

115TH CONGRESS
1ST SESSION

S. _____

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 SENATE OF THE UNITED STATES

Mr. SANDERS (for himself, Mr. REED, Mr. LEAHY, Mrs. GILLIBRAND, Ms. HARRIS, and Mr. FRANKEN) introduced the following bill; which was read twice and referred to the Committee on _____

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare Drug Price
5 Negotiation Act”.

1 **SEC. 2. NEGOTIATION OF LOWER COVERED PART D DRUG**
2 **PRICES ON BEHALF OF MEDICARE BENE-**
3 **FICIARIES AND ESTABLISHMENT AND APPLI-**
4 **CATION OF FORMULARY BY THE SECRETARY**
5 **OF HEALTH AND HUMAN SERVICES UNDER**
6 **MEDICARE PART D.**

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

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

13 “(1) NEGOTIATION.—

14 “(A) IN GENERAL.—Notwithstanding any
15 other provision of law, subject to subparagraph
16 (B), the Secretary shall during a negotiation
17 year and with respect to the negotiation drug
18 grouping identified under subparagraph (C)
19 with respect to such negotiation year—

20 “(i) negotiate with pharmaceutical
21 manufacturers the prices (including dis-
22 counts, rebates, and all other price conces-
23 sions) that may be charged for each plan
24 year during the negotiated price period,
25 with respect to such negotiation year, to
26 PDP sponsors and MA organizations for

1 covered part D drugs identified as included
2 within such negotiation drug grouping for
3 part D eligible individuals who are enrolled
4 under a prescription drug plan or under an
5 MA–PD plan; and

6 “(ii) complete such negotiations 30
7 days before the first day of the application
8 review process for the first plan year dur-
9 ing such negotiated price period for new
10 contracts or expanding existing contracts
11 with PDP sponsors and MA organizations
12 to offer prescription drug plans or MA–PD
13 plans, respectively.

14 “(B) USE OF FALLBACK IF NEGOTIATIONS
15 FAIL.—If, after attempting to negotiate the
16 price during a negotiation year for a covered
17 part D drug that is identified as included with-
18 in the negotiation drug grouping for such nego-
19 tiation year, the Secretary is not successful in
20 obtaining an appropriate price (as determined
21 by the Secretary in accordance with guidance
22 described in subparagraph (E)), the price that
23 may be charged during each plan year during
24 the negotiated price period, with respect to such
25 negotiation year, to PDP sponsors and MA or-

1 organizations for such covered part D drugs for
2 part D eligible individuals who are enrolled
3 under a prescription drug plan or under an
4 MA–PD plan shall be the lowest of—

5 “(i) the contract price applied pursu-
6 ant to section 8126 of title 38, United
7 States Code, for such drug for the contract
8 year (as defined in such section 8126) be-
9 ginning during the first plan year of such
10 negotiated price period;

11 “(ii) the average of the prices avail-
12 able, during the most recent 12-month pe-
13 riod for which data is available prior to the
14 beginning of such negotiated price period,
15 from the manufacturer to any wholesaler,
16 retailer, provider, health maintenance orga-
17 nization, nonprofit entity, or governmental
18 entity in the ten OECD (Organization for
19 Economic Cooperation and Development)
20 countries that have the largest gross do-
21 mestic product with a per capita income
22 that is not less than half the per capita in-
23 come of the United States, as reported by
24 the manufacturer to the Secretary; and

1 “(iii) the best price determined under
2 section 1927(c)(1)(C) for such drug for the
3 most recent rebate period (as defined in
4 section 1927(k)(8)) applicable to such first
5 plan year of such negotiated price period.

6 “(C) IDENTIFICATION OF NEGOTIATION
7 DRUG GROUPINGS.—

8 “(i) IN GENERAL.—For each negotia-
9 tion year, the Secretary shall, during the
10 previous year, in accordance with the sub-
11 sequent clauses of this subparagraph, and
12 pursuant to rulemaking, identify covered
13 part D drugs for which negotiations under
14 subparagraph (A) shall be conducted dur-
15 ing such negotiation year. In this sub-
16 section, all such covered part D drugs so
17 identified for a negotiation year are collec-
18 tively referred to as the negotiation drug
19 grouping, with respect to such year.

