

116TH CONGRESS
1ST SESSION

H. R. 4619

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

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 8, 2019

Ms. SCHAKOWSKY (for herself, Mr. HIGGINS of New York, and Ms. WILD) 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 D 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 “Pharmaceutical Re-
5 bates for Excessive Pricing Above Inflation Act” or the
6 “Pharmaceutical REPAI Act”.

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

3 Part D of title XVIII of the Social Security Act is
 4 amended by inserting after section 1860D–14A (42
 5 U.S.C. 1395w–114a) the following new section:

6 **“SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN**
 7 **DRUGS WITH PRICES INCREASING FASTER**
 8 **THAN INFLATION.**

9 “(a) IN GENERAL.—Subject to the provisions of this
 10 section, in order for coverage to be available under this
 11 part for a part D rebatable drug of a manufacturer dis-
 12 pensed during an applicable year, the manufacturer must
 13 have entered into and have in effect an agreement de-
 14 scribed in subsection (b). For purposes of this section the
 15 term ‘applicable year’ means a year beginning with 2022.

16 “(b) AGREEMENTS.—

17 “(1) TERMS OF AGREEMENT.—An agreement
 18 described in this subsection, with respect to a manu-
 19 facturer of a part D rebatable drug, is an agreement
 20 under which the following applies:

21 “(A) SECRETARIAL PROVISION OF INFOR-
 22 MATION.—Not later than 9 months after the
 23 end of each applicable year with respect to
 24 which the agreement is in effect, the Secretary,
 25 for the part D rebatable drug of the manufac-

1 turer, reports to the manufacturer the following
2 for such year:

3 “(i) Information on the total units (as
4 defined in subsection (g)(2)) dispensed for
5 each dosage form and strength with re-
6 spect to such part D rebatable drug and
7 year.

8 “(ii) Information on the amount (if
9 any) of the excess average manufacturer
10 price increase described in subsection
11 (c)(1)(B) for each dosage form and
12 strength with respect to such drug and
13 year.

14 “(iii) The rebate amount specified
15 under subsection (c) for each dosage form
16 and strength with respect to such drug and
17 year.

18 “(B) MANUFACTURER REQUIREMENTS.—

19 For each applicable year with respect to which
20 the agreement is in effect, the manufacturer of
21 the part D rebatable drug, for each dosage
22 form and strength with respect to such drug,
23 not later than 30 days after the date of receipt
24 from the Secretary of the information described
25 in subparagraph (A) for such year, provides to

1 the Secretary a rebate that is equal to the
2 amount specified in subsection (c) for such dos-
3 age form and strength with respect to such
4 drug for such year.

5 “(2) LENGTH OF AGREEMENT.—

6 “(A) IN GENERAL.—An agreement under
7 this section, with respect to a part D rebatable
8 drug, shall be effective for an initial period of
9 not less than one year and shall be automati-
10 cally renewed for a period of not less than one
11 year unless terminated under subparagraph
12 (B).

13 “(B) TERMINATION.—

14 “(i) BY SECRETARY.—The Secretary
15 may provide for termination of an agree-
16 ment under this section for violation of the
17 requirements of the agreement or other
18 good cause shown. Such termination shall
19 not be effective earlier than 60 days after
20 the date of notice of such termination. The
21 Secretary shall provide, upon request, a
22 manufacturer with a hearing concerning
23 such a termination, but such hearing shall
24 not delay the effective date of the termi-
25 nation.

1 “(ii) BY A MANUFACTURER.—A man-
2 ufacturer may terminate an agreement
3 under this section for any reason. Any
4 such termination shall not be effective
5 until the year beginning at least 60 days
6 after the date the manufacturer provides
7 notice to the Secretary.

8 “(C) EFFECTIVENESS OF TERMINATION.—
9 Any termination under this paragraph shall not
10 affect rebates due under the agreement under
11 this section before the effective date of its ter-
12 mination.

13 “(D) DELAY BEFORE REENTRY.—In the
14 case of any agreement under this section with
15 a manufacturer which is terminated in a plan
16 year, another such agreement with the manu-
17 facturer (or a successor manufacturer) may not
18 be entered into before the subsequent plan year,
19 unless the Secretary finds good cause for an
20 earlier reinstatement of such an agreement.

