) CIVIL MONEY PENALTY.—

23 “(1) IN GENERAL.—The Secretary shall impose  
24 a civil money penalty on a manufacturer that fails  
25 to comply with the requirements under subsection

1 (a)(2) with respect to providing a rebate for a  
2 rebatable covered part D drug for a rebate period  
3 for each such failure in an amount equal to the sum  
4 of—

5 “(A) the rebate amount determined pursu-  
6 ant to subsection (b) for such drug for such re-  
7 bate period; and

8 “(B) 25 percent of such amount.

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

14 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-  
15 tion shall be construed as having any effect on—

16 “(1) any formulary design under section  
17 1860D–4(b)(3); or

18 “(2) any discounts provided under the coverage  
19 gap discount program under section 1860D–14A or  
20 the manufacturer catastrophic discount program  
21 under section 1860D–14B.

22 “(h) REBATE AGREEMENT.—

23 “(1) IN GENERAL.—The Secretary shall enter  
24 into agreements described in paragraph (2) with  
25 manufacturers.

1 “(2) TERMS OF AGREEMENT.—

2 “(A) IN GENERAL.—A rebate agreement  
3 under this paragraph shall require the manu-  
4 facturer to provide to the Secretary rebates re-  
5 quired under subsection (a)(2)(A) with respect  
6 to a rebate period.

7 “(B) MANUFACTURER PROVISION OF  
8 PRICE AND DRUG PRODUCT INFORMATION.—  
9 Each manufacturer with an agreement in effect  
10 under this subsection shall report to the Sec-  
11 retary, with respect to each rebatable covered  
12 part D drug of the manufacturer, at a time  
13 specified by the Secretary—

14 “(i) for each calendar month under  
15 the rebate agreement—

16 “(I) each wholesale acquisition  
17 cost (as defined in section  
18 1847A(c)(6)) applicable during the  
19 month, applicable to each National  
20 Drug Code for the dosage form and  
21 strength of such rebatable covered  
22 part D drug; and

23 “(II) the number of days with re-  
24 spect to which each wholesale acquisi-  
25 tion cost reported was applicable;

1                   “(ii) the wholesale acquisition cost (as  
2                   so defined) applicable on July 1, 2019, ap-  
3                   plicable to each National Drug Code for  
4                   the dosage form and strength of such  
5                   rebtable covered part D drug (or, in the  
6                   case of a rebtable covered part D drug  
7                   first approved or licensed by the Food and  
8                   Drug Administration after July 1, 2019,  
9                   each wholesale acquisition cost applicable  
10                  to each National Drug Code of each dos-  
11                  age form and strength of the rebtable  
12                  covered part D drug of the manufacturer  
13                  during the six month period that begins on  
14                  the day on which the drug was first mar-  
15                  keted); and

16                  “(iii) such other information as the  
17                  Secretary shall require.

18                  Information reported under this subparagraph  
19                  is subject to audit by the Inspector General of  
20                  the Department of Health and Human Services.

21                  “(3) CIVIL MONEY PENALTIES.—The provisions  
22                  of subparagraph (C) of section 1927(b)(3) shall  
23                  apply with respect to information required pursuant  
24                  to paragraph (2)(B) of this subsection and the fail-  
25                  ure to provide such information in the same manner

1 and to the same extent as such provisions apply with  
2 respect to information required under subparagraph  
3 (A) of such section 1927(b)(3) and the failure to  
4 provide such information.

5 “(4) COORDINATION.—The Secretary may co-  
6 ordinate rebate agreements required under this sub-  
7 section with agreements required under section  
8 1860D–14B.

9 “(i) FUNDING.—

10 “(1) IN GENERAL.—There are appropriated to  
11 the Secretary, from the Federal Supplementary  
12 Medical Insurance Trust Fund established under  
13 section 1841—

14 “(A) for each of calendar years 2020  
15 through 2025, \$4,000,000; and

16 “(B) for each subsequent calendar year,  
17 such sums as are necessary to carry out this  
18 section.

19 “(2) AVAILABILITY.—Amounts appropriated  
20 under paragraph (1) shall remain available until ex-  
21 pended.”.

22 (b) CONFORMING AMENDMENTS.—

23 (1) Section 1860D–43(a) of the Social Security  
24 Act (42 U.S.C. 1395w–153(a)), as amended by sec-  
25 tion 10121(g)(7), is amended—

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

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

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

7 “(4) for 2022 and each subsequent year, have  
8 entered into and have in effect an agreement de-  
9 scribed in section 1860D–14C(h)(2) with the Sec-  
10 retary”.

11 (2) Section 1927(c)(1)(C)(VI) of the Social Se-  
12 curity Act (42 U.S.C. 1396r–8(c)(1)(C)(VI)) is  
13 amended—

14 (A) by striking “or any discounts” and in-  
15 sserting “any discounts”; and

16 (B) by inserting “, or any rebates under  
17 section 1860D–14C” before the period.

18 **SEC. 10129. PROHIBITING BRANDING ON PART D BENEFIT**

19 **CARDS.**

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

1 (b) EFFECTIVE DATE.—The amendment made by  
2 subsection (a) shall apply to plan years beginning on or  
3 after January 1, 2022.

4 **SEC. 10130. REQUIRING PRESCRIPTION DRUG PLANS AND**  
5 **MA-PD PLANS TO REPORT POTENTIAL**  
6 **FRAUD, WASTE, AND ABUSE TO THE SEC-**  
7 **RETARY OF HHS.**

8 Section 1860D–4 of the Social Security Act (42  
9 U.S.C. 1395w–104), as amended by section 10125, is  
10 amended by adding at the end the following new sub-  
11 section:

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

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

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



1 **SEC. 10131. ESTABLISHMENT OF PHARMACY QUALITY**  
2 **MEASURES UNDER MEDICARE PART D.**

3 Section 1860D–4(c) of the Social Security Act (42  
4 U.S.C. 1395w–104(c)), as amended by section 10126, is  
5 amended by adding at the end the following new para-  
6 graph:

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

9 “(A) IN GENERAL.—A PDP sponsor that  
10 makes incentive payments to a pharmacy or re-  
11 ceives price concessions paid by a pharmacy  
12 based on quality measures shall, for the pur-  
13 poses of such incentive payments or price con-  
14 ceSSIONS with respect to covered part D drugs  
15 dispensed by such pharmacy, only use meas-  
16 ures—

17 “(i) established or adopted by the Sec-  
18 retary under subparagraph (B), as listed  
19 under clause (ii) of such subparagraph;  
20 and

21 “(ii) that are relevant to the perform-  
22 ance of such pharmacy with respect to  
23 areas that the pharmacy can impact.

24 “(B) STANDARD PHARMACY QUALITY  
25 MEASURES.—

1                   “(i) IN GENERAL.—Notwithstanding  
2                   any other provision of law, the Secretary  
3                   shall establish or adopt quality measures  
4                   from one or more multi-stakeholder, con-  
5                   sensus organizations to be used by a PDP  
6                   sponsor for the purposes of determining in-  
7                   centive payments and price concessions de-  
8                   scribed in subparagraph (A). Such meas-  
9                   ures shall be evidence-based and focus on  
10                  pharmacy performance on patient health  
11                  outcomes and other areas, as determined  
12                  by the Secretary, that the pharmacy can  
13                  impact.

14                  “(ii) MAINTENANCE OF LIST.—The  
15                  Secretary shall maintain a single list of  
16                  measures established or adopted under this  
17                  subparagraph.

18                  “(C) EFFECTIVE DATE.—The requirement  
19                  under subparagraph (A) shall take effect for  
20                  plan years beginning on January 1, 2022, or  
21                  such earlier date specified by the Secretary if  
22                  the Secretary determines there are sufficient  
23                  measures established or adopted under subpara-  
24                  graph (B) for the purposes of the requirement  
25                  under subparagraph (A).”.

1 **SEC. 10132. ADDITION OF NEW MEASURES BASED ON AC-**  
2 **CESS TO BIOSIMILAR BIOLOGICAL PROD-**  
3 **UCTS TO THE 5-STAR RATING SYSTEM UNDER**  
4 **MEDICARE ADVANTAGE.**

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

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

11 “(i) IN GENERAL.—For 2025 and  
12 subsequent years, the Secretary shall add a  
13 new set of measures to the 5-star rating  
14 system based on access to biosimilar bio-  
15 logical products covered under part B and,  
16 in the case of MA–PD plans, such prod-  
17 ucts that are covered part D drugs. Such  
18 measures shall assess the impact a plan’s  
19 benefit structure may have on enrollees’  
20 utilization of or ability to access biosimilar  
21 biological products, including in compari-  
22 son to the reference biological product, and  
23 shall include measures, as applicable, with  
24 respect to the following:

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

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

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

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

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

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

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

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

20   **SEC. 10133. HHS STUDY AND REPORT ON THE INFLUENCE**  
21                   **OF PHARMACEUTICAL MANUFACTURER**  
22                   **THIRD-PARTY REIMBURSEMENT HUBS ON**  
23                   **HEALTH CARE PROVIDERS WHO PRESCRIBE**  
24                   **THEIR DRUGS AND BIOLOGICALS.**

25           (a) STUDY.—

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

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

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

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

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

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

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

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

6 (b) REPORT.—Not later than January 1, 2021, the  
7 Secretary shall submit to Congress a report on the study  
8 conducted under subsection (a), together with rec-  
9 ommendations for such legislation and administrative ac-  
10 tion as the Secretary determines appropriate.

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

## 14 **Subtitle C—Miscellaneous**

### 15 **SEC. 10141. DRUG MANUFACTURER PRICE TRANSPARENCY.**

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

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

21 “(a) IN GENERAL.—

22 “(1) DETERMINATIONS.—Beginning July 1,  
23 2022, the Secretary shall make determinations as to  
24 whether a drug is an applicable drug as described in  
25 subsection (b).

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

8           “(b) APPLICABLE DRUG DESCRIBED.—

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

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

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

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

19                                   “(I) during 2020, of at least 100  
20                                   percent since the date of the enact-  
21                                   ment of this section;

22                                   “(II) during 2021, of at least  
23                                   100 percent in the preceding 12  
24                                   months or of at least 150 percent in  
25                                   the preceding 24 months;



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1                   “(III) during 2022, of at least  
2                   100 percent in the preceding 12  
3                   months or of at least 200 percent in  
4                   the preceding 36 months;

5                   “(IV) during 2023, of at least  
6                   100 percent in the preceding 12  
7                   months or of at least 250 percent in  
8                   the preceding 48 months; or

9                   “(V) on or after January 1,  
10                  2024, of at least 100 percent in the  
11                  preceding 12 months or of at least  
12                  300 percent in the preceding 60  
13                  months.

14                  “(B) HIGH SPENDING WITH INCREASE.—

15                  The drug—

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

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

1                   “(I) during 2020, of at least 15  
2                   percent since the date of the enact-  
3                   ment of this section;

4                   “(II) during 2021, of at least 15  
5                   percent in the preceding 12 months or  
6                   of at least 20 percent in the preceding  
7                   24 months;

8                   “(III) during 2022, of at least 15  
9                   percent in the preceding 12 months or  
10                  of at least 30 percent in the preceding  
11                  36 months;

12                  “(IV) during 2023, of at least 15  
13                  percent in the preceding 12 months or  
14                  of at least 40 percent in the preceding  
15                  48 months; or

16                  “(V) on or after January 1,  
17                  2024, of at least 15 percent in the  
18                  preceding 12 months or of at least 50  
19                  percent in the preceding 60 months.

20                  “(C) HIGH LAUNCH PRICE FOR NEW  
21                  DRUGS.—In the case of a drug that is marketed  
22                  for the first time on or after January 1, 2020,  
23                  and for which the manufacturer has established  
24                  the first wholesale acquisition cost on or after  
25                  such date, such wholesale acquisition cost for a

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

6 “(2) SPECIAL RULES.—

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

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

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

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

8           “(c) JUSTIFICATION DESCRIBED.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 “(d) TIMING.—

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

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

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

8               “(3) POSTING ON INTERNET WEBSITE.—

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

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

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

12       “(f) PENALTIES.—

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

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



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

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

11 “(g) DEFINITIONS.—In this section:

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

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

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

1 **SEC. 10142. STRENGTHENING AND EXPANDING PHARMACY**  
2 **BENEFIT MANAGERS TRANSPARENCY RE-**  
3 **QUIREMENTS.**

4 Section 1150A of the Social Security Act (42 U.S.C.  
5 1320b–23), as amended by section 10123, is amended—

6 (1) in subsection (a)—

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

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

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

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

16 (2) in subsection (b)—

17 (A) in paragraph (2)—

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

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

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

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

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

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

12 “(A) PDP sponsors;

13 “(B) qualified health benefit plans;

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

16 “(D) drug manufacturers.”;

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

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

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

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

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

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

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

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

15 “(A) PBM rebates;

16 “(B) administrative fees;

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

19 “(D) generic dispensing rates; and

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

22 “(2) REPORT.—Not later than July 1, 2020,  
23 and annually thereafter, the Inspector General of the  
24 Department of Health and Human Services shall  
25 submit to Congress a report containing the results

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

7 **SEC. 10143. PRESCRIPTION DRUG PRICING DASHBOARDS.**

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

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

11 “(a) IN GENERAL.—Beginning not later than Janu-  
12 ary 1, 2020, the Secretary shall establish, and annually  
13 update, internet website-based dashboards, through which  
14 beneficiaries, clinicians, researchers, and the public can re-  
15 view information on spending for, and utilization of, pre-  
16 scription drugs and biologicals (and related supplies and  
17 mechanisms of delivery) covered under each of parts B  
18 and D of title XVIII and under a State program under  
19 title XIX, including information on trends of such spend-  
20 ing and utilization over time.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 **SEC. 10144. IMPROVING COORDINATION BETWEEN THE**  
12 **FOOD AND DRUG ADMINISTRATION AND THE**  
13 **CENTERS FOR MEDICARE & MEDICAID SERV-**  
14 **ICES.**

15          (a) IN GENERAL.—

16               (1) PUBLIC MEETING.—

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

1 the availability of novel medical products de-  
2 scribed in subsection (c) on the market in the  
3 United States.

4 (B) ATTENDEES.—The Secretary shall in-  
5 vite the following to the public meeting:

6 (i) Representatives of relevant Federal  
7 agencies, including representatives from  
8 each of the medical product centers within  
9 the Food and Drug Administration and  
10 representatives from the coding, coverage,  
11 and payment offices within the Centers for  
12 Medicare & Medicaid Services.

13 (ii) Stakeholders with expertise in the  
14 research and development of novel medical  
15 products, including manufacturers of such  
16 products.

17 (iii) Representatives of commercial  
18 health insurance payers.

19 (iv) Stakeholders with expertise in the  
20 administration and use of novel medical  
21 products, including physicians.

22 (v) Stakeholders representing patients  
23 and with expertise in the utilization of pa-  
24 tient experience data in medical product  
25 development.

1 (C) TOPICS.—The public meeting agenda  
2 shall include—

3 (i) an overview of the types of prod-  
4 ucts and product categories in the drug  
5 and medical device development pipeline  
6 and the volume of products which may  
7 meet the description of a novel medical  
8 product under subsection (c);

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

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

19 (iv) trends in the differences in the  
20 data necessary to determine the safety and  
21 effectiveness of a novel medical product  
22 and the data necessary to determine  
23 whether a novel medical product meets the  
24 reasonable and necessary requirements for  
25 coverage and payment under title XVIII of

1 the Social Security Act pursuant to section  
2 1862(a)(1)(A) of such Act (42 U.S.C.  
3 1395y(a)(1)(A));

4 (v) the availability of information for  
5 sponsors of such novel medical products to  
6 meet each of those requirements; and

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

13 (D) TRADE SECRETS AND CONFIDENTIAL  
14 INFORMATION.—Nothing under this section  
15 shall be construed as authorizing the Secretary  
16 to disclose any information that is a trade se-  
17 cret or confidential information subject to sec-  
18 tion 552(b)(4) of title 5, United States Code.

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

21 (A) DRAFT GUIDANCE.—Not later than 18  
22 months after the public meeting under para-  
23 graph (1), the Secretary shall update the final  
24 guidance titled “National Coverage Determina-  
25 tions with Data Collection as a Condition of

1 Coverage: Coverage with Evidence Develop-  
2 ment” to address any opportunities to improve  
3 the availability and coordination of information  
4 as described in clauses (iv) through (vi) of para-  
5 graph (1)(C).

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

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

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

25 (2) Recommendations to—

1 (A) incorporate patient experience data  
2 (such as the impact of a disease or condition on  
3 the lives of patients and patient treatment pref-  
4 erences) into the coverage and payment proc-  
5 esses within the Centers for Medicare & Med-  
6 icaid Services;

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

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

17 (D) identify potential mechanisms to incor-  
18 porate novel payment designs similar to those  
19 in development in commercial insurance plans  
20 and State plans under title XIX of such Act  
21 (42 U.S.C. 1396 et seq.) into the Medicare pro-  
22 gram.

23 (c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For  
24 purposes of this section, a novel medical product described  
25 in this subsection is a drug, including a biological product



1 (including gene and cell therapy), or medical device, that  
2 has been designated as a breakthrough therapy under sec-  
3 tion 506(a) of the Federal Food, Drug, and Cosmetic Act  
4 (21 U.S.C. 356(a)), a breakthrough device under section  
5 515B of such Act (21 U.S.C. 360e-3), or a regenerative  
6 advanced therapy under section 506(g) of such Act (21  
7 U.S.C. 356(g)).

8 **SEC. 10145. PATIENT CONSULTATION IN MEDICARE NA-**  
9 **TIONAL AND LOCAL COVERAGE DETERMINA-**  
10 **TIONS IN ORDER TO MITIGATE BARRIERS TO**  
11 **INCLUSION OF SUCH PERSPECTIVES.**

12 Section 1862(l) of the Social Security Act (42 U.S.C.  
13 1395y(l)) is amended by adding at the end the following  
14 new paragraph:

15 “(7) PATIENT CONSULTATION IN NATIONAL  
16 AND LOCAL COVERAGE DETERMINATIONS.—With re-  
17 spect to national coverage determinations, the Sec-  
18 retary, and with respect to local coverage determina-  
19 tions, the Medicare administrative contractor, may  
20 consult with patients and organizations representing  
21 patients, including patients with disabilities, in mak-  
22 ing national and local coverage determinations.”.

1 **SEC. 10146. GAO STUDY ON INCREASES TO MEDICARE AND**  
2 **MEDICAID SPENDING DUE TO COPAYMENT**  
3 **COUPONS AND OTHER PATIENT ASSISTANCE**  
4 **PROGRAMS.**

5 (a) STUDY.—The Comptroller General of the United  
6 States shall conduct a study on the impact of copayment  
7 coupons and other patient assistance programs on pre-  
8 scription drug pricing and expenditures within the Medi-  
9 care and Medicaid programs. The study shall assess the  
10 following:

11 (1) The extent to which copayment coupons and  
12 other patient assistance programs contribute to in-  
13 flated prescription drug prices under such programs.

14 (2) The impact copayment coupons and other  
15 patient assistance programs have in the Medicare  
16 Part D program established under part D of title  
17 XVIII of the Social Security Act (42 U.S.C. 1395w-  
18 101 et seq.) on utilization of higher-cost brand drugs  
19 and lower utilization of generic drugs in that pro-  
20 gram.

21 (3) The extent to which manufacturers report  
22 or obtain tax benefits, including deductions of busi-  
23 ness expenses and charitable contributions, for any  
24 of the following:

25 (A) Offering copayment coupons or other  
26 patient assistance programs.

1 (B) Sponsoring manufacturer patient as-  
2 sistance programs.

3 (C) Paying for sponsorships at outreach  
4 and advocacy events organized by patient as-  
5 sistance programs.

6 (4) The efficacy of oversight conducted to en-  
7 sure that independent charity patient assistance pro-  
8 grams adhere to guidance from the Office of the In-  
9 spector General of the Department of Health and  
10 Human Services on avoiding waste, fraud, and  
11 abuse.

12 (b) DEFINITIONS.—In this section:

13 (1) INDEPENDENT CHARITY PATIENT ASSIST-  
14 ANCE PROGRAM.—The term “independent charity  
15 patient assistance program” means any organization  
16 described in section 501(c)(3) of the Internal Rev-  
17 enue Code of 1986 and exempt from taxation under  
18 section 501(a) of such Code and which is not a pri-  
19 vate foundation (as defined in section 509(a) of such  
20 Code) that offers patient assistance.

21 (2) MANUFACTURER.—The term “manufac-  
22 turer” has the meaning given that term in section  
23 1927(k)(5) of the Social Security Act (42 U.S.C.  
24 1396r–8(k)(5)).



1 and biologicals for which payment is currently made under  
2 part B of title XVIII of the Social Security Act (42 U.S.C.  
3 1395j et seq.) to part D of such title (42 U.S.C. 1395w–  
4 21 et seq.). Such study shall include an analysis of—

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

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

15 (b) REPORT.—

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

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

23 (A) formulary design under such part D;

24 (B) the ability of the benefit structure  
25 under such part D to control total spending on

1 drugs and biologicals for which payment is cur-  
2 rently made under such part B;

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

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

11 **SEC. 10148. TAKING STEPS TO FULFILL TREATY OBLIGA-**  
12 **TIONS TO TRIBAL COMMUNITIES.**

13 (a) GAO STUDY.—The Comptroller General shall  
14 conduct a study regarding access to, and the cost of, pre-  
15 scription drugs among Indians. The study shall include—

16 (1) a review of what Indian health programs  
17 pay for prescription drugs on reservations, in urban  
18 centers, and in Tribal communities relative to other  
19 consumers;

20 (2) recommendations to align the value of pre-  
21 scription drug discounts available under the Med-  
22 icaid drug rebate program established under section  
23 1927 of the Social Security Act (42 U.S.C. 1396r-  
24 8) with prescription drug discounts available to  
25 Tribal communities through the purchased/referred

1 care program of the Indian Health Service for physi-  
2 cian administered drugs; and

3 (3) an examination of how Tribal communities  
4 and urban Indian organizations utilize the Medicare  
5 part D program established under title XVIII of the  
6 Social Security Act (42 U.S.C. 1395w-101 et seq.)  
7 and recommendations to improve enrollment among  
8 Indians in that program.

9 (b) REPORT.—Not later than 18 months after the  
10 date of the enactment of this Act, the Comptroller General  
11 shall submit to Congress a report containing the results  
12 of the study conducted under subsection (a), together with  
13 recommendations for such legislation and administrative  
14 action as the Comptroller General determines appropriate.

15 (c) DEFINITIONS.—In this section:

16 (1) COMPTROLLER GENERAL.—The term  
17 “Comptroller General” means the Comptroller Gen-  
18 eral of the United States.

19 (2) INDIAN; INDIAN HEALTH PROGRAM; INDIAN  
20 TRIBE.—The terms “Indian”, “Indian health pro-  
21 gram”, and “Indian tribe” have the meanings given  
22 those terms in section 4 of the Indian Health Care  
23 Improvement Act (25 U.S.C. 1603).





1           terest, along with appropriate processes to  
2           address any instance where a member fails  
3           to report a conflict of interest.

