

115TH CONGRESS
2D SESSION

H. R. 5150

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

MARCH 1, 2018

Mr. LEVIN 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 “Protecting Medicare
5 from Excessive Price Increases Act of 2018”.

1 **SEC. 2. MEDICARE PART B REBATE BY MANUFACTURERS**
2 **FOR CERTAIN DRUGS WITH PRICES INCREAS-**
3 **ING FASTER THAN INFLATION.**

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

7 “(w) NO PAYMENT WITHOUT REBATE BY MANUFAC-
8 TURERS FOR SINGLE SOURCE DRUGS WITH PRICES IN-
9 CREASING FASTER THAN INFLATION.—

10 “(1) NO PAYMENT FOR NONCOMPLIANT MANU-
11 FACTURERS.—Subject to the subsequent paragraphs
12 of this subsection, no payment shall be available
13 under this part for a unit of a rebatable drug of a
14 manufacturer (as defined in section 1847A(c)(6)(A))
15 for each calendar quarter beginning on or after July
16 1, 2019, if such manufacturer has failed to comply
17 with the requirement under paragraph (2)(B)(i) for
18 the rebate period with respect to such calendar quar-
19 ter.

20 “(2) REQUIREMENTS.—

21 “(A) SECRETARIAL PROVISION OF INFOR-
22 MATION.—Not later than 6 months after the
23 end of each rebate period with respect to a cal-
24 endar quarter beginning on or after July 1,
25 2019, the Secretary shall, for each rebatable

1 drug, report to each manufacturer of such
2 rebatable drug—

3 “(i) information on the total number
4 of units described in subparagraph (A)(i)
5 of paragraph (4) with respect to such drug
6 and rebate period;

7 “(ii) information on the amount (if
8 any) of the excess average sales price in-
9 crease described in subparagraph (A)(ii) of
10 such paragraph for such drug and period;
11 and

12 “(iii) the rebate amount specified
13 under such paragraph for such rebatable
14 drug and period.

15 “(B) MANUFACTURER REQUIREMENTS.—

16 The manufacturer of a rebatable drug, for such
17 drug, shall meet each of the following require-
18 ments for each rebate period with respect to a
19 calendar quarter beginning on or after July 1,
20 2019:

21 “(i) REBATE PAYMENT.—The manu-
22 facturer shall, not later than 30 days after
23 the date of receipt of the information de-
24 scribed in subparagraph (A) from the Sec-
25 retary, provide to the Secretary a rebate

1 that is equal to the amount specified in
2 paragraph (4) for such drug for such re-
3 bate period.

4 “(ii) REPORT OF ASP.—The manufac-
5 turer shall report to the Secretary the in-
6 formation described in section
7 1927(b)(3)(A)(iii) in a time and manner
8 consistent with the reporting under such
9 section, unless such information is already
10 reported in accordance with section
11 1927(b)(3)(C).

12 “(3) REBATABLE DRUG DEFINED.—In this sub-
13 section, the term ‘rebatable drug’ means a drug or
14 biological (as defined in section 1847A(c)(6)(D))
15 paid for under this part, except such term shall not
16 include such a drug or biological—

17 “(A) to the extent the units of such drug
18 or biological are furnished as part of a grouping
19 of items and services and paid for as such a
20 grouping in an ambulatory payment classifica-
21 tion under section 1833(t) or in a single pay-
22 ment under section 1833(i) (instead of sepa-
23 rately payable under such respective section);

24 “(B) to the extent payment for the units
25 of such drug or biological is included under the

1 single payment system for renal dialysis serv-
2 ices under section 1881(b)(14);

3 “(C) to the extent the average total al-
4 lowed charges per year per individual that uses
5 such drug or biological are less than \$100; or

6 “(D) that is a vaccine described in sub-
7 paragraph (A) or (B) of section 1861(s)(10).

