I

116TH CONGRESS
1ST SESSION

H. R. 2915

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

MAY 22, 2019

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

---

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 users'';

(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.

SEC. 3. ELECTRONIC SYSTEM TO FACILITATE REPORTING BY COVERED DEVICE USERS.

(a) IN GENERAL.—Section 519(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(b)), as amended by section 2, is further amended—

(1) by redesignating paragraph (6) as paragraph (7); and

(2) by inserting after paragraph (5) the following new paragraph:

''(6) The Secretary shall establish and operate an electronic reporting system to facilitate compliance with this subsection by covered device users who choose to use such system to submit reports pursuant to this subsection.''.

(b) COMMENCEMENT.—Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall commence operation of the electronic reporting system required by section 519(b)(6) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

SEC. 4. PUBLIC AVAILABILITY OF REPORTS.

Section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) is amended by adding at the end the following new subsection:

''(j) PUBLIC AVAILABILITY OF REPORTS.—

''(1) IN GENERAL.—Notwithstanding any exemption for withholding information under section 552 of title 5, United States Code, but subject to paragraph (2), the Secretary shall make reports submitted under this section publicly available on the website of the Department of Health and Human Services.

''(2) INDIVIDUALLY IDENTIFIABLE PATIENT INFORMATION.—Paragraph (1) does not require the Secretary to make publicly available any individually identifiable patient information.''.

○