4           “(iii) The membership of the pharmacy  
5           and therapeutics committee—

6                   “(I) is made publicly available;

7                   “(II) is composed of members who are  
8           independent and free of any conflict, in-  
9           cluding with respect to manufacturers,  
10          medicaid managed care entities, and phar-  
11          macy benefit managers; and

12                   “(III) includes at least 1 actively  
13          practicing physician and at least 1 actively  
14          practicing pharmacist, each of whom has  
15          expertise in the care of 1 or more Med-  
16          icaid-specific populations such as elderly or  
17          disabled individuals, children with complex  
18          medical needs, or low-income individuals  
19          with chronic illnesses.

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

1           “(v) The State reviews and has final ap-  
 2           proval of the formulary established by the phar-  
 3           macy and therapeutics committee.

4           “(vi) If the Secretary determines it appro-  
 5           priate or necessary based on the findings and  
 6           recommendations of the Comptroller General of  
 7           the United States in the report submitted to  
 8           Congress under section 203 of the Prescription  
 9           Drug Pricing Reduction Act of 2019, the Sec-  
 10          retary shall issue guidance that States must fol-  
 11          low for establishing conflict of interest policies  
 12          for the pharmacy and therapeutics committee in  
 13          accordance with the requirements of clause (ii),  
 14          including appropriate standards and require-  
 15          ments for identifying, addressing, and reporting  
 16          on conflicts of interest.”.

17          (b) APPLICATION TO MEDICAID MANAGED CARE OR-  
 18          GANIZATIONS.—

19           (1) IN GENERAL.—Clause (xiii) of section  
 20          1903(m)(2)(A) of the Social Security Act (42 U.S.C.  
 21          1396b(m)(2)(A)) is amended—

22                   (A) by striking “and (III)” and inserting  
 23                   “(III)”;

24                   (B) by striking the period at the end and  
 25                   inserting “, and (IV) any formulary used by the

1           entity for covered outpatient drugs dispensed to  
2           individuals eligible for medical assistance who  
3           are enrolled with the entity is developed and re-  
4           viewed by a pharmacy and therapeutics com-  
5           mittee that meets the requirements of clauses  
6           (ii) and (iii) of section 1927(d)(4)(A).”; and

7                   (C) by moving the left margin 2 ems to the  
8           left.

9           (2) APPLICATION TO PIHPS AND PAHPS.—Sec-  
10          tion 1903(m) of the Social Security Act (42 U.S.C.  
11          1396b(m)) is amended by adding at the end the fol-  
12          lowing new paragraph:

13                   “(10) No payment shall be made under this  
14          title to a State with respect to expenditures incurred  
15          by the State for payment for services provided by an  
16          other specified entity (as defined in paragraph  
17          (9)(D)(iii)) unless such services are provided in ac-  
18          cordance with a contract between the State and the  
19          entity which satisfies the requirements of paragraph  
20          (2)(A)(xiii).”.

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

1 **SEC. 10202. IMPROVING REPORTING REQUIREMENTS AND**  
2 **DEVELOPING STANDARDS FOR THE USE OF**  
3 **DRUG USE REVIEW BOARDS IN STATE MED-**  
4 **ICAID PROGRAMS.**

5 (a) IN GENERAL.—Section 1927(g)(3) of the Social  
6 Security Act (42 U.S.C. 1396r–8(g)(3)) is amended—

7 (1) by amending subparagraph (B) to read as  
8 follows:

9 “(B) MEMBERSHIP.—

10 “(i) IN GENERAL.—The membership  
11 of the DUR Board shall include health  
12 care professionals who have recognized  
13 knowledge and expertise in one or more of  
14 the following:

15 “(I) The clinically appropriate  
16 prescribing of covered outpatient  
17 drugs.

18 “(II) The clinically appropriate  
19 dispensing and monitoring of covered  
20 outpatient drugs.

21 “(III) Drug use review, evalua-  
22 tion, and intervention.

23 “(IV) Medical quality assurance.

24 “(ii) MEMBERSHIP REQUIREMENTS.—  
25 The membership of the DUR Board  
26 shall—

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1 “(I) be made publicly available;

2 “(II) be composed of members  
3 who are independent and free of any  
4 conflict, including with respect to  
5 manufacturers, medicaid managed  
6 care entities, and pharmacy benefit  
7 managers;

8 “(III) be made up of at least  $\frac{1}{3}$   
9 but no more than 51 percent members  
10 who are licensed and actively prac-  
11 ticing physicians and at least  $\frac{1}{3}$  mem-  
12 bers who are licensed and actively  
13 practicing pharmacists; and

14 “(IV) include at least 1 actively  
15 practicing physician and at least 1 ac-  
16 tively practicing pharmacist, each of  
17 whom has expertise in the care of 1 or  
18 more Medicaid-specific populations  
19 such as elderly or disabled individuals,  
20 children with complex medical needs,  
21 or low-income individuals with chronic  
22 illnesses.

23 “(iii) CONFLICT OF INTEREST POL-  
24 ICY.—The State shall establish and imple-

1                   ment a conflict of interest policy for the  
2                   DUR Board that—

3                               “(I) is publicly accessible;

4                               “(II) requires all board members  
5                   to complete, on at least an annual  
6                   basis, a disclosure of relationships, as-  
7                   sociations, and financial dealings that  
8                   may affect their independence of  
9                   judgement in board matters; and

10                              “(III) contains clear processes,  
11                   such as recusal from voting or discus-  
12                   sion, for those members who report a  
13                   conflict of interest, along with appro-  
14                   priate processes to address any in-  
15                   stance where a member fails to report  
16                   a conflict of interest.”; and

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

19                              “(E) DUR BOARD MEMBERSHIP RE-  
20                   PORTS.—

21                              “(i) DUR BOARD REPORTS.—Each  
22                   State shall require the DUR Board to pre-  
23                   pare and submit to the State an annual re-  
24                   port on the DUR Board membership. Each  
25                   such report shall include any conflicts of

1 interest with respect to members of the  
2 DUR Board that the DUR Board recorded  
3 or was aware of during the period that is  
4 the subject of the report, and the process  
5 applied to address such conflicts of inter-  
6 est, in addition to any other information  
7 required by the State.

8 “(ii) INCLUSION OF DUR BOARD MEM-  
9 BERSHIP INFORMATION IN STATE RE-  
10 PORTS.—Each annual State report to the  
11 Secretary required under subparagraph  
12 (D) shall include—

13 “(I) the number of individuals  
14 serving on the State’s DUR Board;

15 “(II) the names and professions  
16 of the individuals serving on such  
17 DUR Board;

18 “(III) any conflicts of interest or  
19 recusals with respect to members of  
20 such DUR Board reported by the  
21 DUR Board or that the State was  
22 aware of during the period that is the  
23 subject of the report; and

24 “(IV) whether the State has  
25 elected for such DUR Board to serve

1 as the committee responsible for de-  
2 veloping a State formulary under sub-  
3 section (d)(4)(A).”.

4 (b) MANAGED CARE REQUIREMENTS.—Section  
5 1932(i) of the Social Security Act (42 U.S.C. 1396u–2(i))  
6 is amended—

7 (1) by inserting “and each contract under a  
8 State plan with an other specified entity (as defined  
9 in section 1903(m)(9)(D)(iii))” after “under section  
10 1903(m)”;

11 (2) by striking “section 483.3(s)(4)” and in-  
12 serting “section 438.3(s)(4)”;

13 (3) by striking “483.3(s)(5)” and inserting  
14 “438.3(s)(5)”;

15 (4) by adding at the end the following: “Such  
16 a managed care entity or other specified entity shall  
17 not be considered to be in compliance with the re-  
18 quirement of such section 438.3(s)(5) that the entity  
19 provide a detailed description of its drug utilization  
20 review activities unless the entity includes a descrip-  
21 tion of the prospective drug review activities de-  
22 scribed in paragraph (2)(A) of section 1927(g) and  
23 the activities listed in paragraph (3)(C) of section  
24 1927(g), makes the underlying drug utilization re-  
25 view data available to the State and the Secretary,



1 and provides such other information as deemed ap-  
2 propriate by the Secretary.”.

3 (c) DEVELOPMENT OF NATIONAL STANDARDS FOR  
4 MEDICAID DRUG USE REVIEW.—The Secretary of Health  
5 and Human Services may promulgate regulations or guid-  
6 ance establishing national standards for Medicaid drug  
7 use review programs under section 1927(g) of the Social  
8 Security Act (42 U.S.C. 1396r–8) and drug utilization re-  
9 view activities and requirements under section 1932(i) of  
10 such Act (42 U.S.C. 1396u–2(i)), for the purpose of align-  
11 ing review criteria for prospective and retrospective drug  
12 use review across all State Medicaid programs.

13 (d) CMS GUIDANCE.—Not later than 18 months  
14 after the date of enactment of this Act, the Secretary of  
15 Health and Human Services shall issue guidance—

16 (1) outlining steps that States must take to  
17 come into compliance with statutory and regulatory  
18 requirements for prospective and retrospective drug  
19 use review under section 1927(g) of the Social Secu-  
20 rity Act (42 U.S.C. 1396r–8(g)) and drug utilization  
21 review activities and requirements under section  
22 1932(i) of such Act (42 U.S.C. 1396u–2(i)) (includ-  
23 ing with respect to requirements that were in effect  
24 before the date of enactment of this Act); and

1           (2) describing the actions that the Secretary  
2           will take to enforce such requirements.

3           (e) EFFECTIVE DATE.—The amendments made by  
4 this section shall take effect on the date that is 18 months  
5 after the date of enactment of this Act.

6 **SEC. 10203. GAO REPORT ON CONFLICTS OF INTEREST IN**  
7           **STATE MEDICAID PROGRAM DRUG USE RE-**  
8           **VIEW BOARDS AND PHARMACY AND THERA-**  
9           **PEUTICS (P&T) COMMITTEES.**

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

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

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

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

1 (B) States that operate separate P&T  
2 Committees for their fee-for-service Medicaid  
3 program and their Medicaid managed care or-  
4 ganizations or other Medicaid managed care ar-  
5 rangements (including other specified entities  
6 (as defined in section 1903(m)(9)(D)(iii) of the  
7 Social Security Act (42 U.S.C.  
8 1396b(m)(9)(D)(iii)) and collectively referred to  
9 in this section as “Medicaid MCOs”); and

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

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

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

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

1       icaid programs, managed care organizations, and  
2       other entities or individuals in the pharmaceutical  
3       industry.

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

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

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

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

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

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

3 **SEC. 10204. 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 regular 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 FAILURE TO PRO-  
24                                  VIDE                                  TIMELY                                  INFORMATION.—Section  
25                                  1927(b)(3)(C)(i) of the Social Security Act (42

1 U.S.C. 1396r–8(b)(3)(C)(i)) is amended by striking  
2 “increased by \$10,000 for each day in which such  
3 information has not been provided and such amount  
4 shall be paid to the Treasury” and inserting “, for  
5 each covered outpatient drug with respect to which  
6 such information is not provided, \$50,000 for the  
7 first day that such information is not provided on a  
8 timely basis and \$19,000 for each subsequent day  
9 that such information 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. 10205. EXCLUDING AUTHORIZED GENERIC DRUGS**  
20 **FROM CALCULATION OF AVERAGE MANUFAC-**  
21 **TURER PRICE UNDER THE MEDICAID DRUG**  
22 **REBATE PROGRAM.**

23 (a) IN GENERAL.—Subparagraph (C) of section  
24 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r–  
25 8(k)(1)) is amended—

1 (1) in the subparagraph heading, by striking  
2 “INCLUSION” and inserting “EXCLUSION”;

3 (2) by striking “a new drug application” and  
4 inserting “the manufacturer’s new drug applica-  
5 tion”; and

6 (3) by striking “inclusive” and inserting “exclu-  
7 sive”.

8 (b) EXCLUDING MANUFACTURERS FROM DEFINI-  
9 TION OF WHOLESALER.—Section 1927(k)(11) of the So-  
10 cial Security Act (42 U.S.C. 1396r–8(k)(11)) is amend-  
11 ed—

12 (1) by striking “manufacturers,”;

13 (2) by striking “manufacturer’s and”; and

14 (3) by adding at the end the following: “Such  
15 term does not include a manufacturer engaged in  
16 wholesale distribution or a manufacturer’s ware-  
17 houses.”.

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

22 **SEC. 10206. IMPROVING TRANSPARENCY AND PREVENTING**  
23 **THE USE OF ABUSIVE SPREAD PRICING AND**  
24 **RELATED PRACTICES IN MEDICAID.**

25 (a) PASS-THROUGH PRICING REQUIRED.—

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

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

17                   “(A) any payment made by the entity or  
18                   the PBM (as applicable) for such a drug—

19                           “(i) is limited to—

20                                   “(I) ingredient cost; and

21                                   “(II) a professional dispensing  
22                                   fee that is not less than the profes-  
23                                   sional dispensing fee that the State  
24                                   plan or waiver would pay if the plan

1 or waiver was making the payment di-  
2 rectly;

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

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

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

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

1 voice fees, discounts, or related adjustments  
2 such as direct and indirect remuneration fees,  
3 and any and all other remuneration; and

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

15 (2) CONFORMING AMENDMENT.—Section  
16 1903(m)(2)(A)(xiii) of such Act (42 U.S.C.  
17 1396b(m)(2)(A)(xiii)) is amended—

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

20 (B) by inserting before the period at the  
21 end the following: “, and (IV) 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)”; and

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

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

11 (b) SURVEY OF RETAIL PRICES.—

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

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

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

22 “(A) USE OF VENDOR.—The Secretary  
23 may contract services for—

24 “(i) with respect to retail community  
25 pharmacies, the determination on a month-



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

13 (B) by adding at the end of paragraph (1)  
14 the following:

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

1 that has a contract with the State or a man-  
2 aged care entity or other specified entity (as  
3 such terms are defined in section  
4 1903(m)(9)(D)), shall respond to surveys of re-  
5 tail prices conducted under this subsection.

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

10 “(i) The monthly response rate of the  
11 survey including a list of pharmacies not in  
12 compliance with subparagraph (F).

13 “(ii) The sampling frame and number  
14 of pharmacies sampled monthly.

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

19 “(iv) Reporting of a separate national  
20 average drug acquisition cost for each drug  
21 for independent retail pharmacies and  
22 chain operated pharmacies.

23 “(v) Information on price concessions  
24 including on and off invoice discounts, re-  
25 bates, and other price concessions.

1                   “(vi) Information on average profes-  
2                   sional dispensing fees paid.

3                   “(H) PENALTIES.—

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

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

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

1 graph in the same manner as such provi-  
2 sions apply to a penalty or proceeding  
3 under section 1128A(a).

4 “(I) REPORT ON SPECIALTY DRUGS AND  
5 PHARMACIES.—

6 “(i) IN GENERAL.—Not later than 18  
7 months after the effective date of this sub-  
8 paragraph, the Secretary shall submit a re-  
9 port to Congress examining specialty drug  
10 coverage and reimbursement under this  
11 title.

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

1 vey of retail prices to ensure national aver-  
2 age drug acquisition costs capture drugs  
3 sold at specialty pharmacies and how such  
4 specialty pharmacies should be defined.”;

5 (C) in paragraph (2)—

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

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

13 (D) in paragraph (4), by inserting “, and  
14 \$5,000,000 for fiscal year 2020 and each fiscal  
15 year thereafter,” after “2010”.

16 (2) EFFECTIVE DATE.—The amendments made  
17 by this subsection take effect on the 1st day of the  
18 1st quarter that begins on or after the date that is  
19 18 months after the date of enactment of this Act.

20 (c) MANUFACTURER REPORTING OF WHOLESALE  
21 ACQUISITION COST.—Section 1927(b)(3) of such Act (42  
22 U.S.C. 1396r–8(b)(3)) is amended—

23 (1) in subparagraph (A)(i)—

24 (A) in subclause (I), by striking “and”  
25 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 (v), by striking “and” after  
22 the comma;

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

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

3 “(vii) 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. 10207. 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 patterns related to prescriptions filled by pro-  
21 viders under the Medicaid 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 available forms or mod-  
14 els of reimbursement used under the plan  
15 or waiver;

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

18 (iii) by episodes of care for—

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



- 1 (II) procedural groupings; and  
2 (III) rare disease diagnosis codes  
3 (except where the inclusion of such in-  
4 formation would jeopardize the pri-  
5 vacy of an individual, as determined  
6 by the Secretary);  
7 (iv) by patient demographic character-  
8 istics, including race (to the extent that  
9 the Secretary determines that there is suf-  
10 ficient data available with respect to such  
11 characteristic in a majority of States), gen-  
12 der, and age;  
13 (v) by patient high-utilizer or risk sta-  
14 tus; and  
15 (vi) by high and low resource settings  
16 by facility and place of service categories,  
17 as determined by the Secretary.
- 18 (B) In the case of medical assistance for  
19 covered outpatient drugs (as so defined) pro-  
20 vided under a State Medicaid plan or waiver of  
21 such plan in a managed care setting, an anal-  
22 ysis of the differences in managed care pre-  
23 scribing patterns when a covered outpatient  
24 drug is prescribed in a managed care setting as

1 compared to when the drug is prescribed in a  
2 fee-for-service setting.

3 (2) ADDITIONAL CONTENT.—To the extent  
4 available, a report required under subsection (a) for  
5 a calendar year may include State-specific informa-  
6 tion about prescription utilization management tools  
7 under State Medicaid plans or waivers of such plans,  
8 including—

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

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

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

24 (D) a comparison of the prescription utili-  
25 zation management tools applicable to each en-

1 rollment category under a State Medicaid plan  
2 or waiver; and

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

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

10 (A) analyses of national, State, and local  
11 patterns of Medicaid population-based pre-  
12 scribing behaviors (including an analysis of the  
13 impact of non-filled prescriptions on identifying  
14 such patterns); and

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

21 (c) USE OF T-MSIS DATA.—Each report required  
22 under subsection (a) shall, to the extent practicable—

23 (1) be prepared using data and definitions from  
24 the Transformed Medicaid Statistical Information  
25 System (“T-MSIS”) data set (or a successor data

1 set) that is not more than 24 months old on the date  
 2 that the report is published; and

3 (2) as appropriate, include a description with  
 4 respect to each State of the quality and complete-  
 5 ness of the data, as well as any necessary caveats  
 6 describing the limitations of the data reported to the  
 7 Secretary by the State that are sufficient to commu-  
 8 nicate the appropriate uses for the information.

9 (d) PREPARATION OF REPORT.—Each report re-  
 10 quired under subsection (a) shall be prepared by the Ad-  
 11 ministrator for the Centers for Medicare & Medicaid Serv-  
 12 ices.

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

16 **SEC. 10208. RISK-SHARING VALUE-BASED PAYMENT AGREE-**  
 17 **MENTS FOR COVERED OUTPATIENT DRUGS**  
 18 **UNDER MEDICAID.**

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

22 “(1) STATE OPTION TO PAY FOR COVERED OUT-  
 23 PATIENT DRUGS THROUGH RISK-SHARING VALUE-BASED  
 24 AGREEMENTS.—

1           “(1) IN GENERAL.—Beginning January 1,  
2           2022, a State shall have the option to pay (whether  
3           on a fee-for-service or managed care basis) for cov-  
4           ered outpatient drugs that are potentially curative  
5           treatments intended for one-time use that are ad-  
6           ministered to individuals under this title by entering  
7           into a risk-sharing value-based payment agreement  
8           with the manufacturer of the drug in accordance  
9           with the requirements of this subsection.

10           “(2) SECRETARIAL APPROVAL.—

11           “(A) IN GENERAL.—A State shall submit a  
12           request to the Secretary to enter into a risk-  
13           sharing value based payment agreement, and  
14           the Secretary shall not approve a proposed risk-  
15           sharing value-based payment agreement be-  
16           tween a State and a manufacturer for payment  
17           for a covered outpatient drug of the manufac-  
18           turer unless the following requirements are met:

19           “(i) MANUFACTURER HAS IN EFFECT  
20           A REBATE AGREEMENT AND IS IN COMPLI-  
21           ANCE WITH ALL APPLICABLE REQUIRE-  
22           MENTS.—The manufacturer has a rebate  
23           agreement in effect as required under sub-  
24           section (a) and (b) of this section and is in

1 compliance with all applicable requirements  
2 under this title.

3 “(ii) NO INCREASE TO PROJECTED  
4 NET FEDERAL SPENDING.—

5 “(I) IN GENERAL.—The Chief  
6 Actuary certifies that the projected  
7 payments for each covered outpatient  
8 drug under a proposed risk-sharing  
9 value-based payment agreement is not  
10 expected to result in greater estimated  
11 Federal spending under this title than  
12 the net Federal spending that would  
13 result in the absence of such agree-  
14 ment.

15 “(II) NET FEDERAL SPENDING  
16 DEFINED.—For purposes of this sub-  
17 section, the term ‘net Federal spend-  
18 ing’ means the amount of Federal  
19 payments the Chief Actuary estimates  
20 would be made under this title for ad-  
21 ministering a covered outpatient drug  
22 to an individual eligible for medical  
23 assistance under a State plan or a  
24 waiver of such plan, reduced by the  
25 amount of all rebates the Chief Actu-

1           ary estimates would be paid with re-  
2           spect to the administering of such  
3           drug, including all rebates under this  
4           title and any supplemental or other  
5           additional rebates, in the absence of  
6           such an agreement.

7                   “(III) INFORMATION.—The Chief  
8           Actuary shall make the certifications  
9           required under this clause based on  
10          the most recently available and reli-  
11          able drug pricing and product infor-  
12          mation. The State and manufacturer  
13          shall provide the Secretary and the  
14          Chief Actuary with all necessary infor-  
15          mation required to make the estimates  
16          needed for such certifications.

17                   “(iii) LAUNCH AND LIST PRICE JUS-  
18          TIFICATIONS.—The manufacturer submits  
19          all relevant information and supporting  
20          documentation necessary for pricing deci-  
21          sions as deemed appropriate by the Sec-  
22          retary, which shall be truthful and non-  
23          misleading, including manufacturer infor-  
24          mation and supporting documentation for  
25          launch price or list price increases, and

1 any applicable justification required under  
2 section 1128L.

3 “(iv) CONFIDENTIALITY OF INFORMA-  
4 TION; PENALTIES.—The provisions of sub-  
5 paragraphs (C) and (D) of subsection  
6 (b)(3) shall apply to a manufacturer that  
7 fails to submit the information and docu-  
8 mentation required under clauses (ii) and  
9 (iii) on a timely basis, or that knowingly  
10 provides false or misleading information, in  
11 the same manner as such provisions apply  
12 to a manufacturer with a rebate agreement  
13 under this section.

14 “(B) CONSIDERATION OF STATE REQUEST  
15 FOR APPROVAL.—

16 “(i) IN GENERAL.—The Secretary  
17 shall treat a State request for approval of  
18 a risk-sharing value-based payment agree-  
19 ment in the same manner that the Sec-  
20 retary treats a State plan amendment, and  
21 subpart B of part 430 of title 42, Code of  
22 Federal Regulations, including, subject to  
23 clause (ii), the timing requirements of sec-  
24 tion 430.16 of such title (as in effect on  
25 the date of enactment of this subsection),



1 shall apply to a request for approval of a  
2 risk-sharing value-based payment agree-  
3 ment in the same manner as such subpart  
4 applies to a State plan amendment.

