

116TH CONGRESS
1ST SESSION

H. R. 448

To amend title XVIII of the Social Security Act to provide for the negotiation of lower covered part D drug prices on behalf of Medicare beneficiaries and the establishment and application of a formulary by the Secretary of Health and Human Services under Medicare part D, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 10, 2019

Mr. CUMMINGS (for himself, Mr. WELCH, Mr. DOGGETT, Mr. SEAN PATRICK MALONEY of New York, Mr. POCAN, Ms. DELAURO, Ms. GABBARD, Ms. BONAMICI, Ms. OMAR, Mr. KHANNA, Ms. NORTON, Ms. JAYAPAL, Ms. SCHAKOWSKY, Mr. HIGGINS of New York, Mr. NEGUSE, Mr. COHEN, Mr. KRISHNAMOORTHY, and Ms. TLAIB) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to provide for the negotiation of lower covered part D drug prices on behalf of Medicare beneficiaries and the establishment and application of a formulary by the Secretary of Health and Human Services under Medicare part D, 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 “Medicare Drug Price
3 Negotiation Act”.

4 **SEC. 2. NEGOTIATION OF LOWER COVERED PART D DRUG
5 PRICES ON BEHALF OF MEDICARE BENE-
6 FICIARIES; ESTABLISHMENT AND APPLICA-
7 TION OF FORMULARY BY THE SECRETARY OF
8 HEALTH AND HUMAN SERVICES UNDER
9 MEDICARE PART D.**

10 (a) IN GENERAL.—Section 1860D–11 of the Social
11 Security Act (42 U.S.C. 1395w–111) is amended by strik-
12 ing subsection (i) (relating to noninterference) and insert-
13 ing the following:

14 “(i) NEGOTIATION OF LOWER DRUG PRICES; ESTAB-
15 LISHMENT AND APPLICATION OF FORMULARY.—

16 “(1) NEGOTIATION.—

17 “(A) IN GENERAL.—Notwithstanding any
18 other provision of law, subject to subparagraph
19 (B), the Secretary shall, with respect to an ap-
20 plicable period (as defined in subparagraph
21 (H))—

22 “(i) during the negotiation year (as
23 defined in such subparagraph) for such pe-
24 riod, negotiate with pharmaceutical manu-
25 facturers the prices (including discounts,
26 rebates, and all other price concessions)

1 that may be charged to PDP sponsors and
2 MA organizations for applicable covered
3 part D drugs (as defined in such subpara-
4 graph) furnished to enrollees during such
5 period; and

6 “(ii) complete such negotiations not
7 less than 30 days before the first day of
8 the application review process for the first
9 plan year during the applicable period for
10 new contracts or expanding existing con-
11 tracts with PDP sponsors and MA organi-
12 zations to offer prescription drug plans or
13 MA–PD plans, respectively.

14 “(B) USE OF FALLBACK IF NEGOTIATIONS
15 FAIL.—

16 “(i) IN GENERAL.—If, after negotia-
17 tions under subparagraph (A) with respect
18 to an applicable period, the Secretary is
19 not successful in obtaining an appropriate
20 price for applicable covered part D drugs
21 in accordance with clause (ii), the price
22 that may be charged to PDP sponsors and
23 MA organizations for applicable covered
24 part D drugs furnished to enrollees during

1 such period shall be the lowest of the fol-
2 lowing:

3 “(I) The contract price applied
4 pursuant to section 8126 of title 38,
5 United States Code, for such drug for
6 the contract year (as defined in such
7 section 8126).

8 “(II) The average of the prices
9 available, during the most recent 12-
10 month period for which data is avail-
11 able from the manufacturer to any
12 wholesaler, retailer, provider, health
13 maintenance organization, nonprofit
14 entity, or governmental entity in Can-
15 ada, the United Kingdom, Germany,
16 France, and Japan.