21 “(3) INFORMATION.—For purposes of carrying
22 out this section, the Secretary shall use information
23 submitted by manufacturers under section
24 1927(b)(3).

25 “(c) REBATE AMOUNT.—

1 “(1) IN GENERAL.—For purposes of this sec-
 2 tion, the amount specified in this subsection for a
 3 dosage form and strength with respect to a part D
 4 rebtable drug and applicable year is, subject to sub-
 5 paragraphs (B) and (C) of paragraph (3), the
 6 amount equal to the product of—

7 “(A) the total average number of units
 8 weighted by, and dispensed for, such dosage
 9 form and strength with respect to such part D
 10 rebtable drug and year; and

11 “(B) the amount (if any) by which—

12 “(i) the average manufacturer price
 13 (as defined in subsection (g)) paid for such
 14 dosage form and strength with respect to
 15 such part D rebtable drug during the
 16 year; exceeds

17 “(ii) the inflation-adjusted payment
 18 amount determined under paragraph (2)
 19 for such dosage form and strength with re-
 20 spect to such part D rebtable drug during
 21 the year.

22 “(2) DETERMINATION OF INFLATION-ADJUSTED
 23 PAYMENT AMOUNT.—The inflation-adjusted payment
 24 amount determined under this paragraph for a dos-
 25 age form and strength with respect to a part D

1 rebatable drug for an applicable year, subject to sub-
 2 paragraphs (A) and (D) of paragraph (3), is—

3 “(A) the average manufacturer price paid
 4 for such dosage form and strength with respect
 5 to such drug in the payment amount bench-
 6 mark year (as defined in subsection (g)(3)); in-
 7 creased by

8 “(B) the percentage by which the rebate
 9 period CPI-U (as defined in subsection (g)(5))
 10 for the applicable year exceeds the benchmark
 11 period CPI-U (as defined in subsection (g)(4)).

12 “(3) SPECIAL TREATMENT OF CERTAIN DRUGS
 13 AND EXEMPTION.—

14 “(A) SUBSEQUENTLY APPROVED DRUGS.—

15 In the case of a part D rebatable drug first ap-
 16 proved by the Food and Drug Administration
 17 after January 1, 2016, subparagraph (A) of
 18 paragraph (2) shall be applied as if the term
 19 ‘payment amount benchmark year’ were defined
 20 under subsection (g)(3) as the first year begin-
 21 ning after the day on which the drug was first
 22 marketed and subparagraph (B) of paragraph
 23 (2) shall be applied as if the term ‘benchmark
 24 period CPI-U’ were defined under subsection
 25 (g)(4) as if the reference to ‘January 2016’

1 under such subsection were a reference to ‘Jan-
2 uary of the first year beginning after the date
3 on which the drug was first marketed by any
4 manufacturer’.

5 “(B) EXEMPTION FOR SHORTAGES.—The
6 Secretary may reduce or waive the rebate under
7 paragraph (1) with respect to a part D rebata-
8 ble drug in the case of a shortage of such drug
9 or other exigent circumstances, as determined
10 by the Secretary.

11 “(C) TREATMENT OF NEW FORMULA-
12 TIONS.—

13 “(i) IN GENERAL.—In the case of a
14 part D rebatable drug that is a line exten-
15 sion of a single source drug or an inno-
16 vator multiple source drug that is an oral
17 solid dosage form, the Secretary shall es-
18 tablish a formula for determining the
19 amount specified in this subsection with
20 respect to such part D rebatable drug and
21 an applicable year with consideration of
22 the single source drug or an innovator
23 multiple source drug.

24 “(ii) LINE EXTENSION DEFINED.—In
25 this subparagraph, the term ‘line exten-

1 sion’ means, with respect to a part D reba-
2 table drug, a new formulation of the drug
3 (as determined by the Secretary), such as
4 an extended release formulation, but does
5 not include an abuse-deterrent formulation
6 of the drug (as determined by the Sec-
7 retary), regardless of whether such abuse-
8 deterrent formulation is an extended re-
9 lease formulation.

10 “(d) REBATE DEPOSITS.—Amounts paid as rebates
11 under subsection (c) shall be deposited into the Medicare
12 Prescription Drug Account in the Federal Supplementary
13 Medical Insurance Trust Fund established under section
14 1841.

