

116TH CONGRESS
1ST SESSION

H. R. 4663

To amend title XVIII of the Social Security Act to require drug manufacturers to pay a Medicare part B rebate for certain drugs if the price of such drugs increases faster than inflation.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 11, 2019

Ms. PORTER (for herself, Ms. UNDERWOOD, Mr. CROW, and Mr. BLUMENAUER) 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 require drug manufacturers to pay a Medicare part B rebate for certain drugs if the price of such drugs increases faster than inflation.

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 “Freedom from Price
5 Gouging Act”.

1 **SEC. 2. MEDICARE PART B PRESCRIPTION DRUG INFLA-**
2 **TION REBATE BY MANUFACTURERS.**

3 (a) IN GENERAL.—Section 1834 of the Social Secu-
4 rity Act (42 U.S.C. 1395m) is amended by adding at the
5 end the following new subsection:

6 “(x) REBATE BY MANUFACTURERS FOR SINGLE
7 SOURCE DRUGS WITH PRICES INCREASING FASTER
8 THAN INFLATION.—

9 “(1) REQUIREMENTS.—

10 “(A) SECRETARIAL PROVISION OF INFOR-
11 MATION.—Not later than 6 months after the
12 end of each calendar quarter beginning on or
13 after July 1, 2021, the Secretary shall, for each
14 part B rebatable drug, report to each manufac-
15 turer of such part B rebatable drug the fol-
16 lowing for such calendar quarter:

17 “(i) Information on the total number
18 of billing units described in subparagraph
19 (A)(i) of paragraph (3) with respect to
20 such drug and calendar quarter.

21 “(ii) Information on the amount (if
22 any) of the excess average sales price in-
23 crease described in subparagraph (A)(ii) of
24 such paragraph for such drug and calendar
25 quarter.

1 “(iii) The rebate amount specified
2 under such paragraph for such part B
3 rebatable drug and calendar quarter.

4 “(B) MANUFACTURER REQUIREMENT.—
5 For each calendar quarter beginning on or after
6 July 1, 2021, the manufacturer of a part B
7 rebatable drug shall, for such drug, not later
8 than 30 days after the date of receipt from the
9 Secretary of the information described in sub-
10 paragraph (A) for such calendar quarter, pro-
11 vide to the Secretary a rebate that is equal to
12 the amount specified in paragraph (3) for such
13 drug for such calendar quarter.

14 “(2) PART B REBATABLE DRUG DEFINED.—

15 “(A) IN GENERAL.—In this subsection, the
16 term ‘part B rebatable drug’ means a single
17 source drug or biological (as defined in sub-
18 paragraph (D) of section 1847A(c)(6)), includ-
19 ing a biosimilar biological product (as defined
20 in subparagraph (H) of such section), paid for
21 under this part, except such term shall not in-
22 clude such a drug or biological—

23 “(i) if the average total allowed
24 charges for a year per individual that uses
25 such a drug or biological, as determined by

1 the Secretary, are less than, subject to
2 subparagraph (B), \$100; or

3 “(ii) that is a vaccine described in
4 subparagraph (A) or (B) of section
5 1861(s)(10).

6 “(B) INCREASE.—The dollar amount ap-
7 plied under subparagraph (A)(i)—

8 “(i) for 2022, shall be the dollar
9 amount specified under such subparagraph
10 for 2021, increased by the percentage in-
11 crease in the consumer price index for all
12 urban consumers (United States city aver-
13 age) as of the first quarter of the previous
14 year; and

15 “(ii) for a subsequent year, shall be
16 the dollar amount specified in this clause
17 (or clause (i)) for the previous year, in-
18 creased by the percentage increase in the
19 consumer price index for all urban con-
20 sumers (United States city average) as of
21 the first quarter of the previous year.

22 Any dollar amount specified under this sub-
23 paragraph that is not a multiple of \$10 shall be
24 rounded to the nearest multiple of \$10.

25 “(3) REBATE AMOUNT.—

1 “(A) IN GENERAL.—For purposes of para-
2 graph (1)(B), the amount specified in this para-
3 graph for a part B rebatable drug assigned to
4 a billing and payment code for a calendar quar-
5 ter is, subject to paragraph (4), the amount
6 equal to the product of—

7 “(i) subject to subparagraph (B), the
8 total number of billing units, as described
9 in section 1847A(b)(6)(B), for such part B
10 rebatable drug furnished under this part
11 during the calendar quarter; and

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

13 “(I) the payment amount under
14 subparagraph (B) or (C) of section
15 1847A(b)(1), as applicable, for such
16 part B rebatable drug during the cal-
17 endar quarter; exceeds

18 “(II) the inflation-adjusted pay-
19 ment amount determined under sub-
20 paragraph (C) for such part B
21 rebatable drug during the calendar
22 quarter.