17 “(III) The best price determined
18 under section 1927(c)(1)(C) for such
19 drug for the most recent rebate period
20 (as defined in section 1927(k)(8)) ap-
21 plicable to such first plan year of the
22 applicable period.

23 “(ii) GUIDANCE.—Not later than 6
24 months before the Secretary begins nego-
25 tiations under subparagraph (A) with re-

1 spect to the first applicable period, the
2 Secretary shall issue guidance on criteria
3 to be considered for purposes of deter-
4 mining under clause (i) whether or not the
5 Secretary is successful in obtaining an ap-
6 propriate price for an applicable covered
7 part D drug. Such criteria shall include at
8 least the following:

9 “(I) The comparative clinical ef-
10 fectiveness and cost effectiveness, if
11 available, of such covered part D
12 drug.

13 “(II) The budgetary impact of
14 providing coverage under this part for
15 such covered part D drug.

16 “(III) The number of similarly
17 effective drug or alternative treatment
18 regimens for each approved use of
19 such covered part D drug.

20 “(IV) Associated unmet need or
21 severity of illness.

22 “(C) IDENTIFICATION OF APPLICABLE
23 COVERED PART D DRUGS.—

24 “(i) IN GENERAL.—The Secretary
25 shall, for each applicable period, in accord-

1 ance with the subsequent clauses of this
2 subparagraph, and pursuant to rule-
3 making, identify applicable covered part D
4 drugs for which negotiations under sub-
5 paragraph (A) shall be conducted during
6 the negotiation year for such period. In
7 this paragraph, all such covered part D
8 drugs so identified for an applicable period
9 are collectively referred to as applicable
10 covered part D drugs with respect to such
11 period.

12 “(ii) IDENTIFICATION OF PRIORITIZED
13 DRUGS.—In carrying out clause (i), except
14 as provided under clause (iii), the Sec-
15 retary may not identify a covered part D
16 drug that is not a drug prioritized pursu-
17 ant to subparagraph (D) as an applicable
18 covered part D drug until all covered part
19 D drugs that are so prioritized have been
20 identified as an applicable covered part D
21 drug for the applicable period or for a pre-
22 vious applicable period for which the nego-
23 tiated price of such drug has not expired.

24 “(iii) DRUG INCLUSIONS FOR PRICE
25 RENEGOTIATIONS.—In the case of a cov-

1 ered part D drug that is identified as an
2 applicable covered part D drug for an ap-
3 plicable period, such covered part D drug
4 shall be identified as an applicable covered
5 part D drug for each subsequent third ne-
6 gotiation year.

7 “(iv) REASONABLE NOTIFICATION.—
8 The Secretary shall carry out this subpara-
9 graph in such manner as to provide for
10 public notification of applicable covered
11 part D drugs for the applicable period
12 within a reasonable period before the be-
13 ginning of the negotiation year for such
14 period.

15 “(D) PRIORITIZATION OF CERTAIN COV-
16 ERED PART D DRUGS.—For purposes of sub-
17 paragraph (C)(ii), the Secretary shall prioritize
18 covered part D drugs—

19 “(i) that are among—

20 “(I) the 40 covered part D drugs
21 that are utilized by at least 1,000
22 Medicare part D beneficiaries and
23 with respect to which there were the
24 highest total expenditures under this

1 part during the most recent 12-month
2 period for which data is available;

3 “(II) the 40 covered part D
4 drugs that are utilized by at least
5 1,000 Medicare part D beneficiaries
6 with respect to whom the total annual
7 spending per such a beneficiary under
8 this part for coverage of such a drug
9 is at least \$10,000; or

10 “(III) the 20 covered part D
11 drugs that are utilized by at least
12 1,000 Medicare part D beneficiaries
13 and with respect to which there are
14 unit cost increases at or above the
15 95th percentile of overall covered part
16 D drug unit cost increases during the
17 most recent 12-month period prior to
18 the beginning of such negotiation year
19 for which data is available;

