

116TH CONGRESS
1ST SESSION

H. R. 2069

To amend title XI of the Social Security Act to provide for drug manufacturer price transparency.

IN THE HOUSE OF REPRESENTATIVES

APRIL 3, 2019

Mr. HORSFORD (for himself and Mr. REED) 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 XI of the Social Security Act to provide
for drug manufacturer price transparency.

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 “Stopping the Pharma-
5 ceutical Industry from Keeping drugs Expensive Act” or
6 the “SPIKE Act”.

1 **SEC. 2. DRUG MANUFACTURER PRICE TRANSPARENCY.**

2 Title XI of the Social Security Act (42 U.S.C. 1301
3 et seq.) is amended by inserting after section 1128K the
4 following new section:

5 **“SEC. 1128L. DRUG MANUFACTURER PRICE TRANS-**
6 **PARENCY.**

7 “(a) IN GENERAL.—With respect to each year, begin-
8 ning with 2021, the Secretary shall, at least once during
9 such year, determine if there is a triggered SPIKE in-
10 crease (in accordance with subsection (b)) with respect to
11 an applicable drug (as defined in subsection (f)(1)). If the
12 Secretary determines, with respect to a year, there is such
13 an increase with respect to an applicable drug, the manu-
14 facturer of the applicable drug shall submit to the Sec-
15 retary the justification described in subsection (c), subject
16 to subsection (b)(3), for each such triggered SPIKE in-
17 crease in accordance with the timing described in sub-
18 section (d).

19 “(b) TRIGGERED SPIKE INCREASE.—

20 “(1) IN GENERAL.—A triggered SPIKE in-
21 crease occurs, with respect to an applicable drug and
22 year (beginning with 2021), in any of the following
23 cases:

24 “(A) If there is a 10 percent (or \$10,000)
25 increase with respect to the wholesale acquisi-
26 tion cost (or alternative cost measure specified

1 by the Secretary under paragraph (2)) of such
2 drug during any 12-month period beginning
3 and ending within the lookback period that is
4 the 5-year period preceding 2021 or 2022, re-
5 spectively.

6 “(B) If there is a 25 percent (or \$25,000)
7 increase with respect to the wholesale acquisi-
8 tion cost (or such alternative cost measure) of
9 such drug during any 36-month period begin-
10 ning and ending within such respective lookback
11 period.

12 “(C) In the case of such a drug that is
13 first covered under title XVIII with respect to
14 such year, if the estimated cost or spending
15 under such title per individual or per user of
16 such drug (as estimated by the Secretary) for
17 such year (or per course of treatment, as de-
18 fined by the Secretary) is at least \$26,000.

19 “(2) ALTERNATIVE TO WAC.—The Secretary
20 may, for purposes of making determinations under
21 paragraph (1), in addition to using the wholesale ac-
22 quisition cost for an applicable drug, use alternative
23 cost measures of such drug.

24 “(3) EXCEPTION.—A justification under sub-
25 section (c) shall not be required for a triggered

1 SPIKE increase described in paragraph (1) of an
2 applicable drug of a manufacturer if there is any
3 portion of the lookback period described in the re-
4 spective subparagraph of such paragraph for such
5 increase that is included within the lookback period
6 for another triggered SPIKE increase (or combina-
7 tion of such increases) for which a justification is
8 made under this section for such drug by such man-
9 ufacturer.

10 “(4) UNIT DETERMINATION.—For purposes of
11 determining the wholesale acquisition cost in car-
12 rying out this section, the Secretary shall determine
13 a unit (such as a unit size) to apply.

14 “(5) PUBLIC POSTING.—Beginning with respect
15 to 2021, the Secretary shall publicly post on the
16 Internet website of the Department of Health and
17 Human Services—

18 “(A) alternative percentages, dollar
19 amounts, and lookback periods that, if applied
20 under paragraph (1), would be projected to in-
21 crease the number of applicable drugs for which
22 a triggered SPIKE increase would occur for
23 such year; and

24 “(B) the number of applicable drugs for
25 which a triggered SPIKE increase would occur

1 for such year of such an alternative percentage,
2 dollar amount, or period were applied for such
3 year.

4 “(c) JUSTIFICATION DESCRIBED.—

5 “(1) IN GENERAL.—The justification described
6 in this subsection, with respect to a triggered
7 SPIKE increase described in subsection (b)(1) of an
8 applicable drug of a manufacturer, is—

9 “(A) all of the information described in
10 paragraph (2);

11 “(B) all of the information and supporting
12 documentation described in paragraph (3), as
13 applicable to the increase and drug; and

14 “(C) a certification described in paragraph
15 (4).

16 “(2) REQUIRED INFORMATION.—For purposes
17 of paragraph (1), the information described in this
18 paragraph is the following:

19 “(A) The individual factors that have con-
20 tributed to the increase in the wholesale acqui-
21 sition cost.

22 “(B) An explanation of the role of each
23 factor in contributing to such increase.

24 “(3) INFORMATION AS APPLICABLE.—For pur-
25 poses of paragraph (1), the information and sup-

1 porting documentation described in this paragraph is
2 the following:

3 “(A) Total expenditures of the manufac-
4 turer on—

5 “(i) materials and manufacturing for
6 such drug;

7 “(ii) acquiring patents and licensing
8 for each drug of the manufacturer; and

9 “(iii) costs to purchase or acquire the
10 drug from another company, if applicable.

11 “(B) The percentage of total expenditures
12 of the manufacturer on research and develop-
13 ment for such drug that was derived from Fed-
14 eral funds.