8 “(4) REBATE AMOUNT.—

9 “(A) IN GENERAL.—For purposes of para-
10 graph (2)(B)(i), the amount specified in this
11 paragraph for a rebatable drug assigned to a
12 billing and payment code for a rebate period is,
13 subject to paragraph (5), the amount equal to
14 the product of—

15 “(i) the total number of units for
16 which payment was made under this part
17 for such rebatable drug during the rebate
18 period; and

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

20 “(I) the applicable manufactur-
21 er’s average sales price (as determined
22 under subparagraph (B)) for such
23 rebatable drug for sales that occurred
24 two quarters prior to the rebate pe-
25 riod; exceeds

1 “(II) the inflation-adjusted ASP
2 determined under subparagraph (C)
3 for such rebatable drug for sales that
4 occurred two quarters prior to the re-
5 bate period.

6 “(B) DETERMINATION OF APPLICABLE
7 MANUFACTURER’S ASP.—The applicable manu-
8 facturer’s average sales price, with respect to a
9 manufacturer, determined under this subpara-
10 graph for a billing and payment code is the
11 weighted average of the average sales prices of
12 all of the rebatable drugs of the manufacturer
13 identified by a national drug code assigned to
14 such billing and payment code for sales that oc-
15 curred two quarters prior to the rebate period.

16 “(C) DETERMINATION OF INFLATION-AD-
17 JUSTED ASP.—The inflation-adjusted ASP de-
18 termined under this subparagraph for a
19 rebatable drug for a rebate period is—

20 “(i) the average sales price for the
21 billing and payment code for all units of
22 such drug for sales that occurred in the
23 ASP benchmark quarter (as defined in
24 subparagraph (E)); increased by

1 “(ii) the percentage by which the re-
2 bate period CPI–U (as defined in subpara-
3 graph (G) for the rebate period exceeds the
4 benchmark period CPI–U (as defined in
5 subparagraph (F)).

6 “(D) REBATE PERIOD.—For purposes of
7 this subsection, subject to paragraph (5)(E),
8 the term ‘rebate period’ means, with respect to
9 a calendar quarter, the period that is 2 cal-
10 endar quarters prior to such calendar quarter.

11 “(E) ASP BENCHMARK QUARTER.—The
12 term ‘ASP benchmark quarter’ means the cal-
13 endar quarter beginning January 1, 2016.

14 “(F) BENCHMARK PERIOD CPI–U.—The
15 term ‘benchmark period CPI–U’ means the con-
16 sumer price index for all urban consumers
17 (United States city average) for January 2016.

18 “(G) REBATE PERIOD CPI–U.—The term
19 ‘rebate period CPI–U’ means, with respect to a
20 rebate period, the consumer price index for all
21 urban consumers (United States city average)
22 for the first month of the calendar quarter that
23 is two calendar quarters prior to the rebate pe-
24 riod.

1 “(5) SPECIAL TREATMENT OF CERTAIN
2 DRUGS.—

3 “(A) SUBSEQUENTLY APPROVED DRUGS.—
4 Subject to subparagraph (B), in the case of a
5 single source rebatable drug first approved by
6 the Food and Drug Administration after Janu-
7 ary 1, 2016, clause (i) of paragraph (4)(C)
8 shall be applied as if the term ‘ASP benchmark
9 quarter’ were defined under paragraph (4)(E)
10 as the third full calendar quarter after the day
11 on which the drug was first marketed and
12 clause (ii) of paragraph (4)(C) shall be applied
13 as if the term ‘benchmark period CPI–U’ were
14 defined under paragraph (4)(F) as if the ref-
15 erence to ‘January 2016’ under such paragraph
16 were a reference to ‘the first month of the third
17 full calendar quarter after the day on which the
18 drug was first marketed’.

19 “(B) SPECIAL RULE FOR NEW DRUGS.—In
20 applying this subsection in the case of a newly
21 approved single source rebatable drug for which
22 a payment and billing code has not previously
23 been established the first calendar quarter to
24 which this subsection shall apply shall be the

1 sixth full calendar quarter after the day on
2 which the drug was first marketed.

3 “(6) ADJUSTMENT OF COINSURANCE.—With re-
4 spect to coinsurance under this part with respect to
5 a rebatable drug for which a rebate is paid under
6 this subsection, the Secretary shall, on an annual
7 basis, pay the individual an amount as if the coin-
8 surance for a rebatable drug for which payment is
9 made under this part for such individual were com-
10 puted as if the payment amount incurred under this
11 part for such drug were ratably reduced to reflect
12 the rebate amount under this subsection for such
13 drug.