20 “(ii) IDENTIFICATION OF PRIORITIZED
21 DRUGS.—In carrying out clause (i), except
22 as provided under clause (iii), the Sec-
23 retary may not identify for inclusion within
24 the negotiation drug grouping with respect
25 to a negotiation year, a covered part D

1 drug that is not a drug prioritized pursu-
2 ant to subparagraph (D) before all covered
3 part D drugs that are so prioritized have
4 been identified for inclusion in such group-
5 ing or in a negotiation drug grouping with
6 respect to a previous negotiation year for
7 which the negotiated price period has not
8 expired.

9 “(iii) DRUG INCLUSIONS FOR PRICE
10 RENEGOTIATIONS.—In the case of a cov-
11 ered part D drug that is identified as in-
12 cluded in a negotiation drug grouping
13 under this subparagraph, with respect to a
14 negotiation year, such covered part D drug
15 shall be identified as included within the
16 negotiation drug grouping for each subse-
17 quent third negotiation year.

18 “(iv) REASONABLE NOTIFICATION.—
19 The Secretary shall carry out this subpara-
20 graph in such manner as to provide for
21 public notification of the negotiation drug
22 grouping identified with respect to a nego-
23 tiation year within a reasonable period be-
24 fore the beginning of such negotiation
25 year.

1 negotiation year for which data is
2 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; or

20 “(iii) that are single-source drugs or
21 biologicals (as defined in section
22 1847A(c)(6)(D)) and that satisfy at least
23 one other criterion described in a previous
24 clause of this subparagraph.

1 “(E) GUIDANCE.—Not later than 6
2 months before the Secretary begins negotiations
3 under subparagraph (A) for the first negotia-
4 tion year, the Secretary shall issue guidance on
5 criteria to be considered for purposes of deter-
6 mining under subparagraph (B) whether or not
7 the Secretary is successful in obtaining an ap-
8 propriate price for a covered part D drug. Such
9 criteria shall include at least the following:

10 “(i) The comparative clinical effective-
11 ness and cost effectiveness, if available, of
12 such covered part D drug.

13 “(ii) The budgetary impact of pro-
14 viding coverage under this part for such
15 covered part D drug.

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

20 “(iv) Associated unmet need or sever-
21 ity of illness.

22 “(F) PUBLIC EXPLANATION ON NEGOTIA-
23 TIONS OUTCOMES.—Not later than 30 days
24 after the date on which the Secretary completes
25 negotiations under this section during a nego-

1 tiation year with a pharmaceutical manufac-
2 turer, with respect to the price for a covered
3 part D drug for a negotiated price period, with
4 respect to such year, the Secretary shall make
5 publicly available an explanation of the outcome
6 of such negotiations, based on the criteria in-
7 cluded in the guidance issued pursuant to sub-
8 paragraph (E).

9 “(G) MEDPAC REPORT.—

10 “(i) STUDY.—The Medicare Payment
11 Advisory Commission shall conduct a study
12 on the price negotiations conducted by the
13 Secretary under this paragraph, including
14 an analysis of—

15 “(I) the extent to which such
16 price negotiations are achieving lower
17 prices for covered part D drugs for
18 part D eligible individuals who are en-
19 rolled under a prescription drug plan
20 or under an MA–PD plan;

21 “(II) the parties benefitting from
22 such lower prices, such as part D eli-
23 gible individuals described in sub-
24 clause (I), the Federal government,

1 States, prescription drug plans and
2 MA–PD plans, or other entities;

3 “(III) how such price negotia-
4 tions are affecting drug prices in the
5 private market; and

6 “(IV) how such price negotiations
7 are affecting the list price of covered
8 part D drugs.

9 “(ii) REPORT.—Not later than Janu-
10 ary 1, 2022, the Medicare Payment Advi-
11 sory Commission shall submit to Congress
12 a report on the study conducted under
13 clause (i), including recommendations for
14 improving price negotiations described in
15 clause (i).

16 “(H) DEFINITIONS.—For purposes of this
17 paragraph:

18 “(i) NEGOTIATION YEAR.—The term
19 ‘negotiation year’ means a year beginning
20 with 2019.

21 “(ii) NEGOTIATED PRICE PERIOD.—
22 The term ‘negotiated price period’ means,
23 with respect to a negotiation year and ne-
24 gotiation drug grouping, the 3-plan year
25 period beginning with the first plan year

1 beginning after the negotiation year for
2 such grouping.