5 “(ii) TIMING.—The Secretary shall  
6 consult with the Commissioner of Food  
7 and Drugs as required under subpara-  
8 graph (C) and make a determination on  
9 whether to approve a request from a State  
10 for approval of a proposed risk-sharing  
11 value-based payment agreement (or request  
12 additional information necessary to allow  
13 the Secretary to make a determination  
14 with respect to such request for approval)  
15 within the time period, to the extent prac-  
16 ticable, specified in section 430.16 of title  
17 42, Code of Federal Regulations (as in ef-  
18 fect on the date of enactment of this sub-  
19 section), but in no case shall the Secretary  
20 take more than 180 days after the receipt  
21 of such request for approval or response to  
22 such request for additional information to  
23 make such a determination (or request ad-  
24 ditional information).

1           “(C) CONSULTATION WITH THE COMMIS-  
2           SIONER OF FOOD AND DRUGS.—In considering  
3           whether to approve a risk-sharing value-based  
4           payment agreement, the Secretary, to the ex-  
5           tent necessary, shall consult with the Commis-  
6           sioner of Food and Drugs to determine whether  
7           the relevant clinical parameters specified in  
8           such agreement are appropriate.

9           “(3) INSTALLMENT-BASED PAYMENT STRUC-  
10          TURE.—

11           “(A) IN GENERAL.—A risk-sharing value-  
12           based payment agreement shall provide for a  
13           payment structure under which, for every in-  
14           stallment year of the agreement (subject to sub-  
15           paragraph (B)), the State shall pay the total in-  
16           stallment year amount in equal installments to  
17           be paid at regular intervals over a period of  
18           time that shall be specified in the agreement.

19           “(B) REQUIREMENTS FOR INSTALLMENT  
20          PAYMENTS.—

21           “(i) TIMING OF FIRST PAYMENT.—  
22           The State shall make the first of the in-  
23           stallment payments described in subpara-  
24           graph (A) for an installment year not later  
25           than 30 days after the end of such year.

1                   “(ii) LENGTH OF INSTALLMENT PE-  
2                   RIOD.—The period of time over which the  
3                   State shall make the installment payments  
4                   described in subparagraph (A) for an in-  
5                   stallment year shall not be longer than 5  
6                   years.

7                   “(iii) NONPAYMENT OR REDUCED  
8                   PAYMENT OF INSTALLMENTS FOLLOWING  
9                   A FAILURE TO MEET CLINICAL PARAM-  
10                  ETER.—If, prior to the payment date (as  
11                  specified in the agreement) of any install-  
12                  ment payment described in subparagraph  
13                  (A) or any other alternative date or time  
14                  frame (as otherwise specified in the agree-  
15                  ment), the covered outpatient drug which  
16                  is subject to the agreement fails to meet a  
17                  relevant clinical parameter of the agree-  
18                  ment, the agreement shall provide that—

19                         “(I) the installment payment  
20                         shall not be made; or

21                         “(II) the installment payment  
22                         shall be reduced by a percentage spec-  
23                         ified in the agreement that is based  
24                         on the outcome achieved by the drug

1 relative to the relevant clinical param-  
2 eter.

3 “(4) NOTICE OF INTENT.—

4 “(A) IN GENERAL.—Subject to subpara-  
5 graph (B), a manufacturer of a covered out-  
6 patient drug shall not be eligible to enter into  
7 a risk-sharing value-based payment agreement  
8 under this subsection with respect to such drug  
9 unless the manufacturer notifies the Secretary  
10 that the manufacturer is interested in entering  
11 into such an agreement with respect to such  
12 drug. The decision to submit and timing of a  
13 request to enter into a proposed risk-sharing  
14 value-based payment agreement shall remain  
15 solely within the discretion of the State and  
16 shall only be effective upon Secretarial approval  
17 as required under this subsection.

18 “(B) TREATMENT OF SUBSEQUENTLY AP-  
19 PROVED DRUGS.—

20 “(i) IN GENERAL.—In the case of a  
21 manufacturer of a covered outpatient drug  
22 approved under section 505 of the Federal  
23 Food, Drug, and Cosmetic Act or licensed  
24 under section 351 of the Public Health  
25 Service Act after the date of enactment of

1 this subsection, not more than 90 days  
2 after meeting with the Food and Drug Ad-  
3 ministration following phase II clinical  
4 trials for such drug (or, in the case of a  
5 drug described in clause (ii), not later than  
6 March 31, 2022), the manufacturer must  
7 notify the Secretary of the manufacturer’s  
8 intent to enter into a risk-sharing value-  
9 based payment agreement under this sub-  
10 section with respect to such drug. If no  
11 such meeting has occurred, the Secretary  
12 may use discretion as to whether a poten-  
13 tially curative treatment intended for one-  
14 time use may qualify for a risk-sharing  
15 value-based payment agreement under this  
16 section. A manufacturer notification of in-  
17 terest shall not have any influence on a de-  
18 cision for drug approval by the Food and  
19 Drug Administration.

20 “(ii) APPLICATION TO CERTAIN SUB-  
21 SEQUENTLY APPROVED DRUGS.—A drug  
22 described in this clause is a covered out-  
23 patient drug of a manufacturer—

24 “(I) that is approved under sec-  
25 tion 505 of the Federal Food, Drug,

1 and Cosmetic Act or licensed under  
2 section 351 of the Public Health Serv-  
3 ice Act after the date of enactment of  
4 this subsection; and

5 “(II) with respect to which, as of  
6 January 1, 2022, more than 90 days  
7 have passed after the manufacturer’s  
8 meeting with the Food and Drug Ad-  
9 ministration following phase II clinical  
10 trials for such drug.

11 “(iii) PARALLEL APPROVAL.—The  
12 Secretary, in coordination with the Admin-  
13 istrator of the Centers for Medicare &  
14 Medicaid Services and the Commissioner of  
15 Food and Drugs, shall, to the extent prac-  
16 ticable, approve a State’s request to enter  
17 into a proposed risk-sharing value-based  
18 payment agreement that otherwise meets  
19 the requirements of this subsection at the  
20 time that such a drug is approved by the  
21 Food and Drug Administration to help  
22 provide that no State that wishes to enter  
23 into such an agreement is required to pay  
24 for the drug in full at one time if the State

1 is seeking to pay over a period of time as  
2 outlined in the proposed agreement.

3 “(iv) RULE OF CONSTRUCTION.—  
4 Nothing in this paragraph shall be applied  
5 or construed to modify or affect the time-  
6 frames or factors involved in the Sec-  
7 retary’s determination of whether to ap-  
8 prove or license a drug under section 505  
9 of the Federal Food, Drug, and Cosmetic  
10 Act or section 351 of the Public Health  
11 Service Act.

12 “(5) SPECIAL PAYMENT RULES.—

13 “(A) IN GENERAL.—Except as otherwise  
14 provided in this paragraph, with respect to an  
15 individual who is administered a unit of a cov-  
16 ered outpatient drug that is reimbursed under  
17 a State plan by a State Medicaid agency under  
18 a risk-sharing value-based payment agreement  
19 in an installment year, the State shall remain  
20 liable to the manufacturer of such drug for pay-  
21 ment for such unit without regard to whether  
22 the individual remains enrolled in the State  
23 plan under this title (or a waiver of such plan)  
24 for each installment year for which the State is  
25 to make installment payments for covered out-

1 patient drugs purchased under the agreement  
2 in such year.

3 “(B) DEATH.—In the case of an individual  
4 described in subparagraph (A) who dies during  
5 the period described in such subparagraph, the  
6 State plan shall not be liable for any remaining  
7 payment for the unit of the covered outpatient  
8 drug administered to the individual which is  
9 owed under the agreement described in such  
10 subparagraph.

11 “(C) WITHDRAWAL OF APPROVAL.—In the  
12 case of a covered outpatient drug that is the  
13 subject of a risk-sharing value-based payment  
14 agreement between a State and a manufacturer  
15 under this subsection, including a drug ap-  
16 proved in accordance with section 506(c) of the  
17 Federal Food, Drug, and Cosmetic Act, and  
18 such drug is the subject of an application that  
19 has been withdrawn by the Secretary, the State  
20 plan shall not be liable for any remaining pay-  
21 ment that is owed under the agreement.

22 “(D) ALTERNATIVE ARRANGEMENT UNDER  
23 AGREEMENT.—Subject to approval by the Sec-  
24 retary, the terms of a proposed risk-sharing  
25 value-based payment agreement submitted for



1 approval by a State may provide that subpara-  
2 graph (A) shall not apply.

3 “(E) GUIDANCE.—Not later than January  
4 1, 2022, the Secretary shall issue guidance to  
5 States establishing a process for States to no-  
6 tify the Secretary when an individual who is ad-  
7 ministered a unit of a covered outpatient drug  
8 that is purchased by a State plan under a risk-  
9 sharing value-based payment agreement ceases  
10 to be enrolled under the State plan under this  
11 title (or a waiver of such plan) or dies before  
12 the end of the installment period applicable to  
13 such unit under the agreement.

14 “(6) TREATMENT OF PAYMENTS UNDER RISK-  
15 SHARING VALUE-BASED AGREEMENTS FOR PUR-  
16 POSES OF AVERAGE MANUFACTURER PRICE; BEST  
17 PRICE.—The Secretary shall treat any payments  
18 made to the manufacturer of a covered outpatient  
19 drug under a risk-sharing value-based payment  
20 agreement under this subsection during a rebate pe-  
21 riod in the same manner that the Secretary treats  
22 payments made under a State supplemental rebate  
23 agreement under sections 447.504(c)(19) and  
24 447.505(c)(7) of title 42, Code of Federal Regula-  
25 tions (or any successor regulations) for purposes of

1 determining average manufacturer price and best  
2 price under this section with respect to the covered  
3 outpatient drug and a rebate period and for pur-  
4 poses of offsets required under subsection (b)(1)(B).

5 “(7) ASSESSMENTS AND REPORT TO CON-  
6 GRESS.—

7 “(A) ASSESSMENTS.—

8 “(i) IN GENERAL.—Not later than  
9 180 days after the end of each assessment  
10 period of any risk-sharing value-based pay-  
11 ment agreement for a State approved  
12 under this subsection, the Secretary shall  
13 conduct an evaluation of such agreement  
14 which shall include an evaluation by the  
15 Chief Actuary to determine whether pro-  
16 gram spending under the risk-sharing  
17 value-based payment agreement aligned  
18 with the projections for the agreement  
19 made under paragraph (2)(A)(ii), including  
20 an assessment of whether actual Federal  
21 spending under this title under the agree-  
22 ment was less or more than net Federal  
23 spending would have been in the absence  
24 of the agreement.

1                   “(ii) ASSESSMENT PERIOD.—For pur-  
2 poses of clause (i)—

3                   “(I) the first assessment period  
4 for a risk-sharing value-based pay-  
5 ment agreement shall be the period of  
6 time over which payments are sched-  
7 uled to be made under the agreement  
8 for the first 10 individuals who are  
9 administered covered outpatient drugs  
10 under the agreement except that such  
11 period shall not exceed the 5-year pe-  
12 riod after the date on which the Sec-  
13 retary approves the agreement; and

14                   “(II) each subsequent assessment  
15 period for a risk-sharing value-based  
16 payment agreement shall be the 5-  
17 year period following the end of the  
18 previous assessment period.

19                   “(B) RESULTS OF ASSESSMENTS.—

20                   “(i) TERMINATION OPTION.—If the  
21 Secretary determines as a result of the as-  
22 sessment by the Chief Actuary under sub-  
23 paragraph (A) that the actual Federal  
24 spending under this title for any covered  
25 outpatient drug that was the subject of the

1 State’s risk-sharing value-based payment  
2 agreement was greater than the net Fed-  
3 eral spending that would have resulted in  
4 the absence of the agreement, the Sec-  
5 retary may terminate approval of such  
6 agreement and shall immediately conduct  
7 an assessment under this paragraph of any  
8 other ongoing risk-sharing value-based  
9 payment agreement to which the same  
10 manufacturer is a party.

11 “(ii) REPAYMENT REQUIRED.—

12 “(I) IN GENERAL.—If the Sec-  
13 retary determines as a result of the  
14 assessment by the Chief Actuary  
15 under subparagraph (A) that the Fed-  
16 eral spending under the risk-sharing  
17 value-based agreement for a covered  
18 outpatient drug that was subject to  
19 such agreement was greater than the  
20 net Federal spending that would have  
21 resulted in the absence of the agree-  
22 ment, the manufacturer shall repay  
23 the difference to the State and Fed-  
24 eral governments in a timely manner  
25 as determined by the Secretary.

1                   “(II) TERMINATION FOR FAIL-  
2                   URE TO PAY.—The failure of a manu-  
3                   facturer to make repayments required  
4                   under subclause (I) in a timely man-  
5                   ner shall result in immediate termi-  
6                   nation of all risk-sharing value-based  
7                   agreements to which the manufacturer  
8                   is a party.

9                   “(III) ADDITIONAL PEN-  
10                   ALTIES.—In the case of a manufac-  
11                   turer that fails to make repayments  
12                   required under subclause (I), the Sec-  
13                   retary may treat such manufacturer  
14                   in the same manner as a manufac-  
15                   turer that fails to pay required re-  
16                   bates under this section, and the Sec-  
17                   retary may—

18                   “(aa) suspend or terminate  
19                   the manufacturer’s rebate agree-  
20                   ment under this section; and

21                   “(bb) pursue any other rem-  
22                   edy that would be available if the  
23                   manufacturer had failed to pay  
24                   required rebates under this sec-  
25                   tion.

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

7           “(i) an assessment of the impact of  
8 risk-sharing value-based payment agree-  
9 ments on access for individuals who are eli-  
10 gible for benefits under a State plan or  
11 waiver under this title to medically nec-  
12 essary covered outpatient drugs and re-  
13 lated treatments;

14           “(ii) an analysis of the impact of such  
15 agreements on overall State and Federal  
16 spending under this title;

17           “(iii) an assessment of the impact of  
18 such agreements on drug prices, including  
19 launch price and price increases; and

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

22           “(8) GUIDANCE AND REGULATIONS.—

23           “(A) IN GENERAL.—Not later than Janu-  
24 ary 1, 2022, the Secretary shall issue guidance  
25 to States seeking to enter into risk-sharing

1 value-based payment agreements under this  
2 subsection that includes a model template for  
3 such agreements. The Secretary may issue any  
4 additional guidance or promulgate regulations  
5 as necessary to implement and enforce the pro-  
6 visions of this subsection.

7 “(B) MODEL AGREEMENTS.—

8 “(i) IN GENERAL.—If a State ex-  
9 presses an interest in pursuing a risk-shar-  
10 ing value-based payment agreement under  
11 this subsection with a manufacturer for  
12 the purchase of a covered outpatient drug,  
13 the Secretary may share with such State  
14 any risk-sharing value-based agreement be-  
15 tween a State and the manufacturer for  
16 the purchase of such drug that has been  
17 approved under this subsection. While such  
18 shared agreement may serve as a template  
19 for a State that wishes to propose, the use  
20 of a previously approved agreement shall  
21 not affect the submission and approval  
22 process for approval of a proposed risk-  
23 sharing value-based payment agreement  
24 under this subsection, including the re-  
25 quirements under paragraph (2)(A).

1           “(ii) CONFIDENTIALITY.—In the case  
2 of a risk-sharing value-based payment  
3 agreement that is disclosed to a State by  
4 the Secretary under this subparagraph and  
5 that is only in effect with respect to a sin-  
6 gle State, the confidentiality of information  
7 provisions described in subsection  
8 (b)(3)(D) shall apply to such information.

9           “(C) OIG CONSULTATION.—

10           “(i) IN GENERAL.—The Secretary  
11 shall consult with the Office of the Inspec-  
12 tor General of the Department of Health  
13 and Human Services to determine whether  
14 there are potential program integrity con-  
15 cerns (including issues related to compli-  
16 ance with sections 1128B and 1877) with  
17 agreement approvals or templates and ad-  
18 dress accordingly.

19           “(ii) OIG POLICY UPDATES AS NEC-  
20 ESSARY.—The Inspector General of the  
21 Department of Health and Human Serv-  
22 ices shall review and update, as necessary,  
23 any policies or guidelines of the Office of  
24 the Inspector General of the Department  
25 of Human Services (including policies re-



1           lated to the enforcement of section 1128B)  
2           to accommodate the use of risk-sharing  
3           value-based payment agreements in accord-  
4           ance with this section.

5           “(9) RULES OF CONSTRUCTION.—

6           “(A) MODIFICATIONS.—Nothing in this  
7           subsection or any regulations promulgated  
8           under this subsection shall prohibit a State  
9           from requesting a modification from the Sec-  
10          retary to the terms of a risk-sharing value-  
11          based payment agreement. A modification that  
12          is expected to result in any increase to pro-  
13          jected net State or Federal spending under the  
14          agreement shall be subject to recertification by  
15          the Chief Actuary as described in paragraph  
16          (2)(A)(ii) before the modification may be ap-  
17          proved.

18          “(B) REBATE AGREEMENTS.—Nothing in  
19          this subsection shall be construed as requiring  
20          a State to enter into a risk-sharing value-based  
21          payment agreement or as limiting or super-  
22          seding the ability of a State to enter into a sup-  
23          plemental rebate agreement for a covered out-  
24          patient drug.

1           “(C) FFP FOR PAYMENTS UNDER RISK-  
2 SHARING VALUE-BASED PAYMENT AGREE-  
3 MENTS.—Federal financial participation shall  
4 be available under this title for any payment  
5 made by a State to a manufacturer for a cov-  
6 ered outpatient drug under a risk-sharing  
7 value-based payment agreement in accordance  
8 with this subsection, except that no Federal fi-  
9 nancial participation shall be available for any  
10 payment made by a State to a manufacturer  
11 under such an agreement on and after the ef-  
12 fective date of a disapproval of such agreement  
13 by the Secretary.

14           “(D) CONTINUED APPLICATION OF OTHER  
15 PROVISIONS.—Except as expressly provided in  
16 this subsection, nothing in this subsection or in  
17 any regulations promulgated under this sub-  
18 section shall affect the application of any other  
19 provision of this Act.

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

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

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

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

9           “(C) POTENTIALLY CURATIVE TREATMENT  
10           INTENDED FOR ONE-TIME USE.—The term ‘po-  
11           tentially curative treatment intended for one-  
12           time use’ means a treatment that consists of  
13           the administration of a covered outpatient drug  
14           that—

15                   “(i) is a form of gene therapy for a  
16                   rare disease, as defined by the Commis-  
17                   sioner of Food and Drugs, designated  
18                   under section 526 of the Federal Food,  
19                   Drug, and Cosmetics Act, and approved  
20                   under section 505 of such Act or licensed  
21                   under subsection (a) or (k) of section 351  
22                   of the Public Health Service Act to treat  
23                   a serious or life-threatening disease or con-  
24                   dition;

1                   “(ii) if administered in accordance  
2                   with the labeling of such drug, is expected  
3                   to result in either—

4                               “(I) the cure of such disease or  
5                               condition; or

6                               “(II) a reduction in the symp-  
7                               toms of such disease or condition to  
8                               the extent that such disease or condi-  
9                               tion is not expected to lead to early  
10                              mortality; and

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

15                             “(D) RELEVANT CLINICAL PARAMETER.—  
16                             The term ‘relevant clinical parameter’ means,  
17                             with respect to a covered outpatient drug that  
18                             is the subject of a risk-sharing value-based pay-  
19                             ment agreement—

20                               “(i) a clinical endpoint specified in the  
21                               drug’s labeling or supported by one or  
22                               more of the compendia described in section  
23                               1861(t)(2)(B)(ii)(I) that—

24                                       “(I) is able to be measured or  
25                                       evaluated on an annual basis for each

1 year of the agreement on an inde-  
2 pendent basis by a provider or other  
3 entity; and

4 “(II) is required to be achieved  
5 (based on observed metrics in patient  
6 populations) under the terms of the  
7 agreement; or

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

13 “(I) is able to be measured or  
14 evaluated on an annual basis for each  
15 year of the agreement on an inde-  
16 pendent basis by a provider or other  
17 entity; and

18 “(II) has been qualified by the  
19 Food and Drug Administration.

20 “(E) RISK-SHARING VALUE-BASED PAY-  
21 MENT AGREEMENT.—The term ‘risk-sharing  
22 value-based payment agreement’ means an  
23 agreement between a State plan and a manu-  
24 facturer—

1           “(i) for the purchase of a covered out-  
2           patient drug of the manufacturer that is a  
3           potentially curative treatment intended for  
4           one-time use;

5           “(ii) under which payment for such  
6           drug shall be made pursuant to an install-  
7           ment-based payment structure that meets  
8           the requirements of paragraph (3);

9           “(iii) which conditions payment on the  
10          achievement of at least 2 relevant clinical  
11          parameters (as defined in subparagraph  
12          (C));

13          “(iv) which provides that—

14                 “(I) the State plan will directly  
15                 reimburse the manufacturer for the  
16                 drug; or

17                 “(II) a third party will reimburse  
18                 the manufacture in a manner ap-  
19                 proved by the Secretary;

20          “(v) is approved by the Secretary in  
21          accordance with paragraph (2).

22          “(F)     TOTAL     INSTALLMENT     YEAR  
23          AMOUNT.—The term ‘total installment year  
24          amount’ means, with respect to a risk-sharing  
25          value-based payment agreement for the pur-

1           chase of a covered outpatient drug and an in-  
2           stallment year, an amount equal to the product  
3           of—

4                   “(i) the unit price of the drug charged  
5                   under the agreement; and

6                   “(ii) the number of units of such drug  
7                   administered under the agreement during  
8                   such installment year.”.

9           (b) CONFORMING AMENDMENTS.—

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

17           (2) Section 1927(b) of the Social Security Act  
18           (42 U.S.C. 1396r-8(b)) is amended—

19                   (A) in paragraph (1)(A), by inserting “but  
20                   excluding any drugs for which payment is made  
21                   by a State under a risk-sharing value-based  
22                   payment agreement under subsection (l))” after  
23                   “for coverage of such drugs”; and

24                   (B) in paragraph (3)—

1 (i) in subparagraph (C)(i), by insert-  
2 ing “or subsection (l)(2)(A)” after “sub-  
3 paragraph (A)”;

4 (ii) in subparagraph (D), in the mat-  
5 ter preceding clause (i), by inserting “,  
6 under subsection (l)(2)(A),” after “under  
7 this paragraph”.

8 **SEC. 10209. MODIFICATION OF MAXIMUM REBATE AMOUNT**  
9 **UNDER MEDICAID DRUG REBATE PROGRAM.**

10 (a) IN GENERAL.—Subparagraph (D) of section  
11 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r-  
12 8(c)(2)) is amended to read as follows:

13 “(D) MAXIMUM REBATE AMOUNT.—

14 “(i) IN GENERAL.—Except as pro-  
15 vided in clause (ii), in no case shall the  
16 sum of the amounts applied under para-  
17 graph (1)(A)(ii) and this paragraph with  
18 respect to each dosage form and strength  
19 of a single source drug or an innovator  
20 multiple source drug for a rebate period  
21 exceed—

22 “(I) for rebate periods beginning  
23 after December 31, 2009, and before  
24 September 30, 2022, 100 percent of



1 the average manufacturer price of the  
2 drug; and

3 “(II) for rebate periods beginning  
4 on or after October 1, 2022, 125 per-  
5 cent of the average manufacturer  
6 price of the drug.