15 “(e) CIVIL MONEY PENALTY.—In the case of a man-
16 ufacturer of a part D rebatable drug with an agreement
17 in effect under this section who has failed to comply with
18 the terms of the agreement under subsection (b)(1)(B)
19 with respect to such drug for an applicable year, the Sec-
20 retary may impose a civil money penalty on such manufac-
21 turer in an amount equal to 125 percent of the amount
22 specified in subsection (c) for such drug for such year.
23 The provisions of section 1128A (other than subsections
24 (a) (with respect to amounts of penalties or additional as-
25 sessments) and (b)) shall apply to a civil money penalty

1 under this subsection in the same manner as such provi-
2 sions apply to a penalty or proceeding under section
3 1128A(a).

4 “(f) JUDICIAL REVIEW.—There shall be no judicial
5 review of the following:

6 “(1) The determination of units under this sec-
7 tion.

8 “(2) The determination of whether a drug is a
9 part D rebatable drug under this section.

10 “(3) The calculation of the rebate amount
11 under this section.

12 “(g) DEFINITIONS.—In this section:

13 “(1) PART D REBATABLE DRUG DEFINED.—

14 “(A) IN GENERAL.—The term ‘part D
15 rebatable drug’ means a drug or biological that
16 would (without application of this section) be a
17 covered part D drug, except such term shall,
18 with respect to an applicable year, not include
19 such a drug or biological if the average total
20 cost under a prescription drug plan under this
21 part or MA–PD plan under part C for such
22 year per individual who uses such a drug or bi-
23 ological, as determined by the Secretary, are
24 less than, subject to subparagraph (B), \$100,
25 as determined by the Secretary using the most

1 recent data available or, if data is not available,
2 as estimated by the Secretary.

3 “(B) INCREASE.—The dollar amount ap-
4 plied under subparagraph (A)—

5 “(i) for 2023, shall be the dollar
6 amount specified under such subparagraph
7 for 2022, increased by the percentage in-
8 crease in the consumer price index for all
9 urban consumers (United States city aver-
10 age) as of January of 2022; and

11 “(ii) for a subsequent year, shall be
12 the dollar amount specified in this sub-
13 paragraph (or subparagraph (A)) for the
14 previous year, increased by the percentage
15 increase in the consumer price index for all
16 urban consumers (United States city aver-
17 age) as of January of the previous year.

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

21 “(2) UNIT DEFINED.—The term ‘unit’ means,
22 with respect to a part D rebatable drug, the lowest
23 identifiable quantity (such as a capsule or tablet,
24 milligram of molecules, or grams) of the part D
25 rebatable drug that is dispensed to individuals en-

1 rolled under a prescription drug plan under this part
2 or an MA–PD plan under part C.

3 “(3) PAYMENT AMOUNT BENCHMARK YEAR.—
4 The term ‘payment amount benchmark year’ means
5 the year beginning January 1, 2016.

6 “(4) BENCHMARK PERIOD CPI–U.—The term
7 ‘benchmark period CPI–U’ means the consumer
8 price index for all urban consumers (United States
9 city average) for January 2016.

10 “(5) REBATE PERIOD CPI–U.—The term ‘rebate
11 period CPI–U’ means, with respect to an applicable
12 year, the consumer price index for all urban con-
13 sumers (United States city average) for January of
14 such year.

15 “(6) AVERAGE MANUFACTURER PRICE.—The
16 term ‘average manufacturer price’ has the meaning,
17 with respect to a part D rebatable drug of a manu-
18 facturer for an applicable year, given such term in
19 section 1927(k)(1), with respect to a covered out-
20 patient drug of a manufacturer for a rebate period
21 under section 1927. For purposes of applying the
22 previous sentence, with respect to a part D rebatable
23 drug of a manufacturer and an applicable year, the
24 Secretary shall use the information with respect to
25 the average manufacturer price for such drug re-

1 ported by the manufacturer under section
2 1927(b)(3) with respect to each of the quarters in
3 the applicable year and calculate an annual average
4 manufacturer price for such applicable year as the
5 average of such average manufacturer prices for
6 each such quarter, weighted by units of such drug
7 sold or dispensed with respect to such applicable
8 year.”.

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