20 “(ii) with respect to which the cost of
21 such a drug to the part D eligible indi-
22 vidual involved would exceed the annual
23 out-of-pocket threshold applicable under
24 section 1860D–2(b)(4)(B) for such nego-
25 tiation year, if the drug were prescribed to

1 the individual for the period of the year or
2 with respect to which a single treatment
3 regimen is priced above such annual out-
4 of-pocket threshold applicable under such
5 section 1860D–2(b)(4)(B) for the year; or

6 “(iii) that are single-source drugs or
7 biologicals (as defined in section
8 1847A(c)(6)(D)) and that satisfy at least
9 one other criterion described in a previous
10 clause of this subparagraph.

11 “(E) ANNUAL REPORT TO CONGRESS.—

12 Not later than 30 days after the date on which
13 the Secretary completes negotiations under this
14 paragraph for the first negotiation year and
15 each year thereafter, the Secretary shall submit
16 to Congress and make available to the public a
17 report describing the negotiations during the
18 preceding negotiation year, including—

19 “(i) the number of applicable covered
20 part D drug prices negotiated;

21 “(ii) the magnitude of savings
22 achieved as a result of such negotiations;

23 “(iii) the number of times price nego-
24 tiations failed (based on the criteria in-
25 cluded in the guidance issued pursuant to

1 clause (ii) of subparagraph (B)) and re-
2 sulted in the use of fallback prices under
3 clause (i) of such subparagraph, and the
4 rationale for any such decisions;

5 “(iv) the progress made toward nego-
6 tiating the prices of covered part D drugs
7 that are prioritized under subparagraph
8 (D); and

9 “(v) the barriers, if any, to achieving
10 savings through negotiations.

11 “(F) GAO REPORT.—Not later than De-
12 cember 31, 2024, the Comptroller General of
13 the United States shall submit to Congress a
14 report on the negotiations conducted by the
15 Secretary under this paragraph, including a de-
16 scription and analysis of—

17 “(i) the extent to which such price ne-
18 gotiations are achieving lower prices for
19 covered part D drugs for enrollees;

20 “(ii) the parties benefitting from such
21 lower prices, such as enrollees, the Federal
22 government, States, prescription drug
23 plans and MA–PD plans, or other entities;

24 “(iii) how such price negotiations are
25 affecting—

1 “(I) the list price of covered part
2 D drugs; and

3 “(II) drug prices in the private
4 market; and

5 “(iv) recommendations for improving
6 price negotiations, if applicable.

7 “(G) DEFINITIONS.—For purposes of this
8 paragraph:

9 “(i) APPLICABLE COVERED PART D
10 DRUGS.—The term ‘applicable covered part
11 D drugs’ means, for an applicable period,
12 covered part D drugs identified by the Sec-
13 retary under subparagraph (C) for such
14 period.

15 “(ii) APPLICABLE PERIOD.—The term
16 ‘applicable period’ means, with respect to a
17 negotiation year and applicable covered
18 part D drugs, the 3-plan year period be-
19 ginning with the first plan year beginning
20 after the negotiation year for such covered
21 part D drugs.

22 “(iii) NEGOTIATION YEAR.—The term
23 ‘negotiation year’ means, with respect to
24 an applicable period, a plan year, begin-

1 ning with 2020, prior to the first plan year
2 of the applicable period.

3 “(2) ESTABLISHMENT AND APPLICATION OF
4 FORMULARY BY THE SECRETARY OR CHANGES IN
5 FORMULARIES TO BE REQUIRED BY SECRETARY.—

6 “(A) IN GENERAL.—The Secretary shall,
7 for plan years beginning with plan year 2020—

8 “(i) subject to subparagraphs (B) and
9 (C), establish and apply a formulary for
10 required use by sponsors of prescription
11 drug plans and organizations offering MA-
12 PD plans under this part; or

13 “(ii) require changes, as necessary, in
14 the covered part D drugs included on
15 formularies of PDP sponsors of prescrip-
16 tion drug plans (including changes, as nec-
17 essary, in the preferred or tiered cost-shar-
18 ing status of such a drug) to take into ac-
19 count negotiations carried out by the Sec-
20 retary pursuant to paragraph (1), regard-
21 less of whether such a covered part D drug
22 is the subject of such negotiations.