7 “(ii) NO MAXIMUM AMOUNT FOR  
8 DRUGS IF AMP INCREASES OUTPACE IN-  
9 FLATION.—

10 “(I) IN GENERAL.—If the aver-  
11 age manufacturer price with respect  
12 to each dosage form and strength of  
13 a single source drug or an innovator  
14 multiple source drug increases on or  
15 after October 1, 2021, and such in-  
16 creased average manufacturer price  
17 exceeds the inflation-adjusted average  
18 manufacturer price determined with  
19 respect to such drug under subclause  
20 (II) for the rebate period, clause (i)  
21 shall not apply and there shall be no  
22 limitation on the sum of the amounts  
23 applied under paragraph (1)(A)(ii)  
24 and this paragraph for the rebate pe-  
25 riod, and any subsequent rebate pe-

1           riod until the average manufacturer  
2           price of the drug is the same or less  
3           than the inflation-adjusted average  
4           manufacturer price determined with  
5           respect to such drug under subclause  
6           (II) for the rebate period, with respect  
7           to each dosage form and strength of  
8           the single source drug or innovator  
9           multiple source drug.

10                   “(II) INFLATION-ADJUSTED AV-  
11                   ERAGE MANUFACTURER PRICE DE-  
12                   FINED.—In this clause, the term ‘in-  
13                   flation-adjusted average manufacturer  
14                   price’ means, with respect to a single  
15                   source drug or an innovator multiple  
16                   source drug and a rebate period, the  
17                   average manufacturer price for each  
18                   dosage form and strength of the drug  
19                   for the calendar quarter beginning  
20                   July 1, 1990 (without regard to  
21                   whether or not the drug has been sold  
22                   or transferred to an entity, including  
23                   a division or subsidiary of the manu-  
24                   facturer, after the 1<sup>st</sup> day of such  
25                   quarter), increased by the percentage

1 by which the consumer price index for  
2 all urban consumers (United States  
3 city average) for the month before the  
4 month in which the rebate period be-  
5 gins exceeds such index for September  
6 1990.”.

7 (b) TREATMENT OF SUBSEQUENTLY APPROVED  
8 DRUGS.—Section 1927(c)(2)(B) of the Social Security Act  
9 (42 U.S.C. 1396r–8(c)(2)(B)) is amended by inserting  
10 “and clause (ii)(II) of subparagraph (D)” after “clause  
11 (ii)(II) of subparagraph (A)”.

12 (c) TECHNICAL AMENDMENTS.—Section  
13 1927(c)(3)(C)(ii)(IV) of the Social Security Act (42  
14 U.S.C. 1396r–9(c)(3)(C)(ii)(IV)) is amended—

15 (1) by striking “subparagraph (A)” and insert-  
16 ing “paragraph (3)(A)”; and

17 (2) by striking “this subparagraph” and insert-  
18 ing “paragraph (3)(C)”.

19 **SEC. 10210. APPLYING MEDICAID DRUG REBATE REQUIRE-**  
20 **MENT TO DRUGS PROVIDED AS PART OF OUT-**  
21 **PATIENT HOSPITAL SERVICES.**

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

25 “(3) LIMITING DEFINITION.—

1           “(A) IN GENERAL.—The term ‘covered  
2           outpatient drug’ does not include any drug, bio-  
3           logical product, or insulin provided as part of,  
4           or as incident to and in the same setting as,  
5           any of the following (and for which payment  
6           may be made under this title as part of pay-  
7           ment for the following and not as direct reim-  
8           bursement for the drug):

9                   “(i) Inpatient hospital services.

10                   “(ii) Hospice services.

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

15                   “(iv) Physicians’ services.

16                   “(v) Outpatient hospital services.

17                   “(vi) Nursing facility services and  
18           services provided by an intermediate care  
19           facility for the mentally retarded.

20                   “(vii) Other laboratory and x-ray serv-  
21           ices.

22                   “(viii) Renal dialysis.

23           “(B) OTHER EXCLUSIONS.—Such term  
24           also does not include any such drug or product  
25           for which a National Drug Code number is not

1 required by the Food and Drug Administration  
2 or a drug or biological used for a medical indi-  
3 cation which is not a medically accepted indica-  
4 tion.

5 “(C) STATE OPTION.—At the option of a  
6 State, such term may include any drug, biologi-  
7 cal product, or insulin provided on an out-  
8 patient basis as part of, or as incident to and  
9 in the same setting as, described in clause (iv)  
10 or (v) of subparagraph (A) (such as a drug, bi-  
11 ological product, or insulin being provided as  
12 part of a bundled payment).

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           **DIVISION B—HEALTH AND**  
 12           **HUMAN SERVICES EXTENDERS**

13           **SEC. 20100. TABLE OF CONTENTS.**

14           The table of contents of this division is as follows:

DIVISION B—HEALTH AND HUMAN SERVICES EXTENDERS

Sec. 20100. Table of contents.

TITLE I—MEDICARE

Sec. 20101. Extension of work GPCI floor.

Sec. 20102. Permanent extension of increased inpatient hospital payment ad-  
 justment for certain low-volume hospitals.

Sec. 20103. Permanent extension of the medicare-dependent hospital (MDH)  
 program.

Sec. 20104. Extension of funding for quality measure endorsement, input, and  
 selection.

Sec. 20105. Extension of funding outreach and assistance for low-income pro-  
 grams.

Sec. 20106. Extension of the Independence at Home Medical Practice Dem-  
 onstration Program under the Medicare program.

TITLE II—MEDICAID

Sec. 20201. Permanent extension of Money Follows the Person Rebalancing  
 demonstration.

Sec. 20202. Permanent extension of protection for Medicaid recipients of home  
 and community-based services against spousal impoverishment.

Sec. 20203. Extension and expansion of community mental health services dem-  
 onstration program.

- Sec. 20204. Delay in Medicaid DSH reductions; reporting on supplemental payments.
- Sec. 20205. Medicaid funding for territories.
- Sec. 20206. Reporting requirements for electing cost avoidance exceptions for Medicaid and CHIP third party liability.

#### TITLE III—HEALTH AND HUMAN SERVICES

- Sec. 20301. Extension of sexual risk avoidance education.
- Sec. 20302. Extension of personal responsibility education.
- Sec. 20303. Extension of demonstration projects to address health professions workforce needs.
- Sec. 20304. Extension of the Maternal, Infant, and Early Childhood Home Visiting Program.

#### TITLE IV—OTHER HEALTH AND HUMAN SERVICES

- Sec. 20401. Extension of appropriations to the Patient-Centered Outcomes Research Trust Fund; extension of certain health insurance fees.
- Sec. 20402. Extension of the Temporary Assistance for Needy Families Program and related programs.
- Sec. 20403. Addressing expiration of child welfare demonstration projects and supporting Family First implementation.

## 1                   **TITLE I—MEDICARE**

### 2   **SEC. 20101. EXTENSION OF WORK GPCI FLOOR.**

3           Section 1848(e)(1)(E) of the Social Security Act (42  
4 U.S.C. 1395w-4(e)(1)(E)) is amended by striking “Janu-  
5 ary 1, 2020” and inserting “January 1, 2023”.

### 6   **SEC. 20102. PERMANENT EXTENSION OF INCREASED INPA- 7                   TIENT HOSPITAL PAYMENT ADJUSTMENT 8                   FOR CERTAIN LOW-VOLUME HOSPITALS.**

9           (a) IN GENERAL.—Section 1886(d)(12) of the Social  
10 Security Act (42 U.S.C. 1395ww(d)(12)) is amended—

11                   (1) in subparagraph (B)—

12                           (A) in the heading, by striking “APPLICA-  
13 BLE” and inserting “TEMPORARY APPLICA-  
14 BLE”; and

1 (B) in the matter preceding clause (i), by  
2 striking “and for discharges occurring in fiscal  
3 year 2023 and subsequent fiscal years”;

4 (2) in subparagraph (C)(i)—

5 (A) in the matter preceding subclause (I),  
6 by striking “fiscal years 2011 through 2022”  
7 and inserting “fiscal year 2011 and subsequent  
8 fiscal years”;

9 (B) in subclause (II), by adding “and” at  
10 the end;

11 (C) in subclause (III)—

12 (i) by striking “each of fiscal years  
13 2019 through 2022” and inserting “fiscal  
14 year 2019 and each subsequent fiscal  
15 year”; and

16 (ii) by striking “; and” at the end and  
17 inserting a period; and

18 (D) by striking subclause (IV); and

19 (3) in subparagraph (D)—

20 (A) in the heading, by striking “TEM-  
21 PORARY APPLICABLE” and inserting “APPLICA-  
22 BLE”;

23 (B) in the matter preceding clause (i), by  
24 striking “fiscal years 2011 through 2022” and



1 inserting “fiscal year 2011 and subsequent fis-  
2 cal years”; and

3 (C) in clause (ii), by striking “each of fis-  
4 cal years 2019 through 2022” and inserting  
5 “fiscal year 2019 and each subsequent fiscal  
6 year”.

7 **SEC. 20103. PERMANENT EXTENSION OF THE MEDICARE-**  
8 **DEPENDENT HOSPITAL (MDH) PROGRAM.**

9 (a) IN GENERAL.—Section 1886(d)(5)(G) of the So-  
10 cial Security Act (42 U.S.C. 1395ww(d)(5)(G)) is amend-  
11 ed—

12 (1) in clause (i), by striking “, and before Octo-  
13 ber 1, 2022”; and

14 (2) in clause (ii)(II), by striking “, and before  
15 October 1, 2022”.

16 (b) CONFORMING AMENDMENTS.—

17 (1) EXTENSION OF TARGET AMOUNT.—Section  
18 1886(b)(3)(D) of the Social Security Act (42 U.S.C.  
19 1395ww(b)(3)(D)) is amended—

20 (A) in the matter preceding clause (i), by  
21 striking “, and before October 1, 2022”; and

22 (B) in clause (iv), by striking “through fis-  
23 cal year 2022” and inserting “or a subsequent  
24 fiscal year”.

1           (2) PERMITTING HOSPITALS TO DECLINE RE-  
2           CLASSIFICATION.—Section 13501(e)(2) of the Omni-  
3           bus Budget Reconciliation Act of 1993 (42 U.S.C.  
4           1395ww note) is amended by striking “fiscal year  
5           2000 through fiscal year 2022” and inserting “a  
6           subsequent fiscal year”.

7   **SEC. 20104. EXTENSION OF FUNDING FOR QUALITY MEAS-**  
8           **URE ENDORSEMENT, INPUT, AND SELECTION.**

9           (a) EXTENSION.—

10           (1) IN GENERAL.—Section 1890(d)(2) of the  
11           Social Security Act (42 U.S.C. 1395aaa(d)(2)) is  
12           amended—

13                   (A) in the first sentence, by striking “and  
14                   \$1,665,000 for the period beginning on October  
15                   1, 2019, and ending on December 20, 2019”  
16                   and inserting “\$22,000,000 for fiscal year  
17                   2020, and \$20,000,000 for each of fiscal years  
18                   2021 and 2022”; and

19                   (B) in the third sentence, by striking “and  
20                   2019 and for the period beginning on October  
21                   1, 2019, and ending on December 20, 2019,”  
22                   and inserting “through 2022”.

23           (2) PREVENTION OF DUPLICATE APPROPRIA-  
24           TIONS FOR FISCAL YEAR 2020.—Expenditures made  
25           under such section 1890(d)(2) pursuant to the

1 amendments made by the Continuing Appropriations  
2 Act, 2020, and Health Extenders Act of 2019 (Pub-  
3 lic Law 116–59) and the Further Continuing Appro-  
4 priations Act, 2020, and Further Health Extenders  
5 Act of 2019, for fiscal year 2020 shall be charged  
6 to the applicable appropriation provided by the  
7 amendments made by this subsection to such section  
8 1890(d)(2) for such fiscal year.

9 (b) ADDITIONAL REPORTING REQUIREMENTS.—Sec-  
10 tion 1890 of the Social Security Act (42 U.S.C. 1395aaa)  
11 is amended—

12 (1) in subsection (e)—

13 (A) by redesignating paragraphs (1)  
14 through (6) as subparagraphs (A) through (F),  
15 respectively;

16 (B) by striking “CONGRESS.—By not later  
17 than” and inserting “CONGRESS.—

18 “(1) IN GENERAL.—By not later than”;

19 (C) in subparagraph (A), as redesignated  
20 by this paragraph, by striking the last sentence;

21 (D) in subparagraph (D), as so redesi-  
22 gnated, by striking “A description” and inserting  
23 “Subject to paragraph (2)(B), a description”;

1 (E) in subparagraph (E), as so redesignated,  
2 nated, by striking “The amount” and inserting  
3 “Subject to paragraph (2)(B), the amount”;

4 (F) in subparagraph (F), as so redesignated,  
5 nated, by striking “Estimates” and inserting  
6 “Subject to paragraph (2)(B), estimates”; and

7 (G) by adding at the end the following new  
8 paragraph:

9 “(2) ADDITIONAL REQUIREMENTS FOR RE-  
10 PORTS.—

11 “(A) ADDRESSING GAO REPORT.—Each of  
12 the annual reports submitted in 2020 and 2021  
13 pursuant to paragraph (1) shall also include the  
14 following:

15 “(i) A comprehensive analysis detail-  
16 ing the ways in which the Centers for  
17 Medicare & Medicaid Services has ad-  
18 dressed each of the recommendations set  
19 forth in the report by the Government Ac-  
20 countability Office (GAO–19–628) issued  
21 on September 19, 2019, and titled ‘Health  
22 Care Quality: CMS Could More Effectively  
23 Ensure Its Quality Measurement Activities  
24 Promote Its Objectives’.

25 “(ii) A detailed description of—

1                   “(I) any additional steps that the  
2                   Centers for Medicare & Medicaid  
3                   Services expects to take to address the  
4                   findings and recommendations set  
5                   forth in such report; and

6                   “(II) the anticipated timing for  
7                   such steps.

8                   “(B) ENSURING DETAILED INFORMA-  
9                   TION.—

10                   “(i) IN GENERAL.—In the case of an  
11                   annual report submitted in 2020 or a sub-  
12                   sequent year pursuant to paragraph (1),  
13                   the information required under—

14                   “(I) paragraph (1)(D) shall also  
15                   include detailed information on each  
16                   of the activities described in clause  
17                   (ii);

18                   “(II) paragraph (1)(E) shall also  
19                   include detailed information on the  
20                   specific amounts obligated or ex-  
21                   pended on each of the activities de-  
22                   scribed in clause (ii); and

23                   “(III) paragraph (1)(F) shall  
24                   also include detailed information on  
25                   the specific quality measurement ac-

1                   activities required and future funding  
2                   needed for each of the activities de-  
3                   scribed in clause (ii).

4                   “(ii) ACTIVITIES DESCRIBED.—The  
5                   activities described in this clause are the  
6                   following:

7                   “(I) Measure selection activities.

8                   “(II) Measure development ac-  
9                   tivities.

10                  “(III) Public reporting activities.

11                  “(IV) Education and outreach  
12                  activities.

13                  “(iii) BROKEN OUT.—The information  
14                  under subclauses (I), (II), and (III) of  
15                  clause (i) shall also be broken out by—

16                  “(I) site of care, including hos-  
17                  pitals, physician offices, clinics, renal  
18                  dialysis facilities, hospices, and post-  
19                  acute care settings; and

20                  “(II) type of measure, such as  
21                  electronic clinical quality measures  
22                  and outcome measures.”; and

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

1 “(f) ADDITIONAL REPORTING BY THE SECRETARY  
2 TO CONGRESS.—

3 “(1) IN GENERAL.—By not later than Sep-  
4 tember 30 of each year (beginning with 2020), the  
5 Secretary shall submit to Congress a report on the  
6 amount of unobligated balances for appropriations  
7 relating to quality measurement. Such report shall  
8 include detailed plans on how the Secretary expects  
9 to expend such unobligated balances in the upcom-  
10 ing fiscal years.

11 “(2) SEPARATE REPORT.—The annual report  
12 required under paragraph (1) shall be separate from  
13 the annual report required under subsection (e).”.

14 (c) INPUT FOR REMOVAL OF MEASURES.—Section  
15 1890(b) of the Social Security Act (42 U.S.C. 1395aaa(b))  
16 is amended by inserting after paragraph (3) the following  
17 new paragraph:

18 “(4) REMOVAL OF MEASURES.—The entity may  
19 provide input to the Secretary on quality and effi-  
20 ciency measures described in paragraph (7)(B) that  
21 could be considered for removal.”.

22 **SEC. 20105. EXTENSION OF FUNDING OUTREACH AND AS-**  
23 **SISTANCE FOR LOW-INCOME PROGRAMS.**

24 (a) ADDITIONAL FUNDING FOR STATE HEALTH IN-  
25 SURANCE PROGRAMS.—Subsection (a)(1)(B) of section

1 119 of the Medicare Improvements for Patients and Pro-  
2 viders Act of 2008 (42 U.S.C. 1395b–3 note), as amended  
3 by section 3306 of the Patient Protection and Affordable  
4 Care Act (Public Law 111–148), section 610 of the Amer-  
5 ican Taxpayer Relief Act of 2012 (Public Law 112–240),  
6 section 1110 of the Pathway for SGR Reform Act of 2013  
7 (Public Law 113–67), section 110 of the Protecting Ac-  
8 cess to Medicare Act of 2014 (Public Law 113–93), sec-  
9 tion 208 of the Medicare Access and CHIP Reauthoriza-  
10 tion Act of 2015 (Public Law 114–10), section 50207 of  
11 division E of the Bipartisan Budget Act of 2018 (Public  
12 Law 115–123), section 1402 of the Continuing Appropria-  
13 tions Act, 2020, and Health Extenders Act of 2019 (Pub-  
14 lic Law 116–59), and section 1402 of the Further Con-  
15 tinuing Appropriations Act, 2020, and Further Health  
16 Extenders Act of 2019 (Public Law 116–69), is amend-  
17 ed—

18           (1) in clause (ix), by inserting “and” at the  
19           end; and

20           (2) by striking clauses (x) and (xi) and insert-  
21           ing the following new clause:

22                           “(xi) for each of fiscal years 2020  
23                           through 2022, of \$13,000,000.”.



1 (b) ADDITIONAL FUNDING FOR AREA AGENCIES ON  
2 AGING.—Subsection (b)(1)(B) of such section 119, as so  
3 amended, is amended—

4 (1) in clause (ix), by inserting “and” at the  
5 end; and

6 (2) by striking clauses (x) and (xi) and insert-  
7 ing the following new clause:

8 “(xi) for each of fiscal years 2020  
9 through 2022, of \$7, 500,000.”.

10 (c) ADDITIONAL FUNDING FOR AGING AND DIS-  
11 ABILITY RESOURCE CENTERS.—Subsection (c)(1)(B) of  
12 such section 119, as so amended, is amended—

13 (1) in clause (ix), by inserting “and” at the  
14 end; and

15 (2) by striking clauses (x) and (xi) and insert-  
16 ing the following new clause:

17 “(xi) for each of fiscal years 2020  
18 through 2022, of \$5,000,000.”.

19 (d) ADDITIONAL FUNDING FOR CONTRACT WITH  
20 THE NATIONAL CENTER FOR BENEFITS AND OUTREACH  
21 ENROLLMENT.—Subsection (d)(2) of such section 119, as  
22 so amended, is amended—

23 (1) in clause (ix), by inserting “and” at the  
24 end; and

1           (2) by striking clauses (x) and (xi) and insert-  
2           ing the following new clause:

3                       “(xi) for each of fiscal years 2020  
4                       through 2022, of \$12,000,000.”.

5           (e) PREVENTION OF DUPLICATE APPROPRIATIONS  
6 FOR FISCAL YEAR 2020.—Expenditures made under sec-  
7 tion 119 of the Medicare Improvements for Patients and  
8 Providers Act of 2008 (42 U.S.C. 1395b–3 note), as so  
9 amended, pursuant to the amendments made by the Con-  
10 tinuing Appropriations Act, 2020, and Health Extenders  
11 Act of 2019 (Public Law 116–59) and the Further Con-  
12 tinuing Appropriations Act, 2020, and Further Health  
13 Extenders Act of 2019 (Public Law 116–69), for fiscal  
14 year 2020 shall be charged to the applicable appropriation  
15 provided by the amendments made by this section to such  
16 section 119 for such fiscal year.

17 **SEC. 20106. EXTENSION OF THE INDEPENDENCE AT HOME**

18                       **MEDICAL PRACTICE DEMONSTRATION PRO-**

19                       **GRAM UNDER THE MEDICARE PROGRAM.**

20           (a) EXTENSION.—

21                       (1) IN GENERAL.—Section 1866E(e)(1) of the  
22           Social Security Act (42 U.S.C. 1395cc–5(e)(1)) is  
23           amended by striking “7-year” and inserting “10-  
24           year”.



1                   “(G) \$450,000,000 for each fiscal year  
2                   after fiscal year 2019.”;

3                   (2) in paragraph (2)—

4                   (A) by striking “Subject to paragraph (3),  
5                   amounts” and inserting “Amounts”; and

6                   (B) by striking “2021” and inserting  
7                   “2023”; and

8                   (3) by striking paragraph (3).

9                   (b) REDISTRIBUTION OF UNEXPENDED GRANT  
10                   AWARDS.—Section 6701(e)(2) of the Deficit Reduction  
11                   Act of 2005 (42 U.S.C. 1396a note) is amended by adding  
12                   at the end the following new sentence: “Any portion of  
13                   a State grant award for a fiscal year under this section  
14                   that is unexpended by the State at the end of the fourth  
15                   succeeding fiscal year shall be rescinded by the Secretary  
16                   and added to the appropriation for the fifth succeeding  
17                   fiscal year.”.

18                   (c) RESEARCH AND EVALUATION.—Section 6071(g)  
19                   of the Deficit Reduction Act of 2005 (42 U.S.C. 1396a  
20                   note) is amended—

21                   (1) in paragraph (2), by striking “2016” and  
22                   inserting “2023”; and

23                   (2) in paragraph (3), by inserting “and for each  
24                   of fiscal years 2020 through 2023,” after “2016,”.

1 (d) CHANGES TO INSTITUTIONAL RESIDENCY PE-  
2 RIOD REQUIREMENT.—

3 (1) IN GENERAL.—Section 6071(b)(2) of the  
4 Deficit Reduction Act of 2005 (42 U.S.C. 1396a  
5 note) is amended—

6 (A) in subparagraph (A)(i), by striking  
7 “90” and inserting “60”; and

8 (B) by striking the flush sentence after  
9 subparagraph (B).

10 (2) EFFECTIVE DATE.—The amendments made  
11 by paragraph (1) shall take effect on the date that  
12 is 30 days after the date of enactment of this Act.