15 “(C) The total expenditures of the manu-
16 facturer on research and development for such
17 drug.

18 “(D) The total revenue and net profit gen-
19 erated from the applicable drug for each cal-
20 endar year since drug approval.

21 “(E) The total costs associated with mar-
22 keting and advertising for the applicable drug.

23 “(F) Additional information specific to the
24 manufacturer of the applicable drug, such as—

1 “(i) the total revenue and net profit of
2 the manufacturer for the period of such in-
3 crease, as determined by the Secretary;

4 “(ii) metrics used to determine execu-
5 tive compensation;

6 “(iii) total expenditures on—

7 “(I) drug research and develop-
8 ment; or

9 “(II) clinical trials on drugs that
10 failed to receive approval by the Food
11 and Drug Administration; and

12 “(iv) any additional information re-
13 lated to drug pricing decisions of the man-
14 ufacturer.

15 “(G) Any other relevant information and
16 supporting documentation necessary to justify
17 the triggering SPIKE increase.

18 “(H) Any other relevant information and
19 supporting documentation, as specified by the
20 Secretary.

21 “(4) CERTIFICATION.—For purposes of para-
22 graph (1), the certification described in this para-
23 graph is a certification, that all such information
24 and documentation is accurate and complete, by one
25 of the following:

1 “(A) The chief executive officer of the
2 manufacturer.

3 “(B) The chief financial officer of the
4 manufacturer.

5 “(C) An individual who has delegated au-
6 thority to sign for, and who reports directly to,
7 such chief executive officer or chief financial of-
8 ficer.

9 “(d) TIMING.—

10 “(1) NOTIFICATION.—Not later than 60 days
11 after the date on which the Secretary makes the de-
12 termination that there is a triggering SPIKE in-
13 crease with respect to an applicable drug, the Sec-
14 retary shall notify the manufacturer of the applica-
15 ble drug of such determination.

16 “(2) SUBMISSION OF JUSTIFICATION.—Not
17 later than 90 days after the date on which a manu-
18 facturer receives a notification under paragraph (1),
19 subject to subsection (b)(3), the manufacturer shall
20 submit to the Secretary the justification required
21 under subsection (a), including a summary of such
22 justification, in a form and manner specified by the
23 Secretary. In specifying such form, with respect to
24 the summary required under the previous sentence,
25 the Secretary shall provide that such summary shall

1 be in an easily understandable format, as specified
2 by the Secretary, and shall permit the manufacturer
3 to exclude proprietary information from such sum-
4 mary.

5 “(3) POSTING ON INTERNET WEBSITE.—Not
6 later than 30 days after receiving the complete jus-
7 tification under paragraph (2), the Secretary shall
8 post on the Internet website of the Centers for Medi-
9 care & Medicaid Services the summary included for
10 such justification.

11 “(e) PENALTIES.—

12 “(1) FAILURE TO SUBMIT TIMELY JUSTIFICA-
13 TION.—If the Secretary determines that a manufac-
14 turer has failed to submit a justification as required
15 under this section, including in accordance with the
16 timing and form required, with respect to an appli-
17 cable drug, the Secretary shall apply a civil mone-
18 tary penalty in an amount of \$10,000 for each day
19 the manufacturer has failed to submit such justifica-
20 tion as so required.

21 “(2) FALSE INFORMATION.—Any manufacturer
22 that submits a justification under this section that
23 knowingly provides false information in such jus-
24 tification is subject to a civil monetary penalty in an

1 amount not to exceed \$100,000 for each item of
2 false information.

3 “(3) APPLICATION OF PROCEDURES.—The pro-
4 visions of section 1128A (other than subsections (a)
5 and (b)) shall apply to a civil monetary penalty
6 under this subsection in the same manner as such
7 provisions apply to a penalty or proceeding under
8 section 1128A(a). Civil monetary penalties imposed
9 under this subsection are in addition to other pen-
10 alties as may be prescribed by law.

11 “(f) DEFINITIONS.—In this section:

12 “(1) APPLICABLE DRUG.—

13 “(A) IN GENERAL.—Subject to paragraph
14 (2), the term ‘applicable drug’ means, with re-
15 spect to a lookback period described in para-
16 graph (2), a covered outpatient drug (as de-
17 fined in paragraph (2) of section 1927(k), with-
18 out application of paragraph (3) of such sec-
19 tion) that is covered under title XVIII and is
20 not a low cost drug.

21 “(B) EXCLUSION OF LOW COST DRUGS.—

22 For purposes of subparagraph (A)(iii), not later
23 than January 1, 2021, the Secretary shall
24 specify a threshold (such as a cost or spending
25 threshold) for identifying (and shall identify)

1 low cost drugs to be excluded from the defini-
2 tion of the term ‘applicable drug’, such as a
3 drug that has a wholesale acquisition cost of
4 less than \$10 per unit or less than \$100 in av-
5 erage estimated expenditures under title XVIII
6 per individual per year or per user of such drug
7 per year. For purposes of this section, a drug
8 shall not be considered specified as a low cost
9 drug for a lookback period described in para-
10 graph (2) with respect to a year unless such
11 drug is identified as being below the specified
12 threshold for the entirety of the lookback pe-
13 riod.

14 “(2) MANUFACTURER.—The term ‘manufac-
15 turer’ has the meaning given that term in section
16 1847A(c)(6)(A).

17 “(3) WHOLESALE ACQUISITION COST.—The
18 term ‘wholesale acquisition cost’ has the meaning
19 given that term in section 1847A(c)(6)(B).”.

○