23 “(B) REQUIRED INCLUSION OF DRUGS IN
24 ALL THERAPEUTIC CATEGORIES.—A formulary
25 established and applied under subparagraph

1 (A)(i) shall include at least two covered part D
2 drugs in each category and class of covered part
3 D drugs as described in section
4 423.120(b)(2)(i) of title 42, Code of Federal
5 Regulations (as in effect on January 1, 2017).

6 “(C) APPLICATION OF DEVELOPMENT AND
7 REVISION REQUIREMENTS AND REQUIRED IN-
8 CLUSION OF ALL DRUGS IN CERTAIN CAT-
9 EGORIES AND CLASSES.—The requirements de-
10 scribed in subparagraphs (A) and (B) of section
11 1860D–4(b)(3) (relating to development and re-
12 vision requirements of the formulary) and sub-
13 paragraph (G) of such section (relating to re-
14 quired inclusion of all drugs in certain cat-
15 egories and classes) shall apply to a formulary
16 established and applied under subparagraph
17 (A)(i) of this paragraph.

18 “(3) PLAN FLEXIBILITY TO NEGOTIATE GREAT-
19 ER DISCOUNTS.—Nothing in this subsection shall be
20 construed as preventing the sponsor of a prescrip-
21 tion drug plan, or an organization offering an MA-
22 PD plan, from obtaining a discount or reduction of
23 the price for a covered part D drug below the price
24 negotiated under paragraph (1), if applicable, in-

1 cluding through the use of preferred or tiered cost-
2 sharing status.

3 “(4) ENSURING BENEFICIARY ACCESS TO
4 NEEDED DRUGS.—Beginning with plan year 2020,
5 each PDP sponsor of a prescription drug plan and
6 organization offering an MA–PD plan shall have in
7 place a process under which an enrollee in the plan
8 may request coverage under the plan for a covered
9 part D drug that is not on the formulary, or is sub-
10 ject to utilization management controls, such as
11 tiered pricing, prior authorization, or step therapy.”.

12 (b) CONFORMING AMENDMENTS.—

13 (1) IN GENERAL.—Section 1860D–4 of the So-
14 cial Security Act (42 U.S.C. 1395w–104) is amend-
15 ed—

16 (A) in subsection (b)(3), in the matter pre-
17 ceeding subparagraph (A), by striking “If a
18 PDP” and inserting “Subject to section
19 1860D–11(i)(2), if a PDP”;

20 (B) in subsection (g)—

21 (i) in paragraph (1), by inserting be-
22 fore the period at the end the following: “,
23 except that the PDP sponsor of a prescrip-
24 tion drug plan shall treat the presentation
25 of a prescription to a participating phar-

1 macy, which is transmitted to the plan by
2 the pharmacy, as a request for a coverage
3 determination (including with respect to
4 prior authorization, step therapy, or quan-
5 tity limits) and, in applying such para-
6 graphs of section 1852(g), the response to
7 such transmittal shall be treated as a de-
8 termination by the sponsor”; and

9 (ii) in paragraph (2), in the first sen-
10 tence, by inserting “(or a participating
11 pharmacy, on behalf of such individual,
12 through transmission of a prescription as
13 described in paragraph (1))” after “a part
14 D eligible individual who is enrolled in the
15 plan”; and

16 (C) in subsection (h)—

17 (i) in paragraph (1), in the second
18 sentence, by inserting “(or a participating
19 pharmacy, on behalf of such individual)”
20 after “the part D eligible individual”; and

21 (ii) in paragraph (2), by inserting
22 “(or a participating pharmacy, on behalf of
23 such individual)” after “A part D eligible
24 individual who is enrolled in a prescription
25 drug plan offered by a PDP sponsor”.