13 (e) UPDATES TO STATE APPLICATION REQUIRE-  
14 MENTS.—Section 6071(c) of the Deficit Reduction Act of  
15 2005 (42 U.S.C. 1396a note) is amended—

16 (1) in paragraph (3), by striking “, which shall  
17 include” and all that follows through “2007”;

18 (2) in paragraph (7)—

19 (A) in the paragraph heading, by striking  
20 “REBALANCING” and inserting “EXPENDI-  
21 TURES”; and

22 (B) in subparagraph (B)—

23 (i) in clause (i), by striking “and”  
24 after the semicolon;

1 (ii) in clause (ii), by striking the pe-  
2 riod at the end and inserting a semicolon;  
3 and

4 (iii) by adding at the end the fol-  
5 lowing:

6 “(iii) include a work plan that describes  
7 for each Federal fiscal year that occurs during  
8 the proposed MFP demonstration project—

9 “(I) the use of grant funds for each  
10 proposed initiative that is designed to ac-  
11 complish the objective described in sub-  
12 section (a)(1), including a funding source  
13 for each activity that is part of each such  
14 proposed initiative;

15 “(II) an evaluation plan that identi-  
16 fies expected results for each such pro-  
17 posed initiative; and

18 “(III) a sustainability plan for compo-  
19 nents of such proposed initiatives that are  
20 intended to improve transitions, which  
21 shall be updated with actual expenditure  
22 information for each Federal fiscal year  
23 that occurs during the MFP demonstration  
24 project; and

1           “(iv) contain assurances that grant funds  
2           used to accomplish the objective described in  
3           subsection (a)(1) shall be obligated not later  
4           than 24 months after the date on which the  
5           funds are awarded and shall be expended not  
6           later than 60 months after the date on which  
7           the funds are awarded (subject to subsection  
8           (e)(3) or unless the Secretary approves a waiver  
9           of either such requirement).”; and  
10          (3) in paragraph (13)—

11           (A) in subparagraph (A), by striking “;  
12           and” and inserting “, and in such manner as  
13           will meet the reporting requirements set forth  
14           for the Transformed Medicaid Statistical Man-  
15           agement Information System (T-MSIS);”;

16           (B) by redesignating subparagraph (B) as  
17           subparagraph (D); and

18           (C) by inserting after subparagraph (A)  
19           the following:

20           “(B) the State shall report on a quarterly  
21           basis on the use of grant funds by distinct ac-  
22           tivity, as described in the approved work plan,  
23           and by specific population as targeted by the  
24           State;

1           “(C) if the State fails to report the infor-  
2           mation required under subparagraph (B), fails  
3           to report such information on a quarterly basis,  
4           or fails to make progress under the approved  
5           work plan, the State shall implement a correc-  
6           tive action plan and any lack of progress under  
7           the approved work plan may result in with-  
8           holding of grant funds made available to the  
9           State; and”.

10       (f) FUNDING FOR QUALITY ASSURANCE AND IM-  
11       PROVEMENT; TECHNICAL ASSISTANCE; OVERSIGHT.—  
12       Section 6071(f) of the Deficit Reduction Act of 2005 (42  
13       U.S.C. 1396a note) is amended by striking paragraph (2)  
14       and inserting the following:

15           “(2) FUNDING.—From the amounts appro-  
16           priated under subsection (h)(1) for each fiscal year  
17           after 2019, \$1,000,000 shall be available to the Sec-  
18           retary for each such fiscal year to carry out this  
19           subsection.”.

20       (g) BEST PRACTICES EVALUATION.—Section 6071 of  
21       the Deficit Reduction Act of 2005 (42 U.S.C. 1396a note)  
22       is amended by adding at the end the following:

23           “(i) BEST PRACTICES.—

24           “(1) REPORT.—The Secretary, directly or  
25           through grant or contract, shall submit a report to



1 the President and Congress not later than Sep-  
2 tember 30, 2020, that contains findings and conclu-  
3 sions on best practices from the State MFP dem-  
4 onstration projects carried out with grants made  
5 under this section. The report shall include informa-  
6 tion and analyses with respect to the following:

7 “(A) The most effective State strategies  
8 for transitioning beneficiaries from institutional  
9 to qualified community settings carried out  
10 under the State MFP demonstration projects  
11 and how such strategies may vary for different  
12 types of beneficiaries, such as beneficiaries who  
13 are aged, physically disabled, intellectually or  
14 developmentally disabled, or individuals with se-  
15 rious mental illnesses, and other targeted waiv-  
16 er beneficiary populations.

17 “(B) The most common and the most ef-  
18 fective State uses of grant funds carried out  
19 under the State MFP demonstration projects  
20 for transitioning beneficiaries from institutional  
21 to qualified community settings and improving  
22 health outcomes, including differentiating fund-  
23 ing for current initiatives that are designed for  
24 such purpose and funding for proposed initia-  
25 tives that are designed for such purpose.

1           “(C) The most effective State approaches  
2 carried out under State MFP demonstration  
3 projects for improving person-centered care and  
4 planning.

5           “(D) Identification of program, financing,  
6 and other flexibilities available under the State  
7 MFP demonstration projects, that are not  
8 available under the traditional Medicaid pro-  
9 gram, and which directly contributed to suc-  
10 cessful transitions and improved health out-  
11 comes under the State MFP demonstration  
12 projects.

13           “(E) State strategies and financing mecha-  
14 nisms for effective coordination of housing fi-  
15 nanced or supported under State MFP dem-  
16 onstration projects with local housing authori-  
17 ties and other resources.

18           “(F) Effective State approaches for deliv-  
19 ering Money Follows the Person transition serv-  
20 ices through managed care entities.

21           “(G) Other best practices and effective  
22 transition strategies demonstrated by States  
23 with approved MFP demonstration projects, as  
24 determined by the Secretary.

1                   “(H) Identification and analyses of oppor-  
2                   tunities and challenges to integrating effective  
3                   Money Follows the Person practices and State  
4                   strategies into the traditional Medicaid pro-  
5                   gram.

6                   “(2) COLLABORATION.—In preparing the report  
7                   required under this subsection, the Secretary shall  
8                   collect and incorporate information from States with  
9                   approved MFP demonstration projects and bene-  
10                  ficiaries participating in such projects, and providers  
11                  participating in such projects.

12                  “(3) FUNDING.—From the amounts appro-  
13                  priated under subsection (h)(1) for each of fiscal  
14                  years 2019 through 2020, not more than \$300,000  
15                  shall be available to the Secretary for each such fis-  
16                  cal year to carry out this subsection.”.

17                  (h) MACPAC REPORT ON QUALIFIED SETTINGS  
18                  CRITERIA.—Section 6071 of the Deficit Reduction Act of  
19                  2005 (42 U.S.C. 1396a note), as amended by subsection  
20                  (g), is amended by adding at the end the following:

21                  “(j) MACPAC REPORT.—Prior to the final imple-  
22                  mentation date established by the Secretary for the cri-  
23                  teria established for home and community-based settings  
24                  in section 441.301(c)(4) of title 42, Code of Federal Regu-  
25                  lations, as part of final implementation of the Home and

1 Community Based Services (HCBS) Final Rule published  
2 on January 16, 2014 (79 Fed. Reg. 2947) (referred to  
3 in this subsection as the ‘HCBS final rule’), the Medicaid  
4 and CHIP Payment and Access Commission (MACPAC)  
5 shall submit to Congress a report that—

6 “(1) identifies the types of home and commu-  
7 nity-based settings and associated services that are  
8 available to eligible individuals in both the MFP  
9 demonstration program and sites in compliance with  
10 the HCBS final rule; and

11 “(2) if determined appropriate by the Commis-  
12 sion, recommends policies to align the criteria for a  
13 qualified residence under subsection (b)(6) (as in ef-  
14 fect on October 1, 2017) with the criteria in the  
15 HCBS final rule.”.

16 (i) APPLICATION TO CURRENT PROJECTS.—Not later  
17 than 1 year after the date of enactment of this Act, any  
18 State with an approved MFP demonstration project under  
19 section 6071 of the Deficit Reduction Act of 2005 (42  
20 U.S.C. 1396a note) on the date of enactment of this Act  
21 shall submit a revised application to the Secretary that  
22 contains the same information and assurances as are re-  
23 quired for any new State applicant under the amendments  
24 made by this Act.

1 **SEC. 20202. PERMANENT EXTENSION OF PROTECTION FOR**  
2 **MEDICAID RECIPIENTS OF HOME AND COM-**  
3 **MUNITY-BASED SERVICES AGAINST SPOUSAL**  
4 **IMPOVERISHMENT.**

5 (a) IN GENERAL.—Section 2404 of Public Law 111–  
6 148 (42 U.S.C. 1396r–5 note) is amended—

7 (1) by striking “During the period” and all that  
8 follows through “section 1924(h)(1)(A)” and insert-  
9 ing the following:

10 “(a) IN GENERAL.—Subject to subsection (b), section  
11 1924(h)(1)(A)”;

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

14 “(b) REQUIRED INFORMATION ON COMMUNITY  
15 SPOUSES.—

16 “(1) IN GENERAL.—The Administrator of the  
17 Centers for Medicare & Medicaid Services shall—

18 “(A) collect information from States on the  
19 number of individuals in the State who are  
20 community spouses (as such term is defined in  
21 section 1924(h) of the Social Security Act (42  
22 U.S.C. 1396r–5(h)), and applied pursuant to  
23 subsection (a)) and submit such information to  
24 the Administrator; and

25 “(B) make publicly available information  
26 collected from States under subparagraph (A).

1           “(2) SUNSET.—If the Secretary of Health and  
2           Human Services determines at any point after Janu-  
3           ary 1, 2025, that the Administrator of the Centers  
4           for Medicare & Medicaid Services has failed to meet  
5           the requirements of paragraph (1), section  
6           1924(h)(1)(A) of the Social Security Act (42 U.S.C.  
7           1396r-5(h)(1)(A)) shall be applied without regard to  
8           subsection (a) as of the date of such determina-  
9           tion.”.

10          (b) RULE OF CONSTRUCTION.—Nothing in section  
11          2404 of Public Law 111-148 (42 U.S.C. 1396r-5 note)  
12          or section 1902(a)(17) or 1924 of the Social Security Act  
13          (42 U.S.C. 1396a(a)(17), 1396r-5) shall be construed as  
14          prohibiting a State from applying an income or resource  
15          disregard under a methodology authorized under section  
16          1902(r)(2) of such Act (42 U.S.C. 1396a(r)(2))—

17                 (1) to the income or resources of an individual  
18                 described in section 1902(a)(10)(A)(ii)(VI) of such  
19                 Act (42 U.S.C. 1396a(a)(10)(A)(ii)(VI)) (including  
20                 a disregard of the income or resources of such indi-  
21                 vidual’s spouse); or

22                 (2) on the basis of an individual’s need for  
23                 home and community-based services authorized  
24                 under subsection (c), (d) (i), or (k) of section 1915

1 of such Act (42 U.S.C. 1396n) or under section  
2 1115 of such Act (42 U.S.C. 1315).

3 **SEC. 20203. EXTENSION AND EXPANSION OF COMMUNITY**  
4 **MENTAL HEALTH SERVICES DEMONSTRATION PROGRAM.**  
5

6 (a) IN GENERAL.—Section 223(d) of the Protecting  
7 Access to Medicare Act of 2014 (42 U.S.C. 1396a note)  
8 is amended—

9 (1) in paragraph (3)—

10 (A) by striking “Not more than” and in-  
11 serting “Subject to paragraph (8), not more  
12 than”; and

13 (B) by striking “December 20, 2019” and  
14 inserting “December 31, 2021”;

15 (2) in paragraph (7)(B), by striking “December  
16 31, 2021” and inserting “June 30, 2021”; and

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

19 “(8) ADDITIONAL PROGRAMS.—

20 “(A) IN GENERAL.—Not later than 6  
21 months after the date of enactment of this  
22 paragraph, in addition to the 8 States selected  
23 under paragraph (1), the Secretary shall select  
24 11 States to participate in 2-year demonstra-

1           tion programs that meet the requirements of  
2           this subsection.

3           “(B) SELECTION OF STATES.—

4           “(i) IN GENERAL.—Subject to clause  
5           (ii), in selecting States under this para-  
6           graph, the Secretary—

7           “(I) shall select States that—

8           “(aa) were awarded plan-  
9           ning grants under subsection (c);  
10          and

11          “(bb) applied to participate  
12          in the demonstration programs  
13          under this subsection under para-  
14          graph (1) but, as of the date of  
15          enactment of this paragraph,  
16          were not selected to participate  
17          under paragraph (1); and

18          “(II) shall use the results of the  
19          Secretary’s evaluation of each State’s  
20          application under paragraph (1) to  
21          determine which States to select, and  
22          shall not require the submission of  
23          any additional application.

24          “(ii) SELECTION OF OTHER  
25          STATES.—If less than 11 of the States de-



1 scribed in subclause (I) of clause (i) wish  
2 to participate in demonstration programs  
3 under this subsection, the Secretary may  
4 select other States to participate in dem-  
5 onstration programs under this subsection,  
6 but in no case shall the Secretary select  
7 more than 11 States under this paragraph.

8 “(C) REQUIREMENTS FOR SELECTED  
9 STATES.—Before the launch of a demonstration  
10 program in a State selected under this para-  
11 graph, the State shall—

12 “(i) submit a plan to monitor certified  
13 community behavioral health clinics under  
14 the demonstration program to ensure com-  
15 pliance with certified community behavioral  
16 health criteria during the demonstration  
17 period; and

18 “(ii) commit to collecting data, noti-  
19 fying the Secretary of any planned changes  
20 that would deviate from the prospective  
21 payment system methodology outlined in  
22 the State’s demonstration application, and  
23 obtaining approval from the Secretary for  
24 any such change before implementing the  
25 change.”.

1 (b) LIMITATION.—Section 223(d)(5) of the Pro-  
2 tecting Access to Medicare Act of 2014 (42 U.S.C. 1396a  
3 note) is amended—

4 (1) in subparagraph (B), in the matter pre-  
5 ceding clause (i), by striking “The Federal match-  
6 ing” and inserting “Subject to subparagraph  
7 (C)(iii), the Federal matching”; and

8 (2) in subparagraph (C), by adding at the end  
9 the following new clause:

10 “(iii) PAYMENTS FOR AMOUNTS EX-  
11 PENDED AFTER 2019.—The Federal match-  
12 ing percentage applicable under subpara-  
13 graph (B) to amounts expended by a State  
14 participating in the demonstration pro-  
15 gram under this subsection shall—

16 “(I) in the case of a State par-  
17 ticipating in the demonstration pro-  
18 gram as of January 1, 2020, apply to  
19 amounts expended by the State dur-  
20 ing the 8 fiscal quarter period that be-  
21 gins on January 1, 2020; and

22 “(II) in the case of a State se-  
23 lected to participate in the demonstra-  
24 tion program under paragraph (8),  
25 during first 8 fiscal quarter period

1                   that the State participates in a dem-  
2                   onstration program.”.

3           (c) GAO STUDY AND REPORT ON THE COMMUNITY  
4 AND MENTAL HEALTH SERVICES DEMONSTRATION PRO-  
5 GRAM.—

6           (1) IN GENERAL.—Not later than 18 months  
7 after the date of the enactment of this Act, the  
8 Comptroller General of the United States shall sub-  
9 mit to the Committee on Energy and Commerce of  
10 the House of Representatives and the Committee on  
11 Finance of the Senate a report on the community  
12 and mental health services demonstration program  
13 conducted under section 223 of the Protecting Ac-  
14 cess to Medicare Act of 2014 (42 U.S.C. 1396a  
15 note) (referred to in this subsection as the “dem-  
16 onstration program”).

17           (2) CONTENT OF REPORT.—The report re-  
18 quired under paragraph (1) shall include the fol-  
19 lowing information:

20                   (A) Information on States’ experiences  
21 participating in the demonstration program, in-  
22 cluding the extent to which States—

23                           (i) measure the effects of access to  
24 certified community behavioral health clin-

1           ics on patient health and cost of care, in-  
2           cluding—

3                   (I) engagement in treatment for  
4                   behavioral health conditions;

5                   (II) relevant clinical outcomes, to  
6                   the extent collected;

7                   (III) screening and treatment for  
8                   comorbid medical conditions; and

9                   (IV) use of crisis stabilization,  
10                  emergency department, and inpatient  
11                  care.

12                (B) Information on Federal efforts to  
13                evaluate the demonstration program, includ-  
14                ing—

15                   (i) quality measures used to evaluate  
16                   the program;

17                   (ii) assistance provided to States on  
18                   data collection and reporting;

19                   (iii) assessments of the reliability and  
20                   usefulness of State-submitted data; and

21                   (iv) the extent to which such efforts  
22                   provide information on the relative quality,  
23                   scope, and cost of services as compared  
24                   with services not provided under the dem-  
25                   onstration program, and in comparison to

1 Medicaid beneficiaries with mental illness  
2 and substance use disorders not served  
3 under the demonstration program.

4 (C) Recommendations for improvements to  
5 the following:

6 (i) The reporting, accuracy, and vali-  
7 dation of encounter data.

8 (ii) Accuracy in payments to certified  
9 community behavioral health clinics under  
10 State plans or waivers under title XIX of  
11 the Social Security Act (42 U.S.C. 1396 et  
12 seq.).

13 **SEC. 20204. DELAY IN MEDICAID DSH REDUCTIONS; RE-**  
14 **PORTING ON SUPPLEMENTAL PAYMENTS.**

15 (a) DELAY IN DSH REDUCTION.—Section  
16 1923(f)(7)(A) of the Social Security Act (42 U.S.C.  
17 1396r-4(f)(7)(A)) is amended—

18 (1) in clause (i), in the matter preceding sub-  
19 clause (I), by striking “For the period” and all that  
20 follows through “2025” and inserting “For each of  
21 fiscal years 2022 through 2025”; and

22 (2) in clause (ii), by striking “shall be equal  
23 to—” and all that follows through “2025” and in-  
24 serting “shall be equal to \$8,000,000,000 for each  
25 of fiscal years 2022 through 2025”.

1 (b) SUPPLEMENTAL PAYMENT REPORTING RE-  
2 QUIREMENTS.—Section 1903 of the Social Security Act  
3 (42 U.S.C.1396b) is amended by adding at the end the  
4 following new subsection:

5 “(bb) SUPPLEMENTAL PAYMENTS REPORTING RE-  
6 QUIREMENTS.—

7 “(1) COLLECTION AND PUBLIC AVAILABILITY  
8 OF SUPPLEMENTAL PAYMENT DATA.—

9 “(A) IN GENERAL.—Not later than Octo-  
10 ber 1, 2021, the Secretary shall establish a sys-  
11 tem for each State to submit reports on supple-  
12 mental payments data, as a requirement for a  
13 State plan or State plan amendment that would  
14 provide for a supplemental payment.

15 “(B) REQUIREMENTS.—Each report sub-  
16 mitted by a State in accordance with the re-  
17 quirement established under subparagraph (A)  
18 shall include the following:

19 “(i) An explanation of how supple-  
20 mental payments made under the State  
21 plan or a State plan amendment will result  
22 in payments that are consistent with sec-  
23 tion 1902(a)(30)(A), including standards  
24 with respect to efficiency, economy, quality  
25 of care, and access, along with the stated

1 purpose and intended effects of the supple-  
2 mental payment.

3 “(ii) The criteria used to determine  
4 which providers are eligible to receive the  
5 supplemental payment.

6 “(iii) A comprehensive description of  
7 the methodology used to calculate the  
8 amount of, and distribute, the supple-  
9 mental payment to each eligible provider,  
10 including—

11 “(I) data on the amount of the  
12 supplemental payment made to each  
13 eligible provider, if known, or, if the  
14 total amount is distributed using a  
15 formula based on data from 1 or more  
16 fiscal years, data on the total amount  
17 of the supplemental payments for the  
18 fiscal year or years available to all  
19 providers eligible to receive a supple-  
20 mental payment;

21 “(II) if applicable, the specific  
22 criteria with respect to Medicaid serv-  
23 ice, utilization, or cost data to be used  
24 as the basis for calculations regarding

1 the amount or distribution of the sup-  
2 plemental payment; and

3 “(III) the timing of the supple-  
4 mental payment made to each eligible  
5 provider.

6 “(iv) An assurance that the total  
7 Medicaid payments made to an inpatient  
8 hospital provider, including the supple-  
9 mental payment, will not exceed upper  
10 payment limits.

11 “(v) If not already submitted, an  
12 upper payment limit demonstration under  
13 section 447.272 of title 42, Code of Fed-  
14 eral Regulations (as such section is in ef-  
15 fect as of the date of enactment of this  
16 subsection).

17 “(C) PUBLIC AVAILABILITY.—The Sec-  
18 retary shall make all reports and related data  
19 submitted under this paragraph publicly avail-  
20 able on the website of the Centers for Medicare  
21 & Medicaid Services on a timely basis.

22 “(D) SUPPLEMENTAL PAYMENT DE-  
23 FINED.—

24 “(i) IN GENERAL.—Subject to clause  
25 (ii), in this paragraph, the term ‘supple-



1           mental payment’ means a payment to a  
2           provider that is in addition to any base  
3           payment made to the provider under the  
4           State plan under this title or under dem-  
5           onstration authority.

6                   “(ii) DSH PAYMENTS EXCLUDED.—  
7           Such term does not include a dispropor-  
8           tionate share hospital payment made under  
9           section 1923.”.

10           (c) MEDICAID SHORTFALL AND THIRD PARTY PAY-  
11   MENTS.—

12                   (1) IN GENERAL.—Section 1923(g)(1)(A) of the  
13           Social Security Act (42 U.S.C. 1396r-4(g)(1)(A)) is  
14           amended to read as follows:

15                           “(A) DETERMINATION OF UNCOMPEN-  
16           SATED COSTS.—

17                                   “(i) IN GENERAL.—A payment adjust-  
18           ment during a fiscal year shall not be con-  
19           sidered to be consistent with subsection (c)  
20           with respect to a hospital if the payment  
21           adjustment exceeds the costs incurred dur-  
22           ing the year of furnishing hospital services  
23           by the hospital to individuals described in  
24           clause (ii) minus—

1                   “(I) payments under this title  
2                   (other than under this section) for  
3                   such services; and

4                   “(II) payments by uninsured pa-  
5                   tients for such services.

6                   “(ii) INDIVIDUALS DESCRIBED.—For  
7                   purposes of clause (i), the individuals de-  
8                   scribed in this clause are the following:

9                   “(I) Subject to clause (iii), indi-  
10                  viduals who are eligible for medical  
11                  assistance under the State plan or  
12                  under a waiver of such plan and for  
13                  whom the State plan or waiver is the  
14                  primary payor for such services.

15                  “(II) Subject to clause (iv), indi-  
16                  viduals who have no health insurance  
17                  (or other source of third party cov-  
18                  erage) for services provided during the  
19                  year, as determined by the Secretary.

20                  “(iii) EXCLUSION OF CERTAIN PAY-  
21                  MENTS.—For purposes of clause (ii)(II),  
22                  payments made to a hospital for services  
23                  provided to indigent patients made by a  
24                  State or a unit of local government within

1                   a State shall not be considered to be a  
2                   source of third party payment.”.

3                   (2) EFFECTIVE DATE.—The amendment made  
4                   by this subsection takes effect on October 1, 2020.

5                   (d) GAO STUDY AND REPORT ON UNCOMPENSATED  
6 CARE COSTS IN HOSPITALS SERVING A DISPROPOR-  
7 TIONATE SHARE OF MEDICAID BENEFICIARIES AND UN-  
8 INSURED PATIENTS.—Not later than 18 months after the  
9 date of the enactment of this Act, the Comptroller General  
10 of the United States shall submit to the Committee on  
11 Energy and Commerce of the House of Representatives  
12 and to the Committee on Finance of the Senate a report  
13 that examines uncompensated care costs, as defined for  
14 purposes of subsection (g) of section 1923 of the Social  
15 Security Act (42 U.S.C. 1396r-4), for all hospitals receiv-  
16 ing disproportionate share hospital payments under such  
17 section. The report shall include an examination of uncom-  
18 pensated care costs at the State level and provide informa-  
19 tion on each State’s Medicaid uncompensated care costs.

