

.....
(Original Signature of Member)

115TH CONGRESS
1ST SESSION

H. R.

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

Mr. COSTELLO (for himself and Mr. PETERS) introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require the registration of establishments that service 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 Serv-
5 icing Safety and Accountability Act”.

1 **SEC. 2. REGISTRATION OF SERVICERS OF DEVICES.**

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

5 “(r) REGISTRATION OF SERVICING ESTABLISH-
6 MENTS; COMPLAINT HANDLING.—

7 “(1) IN GENERAL.—The Secretary shall, not
8 later than 18 months after the date of the enact-
9 ment of this subsection, issue final regulations re-
10 quiring any person who owns or operates any estab-
11 lishment in any State engaged in the servicing of a
12 device or devices, or is otherwise engaged in the
13 servicing of a device or devices, to register with the
14 Secretary. Such regulations shall—

15 “(A) specify the timing, format, and infor-
16 mation to be submitted by any such person;

17 “(B) require that such a person establish
18 a complaint handling system equivalent to a
19 system meeting the requirements of section
20 820.198 of title 21, Code of Federal Regula-
21 tions (or successor regulations); and

22 “(C) provide for an exemption from such
23 registration that—

24 “(i) applies to servicing operations
25 conducted by a device user facility (as de-
26 fined in section 519(b)(6)), or a physician

1 office operating in accordance with any ap-
2 plicable State or local laws; and

3 “(ii) does not apply to device servicing
4 operations conducted by persons who con-
5 tract with device user facilities or physician
6 offices to service devices.

7 “(2) SERVICING DEFINED.—In this subsection,
8 the term ‘servicing’ includes, with respect to a de-
9 vice, refurbishing, reconditioning, rebuilding, remar-
10 keting, repairing, or other servicing of the device by
11 a person other than the manufacturer of the de-
12 vice.”.

13 (b) REPORTS BY SERVICERS.—

14 (1) IN GENERAL.—Section 519(a) of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C.
16 360i(a)) is amended—

17 (A) by striking “manufacturer or im-
18 porter” each place it appears and inserting
19 “manufacturer, servicer, or importer”;

20 (B) by adding at the end the following:

21 “(9) In this subsection, the term ‘servicer’
22 means any person who is engaged in servicing (as
23 such term is defined in subsection (r) of section
24 510)) and required to register with the Secretary
25 under such subsection.”.

1 (2) REGULATIONS.—Not later than 18 months
2 after the date of the enactment of this Act, the Sec-
3 retary of Health and Human Services shall issue
4 final regulations implementing the amendments
5 made by paragraph (1).