

114TH CONGRESS  
2D SESSION

# H. R. 5404

To amend the Federal Food, Drug, and Cosmetic Act to require physicians and physician's offices to be treated as covered device users required to report on certain adverse events involving medical devices, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 8, 2016

Mr. FITZPATRICK (for himself, Ms. SLAUGHTER, and Mr. ZINKE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require physicians and physician's offices to be treated as covered device users required to report on certain adverse events involving medical devices, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Device Guard-  
5 ians Act of 2016”.

1 **SEC. 2. REPORTING BY PHYSICIANS AND PHYSICIAN'S OF-**  
2 **FICES ON CERTAIN ADVERSE EVENTS IN-**  
3 **VOLVING MEDICAL DEVICES.**

4 (a) **EXTENDING REQUIREMENTS TO APPLY TO PHY-**  
5 **SICIANS AND PHYSICIAN'S OFFICES.**—Subparagraph (A)  
6 of section 519(b)(6) of the Federal Food, Drug, and Cos-  
7 metic Act (21 U.S.C. 360i(b)(6)) is amended to read as  
8 follows:

9 “(A) The term ‘covered device user’ means a  
10 hospital, ambulatory surgical facility, nursing home,  
11 outpatient treatment facility, physician, or physi-  
12 cian’s office. The Secretary may by regulation in-  
13 clude an outpatient diagnostic facility.”

14 (b) **CONFORMING AMENDMENTS.**—Section 519 of the  
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i)  
16 is amended—

17 (1) in subsection (b)—

18 (A) by striking “device user facility” each  
19 place it appears and inserting “covered device  
20 user”;

21 (B) by striking “the facility” each place it  
22 appears and inserting “the user”, except in the  
23 phrase “the facility, individual, or physician” in  
24 the matter following subparagraph (C) in para-  
25 graph (3);

1 (C) in paragraph (1)(D), by striking “that  
2 facility” and inserting “that user”;

3 (D) in paragraph (3)(B), by striking “such  
4 a facility” and inserting “such a user”; and

5 (E) in paragraph (5)—

6 (i) by striking “device user facilities”  
7 and inserting “covered device user”;

8 (ii) by striking “of user facilities” and  
9 inserting “of users”;

10 (iii) by striking “a user facility” and  
11 inserting “a user”; and

12 (2) in subsection (b)(3)—

13 (A) in subparagraph (A), by adding “or”  
14 at the end;

15 (B) in subparagraph (B), by striking “or”  
16 at the end;

17 (C) by striking subparagraph (C); and

18 (3) in subsection (e)(B)(ii), by striking “outside  
19 a device user facility” and inserting “by a person  
20 other than a covered device user (as defined in sub-  
21 section (b))”.

22 (c) APPLICABILITY.—The amendments made by this  
23 section apply beginning on the date that is 3 years after  
24 the date of enactment of this Act.

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