20 **SEC. 20205. MEDICAID FUNDING FOR THE TERRITORIES.**

21                   (a) TREATMENT OF CAP.—Section 1108(g) of the  
22 Social Security Act (42 U.S.C. 1308(g)) is amended—

23                   (1) in paragraph (2)—

24                   (A) in the matter preceding subparagraph

25                   (A), by striking “subject to and section

1 1323(a)(2) of the Patient Protection and Af-  
2 fordable Care Act paragraphs (3) and (5)” and  
3 inserting “subject to section 1323(a)(2) of the  
4 Patient Protection and Affordable Care Act and  
5 paragraphs (3) and (5)”;

6 (B) in subparagraph (A)—

7 (i) by striking “Puerto Rico shall not  
8 exceed the sum of” and inserting “Puerto  
9 Rico shall not exceed—

10 “(i) except as provided in clause (ii),  
11 the sum of”;

12 (ii) by striking “\$100,000;” and in-  
13 serting “\$100,000; and”; and

14 (iii) by adding at the end the fol-  
15 lowing new clause:

16 “(ii) for each of fiscal years 2020  
17 through 2023, the amount specified in  
18 paragraph (6) for each such fiscal year;”;

19 (C) in subparagraph (B)—

20 (i) by striking “the Virgin Islands  
21 shall not exceed the sum of” and inserting  
22 “the Virgin Islands shall not exceed—

23 “(i) except as provided in clause (ii),  
24 the sum of”;

1 (ii) by striking “\$10,000;” and insert-  
2 ing “\$10,000; and”;

3 (iii) by adding at the end the fol-  
4 lowing new clause:

5 “(ii) for each of fiscal years 2020  
6 through 2023, \$126,000,000;”;

7 (D) in subparagraph (C)—

8 (i) by striking “Guam shall not exceed  
9 the sum of” and inserting “Guam shall not  
10 exceed—

11 “(i) except as provided in clause (ii),  
12 the sum of”;

13 (ii) by striking “\$10,000;” and insert-  
14 ing “\$10,000; and”;

15 (iii) by adding at the end the fol-  
16 lowing new clause:

17 “(ii) for each of fiscal years 2020  
18 through 2023, \$127,000,000;”;

19 (E) in subparagraph (D)—

20 (i) by striking “the Northern Mariana  
21 Islands shall not exceed the sum of” and  
22 inserting “the Northern Mariana Islands  
23 shall not exceed—

24 “(i) except as provided in clause (ii),  
25 the sum of”;

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

3 “(ii) for each of fiscal years 2020  
4 through 2023, \$60,000,000; and”;  
5 (F) in subparagraph (E)—

6 (i) by striking “American Samoa shall  
7 not exceed the sum of” and inserting  
8 “American Samoa shall not exceed—

9 “(i) except as provided in clause (ii),  
10 the sum of”;

11 (ii) by striking “\$10,000.” and insert-  
12 ing “\$10,000; and”; and

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

15 “(ii) for each of fiscal years 2020  
16 through 2023, \$84,000,000.”; and

17 (G) by adding at the end the following  
18 flush sentence:

19 ““For each fiscal year after fiscal year 2023, the  
20 total amount certified for Puerto Rico, the Virgin Is-  
21 lands, Guam, the Northern Mariana Islands, and  
22 American Samoa under subsection (f) and this sub-  
23 section for the fiscal year shall be determined as if  
24 the preceding subparagraphs were applied to each of

1 fiscal years 2020 through 2023 without regard to  
2 clause (ii) of each such subparagraph.”; and

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

5 “(6) APPLICATION TO PUERTO RICO FOR FIS-  
6 CAL YEARS 2020 THROUGH 2023.—

7 “(A) IN GENERAL.—Subject to subpara-  
8 graph (B), the amount specified in this para-  
9 graph is—

10 “(i) for fiscal year 2020,  
11 \$2,623,188,000;

12 “(ii) for fiscal year 2021,  
13 \$2,719,072,000;

14 “(iii) for fiscal year 2022,  
15 \$2,812,610,000; and

16 “(iv) for fiscal year 2023,  
17 \$2,914,331,000.

18 “(B) ADDITIONAL INCREASE FOR PUERTO  
19 RICO.—For each of fiscal years 2020 through  
20 2023, the amount specified in this paragraph  
21 shall be equal to the amount specified for such  
22 year under subparagraph (A) increased by  
23 \$200,000,000 if the Secretary certifies that,  
24 with respect to such year, Puerto Rico’s State  
25 plan under title XIX (or a waiver of such plan)

1 provides for payment for outpatient physician  
2 services furnished under the plan (or waiver)  
3 during the fiscal year at a rate that is not less  
4 than 70 percent of the payment rate that would  
5 apply to such services if they were furnished  
6 under part B of title XVIII during such fiscal  
7 year.

8 “(7) PUERTO RICO PROGRAM INTEGRITY RE-  
9 QUIREMENTS.—

10 “(A) INDEPENDENT AUDIT.—

11 “(i) IN GENERAL.—Not later than 6  
12 months after the date of enactment of this  
13 paragraph, Puerto Rico shall select an  
14 independent third party to conduct an  
15 audit of Puerto Rico’s Medicaid program  
16 under title XIX in each of fiscal years  
17 2022 and 2023. Such audit shall include  
18 an examination of any part of the adminis-  
19 tration of Puerto Rico’s Medicaid program,  
20 such as contracting protocols, denials of  
21 care, and financial management, that the  
22 independent third party determines to be  
23 at high risk for waste, fraud, or abuse.

24 “(ii) PENALTY FOR FAILURE TO SE-  
25 LECT A THIRD PARTY.—If Puerto Rico



1 does not select an independent third party  
2 to conduct the audit required under clause  
3 (i) by the date specified in such clause, the  
4 amounts specified for Puerto Rico under  
5 paragraph (6) for fiscal years 2022 and  
6 2023 shall be reduced by \$50,000,000 for  
7 each such year.

8 “(iii) REPORT.—Upon completion of  
9 the audit required under clause (i), the  
10 independent third party that conducted the  
11 audit shall submit a report containing the  
12 results of the audit to Congress, the Gov-  
13 ernor of Puerto Rico, and the Inspector  
14 General of the Department of Health and  
15 Human Services.

16 “(B) ADDITIONAL REQUIREMENTS.—

17 “(i) PROGRAM INTEGRITY LEAD.—  
18 Not later than 6 months after the date of  
19 enactment of this paragraph, the agency  
20 responsible for the administration of Puer-  
21 to Rico’s Medicaid program under title  
22 XIX shall designate an officer (other than  
23 the director of such agency) to serve as the  
24 Program Integrity Lead for such program.

1                   “(ii) PERM REQUIREMENT.—Not  
2 later than 12 months after the date of en-  
3 actment of this paragraph, Puerto Rico  
4 shall publish a plan, developed by Puerto  
5 Rico in coordination with the Adminis-  
6 trator of the Centers for Medicare & Med-  
7 icaid Services and approved by the Admin-  
8 istrator, for how Puerto Rico will develop  
9 measures to satisfy the payment error rate  
10 measurement (PERM) requirements under  
11 subpart Q of part 431 of title 42, Code of  
12 Federal Regulations, including annual  
13 benchmarks and scheduled audits for such  
14 compliance.

15                   “(iii) CONTRACTING REFORM.—Not  
16 later than October 1, 2020, Puerto Rico  
17 shall publish a contracting reform plan to  
18 combat fraudulent, wasteful, or abusive  
19 contracts under Puerto Rico’s Medicaid  
20 program under title XIX that includes—

21                           “(I) metrics for evaluating the  
22 success of the plan; and

23                           “(II) a schedule for publicly re-  
24 leasing status reports on the plan.

1           “(iv) MEQC.—Not later than 12  
2 months after the date of enactment of this  
3 paragraph, Puerto Rico shall publish a  
4 plan, developed by Puerto Rico in coordi-  
5 nation with the Administrator of the Cen-  
6 ters for Medicare & Medicaid Services and  
7 approved by the Administrator, for how  
8 Puerto Rico will comply with the Medicaid  
9 eligibility quality control (MEQC) require-  
10 ments of section 1903(u).

11           “(C) FMAP REDUCTION FOR FAILURE TO  
12 MEET ADDITIONAL REQUIREMENTS.—

13           “(i) IN GENERAL.—For fiscal quar-  
14 ters during the period beginning on Janu-  
15 ary 1, 2020, and ending on September 30,  
16 2023, for each requirement described in  
17 clauses (i) through (iv) of subparagraph  
18 (B) and for each plan described in clauses  
19 (ii) and (iv) of such subparagraph, if Puer-  
20 to Rico fails to satisfy such requirement or  
21 comply with the terms of such plan, the  
22 Federal medical assistance percentage ap-  
23 plicable to Puerto Rico under section  
24 1905(ff) for such quarter shall be reduced  
25 by a number of percentage points (not to

1 exceed 5 percentage points with respect to  
2 each such failure) equal to 0.5 percentage  
3 points for every fiscal quarter during such  
4 period in which Puerto Rico has failed to  
5 satisfy such requirement or comply with  
6 the terms of such plan.

7 “(ii) EXCEPTION FOR EXTENUATING  
8 CIRCUMSTANCES OR REASONABLE  
9 PROGRESS.—For purposes of clause (i),  
10 Puerto Rico shall be deemed to have satis-  
11 fied a requirement of subparagraph (B) or  
12 complied with the terms of a plan de-  
13 scribed in such subparagraph for a fiscal  
14 quarter if—

15 “(I) the Secretary approves an  
16 application from Puerto Rico describ-  
17 ing extenuating circumstances that  
18 prevented Puerto Rico from satisfying  
19 the requirement or complying with the  
20 terms of the plan; or

21 “(II) in the case of a requirement  
22 to comply with the terms of a plan,  
23 Puerto Rico has made objectively rea-  
24 sonable progress towards satisfying  
25 such terms and has submitted a time-

1                   ly request for an exception to the Sec-  
2                   retary.

3                   “(8) PROGRAM INTEGRITY LEAD REQUIREMENT  
4                   FOR THE VIRGIN ISLANDS, GUAM, THE NORTHERN  
5                   MARIANA ISLANDS, AND AMERICAN SAMOA.—

6                   “(A) PROGRAM INTEGRITY LEAD REQUIRE-  
7                   MENT.—Not later than October 1, 2020, the  
8                   agency responsible for the administration of the  
9                   Medicaid program under title XIX of each terri-  
10                  tory specified in subparagraph (C) shall des-  
11                  ignate an officer (other than the director of  
12                  such agency) to serve as the Program Integrity  
13                  Lead for such program.

14                  “(B) FMAP REDUCTION.—If, in any fiscal  
15                  quarter during the period that begins with fis-  
16                  cal year 2021 and ends with fiscal year 2023,  
17                  a territory specified in subparagraph (C) fails  
18                  to satisfy the requirement of subparagraph (A),  
19                  the Federal medical assistance percentage ap-  
20                  plicable to the territory under section 1905(ff)  
21                  for such quarter shall be reduced by 0.25 per-  
22                  centage points for every fiscal quarter during  
23                  such period in which the territory has failed to  
24                  satisfy such requirement, except that in no case

1 shall a reduction under this subparagraph ex-  
2 ceed 5 percentage points.

3 “(C) SCOPE.—This paragraph shall apply  
4 to the Virgin Islands, Guam, the Northern Mar-  
5 iana Islands, and American Samoa.”.

6 (b) TREATMENT OF FUNDING UNDER ENHANCED  
7 ALLOTMENT PROGRAM.—Section 1935(e) of the Social  
8 Security Act (42 U.S.C. 1396u–5(e)) is amended—

9 (1) in paragraph (1)(B), by striking “if the  
10 State” and inserting “subject to paragraph (4), if  
11 the State”;

12 (2) by redesignating paragraph (4) as para-  
13 graph (5); and

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

16 “(4) TREATMENT OF FUNDING FOR CERTAIN  
17 FISCAL YEARS.—

18 “(A) PUERTO RICO.—Notwithstanding  
19 paragraph (1)(B), in the case that Puerto Rico  
20 establishes and submits to the Secretary a plan  
21 described in paragraph (2) with respect to any  
22 of fiscal years 2020 through 2023, the amount  
23 specified in paragraph (3) for Puerto Rico for  
24 such a year shall be taken into account in ap-

1           plying subparagraph (A)(ii) of section  
2           1108(g)(2) for such year.

3           “(B) OTHER TERRITORIES.—Notwith-  
4           standing paragraph (1)(B), in the case that the  
5           Virgin Islands, Guam, the Northern Mariana  
6           Islands, or American Samoa establishes and  
7           submits to the Secretary a plan described in  
8           paragraph (2) with respect to any of fiscal  
9           years 2020 through 2025, the amount specified  
10          in paragraph (3) for the Virgin Islands, Guam,  
11          the Northern Mariana Islands, or American  
12          Samoa, as the case may be, shall be taken into  
13          account in applying, as applicable, subpara-  
14          graph (B)(ii), (C)(ii), (D)(ii), or (E)(ii) of sec-  
15          tion 1108(g)(2) for such year.”.

16          (c) INCREASED FMAP.—Subsection (ff) of section  
17          1905 of the Social Security Act (42 U.S.C. 1396d) is  
18          amended to read as follows:

19          “(ff) TEMPORARY INCREASE IN FMAP FOR TERRI-  
20          TORIES FOR CERTAIN FISCAL YEARS.—Notwithstanding  
21          subsection (b) or (z)(2)—

22                 “(1) for the period beginning October 1, 2019,  
23                 and ending December 20, 2019, the Federal medical  
24                 assistance percentage for Puerto Rico, the Virgin Is-

1 lands, Guam, the Northern Mariana Islands, and  
2 American Samoa shall be equal to 100 percent; and

3 “(2) for the period beginning December 21,  
4 2019, and ending September 30, 2023, the Federal  
5 medical assistance percentage—

6 “(A) for Puerto Rico, shall be equal to 76  
7 percent; and

8 “(B) for the Virgin Islands, Guam, the  
9 Northern Mariana Islands, and American  
10 Samoa shall be equal to 83 percent.”.

11 (d) ANNUAL REPORT.—Section 1108(g) of the Social  
12 Security Act (42 U.S.C. 1308(g)), as amended by sub-  
13 section (a), is further amended by adding at the end the  
14 following new paragraph:

15 “(9) ANNUAL REPORT.—

16 “(A) IN GENERAL.—Not later than the  
17 date that is 30 days after the end of each fiscal  
18 year (beginning with fiscal year 2020 and end-  
19 ing with fiscal year 2023), in the case that a  
20 specified territory receives a Medicaid cap in-  
21 crease, or an increase in the Federal medical  
22 assistance percentage for such territory under  
23 section 1905(ff), for such fiscal year, such terri-  
24 tory shall submit to the Chair and Ranking  
25 Member of the Committee on Energy and Com-



1           merce of the House of Representatives and the  
2           Chair and Ranking Member of the Committee  
3           on Finance of the Senate a report that de-  
4           scribes how such territory has used such Med-  
5           icaid cap increase, or such increase in the Fed-  
6           eral medical assistance percentage, as applica-  
7           ble, to increase access to health care under the  
8           State Medicaid plan of such territory under title  
9           XIX (or a waiver of such plan). Such report  
10          may include—

11                   “(i) the extent to which such territory  
12                   has, with respect to such plan (or waiv-  
13                   er)—

14                           “(I) increased payments to health  
15                           care providers;

16                           “(II) increased covered benefits;

17                           “(III) expanded health care pro-  
18                           vider networks; or

19                           “(IV) improved in any other  
20                           manner the carrying out of such plan  
21                           (or waiver); and

22                           “(ii) any other information as deter-  
23                           mined necessary by such territory.

24                   “(B) DEFINITIONS.—In this paragraph:

1                   “(i) MEDICAID CAP INCREASE.—The  
2                   term ‘Medicaid cap increase’ means, with  
3                   respect to a specified territory and fiscal  
4                   year, any increase in the amounts other-  
5                   wise determined under this subsection for  
6                   such territory for such fiscal year by rea-  
7                   son of the amendments made by section  
8                   20205 Prescription Drug Pricing Reduc-  
9                   tion and Health and Human Services Im-  
10                  provements Act .

11                  “(ii) SPECIFIED TERRITORY.—The  
12                  term ‘specified territory’ means Puerto  
13                  Rico, the Virgin Islands, Guam, the North-  
14                  ern Mariana Islands, and American  
15                  Samoa.”.

16                  (e) APPLICATION OF CERTAIN DATA REPORTING  
17                  AND PROGRAM INTEGRITY REQUIREMENTS TO NORTH-  
18                  ERN MARIANA ISLANDS, AMERICAN SAMOA, AND GUAM.—

19                  (1) IN GENERAL.—Section 1902 of the Social  
20                  Security Act (42 U.S.C. 1396a) is amended by add-  
21                  ing at the end the following new subsection:

22                  “(qq) APPLICATION OF CERTAIN DATA REPORTING  
23                  AND PROGRAM INTEGRITY REQUIREMENTS TO NORTH-  
24                  ERN MARIANA ISLANDS, AMERICAN SAMOA, AND GUAM.—

1 Not later than October 1, 2021, the Northern Mariana  
 2 Islands, American Samoa, and Guam shall—

3 “(1) implement methods, satisfactory to the  
 4 Secretary, for the collection and reporting of reliable  
 5 data to the Transformed Medicaid Statistical Infor-  
 6 mation System (T-MSIS) (or a successor system);  
 7 and

8 “(2) demonstrate progress in establishing a  
 9 State medicaid fraud control unit described in sec-  
 10 tion 1903(q).”.

11 (2) CONFORMING AMENDMENT.—Section  
 12 1902(j) of the Social Security Act (42 U.S.C.  
 13 1396a(j)) is amended—

14 (A) by striking “or the requirement” and  
 15 inserting “, the requirement”; and

16 (B) by inserting before the period at the  
 17 end the following: “, or the requirement under  
 18 subsection (qq)(1) (relating to data reporting)”.

19 (f) ADDITIONAL PROGRAM INTEGRITY REQUIRE-  
 20 MENTS.—

21 (1) DEFINITIONS.—In this subsection:

22 (A) INSPECTOR GENERAL.—The term “In-  
 23 spector General” means the Inspector General  
 24 of the Department of Health and Human Serv-  
 25 ices.

1 (B) PUERTO RICO'S MEDICAID PRO-  
2 GRAM.—The term “Puerto Rico’s Medicaid pro-  
3 gram” means, collectively, Puerto Rico’s State  
4 plan under title XIX of the Social Security Act  
5 (42 U.S.C. 1396 et seq.) and any waiver of  
6 such plan.

7 (2) AUDITS RELATING TO FRAUD, WASTE, AND  
8 ABUSE.—If the independent third party that con-  
9 ducts the program integrity audit of Puerto Rico’s  
10 Medicaid program required under section  
11 1108(g)(7)(A) of the Social Security Act (42 U.S.C.  
12 1308(g)(7)(A)) notifies the Inspector General  
13 (whether in the report required in such section or  
14 otherwise) of areas that the independent third party  
15 has identified as being at a high risk for waste,  
16 fraud, and abuse, the Inspector General shall con-  
17 duct, on a regular basis, audits of the administration  
18 of Puerto Rico’s Medicaid program until the Inspec-  
19 tor General determines that Puerto Rico has taken  
20 reasonable and appropriate steps to address such  
21 high risk areas.

22 (3) TECHNICAL REVIEW OF PUERTO RICO  
23 HEARINGS AND APPEALS PROCESSES.—Not later  
24 than January 1, 2022, the Secretary of Health and  
25 Human Services shall conduct a technical review of

1 the hearings and appeals processes available to indi-  
2 viduals applying for or receiving benefits under  
3 Puerto Rico's Medicaid program and the hearings  
4 and appeals processes available to providers partici-  
5 pating in such program to ensure that such proc-  
6 esses comply with all applicable requirements under  
7 titles XI and XIX of the Social Security Act (42  
8 U.S.C. 1301 et seq., 1396 et seq.) (including appli-  
9 cable regulations promulgated under such titles).

10 (4) AUDITS OF MANAGED CARE PAYMENTS.—  
11 Not later than the date that is 1 year after the date  
12 of enactment of this Act, the Inspector General shall  
13 develop and submit to Congress—

14 (A) a report identifying payments made  
15 under Puerto Rico's Medicaid program to man-  
16 aged care organizations that the Inspector Gen-  
17 eral determines to be at high risk for waste,  
18 fraud, or abuse; and

19 (B) a plan for auditing and investigating  
20 such payments.

21 (5) SYSTEM FOR TRACKING FEDERAL FUNDING  
22 PROVIDED TO PUERTO RICO; MEDICAID AND CHIP  
23 SCORECARD REPORTING.—Section 1902 of the So-  
24 cial Security Act (42 U.S.C. 1396a), as amended by

1 subsection (e), is further amended by adding at the  
2 end the following new subsection:

3 “(rr) PROGRAM INTEGRITY REQUIREMENTS FOR  
4 PUERTO RICO.—

5 “(1) SYSTEM FOR TRACKING FEDERAL FUND-  
6 ING PROVIDED TO PUERTO RICO.—

7 “(A) IN GENERAL.—Puerto Rico shall es-  
8 tablish and maintain a system for tracking any  
9 amounts paid by the Federal Government to  
10 Puerto Rico with respect to the State plan of  
11 Puerto Rico (or a waiver of such plan). Under  
12 such system, Puerto Rico shall ensure that in-  
13 formation is available, with respect to each  
14 quarter in a fiscal year (beginning with the first  
15 quarter beginning on or after the date that is  
16 1 year after the date of the enactment of this  
17 subsection), on the following:

18 “(i) In the case of a quarter other  
19 than the first quarter of such fiscal year—

20 “(I) the total amount expended  
21 by Puerto Rico during any previous  
22 quarter of such fiscal year under the  
23 State plan of Puerto Rico (or a waiver  
24 of such plan); and

1                   “(II) a description of how such  
2                   amount was so expended.

3                   “(ii) The total amount that Puerto  
4                   Rico expects to expend during the quarter  
5                   under the State plan of Puerto Rico (or a  
6                   waiver of such plan), and a description of  
7                   how Puerto Rico expects to expend such  
8                   amount.

9                   “(B) REPORT TO CMS.—For each quarter  
10                  with respect to which Puerto Rico is required  
11                  under subparagraph (A) to ensure that infor-  
12                  mation described in such subparagraph is avail-  
13                  able, Puerto Rico shall submit to the Adminis-  
14                  trator of the Centers for Medicare & Medicaid  
15                  Services a report on such information for such  
16                  quarter.

17                  “(2) SUBMISSION OF DOCUMENTATION ON CON-  
18                  TRACTS UPON REQUEST.—Puerto Rico shall, upon  
19                  request, submit to the Administrator of the Centers  
20                  for Medicare & Medicaid Services all documentation  
21                  requested with respect to contracts awarded under  
22                  the State plan of Puerto Rico (or a waiver of such  
23                  plan).

24                  “(3) REPORTING ON MEDICAID AND CHIP  
25                  SCORECARD MEASURES.—Beginning 12 months after

1 the date of enactment of this subsection, Puerto  
2 Rico shall begin to report to the Administrator of  
3 the Centers for Medicare & Medicaid Services on all  
4 measures included in the Medicaid and CHIP Score-  
5 card developed by the Centers for Medicare & Med-  
6 icaid Services.”.

7 (6) APPROPRIATION.—Out of any funds in the  
8 Treasury not otherwise appropriated, there is appro-  
9 priated to the Secretary of Health and Human Serv-  
10 ices \$5,000,000 for each of fiscal years 2020  
11 through 2023 to carry out this subsection.

