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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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Stopping the Pharmaceutical Industry from Keeping drugs Expensive Act" or the "SPIKE Act".

SEC. 2. DRUG MANUFACTURER PRICE TRANSPARENCY.

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

"SEC. 1128L. DRUG MANUFACTURER PRICE TRANSPARENCY.

"(a) IN GENERAL.—With respect to each year, beginning with 2021, the Secretary shall, at least once during such year, determine if there is a triggered SPIKE increase (in accordance with subsection (b)) with respect to an applicable drug (as defined in subsection (f)(1)). If the Secretary determines, with respect to a year, there is such an increase with respect to an applicable drug, the manufacturer of the applicable drug shall submit to the Secretary the justification described in subsection (c), subject to subsection (b)(3), for each such triggered SPIKE increase in accordance with the timing described in subsection (d).

"(b) TRIGGERED SPIKE INCREASE.—

"(1) IN GENERAL.—A triggered SPIKE increase occurs, with respect to an applicable drug and year (beginning with 2021), in any of the following cases:

"(A) If there is a 10 percent (or $10,000) increase with respect to the wholesale acquisition cost (or alternative cost measure specified

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

''(B) If there is a 25 percent (or $25,000) increase with respect to the wholesale acquisition cost (or such alternative cost measure) of such drug during any 36-month period beginning and ending within such respective lookback period.

''(C) In the case of such a drug that is first covered under title XVIII with respect to such year, if the estimated cost or spending under such title per individual or per user of such drug (as estimated by the Secretary) for such year (or per course of treatment, as defined by the Secretary) is at least $26,000.

''(2) ALTERNATIVE TO WAC.—The Secretary may, for purposes of making determinations under paragraph (1), in addition to using the wholesale acquisition cost for an applicable drug, use alternative cost measures of such drug.

''(3) EXCEPTION.—A justification under subsection (c) shall not be required for a triggered

SPIKE increase described in paragraph (1) of an applicable drug of a manufacturer if there is any portion of the lookback period described in the respective subparagraph of such paragraph for such increase that is included within the lookback period for another triggered SPIKE increase (or combination of such increases) for which a justification is made under this section for such drug by such manufacturer.

''(4) UNIT DETERMINATION.—For purposes of determining the wholesale acquisition cost in carrying out this section, the Secretary shall determine a unit (such as a unit size) to apply.

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

''(A) alternative percentages, dollar amounts, and lookback periods that, if applied under paragraph (1), would be projected to increase the number of applicable drugs for which a triggered SPIKE increase would occur for such year; and

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

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

''(c) JUSTIFICATION DESCRIBED.—

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

''(A) all of the information described in paragraph (2);

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

''(C) a certification described in paragraph (4).

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

''(A) The individual factors that have contributed to the increase in the wholesale acquisition cost.

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

''(3) INFORMATION AS APPLICABLE.—For purposes of paragraph (1), the information and sup-

porting documentation described in this paragraph is the following:

"(A) Total expenditures of the manufacturer on—

"(i) materials and manufacturing for such drug;

"(ii) acquiring patents and licensing for each drug of the manufacturer; and

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

"(B) The percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds.

"(C) The total expenditures of the manufacturer on research and development for such drug.

"(D) The total revenue and net profit generated from the applicable drug for each calendar year since drug approval.

"(E) The total costs associated with marketing and advertising for the applicable drug.

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

''(i) the total revenue and net profit of the manufacturer for the period of such increase, as determined by the Secretary;

''(ii) metrics used to determine executive compensation;

''(iii) total expenditures on—

''(I) drug research and development; or

''(II) clinical trials on drugs that failed to receive approval by the Food and Drug Administration; and

''(iv) any additional information related to drug pricing decisions of the manufacturer.

''(G) Any other relevant information and supporting documentation necessary to justify the triggering SPIKE increase.

''(H) Any other relevant information and supporting documentation, as specified by the Secretary.

''(4) CERTIFICATION.—For purposes of paragraph (1), the certification described in this paragraph is a certification, that all such information and documentation is accurate and complete, by one of the following:

''(A) The chief executive officer of the manufacturer.

''(B) The chief financial officer of the manufacturer.

''(C) An individual who has delegated authority to sign for, and who reports directly to, such chief executive officer or chief financial officer.

''(d) TIMING.—

''(1) NOTIFICATION.—Not later than 60 days after the date on which the Secretary makes the determination that there is a triggering SPIKE increase with respect to an applicable drug, the Secretary shall notify the manufacturer of the applicable drug of such determination.

''(2) SUBMISSION OF JUSTIFICATION.—Not later than 90 days after the date on which a manufacturer receives a notification under paragraph (1), subject to subsection (b)(3), the manufacturer shall submit to the Secretary the justification required under subsection (a), including a summary of such justification, in a form and manner specified by the Secretary. In specifying such form, with respect to the summary required under the previous sentence, the Secretary shall provide that such summary shall

be in an easily understandable format, as specified by the Secretary, and shall permit the manufacturer to exclude proprietary information from such summary.

''(3) POSTING ON INTERNET WEBSITE.—Not later than 30 days after receiving the complete justification under paragraph (2), the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services the summary included for such justification.

''(e) PENALTIES.—

''(1) FAILURE TO SUBMIT TIMELY JUSTIFICATION.—If the Secretary determines that a manufacturer has failed to submit a justification as required under this section, including in accordance with the timing and form required, with respect to an applicable drug, the Secretary shall apply a civil monetary penalty in an amount of $10,000 for each day the manufacturer has failed to submit such justification as so required.

''(2) FALSE INFORMATION.—Any manufacturer that submits a justification under this section that knowingly provides false information in such justification is subject to a civil monetary penalty in an

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

''(3) APPLICATION OF PROCEDURES.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). Civil monetary penalties imposed under this subsection are in addition to other penalties as may be prescribed by law.

''(f) DEFINITIONS.—In this section:

''(1) APPLICABLE DRUG.—

''(A) IN GENERAL.—Subject to paragraph (2), the term 'applicable drug' means, with respect to a lookback period described in paragraph (2), a covered outpatient drug (as defined in paragraph (2) of section 1927(k), without application of paragraph (3) of such section) that is covered under title XVIII and is not a low cost drug.

''(B) EXCLUSION OF LOW COST DRUGS.—For purposes of subparagraph (A)(iii), not later than January 1, 2021, the Secretary shall specify a threshold (such as a cost or spending threshold) for identifying (and shall identify)

low cost drugs to be excluded from the definition of the term 'applicable drug', such as a drug that has a wholesale acquisition cost of less than $10 per unit or less than $100 in average estimated expenditures under title XVIII per individual per year or per user of such drug per year. For purposes of this section, a drug shall not be considered specified as a low cost drug for a lookback period described in paragraph (2) with respect to a year unless such drug is identified as being below the specified threshold for the entirety of the lookback period.

''(2) MANUFACTURER.—The term 'manufacturer' has the meaning given that term in section 1847A(c)(6)(A).

''(3) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given that term in section 1847A(c)(6)(B).''.

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