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

1 units for part B rebatable drugs furnished dur-
2 ing a calendar quarter shall not include—

3 “(i) units packaged into the payment
4 for a related procedure or service under
5 section 1833(t) or under section 1833(i)
6 (instead of separately payable under such
7 respective section);

8 “(ii) units included under the single
9 payment system for renal dialysis services
10 under section 1881(b)(14); or

11 “(iii) units of a part B rebatable drug
12 of a manufacturer that is furnished to an
13 individual, if such manufacturer, with re-
14 spect to the furnishing of such units of
15 such drug, provides for discounts under
16 section 340B of the Public Health Service
17 Act or for rebates under section 1927.

18 “(C) DETERMINATION OF INFLATION-AD-
19 JUSTED PAYMENT AMOUNT.—The inflation-ad-
20 justed payment amount determined under this
21 subparagraph for a part B rebatable drug for
22 a calendar quarter is—

23 “(i) the payment amount for the bill-
24 ing and payment code for such drug in the

1 payment amount benchmark quarter (as
2 defined in subparagraph (D)); increased by
3 “(ii) the percentage by which the re-
4 bate period CPI–U (as defined in subpara-
5 graph (F)) for the calendar quarter ex-
6 ceeds the benchmark period CPI–U (as de-
7 fined in subparagraph (E)).

8 “(D) PAYMENT AMOUNT BENCHMARK
9 QUARTER.—The term ‘payment amount bench-
10 mark quarter’ means the calendar quarter be-
11 ginning January 1, 2016.

12 “(E) BENCHMARK PERIOD CPI–U.—The
13 term ‘benchmark period CPI–U’ means the con-
14 sumer price index for all urban consumers
15 (United States city average) for July 2015.

16 “(F) REBATE PERIOD CPI–U.—The term
17 ‘rebate period CPI–U’ means, with respect to a
18 calendar quarter described in subparagraph
19 (C), the greater of the benchmark period CPI–
20 U and the consumer price index for all urban
21 consumers (United States city average) for the
22 first month of the calendar quarter that is two
23 calendar quarters prior to such described cal-
24 endar quarter.

1 “(4) SPECIAL TREATMENT OF CERTAIN DRUGS
2 AND EXEMPTION.—

3 “(A) SUBSEQUENTLY APPROVED DRUGS.—

4 Subject to subparagraph (B), in the case of a
5 part B rebatable drug first approved by the
6 Food and Drug Administration after July 1,
7 2015, clause (i) of paragraph (3)(C) shall be
8 applied as if the term ‘payment amount bench-
9 mark quarter’ were defined under paragraph
10 (3)(D) as the third full calendar quarter after
11 the day on which the drug was first marketed
12 and clause (ii) of paragraph (3)(C) shall be ap-
13 plied as if the term ‘benchmark period CPI–U’
14 were defined under paragraph (3)(E) as if the
15 reference to ‘July 2015’ under such paragraph
16 were a reference to ‘the first month of the first
17 full calendar quarter after the day on which the
18 drug was first marketed’.

19 “(B) TIMELINE FOR PROVISION OF RE-
20 BATES FOR NEW DRUGS.—In the case of a part
21 B rebatable drug first approved by the Food
22 and Drug Administration after July 1, 2015,
23 clause (i) of paragraph (1)(B) shall be applied
24 as if the reference to ‘July 1, 2021’ under such
25 paragraph were a reference to the later of the

1 6th full calendar quarter after the day on which
2 the drug was first marketed or July 1, 2021.

3 “(C) EXEMPTION FOR SHORTAGES.—The
4 Secretary may reduce or waive the rebate under
5 paragraph (1)(B) with respect to a part B
6 rebatable drug that appears on the drug short-
7 age list in effect under section 506(e) of the
8 Federal Food, Drug, and Cosmetic Act or in
9 the case of other exigent circumstances, as de-
10 termined by the Secretary.

