

116TH CONGRESS
1ST SESSION

S. 2081

To amend title XVIII of the Social Security Act to require drug manufacturers to provide rebates for drugs furnished under Medicare part B for which the growth in average sales price has exceeded inflation, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 10, 2019

Mr. PETERS (for himself and Ms. STABENOW) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to require drug manufacturers to provide rebates for drugs furnished under Medicare part B for which the growth in average sales price has exceeded inflation, 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 “Stop Drug Companies
5 from Overcharging Seniors in Medicare Part B Act of
6 2019”.

1 **SEC. 2. REQUIRING DRUG MANUFACTURERS TO PROVIDE**
2 **REBATES FOR DRUGS FURNISHED UNDER**
3 **MEDICARE PART B FOR WHICH ASP GROWTH**
4 **HAS EXCEEDED INFLATION.**

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

8 “(h) **PRESCRIPTION DRUG REBATE AGREEMENT.**—

9 “(1) **REQUIREMENT.**—

10 “(A) **IN GENERAL.**—Subject to subpara-
11 graphs (B) and (C), in order for payment to be
12 made under this part for an applicable part B
13 drug (as defined in paragraph (7)(A)) of a
14 manufacturer furnished on or after January 1,
15 2020, the manufacturer shall have entered into
16 and have in effect a rebate agreement described
17 in paragraph (2) with the Secretary.

18 “(B) **EXCEPTIONS.**—This subsection shall
19 not apply with respect to an applicable part B
20 drug of a manufacturer—

21 “(i) if the Secretary determines that
22 the estimated average annual cost per user
23 for the associated drug billing code as de-
24 termined in such manner as the Secretary
25 determines appropriate, including with re-
26 spect to an applicable part B drug for

1 which a HCPCS code has not been as-
2 signed, is less than—

3 “(I) for 2020, \$100; and

4 “(II) for a subsequent year, the
5 amount determined under this clause
6 for the preceding year increased by
7 the percentage increase in the con-
8 sumer price index for all urban con-
9 sumers (U.S. city average) for the 12-
10 month period ending with June of the
11 previous year;

12 “(ii) if the drug is included on the
13 drug shortage list under section 506E of
14 the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 356e).

16 “(C) ESTABLISHMENT OF PROCEDURES TO
17 AVOID DUPLICATION.—The Secretary shall es-
18 tablish procedures to ensure that there is no
19 duplication with respect to drug rebates pro-
20 vided by manufacturers with respect to applica-
21 ble part B drugs under this subsection and ei-
22 ther of the following:

23 “(i) Purchase by a covered entity of
24 covered outpatient drugs pursuant to an

1 agreement under section 340B of the Pub-
2 lic Health Service Act (42 U.S.C. 256b).

3 “(ii) Drug rebates provided by manu-
4 facturers with respect to covered out-
5 patient drugs pursuant to section 1927.

6 “(2) REBATE AGREEMENT.—A rebate agree-
7 ment under this subsection shall require the manu-
8 facturer to provide to the Secretary (to be deposited
9 in the Treasury to the credit of the Federal Supple-
10 mentary Medical Insurance Trust Fund) a rebate
11 for each rebate period (as defined in paragraph
12 (7)(B)) ending after December 31, 2019, in an
13 amount specified in paragraph (4) for applicable
14 part B drugs of the manufacturer furnished after
15 December 31, 2019, for which payment was made
16 under this section or under a separate ambulatory
17 classification group pursuant to section 1833(t) for
18 such period. Such rebate shall be paid by the manu-
19 facturer not later than 30 days after the date of re-
20 ceipt of the information described in paragraph (3)
21 for the period involved.

22 “(3) SECRETARY PROVISION OF INFORMA-
23 TION.—

24 “(A) IN GENERAL.—The Secretary shall
25 report to each manufacturer not later than 180

1 days after the end of each rebate period and in
2 a form consistent with a standard reporting for-
3 mat established by the Secretary, information
4 on the total number of units of each dosage
5 form and strength and package size of each ap-
6 plicable part B drug of the manufacturer fur-
7 nished after December 31, 2019, for which pay-
8 ment was made under this section or under a
9 separate ambulatory classification group pursu-
10 ant to section 1833(t) during the period.