12 **SEC. 20206. REPORTING REQUIREMENTS FOR ELECTING**  
13 **COST AVOIDANCE EXCEPTIONS FOR MED-**  
14 **ICAID AND CHIP THIRD PARTY LIABILITY.**

15 Section 1902 of the Social Security Act (42 U.S.C.  
16 1396a) is amended—

17 (1) in subsection (a)(25)—

18 (A) in subparagraph (E)(i), by inserting “,  
19 and the State satisfies the reporting require-  
20 ments specified in subsection (qq)” after “ac-  
21 cess to care”; and

22 (B) in subparagraph (F)(i), by striking  
23 “care.” and inserting “care, and the State sat-  
24 isfies the reporting requirements specified in  
25 subsection (qq)”;



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

2 “(qq) REPORTING REQUIRE-  
3 MENTS FOR ELECTING COST  
4 AVOIDANCE EXCEPTIONS FOR  
5 THIRD PARTY LIABILITY.—For  
6 purposes of subparagraphs (E)(i)  
7 and (F)(i) of subsection (a)(25),  
8 the reporting requirements of  
9 this subsection are the following:

10 “(1) PRE-IMPLEMENTATION.—Prior to imple-  
11 mentation of a cost avoidance exception under either  
12 such subparagraph (or, in the case of a State that  
13 on the date of enactment of this subsection has im-  
14 plemented a cost avoidance exception under either or  
15 both of such subparagraphs, not later than 9 months  
16 after such date of enactment), a State shall submit  
17 a baseline report on third party liability to the Sec-  
18 retary that—

19 “(A) lists the actions taken by the State to  
20 update and improve systems to verify third  
21 party liability;

22 “(B) includes an assessment, based on  
23 data from the 3 most recent calendar years, ex-  
24 amining the overlap of coverage provided under  
25 the State plan under this title or under a waiv-

1 er of such plan and third party coverage for  
2 preventive pediatric care (including early and  
3 periodic screening, diagnostic and treatment  
4 services under section 1905(a)(4)(B)) and serv-  
5 ices provided to an individual on whose behalf  
6 child support enforcement is being carried out;

7 “(C) provides information on—

8 “(i) the proportion of children covered  
9 under the State plan or under any waiver  
10 of such plan identified as having third  
11 party coverage;

12 “(ii) the number and proportion of  
13 such beneficiaries whose third party cov-  
14 erage status was determined to be inac-  
15 curate, to the extent available;

16 “(iii) the number and proportion of  
17 such beneficiaries with claims under the  
18 State plan or under any waiver of such  
19 plan for pediatric preventive services;

20 “(iv) the number and costs of claims  
21 for child support enforcement beneficiaries  
22 that would not be categorized as pediatric  
23 preventive services;

24 “(v) in the case of a State that on the  
25 date of enactment of this subsection has

1 implemented a cost avoidance exception  
2 under subparagraph (E)(i) of subsection  
3 (a)(25), the number and proportion of  
4 claims for pediatric preventive care for  
5 which the State (or any contracted entity)  
6 employed such an exception and for which  
7 third party payment was recovered; and

8 “(vi) in the case of a State that on  
9 the date of enactment of this subsection  
10 has implemented a cost avoidance excep-  
11 tion under subparagraph (F)(i) of sub-  
12 section (a)(25), the number and proportion  
13 of claims for services provided to an indi-  
14 vidual on whose behalf child support en-  
15 forcement is being carried out by the State  
16 for which the State (or any contracted en-  
17 tity) employed such an exception and for  
18 which third party payment was recovered;  
19 and

20 “(D) includes information on sources used  
21 by the State to identify possible third party cov-  
22 erage for—

23 “(i) Medicaid beneficiaries eligible for  
24 pediatric preventive services; and

1                   “(ii) claims for services covered under  
2                   the State plan or a waiver of such plan  
3                   which are provided to an individual on  
4                   whose behalf child support enforcement is  
5                   being carried out by the State.

6                   “(2) IMPLEMENTATION.—Upon implementation  
7                   by State of a cost avoidance exception under sub-  
8                   paragraph (E)(i) or (F)(i) of subsection (a)(25) (or,  
9                   in the case of a State that on the date of enactment  
10                  of this subsection has implemented a cost avoidance  
11                  exception under either or both of such subpara-  
12                  graphs, not later than 9 months after such date of  
13                  enactment), the State shall submit a baseline report  
14                  on access to care to the Secretary that—

15                  “(A) in the case of a State that has imple-  
16                  mented a cost avoidance exception under sub-  
17                  paragraph (E)(i) of such subsection, includes  
18                  an analysis of access to pediatric preventive  
19                  care services under the State plan or a waiver  
20                  of such plan (through both fee-for-service and  
21                  managed care) examining measures of access to  
22                  care, including provider availability and accessi-  
23                  bility, beneficiary utilization, and beneficiary  
24                  perceptions and experiences; and

1           “(B) in the case of a State that has imple-  
2           mented a cost avoidance exception under sub-  
3           paragraph (F)(i) of such subsection, includes  
4           an analysis of access to services provided under  
5           the State plan or a waiver of such plan to an  
6           individual on whose behalf child support en-  
7           forcement is being carried out by the State  
8           (through both fee-for-service and managed care)  
9           examining measures of access to care, including  
10          provider availability and accessibility, bene-  
11          ficiary utilization, and beneficiary perceptions  
12          and experiences.

13          “(3) ADDITIONAL REPORTS.—

14                 “(A) ANNUAL NOTICE OF IMPLEMENTA-  
15                 TION REPORT.—A State annually shall submit a  
16                 notice to the Secretary regarding whether the  
17                 State has implemented a cost avoidance excep-  
18                 tion under subparagraph (E)(i) or (F)(i) of  
19                 subsection (a)(25) (or both).

20                 “(B) UPDATED BASELINE REPORTS.—  
21                 Every 3 years after implementation of a cost  
22                 avoidance exception under subparagraph (E)(i)  
23                 or (F)(i) of subsection (a)(25), a State shall  
24                 submit to the Secretary an updated version of  
25                 the baseline reports submitted by the State

1 under paragraphs (1) and (2) (as applicable).  
2 Each updated report submitted in accordance  
3 with this subparagraph shall include informa-  
4 tion regarding—

5 “(i) trends relative to the analyses of  
6 access included in the baseline report sub-  
7 mitted under paragraph (2);

8 “(ii) the number of grievances from  
9 beneficiaries and providers related to cost  
10 avoidance measures;

11 “(iii) the number and proportion of  
12 cost-avoided claims for pediatric preventive  
13 services and for services provided to child  
14 support enforcement beneficiaries paid by  
15 the State (including under managed care);  
16 and

17 “(iv) the overall cost-effectiveness of  
18 implementing such cost avoidance meas-  
19 ures for each group for which such meas-  
20 ures are employed.

21 “(4) REPORT TO CONGRESS.—Beginning with  
22 the date of enactment of this subsection, the Sec-  
23 retary shall submit a report to Congress, on not less  
24 than an annual basis, that lists any States that have  
25 implemented a cost avoidance exception under sub-

1 paragraph (E)(i) or (F)(i) of subsection (a)(25) (or  
 2 both) and any States that have failed to submit  
 3 timely reports required under paragraphs (1), (2),  
 4 and (3).

5 “(5) FAILURE TO REPORT.—Any State that  
 6 fails to submit a timely report required under this  
 7 subsection shall immediately cease to have the option  
 8 to employ a cost avoidance exception under subpara-  
 9 graph (E)(i) or (F)(i) of subsection (a)(25) (or both)  
 10 until all required reports are submitted to the Sec-  
 11 retary and meeting the requirements of this sub-  
 12 section, and made publicly available as required  
 13 under paragraph (6).

14 “(6) PUBLIC AVAILABILITY OF REPORTS.—The  
 15 Secretary shall make all notices and reports sub-  
 16 mitted under this subsection publicly available on  
 17 the website of the Centers for Medicare & Medicaid  
 18 Services on a timely basis.”.

19 **TITLE III—HEALTH AND HUMAN**  
 20 **SERVICES**

21 **SEC. 20301. EXTENSION OF SEXUAL RISK AVOIDANCE EDU-**  
 22 **CATION.**

23 (a) IN GENERAL.—Section 510 of the Social Security  
 24 Act (42 U.S.C. 710) is amended—

25 (1) in subsection (a)—

1 (A) in paragraph (1)—

2 (i) in the matter preceding subpara-  
3 graph (A)—

4 (I) by striking “for each of fiscal  
5 years 2018 and 2019 and for the pe-  
6 riod beginning October 1, 2019, and  
7 ending December 20, 2019” and in-  
8 serting “for each of fiscal years 2020  
9 through 2022”; and

10 (II) by striking “(or, with respect  
11 to such period, for fiscal year 2020”;  
12 and

13 (ii) in subparagraph (A), by striking  
14 “or period” after “fiscal year” each place  
15 it appears; and

16 (B) in paragraph (2)—

17 (i) in subparagraph (A)—

18 (I) by striking “for each of fiscal  
19 years 2018 and 2019 and for the pe-  
20 riod beginning October 1, 2019, and  
21 ending December 20, 2019” and in-  
22 serting “for each of fiscal years 2020  
23 through 2022”; and



1 (II) by striking “(or, with respect  
2 to such period, for fiscal year 2020)”;

3 and

4 (ii) in subparagraph (B)(i), by strik-  
5 ing “(or, with respect to such period, for  
6 fiscal year 2020)”;

7 (2) in subsection (f)—

8 (A) in paragraph (1), by striking  
9 “\$75,000,000 for each of fiscal years 2018 and  
10 2019 and \$16,643,836 for the period beginning  
11 October 1, 2019, and ending December 20,  
12 2019” and inserting “\$75,000,000 for each of  
13 fiscal years 2020 through 2022”; and

14 (B) in paragraph (2)—

15 (i) by striking “The Secretary shall  
16 reserve, for each of fiscal years 2018 and  
17 2019 and for the period described in para-  
18 graph (1),” and inserting “For each fiscal  
19 year for which amounts are appropriated  
20 under paragraph (1), the Secretary shall  
21 reserve”; and

22 (ii) by striking “of the amount appro-  
23 priated pursuant to paragraph (1)” and in-  
24 serting “of such amounts”.

1           (b) PREVENTION OF DUPLICATE APPROPRIATIONS  
2 FOR FISCAL YEAR 2020.—Expenditures made under sec-  
3 tion 510 of the Social Security Act (42 U.S.C. 710) pursu-  
4 ant to the amendments made by the Continuing Appro-  
5 priations Act, 2020, and Health Extenders Act of 2019  
6 (Public Law 116–59) and the Further Continuing Appro-  
7 priations Act, 2020, and Further Health Extenders Act  
8 of 2019 (Public Law 116-69) for fiscal year 2020 shall  
9 be charged to the applicable appropriation or authoriza-  
10 tion provided by the amendments made by subsection (a)  
11 to such section for such fiscal year.

12 **SEC. 20302. EXTENSION OF PERSONAL RESPONSIBILITY**  
13 **EDUCATION.**

14           (a) IN GENERAL.—Section 513 of the Social Security  
15 Act (42 U.S.C. 713) is amended—

16                   (1) in subsection (a)—

17                           (A) in paragraph (1)—

18                                   (i) in subparagraph (A)—

19   (I) in the matter preceding clause

20   (i), by striking “for each of fiscal

21   years 2010 through 2019 and for the

22   period beginning October 1, 2019,

23   and ending December 20, 2019” and

24   inserting “for each of fiscal years

25   2020 through 2022”; and

1 (II) in clause (i), by striking “or  
2 period”;

3 (ii) in subparagraph (B)(i), by strik-  
4 ing “The previous sentence shall not apply  
5 with respect to State allotments under this  
6 paragraph for the period beginning Octo-  
7 ber 1, 2019, and ending December 20,  
8 2019.”; and

9 (iii) in subparagraph (C)(i)—  
10 (I) by striking “or the period de-  
11 scribed in subparagraph (A)”;

12 (II) by striking “or period”;

13 (B) in paragraph (3)—

14 (i) by striking “or the period de-  
15 scribed in paragraph (1)(A)”;

16 (ii) by striking “or period”;

17 (C) in paragraph (4)—

18 (i) in subparagraph (A)—

19 (I) by striking “2019 and for the  
20 period described in paragraph (1)(A)”  
21 and inserting “2022”;

22 (II) by striking “2019 and for  
23 the period so described” and inserting  
24 “2022”; and

1 (III) by striking “or the period  
2 so described”;

3 (ii) in subsection (B)(i), by striking  
4 “the period described in paragraph (1)(A)”  
5 and inserting “fiscal year 2022”;

6 (2) in subsection (c)—

7 (A) in paragraph (1), by striking “Subject  
8 to paragraph (3), from the amount” and insert-  
9 ing “From the amount”;

10 (B) in paragraph (2), by striking “Subject  
11 to paragraph (3), from the amount” and insert-  
12 ing “From the amount”; and

13 (C) by striking paragraph (3); and

14 (3) in subsection (f), by striking “\$75,000,000  
15 for each of fiscal years 2010 through 2019 and  
16 \$16,643,836 for the period beginning October 1,  
17 2019, and ending December 20, 2019” and inserting  
18 “\$75,000,000 for each of fiscal years 2020 through  
19 2022”.

20 (b) PREVENTION OF DUPLICATE APPROPRIATIONS  
21 FOR FISCAL YEAR 2020.—Expenditures made under sec-  
22 tion 513 of the Social Security Act (42 U.S.C. 713) pursu-  
23 ant to the amendments made by the Continuing Appro-  
24 priations Act, 2020, and Health Extenders Act of 2019  
25 (Public Law 116–59) and the Further Continuing Appro-

1 priations Act, 2020, and Further Health Extenders Act  
2 of 2019 (Public Law 116-69) for fiscal year 2020 shall  
3 be charged to the applicable appropriation or authoriza-  
4 tion provided by the amendments made by subsection (a)  
5 to such section for such fiscal year.

6 **SEC. 20303. EXTENSION OF DEMONSTRATION PROJECTS TO**  
7 **ADDRESS HEALTH PROFESSIONS WORK-**  
8 **FORCE NEEDS.**

9 (a) IN GENERAL.—Section 2008(c)(1) of the Social  
10 Security Act (42 U.S.C. 1397g(c)(1)) is amended by strik-  
11 ing “2019” and inserting “2022”.

12 (b) PREVENTION OF DUPLICATE APPROPRIATIONS  
13 FOR FISCAL YEAR 2020.—Expenditures made under sec-  
14 tion 2008 of the Social Security Act (42 U.S.C. 1397g)  
15 pursuant to the amendments made by the Continuing Ap-  
16 propriations Act, 2020, and Health Extenders Act of 2019  
17 (Public Law 116–59) and the Further Continuing Appro-  
18 priations Act, 2020, and Further Health Extenders Act  
19 of 2019 (Public Law 116-69) for fiscal year 2020 shall  
20 be charged to the applicable appropriation or authoriza-  
21 tion provided by the amendment made by subsection (a)  
22 to such section for such fiscal year.

1 **SEC. 20304. EXTENSION OF THE MATERNAL, INFANT, AND**  
 2 **EARLY CHILDHOOD HOME VISITING PRO-**  
 3 **GRAM.**

4 Section 511(j)(1)(H) of the Social Security Act (42  
 5 U.S.C. 711(j)(1)(H)) is amended by striking “2022” and  
 6 inserting “2024”.

7 **TITLE IV—OTHER HEALTH AND**  
 8 **HUMAN SERVICES**

9 **SEC. 20401. EXTENSION OF APPROPRIATIONS TO THE PA-**  
 10 **TIENT-CENTERED OUTCOMES RESEARCH**  
 11 **TRUST FUND; EXTENSION OF CERTAIN**  
 12 **HEALTH INSURANCE FEES.**

13 (a) IN GENERAL.—Section 9511(b)(1) of the Internal  
 14 Revenue Code of 1986 is amended—

15 (1) in subsection (b)(1)—

16 (A) by inserting after subparagraph (E)  
 17 the following new subparagraph:

18 “(F) For each of fiscal years 2020 through  
 19 2029—

20 “(i) an amount equivalent to the net  
 21 revenues received in the Treasury from the  
 22 fees imposed under subchapter B of chap-  
 23 ter 34 (relating to fees on health insurance  
 24 and self-insured plans) for such fiscal year;  
 25 and

1                   “(ii) an amount equal to the excess, if  
2                   any, of—  
3                   “(I) an amount equal to—  
4                    “(aa) for fiscal year 2020,  
5                    \$655,500,000,  
6                    “(bb) for fiscal year 2021,  
7                    \$665,000,000,  
8                    “(cc) for fiscal year 2022,  
9                    \$693,500,000,  
10                  “(dd) for fiscal year 2023,  
11                  \$731,500,000,  
12                  “(ee) for fiscal year 2024,  
13                  \$760,000,000,  
14                  “(ff) for fiscal year 2025,  
15                  \$798,000,000,  
16                  “(gg) for fiscal year 2026,  
17                  \$845,500,000,  
18                  “(hh) for fiscal year 2027,  
19                  \$883,500,000,  
20                  “(ii) for fiscal year 2028,  
21                  \$931,000,000, and  
22                  “(jj) for fiscal year 2029,  
23                  \$969,000,000, over  
24                  “(II) the amount described in  
25                  clause (i) for such fiscal year.”; and

1 (B) by striking “and (E)(ii)” in the last  
2 sentence and inserting “(E)(ii), and (F)(ii)”;

3 (2) in subsection (d)(2)(A), by striking “2019”  
4 and inserting “2029”; and

5 (3) in subsection (f), by striking “December 20,  
6 2019” and inserting “September 30, 2029”.

7 (b) HEALTH INSURANCE POLICIES.—Section  
8 4375(e) of the Internal Revenue Code of 1986 is amended  
9 by striking “2019” and inserting “2029”.

10 (c) SELF-INSURED HEALTH PLANS.—Section  
11 4376(e) of the Internal Revenue Code of 1986 is amended  
12 by striking “2019” and inserting “2029”.

13 (d) IDENTIFICATION OF RESEARCH PRIORITIES.—  
14 Subsection (d)(1)(A) of section 1181 of the Social Secu-  
15 rity Act (42 U.S.C. 1320e) is amended by adding at the  
16 end the following: “Such national priorities shall include  
17 research with respect to intellectual and developmental  
18 disabilities. Such priorities should reflect a balance be-  
19 tween long-term priorities and short-term priorities, and  
20 be responsive to changing medical evidence and health  
21 care treatments.”.

22 (e) CONSIDERATION OF FULL RANGE OF OUTCOMES  
23 DATA.—Subsection (d)(2) of such section 1181 is amend-  
24 ed by adding at the end the following subparagraph:



1                   “(F) CONSIDERATION OF FULL RANGE OF  
2                   OUTCOMES DATA.—Research shall be designed,  
3                   as appropriate, to take into account and cap-  
4                   ture the full range of clinical and patient-cen-  
5                   tered outcomes relevant to, and that meet the  
6                   needs of, patients, clinicians, purchasers, and  
7                   policy-makers in making informed health deci-  
8                   sions. In addition to the relative health out-  
9                   comes and clinical effectiveness, clinical and pa-  
10                  tient-centered outcomes shall include the poten-  
11                  tial burdens and economic impacts of the utili-  
12                  zation of medical treatments, items, and serv-  
13                  ices on different stakeholders and decision-mak-  
14                  ers respectively. These potential burdens and  
15                  economic impacts include medical out-of-pocket  
16                  costs, including health plan benefit and for-  
17                  mulary design, non-medical costs to the patient  
18                  and family, including caregiving, effects on fu-  
19                  ture costs of care, workplace productivity and  
20                  absenteeism, and healthcare utilization.”.

21                  (f) BOARD COMPOSITION.—Subsection (f) of such  
22 section 1181 is amended—

23                         (1) in paragraph (1)—

24                                 (A) in subparagraph (C)—

1 (i) in the matter preceding clause

2 (i)—

3 (I) by striking “Seventeen” and  
4 inserting “At least nineteen, but no  
5 more than twenty-one”; and

6 (II) by striking “, not later than  
7 6 months after the date of enactment  
8 of this section,”; and

9 (ii) in clause (iii), by striking “3” and  
10 inserting “at least 3, but no more than 5”;  
11 and

12 (2) in paragraph (3)—

13 (A) in the first sentence—

14 (i) by striking the “the members” and  
15 inserting “members”; and

16 (ii) by inserting the following before  
17 the period at the end: “to the extent nec-  
18 essary to preserve the evenly staggered  
19 terms of the Board.”; and

20 (B) by inserting the following after the  
21 first sentence: “Any member appointed to fill a  
22 vacancy occurring before the expiration of the  
23 term for which the member’s predecessor was  
24 appointed shall be appointed for the remainder  
25 of that term and thereafter may be eligible for

1           reappointment to a full term. A member may  
2           serve after the expiration of that member’s  
3           term until a successor has been appointed.”.

4           (g) **METHODOLOGY COMMITTEE APPOINTMENTS.**—

5   Such section 1181 is amended—

6           (1) in subsection (d)(6)(B), by striking “Comp-  
7           troller General of the United States” and inserting  
8           “Board”; and

9           (2) in subsection (h)(4)—

10           (A) in subparagraph (A)(ii), by striking  
11           “Comptroller General” and inserting “Board”;  
12           and

13           (B) in the first sentence of subparagraph  
14           (B), by striking “and of the Government Ac-  
15           countability Office”.

16           (h) **REPORTS BY THE COMPTROLLER GENERAL OF**  
17 **THE UNITED STATES.**—Subsection (g)(2)(A) of such sec-  
18 tion 1181 is amended—

19           (1) by striking clause (iv) and inserting the fol-  
20           lowing:

21                   “(iv) Not less frequently than every 5  
22                   years, the overall effectiveness of activities  
23                   conducted under this section and the dis-  
24                   semination, training, and capacity building  
25                   activities conducted under section 937 of

1 the Public Health Service Act. Such review  
2 shall include the following:

3 “(I) A description of those activi-  
4 ties and the financial commitments re-  
5 lated to research, training, data ca-  
6 pacity building, and dissemination and  
7 uptake of research findings.

8 “(II) The extent to which the In-  
9 stitute and the Agency for Healthcare  
10 Research and Quality have collabo-  
11 rated with stakeholders, including pro-  
12 vider and payer organizations, to fa-  
13 cilitate the dissemination and uptake  
14 of research findings.

15 “(III) An analysis of available  
16 data and performance metrics, such  
17 as the estimated public availability  
18 and dissemination of research findings  
19 and uptake and utilization of research  
20 findings in clinical guidelines and de-  
21 cision support tools, on the extent to  
22 which such research findings are used  
23 by health care decision-makers, the ef-  
24 fect of the dissemination of such find-  
25 ings on changes in medical practice

1 and reducing practice variation and  
2 disparities in health care, and the ef-  
3 fect of the research conducted and  
4 disseminated on innovation and the  
5 health care economy of the United  
6 States.”; and

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

9 “(vi) Not less frequently than every 5  
10 years, any barriers that researchers funded  
11 by the Institute have encountered in con-  
12 ducting studies or clinical trials, including  
13 challenges covering the cost of any medical  
14 treatments, services, and items described  
15 in subsection (a)(2)(B) for purposes of the  
16 research study.”.