11 “(5) APPLICATION TO BENEFICIARY COINSUR-
12 ANCE.—In the case of a part B rebatable drug for
13 which a rebate is payable under this subsection—

14 “(A) in computing the amount of any coin-
15 surance applicable under this title to an indi-
16 vidual with respect to such drug, the computa-
17 tion of such coinsurance shall be based on the
18 inflation-adjusted payment amount determined
19 under paragraph (3)(C) for such part B
20 rebatable drug; and

21 “(B) the amount of such coinsurance is
22 equal to 20 percent of such inflation-adjusted
23 payment amount so determined.

24 “(6) REBATE DEPOSITS.—Amounts paid as re-
25 bates under paragraph (1)(B) shall be deposited into

1 the Federal Supplementary Medical Insurance Trust
2 Fund established under section 1841.

3 “(7) CIVIL MONEY PENALTY.—If a manufac-
4 turer of a part B rebatable drug has failed to com-
5 ply with the requirements under paragraph (1)(B)
6 for such drug for a calendar quarter, the manufac-
7 turer shall be subject to, in accordance with a proc-
8 ess established by the Secretary pursuant to regula-
9 tions, a civil money penalty in an amount equal to
10 at least 125 percent of the amount specified in para-
11 graph (3) for such drug for such calendar quarter.
12 The provisions of section 1128A (other than sub-
13 sections (a) (with respect to amounts of penalties or
14 additional assessments) and (b)) shall apply to a
15 civil money penalty under this paragraph in the
16 same manner as such provisions apply to a penalty
17 or proceeding under section 1128A(a).

18 “(8) STUDY AND REPORT.—

19 “(A) STUDY.—The Secretary shall conduct
20 a study of the feasibility of and operational
21 issues involved with the following:

22 “(i) Including multiple source drugs
23 (as defined in section 1847A(c)(6)(C)) in
24 the rebate system under this subsection.

1 “(ii) Including drugs and biologicals
2 paid for under MA plans under part C in
3 the rebate system under this subsection.

4 “(iii) Including drugs excluded under
5 paragraph (2)(A) and billing units of
6 drugs excluded under paragraph (3)(B) in
7 the rebate system under this subsection.

8 “(B) REPORT.—Not later than 3 years
9 after the date of the enactment of this sub-
10 section, the Secretary shall submit to Congress
11 a report on the study conducted under subpara-
12 graph (A).

13 “(9) APPLICATION TO MULTIPLE SOURCE
14 DRUGS.—The Secretary may, based on the report
15 submitted under paragraph (8) and pursuant to
16 rulemaking, apply the provisions of this subsection
17 to multiple source drugs (as defined in section
18 1847A(c)(6)(C)), including, for purposes of deter-
19 mining the rebate amount under paragraph (3), by
20 calculating manufacturer-specific average sales
21 prices for the benchmark period and the rebate pe-
22 riod.”.

23 (b) AMOUNTS PAYABLE; COST-SHARING.—Section
24 1833(a) of the Social Security Act (42 U.S.C. 1395l(a))
25 is amended—

1 (1) in paragraph (1)—

2 (A) in subparagraph (S), by striking “with
3 respect to” and inserting “subject to subpara-
4 graph (DD), with respect to”;

5 (B) by striking “and (CC)” and inserting
6 “(CC)”; and

7 (C) by inserting before the semicolon at
8 the end the following: “, and (DD) with respect
9 to a part B rebatable drug (as defined in para-
10 graph (2) of section 1834(x)) for which a rebate
11 is payable under such section, the amounts paid
12 shall be the difference between (i) the payment
13 amount under paragraph (3)(A)(ii)(I) of such
14 section for such drug, and (ii) 20 percent of the
15 inflation-adjusted payment amount under para-
16 graph (3)(A)(ii)(II) of such section for such
17 drug”; and

18 (2) by adding at the end of the flush left matter
19 following paragraph (9), the following:

20 “For purposes of applying paragraph (1)(DD) and section
21 1834(x)(5), the Secretary shall make such estimates and
22 use such data as the Secretary determines appropriate.”.

23 (c) CONFORMING AMENDMENT TO PART B ASP CAL-
24 CULATION.—Section 1847A(c)(3) of the Social Security

- 1 Act (42 U.S.C. 1395w-3a(c)(3)) is amended by inserting
- 2 “or section 1834(x)” after “section 1927”.

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