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 2019—

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 2019,
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.—Section 1860D–4
13 of the Social Security Act (42 U.S.C. 1395w–104) is
14 amended—

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

19 (2) in subsection (g)—

20 (A) in paragraph (1), by inserting before
21 the period at the end the following: “, except
22 that the PDP sponsor of a prescription drug
23 plan shall treat the presentation of a prescrip-
24 tion to a participating pharmacy, which is
25 transmitted to the plan by the pharmacy, as a

1 request for a coverage determination (including
2 with respect to prior authorization, step ther-
3 apy, or quantity limits) and, in applying such
4 paragraphs of section 1852(g), the response to
5 such transmittal shall be treated as a deter-
6 mination by the sponsor”; and

7 (B) in paragraph (2), in the first sentence,
8 by inserting “(or a participating pharmacy, on
9 behalf of such individual, through transmission
10 of a prescription as described in paragraph
11 (1))” after “a part D eligible individual who is
12 enrolled in the plan”; and

13 (3) in subsection (h)—

14 (A) in paragraph (1), in the second sen-
15 tence, by inserting “(or a participating phar-
16 macy, on behalf of such individual)” after “the
17 part D eligible individual”; and

18 (B) in paragraph (2), by inserting “(or a
19 participating pharmacy, on behalf of such indi-
20 vidual)” after “A part D eligible individual who
21 is enrolled in a prescription drug plan offered
22 by a PDP sponsor”.

23 (4) EFFECTIVE DATE.—The amendments made
24 by paragraphs (2) and (3) shall apply to plans years
25 beginning on or after January 1, 2019.

1 **SEC. 3. REQUIRING DRUG MANUFACTURERS TO PROVIDE**
2 **DRUG REBATES FOR DRUGS DISPENSED TO**
3 **LOW-INCOME INDIVIDUALS.**

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

6 (1) in subsection (e)(1), in the matter preceding
7 subparagraph (A), by inserting “and subsection (f)”
8 after “this subsection”; and

9 (2) by adding at the end the following new sub-
10 section:

11 “(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR
12 REBATE ELIGIBLE INDIVIDUALS.—

13 “(1) REQUIREMENT.—

14 “(A) IN GENERAL.—For plan years begin-
15 ning on or after January 1, 2019, in this part,
16 the term ‘covered part D drug’ does not include
17 any drug or biological product that is manufac-
18 tured by a manufacturer that has not entered
19 into and have in effect a rebate agreement de-
20 scribed in paragraph (2).

21 “(B) 2019 PLAN YEAR REQUIREMENT.—

22 Any drug or biological product manufactured by
23 a manufacturer that declines to enter into a re-
24 bate agreement described in paragraph (2) for
25 the period beginning on January 1, 2019, and
26 ending on December 31, 2019, shall not be in-

1 cluded as a ‘covered part D drug’ for the subse-
2 quent plan year.

3 “(2) REBATE AGREEMENT.—A rebate agree-
4 ment under this subsection shall require the manu-
5 facturer to provide to the Secretary a rebate for
6 each rebate period (as defined in paragraph (6)(B))
7 ending after December 31, 2018, in the amount
8 specified in paragraph (3) for any covered part D
9 drug of the manufacturer dispensed after December
10 31, 2018, to any rebate eligible individual (as de-
11 fined in paragraph (6)(A)) for which payment was
12 made by a PDP sponsor or MA organization under
13 this part for such period, including payments passed
14 through the low-income and reinsurance subsidies
15 under sections 1860D–14 and 1860D–15(b), respec-
16 tively. Such rebate shall be paid by the manufac-
17 turer to the Secretary not later than 30 days after
18 the date of receipt of the information described in
19 section 1860D–12(b)(7), including as such section is
20 applied under section 1857(f)(3), or 30 days after
21 the receipt of information under subparagraph (D)
22 of paragraph (3), as determined by the Secretary.
23 Insofar as not inconsistent with this subsection, the
24 Secretary shall establish terms and conditions of
25 such agreement relating to compliance, penalties,

1 and program evaluations, investigations, and audits
2 that are similar to the terms and conditions for re-
3 bate agreements under paragraphs (3) and (4) of
4 section 1927(b).

5 “(3) REBATE FOR REBATE ELIGIBLE MEDICARE
6 DRUG PLAN ENROLLEES.—

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

14 “(i) the total number of units of such
15 dosage form and strength of the drug so
16 provided and dispensed for which payment
17 was made by a PDP sponsor or an MA or-
18 ganization under this part for the rebate
19 period, including payments passed through
20 the low-income and reinsurance subsidies
21 under sections 1860D–14 and 1860D–
22 15(b), respectively; and

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

24 “(I) the Medicaid rebate amount
25 (as defined in subparagraph (B)) for

1 such form, strength, and period, ex-
2 ceeds

3 “(II) the average Medicare drug
4 program rebate eligible rebate amount
5 (as defined in subparagraph (C)) for
6 such form, strength, and period.

