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115TH CONGRESS
1ST SESSION

H. R. 2163

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.

IN THE HOUSE OF REPRESENTATIVES

APRIL 26, 2017

Mr. FITZPATRICK (for himself, Ms. SLAUGHTER, and Ms. DELAURO) 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.

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 ''Medical Device Guardians Act''.

SEC. 2. REPORTING BY PHYSICIANS AND PHYSICIAN'S OFFICES ON CERTAIN ADVERSE EVENTS INVOLVING MEDICAL DEVICES.

(a) EXTENDING REQUIREMENTS TO APPLY TO PHYSICIANS AND PHYSICIAN'S OFFICES.—Subparagraph (A) of section 519(b)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(b)(6)) is amended to read as follows:

''(A) The term 'covered device user' means a hospital, ambulatory surgical facility, nursing home, outpatient treatment facility, physician, or physician's office. The Secretary may by regulation include an outpatient diagnostic facility.''.

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

(1) in subsection (b)—

(A) by striking ''device user facility'' each place it appears and inserting ''covered device user'';

(B) by striking ''the facility'' each place it appears and inserting ''the user'', except in the phrase ''the facility, individual, or physician'' in the matter following subparagraph (C) in paragraph (3);

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

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

(E) in paragraph (5)—

(i) by striking ''device user facilities'' and inserting ''covered device user'';

(ii) by striking ''of user facilities'' and inserting ''of users''; and

(iii) by striking ''a user facility'' and inserting ''a user'';

(2) in subsection (b)(3)—

(A) in subparagraph (A), by adding ''or'' at the end;

(B) in subparagraph (B), by striking ''or'' at the end; and

(C) by striking subparagraph (C); and

(3) in subsection (e)(1)(B)(ii), by striking ''outside a device user facility'' and inserting ''by a person other than a covered device user (as defined in subsection (b))''.

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

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