

116TH CONGRESS  
1ST SESSION

# 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.

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## 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

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## 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.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. REQUIREMENT FOR MANUFACTURERS OF CER-**  
2 **TAIN DRUGS, DEVICES, BIOLOGICALS, AND**  
3 **MEDICAL SUPPLIES TO REPORT ON PROD-**  
4 **UCT SAMPLES PROVIDED TO CERTAIN**  
5 **HEALTH CARE PROVIDERS.**

6 (a) IN GENERAL.—Section 1128G(a) of the Social  
7 Security Act (42 U.S.C. 1320a–7h(a)) is amended by add-  
8 ing at the end the following new paragraph:

9 “(3) CERTAIN PRODUCT SAMPLES.—

10 “(A) IN GENERAL.—In addition to the re-  
11 quirements under paragraphs (1)(A) and (2),  
12 on the 90th day of each calendar year (begin-  
13 ning with 2023), any applicable manufacturer  
14 that provides a payment or other transfer of  
15 value that is a product sample described in sub-  
16 paragraph (B) to any covered recipient (or to  
17 an entity or individual at the request of, or des-  
18 ignated on behalf of, such a covered recipient)  
19 shall submit to the Secretary, in such electronic  
20 form as the Secretary shall require, the fol-  
21 lowing information with respect to the pre-  
22 ceding calendar year:

23 “(i) The total quantity of all such  
24 payments or other transfers of value pro-  
25 vided to covered recipients.

1 “(ii) The total value of all such pay-  
 2 ments or other transfers of value provided  
 3 to covered recipients.

4 “(iii) If applicable, information de-  
 5 scribed in clauses (vii) and (viii) of para-  
 6 graph (1)(A) with respect to such a pay-  
 7 ment or other transfer of value.

8 “(B) PRODUCT SAMPLE DESCRIBED.—For  
 9 purposes of subparagraph (A), a product sam-  
 10 ple described in this subparagraph is a product  
 11 sample that is not intended to be sold and is in-  
 12 tended for patient use.”.

13 (b) PUBLIC AVAILABILITY OF INFORMATION.—Sec-  
 14 tion 1128G(c)(1)(C) of the Social Security Act (42 U.S.C.  
 15 1320a–7h(c)(1)(C)) is amended—

16 (1) in clause (ii)—

17 (A) by striking “(ii) contains” and insert-  
 18 ing “(ii)(I) with respect to information that is  
 19 not information submitted under paragraph (3)  
 20 of subsection (a), contains”;

21 (B) by striking “, as applicable;” and in-  
 22 serting “, as applicable; and”; and

23 (C) by adding at the end the following new  
 24 subclause:

1 “(II) with respect to information sub-  
2 mitted under paragraph (3) of subsection  
3 (a), contains information that is presented  
4 by the name of the applicable manufac-  
5 turer, the total amount of all payments or  
6 other transfers of value described in such  
7 paragraph provided to covered recipients,  
8 the total value of all such payments or  
9 other transfers of value provided to covered  
10 recipients, and the name of the covered  
11 drug, device, biological, or medical supply,  
12 as applicable;”;

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

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

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

19 “(x) in the case of information sub-  
20 mitted under paragraph (3) of subsection  
21 (a), lists such information separately from  
22 the other information submitted under  
23 subsection (a) and presents such informa-  
24 tion by the name of the applicable manu-  
25 facturer, the total quantity of all payments

1 or other transfers of value described in  
2 such paragraph provided to covered recipi-  
3 ents, the total value of all such payments  
4 or other transfers of value provided to cov-  
5 ered recipients, and the name of the cov-  
6 ered drug, device, biological, or medical  
7 supply, as applicable.”.

8 (c) CONFORMING AMENDMENT.—Section  
9 1128G(e)(10)(B)(ii) of the Social Security Act (42 U.S.C.  
10 1320a–7h(e)(10)(B)(ii)) is amended by striking “Product  
11 samples” and inserting “Except for purposes of paragraph  
12 (3) of subsection (a), product samples”.

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