7 “(B) MEDICAID REBATE AMOUNT.—For
8 purposes of this paragraph, the term ‘Medicaid
9 rebate amount’ means, with respect to each
10 dosage form and strength of a covered part D
11 drug provided by the manufacturer for a rebate
12 period—

13 “(i) in the case of a single source
14 drug or an innovator multiple source drug,
15 the amount specified in paragraph
16 (1)(A)(ii)(II) or (2)(C) of section 1927(c)
17 plus the amount, if any, specified in sub-
18 paragraph (A)(ii) of paragraph (2) of such
19 section, for such form, strength, and pe-
20 riod; or

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

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

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

13 “(I) the sum of all rebates, dis-
14 counts, or other price concessions (not
15 taking into account any rebate pro-
16 vided under paragraph (2) or any dis-
17 counts under the program under sec-
18 tion 1860D–14A) for such dosage
19 form and strength of the drug dis-
20 pensed, calculated on a per-unit basis,
21 but only to the extent that any such
22 rebate, discount, or other price con-
23 cession applies equally to drugs dis-
24 pensed to rebate eligible Medicare
25 drug plan enrollees and drugs dis-

1 pensed to PDP and MA–PD enrollees
2 who are not rebate eligible individuals;
3 and

4 “(II) the number of the units of
5 such dosage and strength of the drug
6 dispensed during the rebate period to
7 rebate eligible individuals enrolled in
8 the prescription drug plans adminis-
9 tered by the PDP sponsor or the MA–
10 PD plans administered by the MA or-
11 ganization; divided by

12 “(ii) the total number of units of such
13 dosage and strength of the drug dispensed
14 during the rebate period to rebate eligible
15 individuals enrolled in all prescription drug
16 plans administered by PDP sponsors and
17 all MA–PD plans administered by MA or-
18 ganizations.

19 “(D) USE OF ESTIMATES.—The Secretary
20 may establish a methodology for estimating the
21 average Medicare drug program rebate eligible
22 rebate amounts for each rebate period based on
23 bid and utilization information under this part
24 and may use these estimates as the basis for
25 determining the rebates under this section. If

1 the Secretary elects to estimate the average
2 Medicare drug program rebate eligible rebate
3 amounts, the Secretary shall establish a rec-
4 onciliation process for adjusting manufacturer
5 rebate payments not later than 3 months after
6 the date that manufacturers receive the infor-
7 mation collected under section 1860D-
8 12(b)(7)(B).

9 “(4) LENGTH OF AGREEMENT.—The provisions
10 of paragraph (4) of section 1927(b) (other than
11 clauses (iv) and (v) of subparagraph (B)) shall apply
12 to rebate agreements under this subsection in the
13 same manner as such paragraph applies to a rebate
14 agreement under such section.

15 “(5) OTHER TERMS AND CONDITIONS.—The
16 Secretary shall establish other terms and conditions
17 of the rebate agreement under this subsection, in-
18 cluding terms and conditions related to compliance,
19 that are consistent with this subsection.

20 “(6) DEFINITIONS.—In this subsection and sec-
21 tion 1860D-12(b)(7):

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

24 “(i) a subsidy eligible individual (as
25 defined in section 1860D-14(a)(3)(A));

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

4 “(iii) any part D eligible individual
5 not described in clause (i) or (ii) who is de-
6 termined for purposes of the State plan
7 under title XIX to be eligible for medical
8 assistance under clause (i), (iii), or (iv) of
9 section 1902(a)(10)(E).

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

13 (b) REPORTING REQUIREMENT FOR THE DETER-
14 MINATION AND PAYMENT OF REBATES BY MANUFACTUR-
15 ERS RELATED TO REBATE FOR REBATE ELIGIBLE MEDI-
16 CARE DRUG PLAN ENROLLEES.—

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

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

1 “(A) IN GENERAL.—For purposes of the
2 rebate under section 1860D–2(f) for contract
3 years beginning on or after January 1, 2019,
4 each contract entered into with a PDP sponsor
5 under this part with respect to a prescription
6 drug plan shall require that the sponsor comply
7 with subparagraphs (B) and (C).