11 “(B) AUDITS BY MANUFACTURER OF IN-
12 FORMATION PROVIDED.—A manufacturer may,
13 as determined by the Secretary, audit the infor-
14 mation provided (or required to be provided)
15 under subparagraph (A).

16 “(C) AUDITS BY SECRETARY.—The Sec-
17 retary may audit the information provided (or
18 required to be provided) under subparagraph
19 (A) and the determination of the billing-code
20 level rebate amount, including the manufac-
21 turer-level billing-code level ASP and inflation-
22 adjusted billing-code level ASP, under para-
23 graph (4).

24 “(D) ADJUSTMENTS BASED ON AUDIT RE-
25 SULTS.—The Secretary shall make adjustments

1 to rebates and average sales price as appro-
2 priate based on the results of an audit con-
3 ducted under subparagraph (B) or (C).

4 “(4) DETERMINATION OF BILLING-CODE LEVEL
5 REBATE AMOUNT.—

6 “(A) IN GENERAL.—The amount of the re-
7 bate specified under this paragraph for a manu-
8 facturer for a rebate period, with respect to ap-
9 plicable part B drugs of a manufacturer as-
10 signed to a billing code, shall be equal to the
11 product of—

12 “(i) the total number of units of such
13 drugs of the manufacturer assigned to the
14 billing code for which payment was made
15 under this section or under a separate am-
16 bulatory classification group pursuant to
17 section 1833(t) for the rebate period; and

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

19 “(I) the manufacturer-level bill-
20 ing-code level ASP (as defined in sub-
21 paragraph (B)) for the manufacturer
22 for the rebate period, exceeds

23 “(II) the inflation-adjusted bill-
24 ing-code level ASP (as defined in sub-
25 paragraph (C)) for the rebate period.

1 “(B) MANUFACTURER-LEVEL BILLING-
2 CODE LEVEL ASP DEFINED.—In this subsection,
3 the term ‘manufacturer-level billing-code level
4 ASP’ means, with respect to a manufacturer
5 and a billing code for a rebate period, subject
6 to subparagraph (E)(i), the weighted average
7 sales price (per unit) across all of the National
8 Drug Codes for a manufacturer assigned to the
9 billing code, as determined by the Secretary, for
10 the quarter used to establish payment rates for
11 such Codes during the rebate period.

12 “(C) INFLATION-ADJUSTED BILLING-CODE
13 LEVEL ASP DEFINED.—In this subsection, the
14 term ‘inflation-adjusted billing-code level ASP’
15 means, with respect to a billing code and a re-
16 bate period, the product of—

17 “(i) subject to subparagraph (E)(ii),
18 the average sales price for all National
19 Drug Codes, regardless of manufacturer,
20 assigned to the billing code, as determined
21 by the Secretary, for the calendar quarter
22 beginning January 1, 2017; and

23 “(ii) the percentage increase in the
24 consumer price index for all urban con-
25 sumers (United States city average) be-

1 tween December 2016, and the month
2 prior to the quarter described in subpara-
3 graph (B).

4 “(D) TREATMENT OF SUBSEQUENTLY AP-
5 PROVED DRUGS.—In the case of an applicable
6 part B drug first marketed after September 30,
7 2016, clause (i) of subparagraph (C) shall be
8 applied by substituting ‘the second full calendar
9 quarter after the day on which the drug was
10 first marketed’ for ‘the calendar quarter begin-
11 ning January 1, 2017’ and clause (ii) of such
12 subparagraph shall be applied by substituting
13 ‘the month prior to the first month of the sec-
14 ond full calendar quarter after the day on which
15 the drug was first marketed’ for ‘December
16 2016’.

17 “(E) AUTHORITY TO MODIFY METHOD-
18 OLOGY.—

19 “(i) DETERMINATION OF MANUFAC-
20 TURER-LEVEL BILLING-CODE LEVEL
21 ASP.—In the case where the Secretary does
22 not have manufacturer level data with re-
23 spect to a billing code, the Secretary may
24 request such additional data as needed, al-
25 locate total volume for all National Drug

1 Codes, regardless of manufacturer, as-
2 signed to the billing Code as determined by
3 the Secretary, or use an alternate method-
4 ology as necessary in order to determine
5 the manufacturer-level billing-code level
6 ASP under subparagraph (B).