1 (2) EFFECTIVE DATE.—The amendments made
2 by subparagraphs (B) and (C) of paragraph (1)
3 shall apply to plans years beginning on or after Jan-
4 uary 1, 2020.

5 **SEC. 3. REQUIRING DRUG MANUFACTURERS TO PROVIDE**
6 **DRUG REBATES FOR DRUGS DISPENSED TO**
7 **LOW-INCOME INDIVIDUALS.**

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

10 (1) in subsection (e)(1), in the matter preceding
11 subparagraph (A), by inserting “and subsection (f)”
12 after “this subsection”; and

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

15 “(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR
16 REBATE ELIGIBLE INDIVIDUALS.—

17 “(1) REQUIREMENT.—

18 “(A) IN GENERAL.—For plan years begin-
19 ning on or after January 1, 2020, in this part,
20 the term ‘covered part D drug’ does not include
21 any drug or biological product that is manufac-
22 tured by a manufacturer that has not entered
23 into and have in effect a rebate agreement de-
24 scribed in paragraph (2).

1 “(B) 2020 PLAN YEAR REQUIREMENT.—
2 Any drug or biological product manufactured by
3 a manufacturer that declines to enter into a re-
4 bate agreement described in paragraph (2) for
5 the period beginning on January 1, 2020, and
6 ending on December 31, 2020, shall not be in-
7 cluded as a ‘covered part D drug’ for the subse-
8 quent plan year.

9 “(2) REBATE AGREEMENT.—A rebate agree-
10 ment under this subsection shall require the manu-
11 facturer to provide to the Secretary a rebate for
12 each rebate period (as defined in paragraph (6)(B))
13 ending after December 31, 2019, in the amount
14 specified in paragraph (3) for any covered part D
15 drug of the manufacturer dispensed after December
16 31, 2019, to any rebate eligible individual (as de-
17 fined in paragraph (6)(A)) for which payment was
18 made by a PDP sponsor or MA organization under
19 this part for such period, including payments passed
20 through the low-income and reinsurance subsidies
21 under sections 1860D–14 and 1860D–15(b), respec-
22 tively. Such rebate shall be paid by the manufac-
23 turer to the Secretary not later than 30 days after
24 the date of receipt of the information described in
25 section 1860D–12(b)(8), including as such section is

1 applied under section 1857(f)(3), or 30 days after
2 the receipt of information under subparagraph (D)
3 of paragraph (3), as determined by the Secretary.
4 Insofar as not inconsistent with this subsection, the
5 Secretary shall establish terms and conditions of
6 such agreement relating to compliance, penalties,
7 and program evaluations, investigations, and audits
8 that are similar to the terms and conditions for re-
9 bate agreements under paragraphs (3) and (4) of
10 section 1927(b).

11 “(3) REBATE FOR REBATE ELIGIBLE MEDICARE
12 DRUG PLAN ENROLLEES.—

13 “(A) IN GENERAL.—The amount of the re-
14 bate specified under this paragraph for a manu-
15 facturer for a rebate period, with respect to
16 each dosage form and strength of any covered
17 part D drug provided by such manufacturer
18 and dispensed to a rebate eligible individual,
19 shall be equal to the product of—

20 “(i) the total number of units of such
21 dosage form and strength of the drug so
22 provided and dispensed for which payment
23 was made by a PDP sponsor or an MA or-
24 ganization under this part for the rebate
25 period, including payments passed through

1 the low-income and reinsurance subsidies
2 under sections 1860D–14 and 1860D–
3 15(b), respectively; and

4 “(ii) the amount (if any) by which—

5 “(I) the Medicaid rebate amount
6 (as defined in subparagraph (B)) for
7 such form, strength, and period, ex-
8 ceeds

9 “(II) the average Medicare drug
10 program rebate eligible rebate amount
11 (as defined in subparagraph (C)) for
12 such form, strength, and period.