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

12 “(i) information (by National Drug
13 Code number) on the total number of units
14 of each dosage, form, and strength of each
15 drug of such manufacturer dispensed to re-
16 bate eligible Medicare drug plan enrollees
17 under any prescription drug plan operated
18 by the PDP sponsor during the rebate pe-
19 riod;

20 “(ii) information on the price dis-
21 counts, price concessions, and rebates for
22 such drugs for such form, strength, and
23 period;

24 “(iii) information on the extent to
25 which such price discounts, price conces-

1 sions, and rebates apply equally to rebate
2 eligible Medicare drug plan enrollees and
3 PDP enrollees who are not rebate eligible
4 Medicare drug plan enrollees; and

5 “(iv) any additional information that
6 the Secretary determines is necessary to
7 enable the Secretary to calculate the aver-
8 age Medicare drug program rebate eligible
9 rebate amount (as defined in paragraph
10 (3)(C) of such section), and to determine
11 the amount of the rebate required under
12 this section, for such form, strength, and
13 period.

14 Such report shall be in a form consistent with
15 a standard reporting format established by the
16 Secretary.

17 “(C) SUBMISSION TO SECRETARY.—Each
18 PDP sponsor shall promptly transmit a copy of
19 the information reported under subparagraph
20 (B) to the Secretary for the purpose of audit
21 oversight and evaluation.

22 “(D) CONFIDENTIALITY OF INFORMA-
23 TION.—The provisions of subparagraph (D) of
24 section 1927(b)(3), relating to confidentiality of
25 information, shall apply to information reported

1 by PDP sponsors under this paragraph in the
2 same manner that such provisions apply to in-
3 formation disclosed by manufacturers or whole-
4 salers under such section, except—

5 “(i) that any reference to ‘this sec-
6 tion’ in clause (i) of such subparagraph
7 shall be treated as being a reference to this
8 section;

9 “(ii) the reference to the Director of
10 the Congressional Budget Office in clause
11 (iii) of such subparagraph shall be treated
12 as including a reference to the Medicare
13 Payment Advisory Commission; and

14 “(iii) clause (iv) of such subparagraph
15 shall not apply.

16 “(E) OVERSIGHT.—Information reported
17 under this paragraph may be used by the In-
18 spector General of the Department of Health
19 and Human Services for the statutorily author-
20 ized purposes of audit, investigation, and eval-
21 uations.

22 “(F) PENALTIES FOR FAILURE TO PRO-
23 VIDE TIMELY INFORMATION AND PROVISION OF
24 FALSE INFORMATION.—In the case of a PDP
25 sponsor—

1 “(i) that fails to provide information
2 required under subparagraph (B) on a
3 timely basis, the sponsor is subject to a
4 civil money penalty in the amount of
5 \$10,000 for each day in which such infor-
6 mation has not been provided; or

7 “(ii) that knowingly (as defined in
8 section 1128A(i)) provides false informa-
9 tion under such subparagraph, the sponsor
10 is subject to a civil money penalty in an
11 amount not to exceed \$100,000 for each
12 item of false information.

13 Such civil money penalties are in addition to
14 other penalties as may be prescribed by law.
15 The provisions of section 1128A (other than
16 subsections (a) and (b)) shall apply to a civil
17 money penalty under this subparagraph in the
18 same manner as such provisions apply to a pen-
19 alty or proceeding under section 1128A(a).”.

20 (2) APPLICATION TO MA ORGANIZATIONS.—Sec-
21 tion 1857(f)(3) of the Social Security Act (42
22 U.S.C. 1395w-27(f)(3)) is amended by adding at
23 the end the following:

24 “(D) REPORTING REQUIREMENT RELATED
25 TO REBATE FOR REBATE ELIGIBLE MEDICARE

1 DRUG PLAN ENROLLEES.—Section 1860D–
2 12(b)(7).”.

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

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

11 (d) EXCLUSION FROM DETERMINATION OF BEST
12 PRICE AND AVERAGE MANUFACTURER PRICE UNDER
13 MEDICAID.—

14 (1) EXCLUSION FROM BEST PRICE DETERMINA-
15 TION.—Section 1927(c)(1)(C)(ii)(I) of the Social Se-
16 curity Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is
17 amended by inserting “and amounts paid under a
18 rebate agreement under section 1860D–2(f)” after
19 “this section”.

20 (2) EXCLUSION FROM AVERAGE MANUFAC-
21 Turer Price Determination.—Section
22 1927(k)(1)(B)(i) of the Social Security Act (42
23 U.S.C. 1396r–8(k)(1)(B)(i)) is amended—

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

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

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

4 “(VI) amounts paid under a re-
5 bate agreement under section 1860D-
6 2(f).”.