

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. SCHA-KOWSKY) 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.

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”.

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 users”;

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

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

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; and

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

18 (3) in subsection (e)(1)(B)(ii), by striking “out-
19 side a device user facility” and inserting “by a per-
20 son other than a covered device user (as defined in
21 subsection (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.

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

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

6 (1) by redesignating paragraph (6) as para-
7 graph (7); and

8 (2) by inserting after paragraph (5) the fol-
9 lowing new paragraph:

10 “(6) The Secretary shall establish and operate
11 an electronic reporting system to facilitate compli-
12 ance with this subsection by covered device users
13 who choose to use such system to submit reports
14 pursuant to this subsection.”.

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

22 **SEC. 4. PUBLIC AVAILABILITY OF REPORTS.**

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

26 “(j) PUBLIC AVAILABILITY OF REPORTS.—

1 “(1) IN GENERAL.—Notwithstanding any ex-
2 emption for withholding information under section
3 552 of title 5, United States Code, but subject to
4 paragraph (2), the Secretary shall make reports sub-
5 mitted under this section publicly available on the
6 website of the Department of Health and Human
7 Services.

8 “(2) INDIVIDUALLY IDENTIFIABLE PATIENT IN-
9 FORMATION.—Paragraph (1) does not require the
10 Secretary to make publicly available any individually
11 identifiable patient information.”.

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