H. R. 2064

To amend title XI of the Social Security Act to require manufacturers of certain drugs, devices, biologicals, and medical supplies to report on product samples provided to certain health care providers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 3, 2019

Ms. JUDY CHU of California (for herself and Mr. NUNES) 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 require manufacturers of certain drugs, devices, biologicals, and medical supplies to report on product samples provided to certain health care providers, and for other purposes.

Be it enacted by the Senate and House of Representa-

tives of the United States of America in Congress assembled,
SECTION 1. REQUIREMENT FOR MANUFACTURERS OF CERTAIN DRUGS, DEVICES, BIOLOGICALS, AND MEDICAL SUPPLIES TO REPORT ON PRODUCT SAMPLES PROVIDED TO CERTAIN HEALTH CARE PROVIDERS.

(a) In General.—Section 1128G(a) of the Social Security Act (42 U.S.C. 1320a–7h(a)) is amended by adding at the end the following new paragraph:

"(3) CERTAIN PRODUCT SAMPLES.—

"(A) In General.—In addition to the requirements under paragraphs (1)(A) and (2), on the 90th day of each calendar year (beginning with 2023), any applicable manufacturer that provides a payment or other transfer of value that is a product sample described in subparagraph (B) to any covered recipient (or to an entity or individual at the request of, or designated on behalf of, such a covered recipient) shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information with respect to the preceding calendar year:

"(i) The total quantity of all such payments or other transfers of value provided to covered recipients."
“(ii) The total value of all such payments or other transfers of value provided to covered recipients.

“(iii) If applicable, information described in clauses (vii) and (viii) of paragraph (1)(A) with respect to such a payment or other transfer of value.

“(B) PRODUCT SAMPLE DESCRIBED.—For purposes of subparagraph (A), a product sample described in this subparagraph is a product sample that is not intended to be sold and is intended for patient use.”.

(b) PUBLIC AVAILABILITY OF INFORMATION.—Section 1128G(e)(1)(C) of the Social Security Act (42 U.S.C. 1320a–7h(e)(1)(C)) is amended—

(1) in clause (ii)—

(A) by striking “(ii) contains” and inserting “(ii)(I) with respect to information that is not information submitted under paragraph (3) of subsection (a), contains”;

(B) by striking “, as applicable;” and inserting “, as applicable; and”; and

(C) by adding at the end the following new subclause:
“(II) with respect to information submitted under paragraph (3) of subsection (a), contains information that is presented by the name of the applicable manufacturer, the total amount of all payments or other transfers of value described in such paragraph provided to covered recipients, the total value of all such payments or other transfers of value provided to covered recipients, and the name of the covered drug, device, biological, or medical supply, as applicable;”;

(2) in clause (viii), by striking “, and” at the end and inserting a semicolon;

(3) in clause (ix), by striking the period at the end and inserting “; and”; and

(4) by adding at the end the following new clause:

“(x) in the case of information submitted under paragraph (3) of subsection (a), lists such information separately from the other information submitted under subsection (a) and presents such information by the name of the applicable manufacturer, the total quantity of all payments
or other transfers of value described in such paragraph provided to covered recipients, the total value of all such payments or other transfers of value provided to covered recipients, and the name of the covered drug, device, biological, or medical supply, as applicable.”.

(c) Conforming Amendment.—Section 1128G(e)(10)(B)(ii) of the Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)(ii)) is amended by striking “Product samples” and inserting “Except for purposes of paragraph (3) of subsection (a), product samples”.

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