7 “(ii) DETERMINATION OF INFLATION-
8 ADJUSTED BILLING-CODE LEVEL ASP.—In
9 the case where the Secretary does not have
10 sufficient data with respect to the average
11 sales price for applicable part B drugs as-
12 signed to a billing code in order to deter-
13 mine the inflation-adjusted billing-code
14 level ASP for the period described in sub-
15 paragraph (C)(i), including through the
16 application of subparagraph (D) to such
17 subparagraph (C)(i), the Secretary may
18 modify the methodology or period as nec-
19 essary for purposes of determining an in-
20 flation-adjusted billing-code level ASP for
21 such period.

22 “(5) SUBMISSION OF DATA.—A rebate agree-
23 ment under this subsection shall require a manufac-
24 turer of an applicable part B drug to submit to the
25 Secretary at such time, and in such manner, as the

1 Secretary may specify such data as the Secretary de-
2 termines is necessary in order to carry out this sub-
3 section.

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

10 “(7) OTHER TERMS AND CONDITIONS.—The
11 Secretary shall establish other terms and conditions
12 of the rebate agreement under this subsection, in-
13 cluding terms and conditions related to compliance,
14 that are consistent with this subsection.

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

16 “(A) APPLICABLE PART B DRUG.—The
17 term ‘applicable part B drug’ means—

18 “(i) a drug or biological described in
19 section 1842(o)(1)(C) for which payment is
20 made under this section; or

21 “(ii) a drug or biological for which the
22 Secretary has established a separate ambu-
23 latory classification group under the pro-
24 spective payment system for hospital out-

1 patient department services under section
2 1833(t).

3 “(B) REBATE PERIOD.—The term ‘rebate
4 period’ means, with respect to an agreement
5 under paragraph (2), a calendar quarter or
6 other period specified by the Secretary with re-
7 spect to the payment of rebates under such
8 agreement.”.

9 **SEC. 3. PROTECTION AGAINST HIGH OUT-OF-POCKET EX-**
10 **PENDITURES FOR PART B DRUGS.**

11 Title XVIII of the Social Security Act (42 U.S.C.
12 1395 et seq.) is amended by inserting after section 1847B
13 the following new section:

14 **“SEC. 1847C. PROTECTION AGAINST HIGH OUT-OF-POCKET**
15 **EXPENDITURES FOR PART B DRUGS.**

16 “(a) IN GENERAL.—Notwithstanding any other pro-
17 vision of this title, in the case of an individual enrolled
18 under this part, if the amount of the out-of-pocket cost-
19 sharing for part B drugs (as defined in subsection (b))
20 of such individual for a year (beginning with 2020) equals
21 or exceeds the part B drug annual out-of-pocket threshold
22 specified in subsection (c) for the year, section
23 1833(a)(1)(S) shall be applied by substituting ‘100 per-
24 cent’ for ‘80 percent’.

1 “(b) OUT-OF-POCKET COST-SHARING FOR PART B
2 DRUGS DEFINED.—In this section, the term ‘out-of-pock-
3 et cost-sharing for part B drugs’ means, with respect to
4 an individual, the amount of the expenses incurred by the
5 individual that are attributable to drugs or biologicals fur-
6 nished under this part.

7 “(c) PART B DRUG ANNUAL OUT-OF-POCKET
8 THRESHOLD.—

9 “(1) IN GENERAL.—For purposes of this sec-
10 tion, the ‘part B drug annual out-of-pocket thresh-
11 old’ specified in this subsection—

12 “(A) for 2020, is equal to the annual out-
13 of-pocket threshold specified in section 1860D-
14 2(b)(4)(B) for 2019, increased by the annual
15 percentage increase in the consumer price index
16 for all urban consumers (United States city av-
17 erage) for the 12-month period ending in July
18 of the 2019; and

19 “(B) for a subsequent year, is equal to the
20 amount specified in this subsection for the pre-
21 vious year, increased by the annual percentage
22 increase in the consumer price index for all
23 urban consumers (United States city average)
24 for the 12-month period ending in July of the
25 previous year.

1 “(2) ROUNDING.—Any amount determined
2 under paragraph (1) that is not a multiple of \$50
3 shall be rounded to the nearest multiple of \$50.”.

○