14 “(7) REBATE DEPOSITS.—Amounts paid as re-
15 bates under paragraph (2)(B)(i) shall be deposited
16 into the Federal Supplementary Medical Insurance
17 Trust Fund established under section 1841.

18 “(8) EXEMPTIONS.—

19 “(A) OTHER REBATES OR DISCOUNTS.—
20 The Secretary shall waive the rebate under
21 paragraph (2)(B)(i) with respect to the units of
22 a rebatable drug of a manufacturer that is fur-
23 nished to an individual, if such manufacturer,
24 with respect to the furnishing of such units of
25 such drug, provides for discounts under section

1 340B of the Public Health Service Act or for
2 rebates under section 1927.

3 “(B) SHORTAGES.—The Secretary may re-
4 duce or waive the rebate under paragraph
5 (2)(B)(i) with respect to a rebatable drug in the
6 case of a shortage of such drug or other exigent
7 circumstances, as determined by the Secretary.

8 “(9) VERIFICATION SURVEYS.—The Secretary
9 may survey wholesalers and manufacturers that di-
10 rectly distribute rebatable drugs, when necessary, to
11 verify the manufacturer’s average sales prices (in-
12 cluding wholesale acquisition cost) reported under
13 paragraph (2)(B)(ii). The Secretary may impose a
14 civil monetary penalty in an amount not to exceed
15 \$100,000 on a wholesaler or manufacturer that re-
16 fuses a request for information about charges or
17 prices by the Secretary in connection with a survey
18 under this subparagraph or knowingly provides false
19 information. The provisions of section 1128A (other
20 than subsections (a) (with respect to amounts of
21 penalties or additional assessments) and (b)) shall
22 apply to a civil money penalty under this subpara-
23 graph in the same manner as such provisions apply
24 to a penalty or proceeding under section 1128A(a).

1 “(10) CIVIL MONETARY PENALTY.—In lieu of
2 applying paragraph (1) for a calendar quarter, in
3 the case of a manufacturer of a rebatable drug who
4 has failed to comply with the requirements under
5 paragraph (2)(B)(i) for such drug for the rebate pe-
6 riod with respect to such calendar quarter, the Sec-
7 retary may, pursuant to regulations, impose a civil
8 monetary penalty on such manufacturer in an
9 amount not to exceed 2 percent of the total expendi-
10 tures under this part for such drug for such failure
11 with respect to such drug and quarter. The provi-
12 sions of section 1128A (other than subsections (a)
13 (with respect to amounts of penalties or additional
14 assessments) and (b)) shall apply to a civil money
15 penalty under this subparagraph in the same man-
16 ner as such provisions apply to a penalty or pro-
17 ceeding under section 1128A(a).

18 “(11) 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 multisource drugs (as
23 defined in section 1847A(c)(3)(C)) in the
24 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 (3) in the rebate system under
 6 this subsection.

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

12 “(12) APPLICATION TO MULTISOURCE
 13 DRUGS.—The Secretary may, based on the report
 14 submitted under paragraph (11) and pursuant to
 15 rulemaking, apply the provisions of this subsection
 16 to multisource drugs (as defined in section
 17 1847A(c)(3)(C)).”.

18 (b) PROVIDING MEDPAC ACCESS TO INFORMA-
 19 TION.—Section 1927(b)(3)(D) of the Social Security Act
 20 is amended—

21 (1) in clause (iv), by striking at the end “and”;

22 (2) in clause (v), by striking at the end the pe-
 23 riod and inserting “, and”; and

24 (3) by inserting after clause (v) the following
 25 new clause:

1 “(vi) to permit the Medicare Payment
2 Advisory Commission to review the infor-
3 mation provided.”.

4 (c) CONFORMING AMENDMENT TO PART B ASP CAL-
5 CULATION.—Section 1847A(c)(3) of the Social Security
6 Act (42 U.S.C. 1395w–3a(c)(3)) is amended by inserting
7 “or section 1834(w)” after “section 1927”.

○