13 “(B) MEDICAID REBATE AMOUNT.—For
14 purposes of this paragraph, the term ‘Medicaid
15 rebate amount’ means, with respect to each
16 dosage form and strength of a covered part D
17 drug provided by the manufacturer for a rebate
18 period—

19 “(i) in the case of a single source
20 drug or an innovator multiple source drug,
21 the amount specified in paragraph
22 (1)(A)(ii)(II) or (2)(C) of section 1927(c)
23 plus the amount, if any, specified in sub-
24 paragraph (A)(ii) of paragraph (2) of such

1 section, for such form, strength, and pe-
2 riod; or

3 “(ii) in the case of any other covered
4 outpatient drug, the amount specified in
5 paragraph (3)(A)(i) of such section for
6 such form, strength, and period.

7 “(C) AVERAGE MEDICARE DRUG PROGRAM
8 REBATE ELIGIBLE REBATE AMOUNT.—For pur-
9 poses of this subsection, the term ‘average
10 Medicare drug program rebate eligible rebate
11 amount’ means, with respect to each dosage
12 form and strength of a covered part D drug
13 provided by a manufacturer for a rebate period,
14 the sum, for all PDP sponsors under part D
15 and MA organizations administering an MA-
16 PD plan under part C, of—

17 “(i) the product, for each such spon-
18 sor or organization, of—

19 “(I) the sum of all rebates, dis-
20 counts, or other price concessions (not
21 taking into account any rebate pro-
22 vided under paragraph (2) or any dis-
23 counts under the program under sec-
24 tion 1860D–14A) for such dosage
25 form and strength of the drug dis-

1 pensed, calculated on a per-unit basis,
2 but only to the extent that any such
3 rebate, discount, or other price con-
4 cession applies equally to drugs dis-
5 pensed to rebate eligible Medicare
6 drug plan enrollees and drugs dis-
7 pensed to PDP and MA–PD enrollees
8 who are not rebate eligible individuals;
9 and

10 “(II) the number of the units of
11 such dosage and strength of the drug
12 dispensed during the rebate period to
13 rebate eligible individuals enrolled in
14 the prescription drug plans adminis-
15 tered by the PDP sponsor or the MA–
16 PD plans administered by the MA or-
17 ganization; divided by

18 “(ii) the total number of units of such
19 dosage and strength of the drug dispensed
20 during the rebate period to rebate eligible
21 individuals enrolled in all prescription drug
22 plans administered by PDP sponsors and
23 all MA–PD plans administered by MA or-
24 ganizations.

1 “(D) USE OF ESTIMATES.—The Secretary
2 may establish a methodology for estimating the
3 average Medicare drug program rebate eligible
4 rebate amounts for each rebate period based on
5 bid and utilization information under this part
6 and may use these estimates as the basis for
7 determining the rebates under this section. If
8 the Secretary elects to estimate the average
9 Medicare drug program rebate eligible rebate
10 amounts, the Secretary shall establish a rec-
11 onciliation process for adjusting manufacturer
12 rebate payments not later than 3 months after
13 the date that manufacturers receive the infor-
14 mation collected under section 1860D–
15 12(b)(8)(B).

16 “(4) LENGTH OF AGREEMENT.—The provisions
17 of paragraph (4) of section 1927(b) (other than
18 clauses (iv) and (v) of subparagraph (B)) shall apply
19 to rebate agreements under this subsection in the
20 same manner as such paragraph applies to a rebate
21 agreement under such section.

22 “(5) OTHER TERMS AND CONDITIONS.—The
23 Secretary shall establish other terms and conditions
24 of the rebate agreement under this subsection, in-

1 including terms and conditions related to compliance,
2 that are consistent with this subsection.

