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115TH CONGRESS
1ST SESSION

H. R. 2118

To amend the Federal Food, Drug, and Cosmetic Act to require the registration of establishments that service devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 25, 2017

Mr. COSTELLO of Pennsylvania (for himself and Mr. PETERS) 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 the registration of establishments that service 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 Servicing Safety and Accountability Act''.

SEC. 2. REGISTRATION OF SERVICERS OF DEVICES.

(a) IN GENERAL.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended by adding at the end the following:

''(r) REGISTRATION OF SERVICING ESTABLISHMENTS; COMPLAINT HANDLING.—

''(1) IN GENERAL.—The Secretary shall, not later than 18 months after the date of the enactment of this subsection, issue final regulations requiring any person who owns or operates any establishment in any State engaged in the servicing of a device or devices, or is otherwise engaged in the servicing of a device or devices, to register with the Secretary. Such regulations shall—

''(A) specify the timing, format, and information to be submitted by any such person;

''(B) require that such a person establish a complaint handling system equivalent to a system meeting the requirements of section 820.198 of title 21, Code of Federal Regulations (or successor regulations); and

''(C) provide for an exemption from such registration that—

''(i) applies to servicing operations conducted by a device user facility (as defined in section 519(b)(6)), or a physician office operating in accordance with any applicable State or local laws; and

''(ii) does not apply to device servicing operations conducted by persons who contract with device user facilities or physician offices to service devices.

''(2) SERVICING DEFINED.—In this subsection, the term 'servicing' includes, with respect to a device, refurbishing, reconditioning, rebuilding, remarketing, repairing, or other servicing of the device by a person other than the manufacturer of the device.''.

(b) REPORTS BY SERVICERS.—

(1) IN GENERAL.—Section 519(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(a)) is amended—

(A) by striking ''manufacturer or importer'' each place it appears and inserting ''manufacturer, servicer, or importer'';

(B) by adding at the end the following:

''(9) In this subsection, the term 'servicer' means any person who is engaged in servicing (as such term is defined in subsection (r) of section 510)) and required to register with the Secretary under such subsection.''.

(2) REGULATIONS.—Not later than 18 months after the date of the enactment of this Act, the Sec-

retary of Health and Human Services shall issue final regulations implementing the amendments made by paragraph (1).

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