17 **SEC. 20402. EXTENSION OF THE TEMPORARY ASSISTANCE**  
18 **FOR NEEDY FAMILIES PROGRAM AND RE-**  
19 **LATED PROGRAMS.**

20 (a) TANF AND RELATED PROGRAMS.—

21 (1) FAMILY ASSISTANCE GRANTS.—Section  
22 403(a)(1) of the Social Security Act (42 U.S.C.  
23 603(a)(1)) is amended in each of subparagraphs (A)  
24 and (C) by striking “2017 and 2018” and inserting  
25 “2020 through 2022”.

1           (2) HEALTHY MARRIAGE PROMOTION AND RE-  
2           SPONSIBLE       FATHERHOOD       GRANTS.—Section  
3           403(a)(2)(D) of such Act (42 U.S.C. 603(a)(2)(D))  
4           is amended—

5                   (A) by striking “2017 and 2018” and in-  
6                   serting “2020 through 2022”; and

7                   (B) by striking “for fiscal year 2017 or  
8                   2018”.

9           (3) CONTINGENCY FUND.—Section 403(b)(2) of  
10          such Act (42 U.S.C. 603(b)(2)) is amended by strik-  
11          ing “for fiscal year 2018” and inserting “for each  
12          of fiscal years 2020 through 2022”.

13          (4) TRIBAL FAMILY ASSISTANCE GRANTS.—  
14          Paragraphs (1)(A) and (2)(A) of section 412(a) of  
15          such Act (42 U.S.C. 612(a)) are each amended by  
16          striking “2017 and 2018” and inserting “2020  
17          through 2022”.

18          (5) CHILD CARE.—Section 418(a)(3) of such  
19          Act (42 U.S.C. 618(a)(3)) is amended by striking  
20          “2017 and 2018” and inserting “2020 through  
21          2022”.

22          (6) GRANTS TO THE TERRITORIES.—Section  
23          1108(b)(2) of such Act (42 U.S.C. 1308(b)(2)) is  
24          amended by striking “2017 and 2018” and inserting  
25          “2020 through 2022”.

1           (7) PREVENTION OF DUPLICATE APPROPRIA-  
2           TIONS FOR FISCAL YEAR 2020.—Expenditures made  
3           under part A of title IV of the Social Security  
4           Act(42 U.S.C. 601 et seq.) and section 1108(b) of  
5           such Act (42 U.S.C. 1308(b)) pursuant to the  
6           amendments made by the Continuing Appropriations  
7           Act, 2020, and Health Extenders Act of 2019 (Pub-  
8           lic Law 116–59) and the Further Continuing Approp-  
9           riations Act, 2020, and Further Health Extenders  
10          Act of 2019 (Public Law 116-69) for fiscal year  
11          2020 shall be charged to the applicable appropria-  
12          tion or authorization provided by the amendments  
13          made by this subsection to such part and such sec-  
14          tion 1108(b) for such fiscal year.

15          (b) MEASURING AND UNDERSTANDING OUT-  
16          COMES.—Section 411(a) of the Social Security Act (42  
17          U.S.C. 611(a)) is amended by redesignating paragraph (7)  
18          as paragraph (8) and inserting after paragraph (6) the  
19          following:

20                 “(7) REPORT ON ENGAGEMENT, EMPLOYMENT  
21                 AND OUTCOMES.—

22                         “(A) IN GENERAL.—The Secretary shall  
23                         publish on the website of the Department of  
24                         Health and Human Services the information  
25                         described in this paragraph beginning in fiscal

1 year 2021, and shall enter into an agreement  
2 with each State specifying the manner by which  
3 the information and data described in this para-  
4 graph shall be collected and reported to the  
5 Secretary (if such information is not already  
6 provided to the Secretary).

7 “(i) OUTCOMES FOR EXITING RECIPI-  
8 ENTS.—Information and data regarding  
9 individuals in families who formerly re-  
10 ceived assistance (disaggregated by type of  
11 family, reason for exit, and participation in  
12 work activities during the preceding fiscal  
13 year) under the State program funded  
14 under this part or under any State pro-  
15 gram funded with qualified State expendi-  
16 tures (as defined in section  
17 409(a)(7)(B)(i)), with respect to the fol-  
18 lowing:

19 “(I) The percentage with at least  
20 1 formerly work-eligible individual em-  
21 ployed during the 2nd quarter after  
22 exiting from the program.

23 “(II) The percentage with at  
24 least 1 formerly work-eligible indi-



1           vidual employed during the 4th quar-  
2           ter after exiting from the program.

3                   “(III) The median earnings when  
4           at least 1 formerly work-eligible indi-  
5           vidual is employed during the 2d  
6           quarter after exiting from the pro-  
7           gram.

8                   “(IV) The percentage with at  
9           least 1 formerly work-eligible indi-  
10          vidual employed during any of the  
11          first 4 quarters after exiting from the  
12          program.

13                   “(V) The distribution of income  
14          and earnings, including relative to  
15          poverty and deep poverty, for each of  
16          the first 4 quarters ending after the  
17          quarter of exit from assistance.

18                   “(VI) The percentage who, at the  
19          time of exit from the program, were  
20          subject to the following:

21                           “(aa) A penalty under sec-  
22                           tion 407(e).

23                           “(bb) A sanction or penalty  
24                           described in section 404 or 408.

1                   “(cc) A penalty or sanction  
2                   not described in item (aa) or  
3                   (bb).

4                   “(ii) ENGAGEMENT AND OUTCOMES  
5                   OF RECIPIENTS.—

6                   “(I) ESTABLISHMENT OF ENTRY  
7                   COHORT; REPORTS.—Each eligible  
8                   State shall annually establish an entry  
9                   cohort of work-eligible individuals who  
10                  enter the State program funded under  
11                  this part or under any State program  
12                  funded with qualified State expendi-  
13                  tures (as defined in section  
14                  409(a)(7)(B)(i)), and shall collect and  
15                  report the following information rel-  
16                  ative to the current quarter being re-  
17                  ported:

18                   “(aa) Earnings in each of  
19                   the 4 quarters immediately pre-  
20                   ceding the assignment into the  
21                   entry cohort quarter.

22                   “(bb) Standard measures of  
23                   employment, earnings, receipt of  
24                   assistance, and participation in  
25                   work activities (as defined in sec-

1                   tion 407(d)) in each of the first  
2                   8 quarters following the assign-  
3                   ment into the entry cohort quar-  
4                   ter.

5                   “(II) ALL RECIPIENTS.—The  
6                   percentage of recipients of assistance  
7                   under the State program funded  
8                   under this part or under any State  
9                   program funded with qualified State  
10                  expenditures (as defined in section  
11                  409(a)(7)(B)(i)) who have not at-  
12                  tained 24 years of age and who obtain  
13                  a high school degree or its recognized  
14                  equivalent while receiving the assist-  
15                  ance.

16                  “(B) STATISTICAL ADJUSTMENT MODEL  
17                  FOR EMPLOYMENT OUTCOMES.—The Secretary,  
18                  in consultation with the Secretary of Labor and  
19                  relevant experts, shall develop recommendations  
20                  by October 1, 2020, on how to establish and  
21                  disseminate an objective statistical model that  
22                  will allow the Secretary to make adjustments to  
23                  the data reported pursuant to subclauses (I)  
24                  through (IV) of subparagraph (A)(i) of this  
25                  paragraph, based on economic conditions and

1 the characteristics of participants. To the ex-  
2 tent practicable, the recommendations shall be  
3 compatible with the statistical adjustment  
4 model developed under section  
5 116(b)(3)(A)(viii) of the Workforce Innovation  
6 and Opportunity Act (29 U.S.C.  
7 3141(b)(3)(A)(viii)) and, with respect to a  
8 State, the State adjusted levels of performance  
9 established for the State under that section.”.

10 (c) UNIFORM WORK REQUIREMENT FOR FAMI-  
11 LIES.—

12 (1) ELIMINATION OF SEPARATE PARTICIPATION  
13 RATE REQUIREMENTS FOR 2-PARENT FAMILIES.—  
14 Section 407 of the Social Security Act (42 U.S.C.  
15 607) is amended—

16 (A) in subsection (a)—

17 (i) by striking all through “A State”  
18 the 1st place it appears and inserting the  
19 following:

20 “(a) PARTICIPATION RATE REQUIREMENTS.—A  
21 State”; and

22 (B) by striking paragraph (2);

23 (C) in subsection (b)—

24 (i) in the subsection heading, by strik-  
25 ing “RATES” and inserting “RATE”;

1 (ii) in paragraph (1)(A), by striking  
2 “(a)(1)” and inserting “(a)”;

3 (iii) by striking paragraph (2);

4 (iv) by redesignating paragraphs (3)  
5 through (5) as paragraphs (2) through (4),  
6 respectively;

7 (v) in paragraph (3) (as redesignated  
8 by subparagraph (D)), by striking “para-  
9 graphs (1)(B) and (2)(B)” and inserting  
10 “paragraph (1)(B)”; and

11 (vi) in paragraph (4), (as so redesi-  
12 gnated), by striking “rates” and inserting  
13 “rate”; and

14 (D) in subsection (c)—

15 (i) in paragraph (1), by striking all  
16 through “For purposes” the 1st place it  
17 appears and inserting the following:

18 “(1) GENERAL RULES.—For purposes”; and

19 (ii) in paragraph (2)(D)—

20 (I) by striking “paragraphs  
21 (1)(B)(i) and (2)(B) of subsection  
22 (b)” and inserting “subsection  
23 (b)(1)(B)(i)”; and

1 (II) by striking “in all families  
2 and in 2-parent families, respec-  
3 tively,”.

4 (2) CONFORMING AMENDMENT.—The para-  
5 graph heading for section 409(a)(3) of such Act (42  
6 U.S.C. 609(a)(3)) is amended by striking “RATES”  
7 and inserting “RATE”.

8 (d) MEASURING TANF SPENDING ON LOW-INCOME  
9 FAMILIES.—Section 411 of the Social Security Act (42  
10 U.S.C. 611) is amended by adding at the end the fol-  
11 lowing:

12 “(e) REQUIREMENT TO REPORT SPENDING ON LOW-  
13 INCOME FAMILIES.—

14 “(1) STATE REPORTING.—With respect to fiscal  
15 year 2020, not later than July 1, 2021, and, with  
16 respect to each fiscal year beginning after that date,  
17 not later than such date as the Secretary shall re-  
18 quire, each eligible State shall submit to the Sec-  
19 retary an estimate with respect to the fiscal year of  
20 the amount and percent of State spending of the  
21 grant made under section 403(a)(1) and any quali-  
22 fied State expenditures (as so defined) that consists  
23 of benefits and services—

24 “(A) for families in the State whose in-  
25 come is below the income official poverty line

1 (as defined by the Office of Management and  
2 Budget, and revised annually in accordance  
3 with section 673(2) of the Omnibus Budget  
4 Reconciliation Act of 1981) applicable to a fam-  
5 ily of the size involved; and

6 “(B) for families in the State whose in-  
7 come is below twice the income official poverty  
8 line (as so defined) applicable to a family of the  
9 size involved.

10 “(2) REPORT BY THE SECRETARY.—For any  
11 State that reports State spending on families with  
12 income above the level specified in paragraph (1)(B),  
13 the Secretary shall request information from the  
14 State on the types of benefits and services provided  
15 to such families and report this information on the  
16 Internet website of the Department of Health and  
17 Human Services.”.

18 (e) INCLUSION OF POVERTY REDUCTION AS A PRO-  
19 GRAM PURPOSE.—Section 401(a) of the Social Security  
20 Act (42 U.S.C. 601(a)) is amended in the matter pre-  
21 ceding paragraph (1), by striking “in operating” and in-  
22 serting “to reduce child poverty by operating”.

23 (f) TECHNICAL CORRECTIONS.—

1           (1) DATA EXCHANGE STANDARDS.—Section  
2           411(d) of the Social Security Act 42 U.S.C. 611(d))  
3           is amended to read as follows:

4           “(d) DATA EXCHANGE STANDARDIZATION FOR IM-  
5           PROVED INTEROPERABILITY.—The Secretary shall des-  
6           ignate data exchange standards to govern programs fund-  
7           ed under this part using the same process, and subject  
8           to the same requirements, to designate such standards as  
9           the process and requirements that apply to the designation  
10          of data exchange standards for parts B and E under sec-  
11          tion 440.”.

12           (2) APPLICATION OF CERTAIN PROVISIONS TO  
13          TRIBAL FAMILY ASSISTANCE PLANS.—Section  
14          412(h) of such Act (42 U.S.C. 612(h)) is amended  
15          to read as follows:

16          “(h) APPLICATION OF OTHER PROVISIONS OF THIS  
17          PART.—The following sections of this part shall apply to  
18          an Indian tribe with an approved tribal family assistance  
19          plan:

20                 “(1) Section 411 (relating to data collection  
21                 and reporting).

22                 “(2) Section 413 (relating to evaluations and  
23                 technical assistance).”.



1 **SEC. 20403. ADDRESSING EXPIRATION OF CHILD WELFARE**  
2 **DEMONSTRATION PROJECTS AND SUP-**  
3 **PORTING FAMILY FIRST IMPLEMENTATION.**

4 (a) **SHORT TITLE.**—This section may be cited as the  
5 “Family First Transition Act”.

6 (b) **EVIDENCE STANDARD TRANSITION.**—

7 (1) **TEMPORARY SUSPENSION OF REQUIREMENT**  
8 **THAT AT LEAST 50 PERCENT OF A STATE’S REIM-**  
9 **BURSEMENT FOR PREVENTION AND FAMILY SERV-**  
10 **ICES AND PROGRAMS BE FOR PROGRAMS AND SERV-**  
11 **ICES THAT MEET THE WELL-SUPPORTED PRACTICE**  
12 **REQUIREMENT.**—With respect to quarters in fiscal  
13 years 2020 and 2021, section 474(a)(6)(A) of the  
14 Social Security Act (42 U.S.C. 674(a)(6)(A)) shall  
15 be applied without regard to clause (ii) of such sec-  
16 tion.

17 (2) **SUPPORTED PRACTICES TEMPORARILY**  
18 **TREATED AS WELL-SUPPORTED PRACTICES.**—With  
19 respect to quarters in fiscal years 2022 and 2023,  
20 practices that meet the criteria specified for sup-  
21 ported practices in section 471(e)(4)(C) of the Social  
22 Security Act (42 U.S.C. 671(e)(4)(C)) shall be con-  
23 sidered well-supported practices for purposes of sec-  
24 tion 474(a)(6)(A)(ii) of such Act (42 U.S.C.  
25 674(a)(6)(A)(ii)).

1           (c) ENHANCED FUNDING FOR TRANSITION ACTIVI-  
2 TIES.—

3           (1) TRANSITION FUNDING.—

4                   (A) APPROPRIATION.—Out of any money  
5 in the Treasury of the United States not other-  
6 wise appropriated, there are appropriated to the  
7 Secretary of Health and Human Services (in  
8 this section referred to as the “Secretary”) to  
9 carry out this subsection \$500,000,000 for fis-  
10 cal year 2020, which shall remain available  
11 through fiscal year 2021.

12           (B) DISTRIBUTION OF FUNDS.—

13                   (i) IN GENERAL.—The Secretary shall  
14 allot the amount appropriated by subpara-  
15 graph (A) of this paragraph in accordance  
16 with section 423 of the Social Security Act  
17 (42 U.S.C. 623), and shall pay each State  
18 to which an allotment is so made, the total  
19 amount so allotted, subject to clause (ii) of  
20 this subparagraph.

21                   (ii) RESERVATION OF FUNDS FOR IN-  
22 DIAN TRIBES AND TRIBAL ORGANIZA-  
23 TIONS.—Before applying clause (i) of this  
24 subparagraph, the Secretary shall reserve  
25 3 percent of the amount appropriated by

1           subparagraph (A) of this paragraph for al-  
2           lotment to the Indian tribes and tribal or-  
3           ganizations with a plan approved under  
4           subpart 1 of part B of title IV of the So-  
5           cial Security Act, based on each tribe or  
6           tribal organization's share of the total trib-  
7           al child population among all such tribes  
8           and tribal organizations.

9           (2) FUNDING CERTAINTY FOR STATES WITH  
10          EXPIRING DEMONSTRATION PROJECTS.—

11           (A) IN GENERAL.—Out of any money in  
12          the Treasury of the United States not otherwise  
13          appropriated, there are appropriated to the Sec-  
14          retary, for payment to each State that was op-  
15          erating a demonstration project approved under  
16          section 1130 of the Social Security Act on Sep-  
17          tember 30, 2019, for each fiscal year specified  
18          in subparagraph (B) of this paragraph, an  
19          amount equal to the amount (if any) by  
20          which—

21           (i)(I) the applicable percentage for the  
22          fiscal year so specified of the maximum  
23          capped allocation due to the State or sub-  
24          State jurisdiction for fiscal year 2019 for  
25          foster care maintenance, administration, or

1 training costs, under the demonstration  
2 project, as specified in section 4.3 of the  
3 State waiver terms and conditions docu-  
4 ment capped allocation payment table in  
5 effect on August 31, 2019; or

6 (II) if the terms and conditions do not  
7 specify a maximum amount payable for fis-  
8 cal year 2019 for the State or sub-State  
9 jurisdiction (due to the use of a compari-  
10 son jurisdiction to ensure cost neutrality),  
11 the final cost neutrality limit for the State  
12 or sub-State jurisdiction for fiscal year  
13 2018, as most recently reported by the  
14 State or sub-State jurisdiction as of Sep-  
15 tember 30, 2019, for foster care mainte-  
16 nance, administration, or training costs  
17 under the demonstration project that were  
18 included in the waiver; exceeds

19 (ii) the total amount payable to the  
20 State or sub-State jurisdiction under part  
21 E of title IV of such Act for the fiscal year  
22 so specified for foster care expenditures  
23 (whether payable under paragraph (1) or  
24 (3) of section 474(a) of such Act) that  
25 were maintenance, administration, or

1 training costs of the demonstration project  
2 taken into account by the Secretary in de-  
3 termining the total amount referred to in  
4 clause (i) of this subparagraph.

5 (B) APPLICABLE PERCENTAGE DE-  
6 FINED.—In this subparagraph, the term “appli-  
7 cable percentage” means—

8 (i) 90 percent, in the case of fiscal  
9 year 2020; or

10 (ii) 75 percent, in the case of fiscal  
11 year 2021.

12 (C) SPECIAL RULE.—The calculation  
13 under subparagraph (A) with respect to a State  
14 shall be made without regard to—

15 (i) any change approved after August  
16 31, 2019, in the capped allocation or the  
17 terms and conditions referred to in clause  
18 (i) of subparagraph (A) with respect to the  
19 State; or

20 (ii) any change made after such date  
21 to the financial form submitted by the  
22 State that is used in determining the  
23 capped allocation.

24 (D) DISTRIBUTION OF FUNDS.—Each  
25 State that receives funds under this paragraph

1 shall distribute the funds to jurisdictions in the  
2 State that were operating demonstration  
3 projects under section 1130 of the Social Secu-  
4 rity Act in a manner consistent with each sub-  
5 State jurisdiction's proportionate loss as com-  
6 pared with fiscal year 2019.

7 (E) RECONCILIATION PROCESS.—Each  
8 State seeking a payment under this paragraph  
9 shall report expenditures pursuant to part E of  
10 title IV of the Social Security Act (42 U.S.C.  
11 670 et seq.) in a manner determined by the  
12 Secretary and the Secretary shall account for  
13 any revisions to spending for fiscal years 2020  
14 and 2021 after the end of the respective fiscal  
15 year that are reported by the State agency ad-  
16 ministering the State plan approved under such  
17 part, and received by the Department of Health  
18 and Human Services, within 2 years after the  
19 last day of the fiscal quarter in which the ex-  
20 penditure was made.

21 (F) AVAILABILITY OF FUNDS.—The  
22 amounts made available for payments to States  
23 under this paragraph for a fiscal year shall re-  
24 main available through the end of the third suc-  
25 ceeding fiscal year.

1 (3) USE OF FUNDS.—

2 (A) IN GENERAL.—In addition to the pur-  
3 poses specified in part B of title IV of the So-  
4 cial Security Act (42 U.S.C. 671 et seq.), a  
5 State may use funds provided under this sub-  
6 section for activities previously funded under a  
7 demonstration project under section 1130 of  
8 such Act (42 U.S.C. 1320a–9) to reduce any  
9 adverse fiscal impacts as jurisdictions transition  
10 funding sources for the projects, and for activi-  
11 ties directly associated with the implementation  
12 of title VII of division E of Public Law 115–  
13 123 (also known as the Family First Preven-  
14 tion Services Act).

15 (B) LIMITATION.—None of the funds pro-  
16 vided under this subsection may be used to  
17 match Federal funds under any program.

18 (d) REPORTING ON ENHANCED FUNDING FOR TRAN-  
19 SITION ACTIVITIES.—

20 (1) IN GENERAL.—Each State to which funds  
21 are paid under subsection (c) of this section shall  
22 submit to the Secretary, in a manner specified by  
23 the Secretary, a written report on—

24 (A) how the grant is used to implement  
25 each part of title VII of division E of Public

1 Law 115–123 (also known as the Family First  
2 Prevention Services Act), with a separate state-  
3 ment with respect to each such part;

4 (B) all programs, services, and operational  
5 costs to which the grant is put;

6 (C) the characteristics of the families and  
7 children served by use of the grant; and

8 (D)(i) the use by the State of amounts  
9 provided for each fiscal year to continue activi-  
10 ties previously funded under a waiver provided  
11 under section 1130 of the Social Security Act  
12 (42 U.S.C. 1320a–9); and

13 (ii)(I) the plan of the State to transition  
14 the activities so that needed activities can be  
15 provided under the State plan approved under  
16 part E of title IV of the Social Security Act (42  
17 U.S.C. 670 et seq.); or

18 (II) if expenditures for the activities would  
19 not be eligible for payment under the State plan  
20 approved under such part E—

21 (aa) the reason therefor; and

22 (bb) the funding sources the State  
23 plans to use to cover the costs of needed  
24 activities.



1           (2) APPLICABILITY OF OTHER LAWS.—For pur-  
2           poses of subpart 2 of part B of title IV of the Social  
3           Security Act (42 U.S.C. 629 et seq.), each report re-  
4           quired by paragraph (1) of this subsection shall be  
5           considered to be required by section 432(a)(8) of  
6           such Act (42 U.S.C. 629b(a)(8)), and shall contain  
7           such additional information as the Secretary may re-  
8           quire.

9           (e) DEFINITION OF STATE.—In this section, the term  
10          “State” has the meaning given the term in section  
11          431(a)(4) of the Social Security Act (42 U.S.C.  
12          629a(a)(4)).

13          (f) RENAMING OF TITLE IV–B–2 OF THE SOCIAL SE-  
14          curity Act.—The subpart heading for subpart 2 of part  
15          B of title IV of the Social Security Act is amended by  
16          striking “**Promoting Safe and Stable Families**”  
17          and inserting “**MaryLee Allen Promoting Safe**  
18          **and Stable Families Program**”.

19          (g) EFFECTIVE DATE.—This section and the amend-  
20          ments made by this section shall take effect as if included  
21          in the Bipartisan Budget Act of 2018 on the date of the  
22          enactment of such Act.

23          (h) TECHNICAL CORRECTION.—Section 50701 of the  
24          Bipartisan Budget Act of 2018 (42 U.S.C. 1305 note;  
25          Public Law 115–123) is amended by striking “Bipartisan

1 Budget Act of 2018” and inserting “Family First Preven-  
2 tion Services Act”.