3 “(6) DEFINITIONS.—In this subsection and sec-
4 tion 1860D–12(b)(8):

5 “(A) REBATE ELIGIBLE INDIVIDUAL.—The
6 term ‘rebate eligible individual’ means—

7 “(i) a subsidy eligible individual (as
8 defined in section 1860D–14(a)(3)(A));

9 “(ii) a Medicaid beneficiary treated as
10 a subsidy eligible individual under clause
11 (v) of section 1860D–14(a)(3)(B); and

12 “(iii) any part D eligible individual
13 not described in clause (i) or (ii) who is de-
14 termined for purposes of the State plan
15 under title XIX to be eligible for medical
16 assistance under clause (i), (iii), or (iv) of
17 section 1902(a)(10)(E).

18 “(B) REBATE PERIOD.—The term ‘rebate
19 period’ has the meaning given such term in sec-
20 tion 1927(k)(8).”.

21 (b) REPORTING REQUIREMENT FOR THE DETER-
22 MINATION AND PAYMENT OF REBATES BY MANUFACTUR-
23 ERS RELATED TO REBATE FOR REBATE ELIGIBLE MEDI-
24 CARE DRUG PLAN ENROLLEES.—

1 (1) REQUIREMENTS FOR PDP SPONSORS.—Sec-
2 tion 1860D–12(b) of the Social Security Act (42
3 U.S.C. 1395w–112(b)) is amended by adding at the
4 end the following new paragraph:

5 “(8) REPORTING REQUIREMENT FOR THE DE-
6 TERMINATION AND PAYMENT OF REBATES BY MANU-
7 FACTURERS RELATED TO REBATE FOR REBATE ELI-
8 GIBLE MEDICARE DRUG PLAN ENROLLEES.—

9 “(A) IN GENERAL.—For purposes of the
10 rebate under section 1860D–2(f) for contract
11 years beginning on or after January 1, 2020,
12 each contract entered into with a PDP sponsor
13 under this part with respect to a prescription
14 drug plan shall require that the sponsor comply
15 with subparagraphs (B) and (C).

16 “(B) REPORT FORM AND CONTENTS.—Not
17 later than a date specified by the Secretary, a
18 PDP sponsor of a prescription drug plan under
19 this part shall report to each manufacturer—

20 “(i) information (by National Drug
21 Code number) on the total number of units
22 of each dosage, form, and strength of each
23 drug of such manufacturer dispensed to re-
24 bate eligible Medicare drug plan enrollees
25 under any prescription drug plan operated

1 by the PDP sponsor during the rebate pe-
2 riod;

3 “(ii) information on the price dis-
4 counts, price concessions, and rebates for
5 such drugs for such form, strength, and
6 period;

7 “(iii) information on the extent to
8 which such price discounts, price conces-
9 sions, and rebates apply equally to rebate
10 eligible Medicare drug plan enrollees and
11 PDP enrollees who are not rebate eligible
12 Medicare drug plan enrollees; and

13 “(iv) any additional information that
14 the Secretary determines is necessary to
15 enable the Secretary to calculate the aver-
16 age Medicare drug program rebate eligible
17 rebate amount (as defined in paragraph
18 (3)(C) of such section), and to determine
19 the amount of the rebate required under
20 this section, for such form, strength, and
21 period.

22 Such report shall be in a form consistent with
23 a standard reporting format established by the
24 Secretary.

1 “(C) SUBMISSION TO SECRETARY.—Each
2 PDP sponsor shall promptly transmit a copy of
3 the information reported under subparagraph
4 (B) to the Secretary for the purpose of audit
5 oversight and evaluation.

