116TH CONGRESS
1ST SESSION

S. 2051

To amend XVIII of the Social Security Act to require certain manufacturers to report drug pricing information with respect to drugs under the Medicare program.

IN THE SENATE OF THE UNITED STATES

JUNE 28 (legislative day, JUNE 27), 2019

Mr. MENENDEZ (for himself and Mr. YOUNG) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend XVIII of the Social Security Act to require certain manufacturers to report drug pricing information with respect to drugs under the Medicare program.

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 ''Strengthening Average Sales Price Reporting Act of 2019''.

SEC. 2. REQUIRING CERTAIN MANUFACTURERS TO REPORT DRUG PRICING INFORMATION WITH RESPECT TO DRUGS UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—Section 1847A of the Social Security Act (42 U.S.C. 1395w–3a) is amended—

(1) in subsection (b)—

(A) in paragraph (2)(A), by inserting ''or subsection (f)(2), as applicable'' before the period at the end;

(B) in paragraph (3), in the matter preceding subparagraph (A), by inserting ''or subsection (f)(2), as applicable,'' before ''determined by''; and

(C) in paragraph (6)(A), in the matter preceding clause (i), by inserting ''or subsection (f)(2), as applicable,'' before ''determined by''; and

(2) in subsection (f)—

(A) by striking ''For requirements'' and inserting the following:

''(1) IN GENERAL.—For requirements''; and

(B) by adding at the end the following new paragraph:

''(2) MANUFACTURERS WITHOUT A REBATE AGREEMENT UNDER TITLE XIX.—

"(A) IN GENERAL.—In the case of a manufacturer of an applicable drug or biological that does not have a rebate agreement in effect under section 1927, for calendar quarters beginning on or after January 1, 2020, such manufacturer shall report to the Secretary the information described in subsection (b)(3)(A)(iii) of such section 1927 with respect to such applicable drug or biological in a time and manner specified by the Secretary.

"(B) DEFINITION OF APPLICABLE DRUG OR BIOLOGICAL.—In this paragraph, the term 'applicable drug or biological' means—

"(i) a drug or biological described in—

"(I) subparagraph (C), (E), or (G) of section 1842(o)(1); or

"(II) clause (ii) or (iii) of section 1881(b)(14)(B); and

"(ii) an item for which payment is established under this section.

"(C) AUDIT.—Information reported under subparagraph (A) is subject to audit by the Inspector General of the Department of Health and Human Services.

''(D) VERIFICATION.—The Secretary may survey wholesalers and manufacturers that directly distribute an applicable drug or biological, when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of such a drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(E) CONFIDENTIALITY.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers

under this paragraph (other than the wholesale acquisition cost for purposes of carrying out this section) is confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for an applicable drug or biological by such manufacturer or wholesaler, except—

''(i) as the Secretary determines to be necessary to carry out this section (including the determination and implementation of the payment amount), or to carry out section 1847B;

''(ii) to permit the Comptroller General to review the information provided; and

''(iii) to permit the Director of the Congressional Budget Office to review the information provided.''.

(b) ENFORCEMENT.—Section 1847A such Act (42 U.S.C. 1395w–3a) is further amended—

(1) in subsection (d)(4)—

(A) in subparagraph (A), by striking ''IN GENERAL'' and inserting ''MISREPRESENTATION'';

(B) in subparagraph (B), by striking ''subparagraph (B)'' and inserting ''subparagraph (A), (B), or (C)'';

(C) by redesignating subparagraph (B) as subparagraph (D); and

(D) by inserting after subparagraph (A) the following new subparagraphs:

''(B) FAILURE TO PROVIDE TIMELY INFORMATION.—If the Secretary determines that a manufacturer described in subsection (f)(2) has failed to report on information described in section 1927(b)(3)(A)(iii) with respect to an applicable drug or biological in accordance with such subsection, the Secretary shall apply a civil money penalty in an amount of $10,000 for each day the manufacturer has failed to report such information and such amount shall be paid to the Treasury.

''(C) FALSE INFORMATION.—Any manufacturer required to submit information under subsection (f)(2) that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money pen-

alties are in addition to other penalties as may be prescribed by law.''; and

(2) in subsection (c)(6)(A), by striking the period at the end and inserting ``, except that, for purposes of subsection (f)(2), the Secretary may, if the Secretary determines appropriate, exclude repackagers of an applicable drug or biological from such term.''.

(c) REPORT.—Not later than January 1, 2021, the Inspector General of the Department of Health and Human Services shall assess and submit to Congress a report on the accuracy of average sales price information submitted by manufacturers under section 1847A of the Social Security Act (42 U.S.C. 1395w–3a). Such report shall include any recommendations on how to improve the accuracy of such information.

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