6 “(D) CONFIDENTIALITY OF INFORMA-
7 TION.—The provisions of subparagraph (D) of
8 section 1927(b)(3), relating to confidentiality of
9 information, shall apply to information reported
10 by PDP sponsors under this paragraph in the
11 same manner that such provisions apply to in-
12 formation disclosed by manufacturers or whole-
13 salers under such section, except—

14 “(i) that any reference to ‘this sec-
15 tion’ in clause (i) of such subparagraph
16 shall be treated as being a reference to this
17 section;

18 “(ii) the reference to the Director of
19 the Congressional Budget Office in clause
20 (iii) of such subparagraph shall be treated
21 as including a reference to the Medicare
22 Payment Advisory Commission; and

23 “(iii) clause (iv) of such subparagraph
24 shall not apply.

1 “(E) OVERSIGHT.—Information reported
2 under this paragraph may be used by the In-
3 spector General of the Department of Health
4 and Human Services for the statutorily author-
5 ized purposes of audit, investigation, and eval-
6 uations.

7 “(F) PENALTIES FOR FAILURE TO PRO-
8 VIDE TIMELY INFORMATION AND PROVISION OF
9 FALSE INFORMATION.—In the case of a PDP
10 sponsor—

11 “(i) that fails to provide information
12 required under subparagraph (B) on a
13 timely basis, the sponsor is subject to a
14 civil money penalty in the amount of
15 \$10,000 for each day in which such infor-
16 mation has not been provided; or

17 “(ii) that knowingly (as defined in
18 section 1128A(i)) provides false informa-
19 tion under such subparagraph, the sponsor
20 is subject to a civil money penalty in an
21 amount not to exceed \$100,000 for each
22 item of false information.

23 Such civil money penalties are in addition to
24 other penalties as may be prescribed by law.
25 The provisions of section 1128A (other than

1 subsections (a) and (b)) shall apply to a civil
2 money penalty under this subparagraph in the
3 same manner as such provisions apply to a pen-
4 alty or proceeding under section 1128A(a).”.

5 (2) APPLICATION TO MA ORGANIZATIONS.—Sec-
6 tion 1857(f)(3) of the Social Security Act (42
7 U.S.C. 1395w–27(f)(3)) is amended by adding at
8 the end the following:

9 “(E) REPORTING REQUIREMENT RELATED
10 TO REBATE FOR REBATE ELIGIBLE MEDICARE
11 DRUG PLAN ENROLLEES.—Section 1860D–
12 12(b)(8).”.

13 (c) DEPOSIT OF REBATES INTO MEDICARE PRE-
14 SCRIPTON DRUG ACCOUNT.—Section 1860D–16(c) of the
15 Social Security Act (42 U.S.C. 1395w–116(c)) is amended
16 by adding at the end the following new paragraph:

17 “(6) REBATE FOR REBATE ELIGIBLE MEDICARE
18 DRUG PLAN ENROLLEES.—Amounts paid under a re-
19 bate agreement under section 1860D–2(f) shall be
20 deposited into the Account.”.

21 (d) EXCLUSION FROM DETERMINATION OF BEST
22 PRICE AND AVERAGE MANUFACTURER PRICE UNDER
23 MEDICAID.—

24 (1) EXCLUSION FROM BEST PRICE DETERMINA-
25 TION.—Section 1927(c)(1)(C)(ii)(I) of the Social Se-

1 security Act (42 U.S.C. 1396r-8(c)(1)(C)(ii)(I)) is
2 amended by inserting “and amounts paid under a
3 rebate agreement under section 1860D-2(f)” after
4 “this section”.

5 (2) EXCLUSION FROM AVERAGE MANUFAC-
6 Turer PRICE DETERMINATION.—Section
7 1927(k)(1)(B)(i) of the Social Security Act (42
8 U.S.C. 1396r-8(k)(1)(B)(i)) is amended—

9 (A) in subclause (IV), by striking “and”
10 after the semicolon;

11 (B) in subclause (V), by striking the period
12 at the end and inserting “; and”; and

13 (C) by adding at the end the following:

14 “(VI) amounts paid under a re-
15 bate agreement under section 1860D-
16 2(f).”.

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