

119TH CONGRESS
1ST SESSION

S. 3421

To improve medical device recall notifications by amending the Federal Food, Drug, and Cosmetic Act to establish an electronic format for device recall notifications, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 10, 2025

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To improve medical device recall notifications by amending the Federal Food, Drug, and Cosmetic Act to establish an electronic format for device recall notifications, 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 Recall
5 Improvement Act of 2025”.

1 **SEC. 2. REGULATION OF MEDICAL DEVICE RECALLS.**

2 Chapter V of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 351 et seq.), is amended by inserting after
4 section 518A of such Act the following:

5 **“SEC. 518B. ELECTRONIC NOTIFICATION FORMAT FOR DE-**
6 **VICE RECALLS.**

7 **“(a) ELECTRONIC NOTIFICATION FORMAT FOR DE-**
8 **VICE RECALLS.—**

9 **“(1) IN GENERAL.—**Not later than 2 years
10 after the date of enactment of the Medical Device
11 Recall Improvement Act of 2025, the Secretary shall
12 publish a form and manner for notifications of a re-
13 call.

14 **“(2) CONTENT.—**The form and manner pre-
15 scribed by the Secretary under paragraph (1)
16 shall—

17 **“(A) be electronic;**

18 **“(B) include mandatory data elements, in-**
19 **cluding—**

20 **“(i) the name of the manufacturer or**
21 **importer;**

22 **“(ii) the contact information and ad-**
23 **dress of the manufacturer or importer;**

24 **“(iii) the specific reason for the cor-**
25 **rection or removal from the market of the**
26 **device;**

1 “(iv) the specific device of the manu-
2 facturer or importer subject to such recall;

3 “(v) the unique device identifier of the
4 device, including, as applicable, the device
5 identifier and any production identifier;

6 “(vi) information for device user fa-
7 cilities and health professionals with re-
8 gard to the device and such recall; and

9 “(vii) information for patients with re-
10 gard to the device and such recall, includ-
11 ing—

12 “(I) the risk presented by the de-
13 vice; and

14 “(II) any action that may be
15 taken by, or on behalf of, such pa-
16 tients to eliminate or reduce such risk;
17 and

18 “(C) include optional data elements as the
19 Secretary determines to be appropriate.

20 “(b) NOTIFICATIONS.—

21 “(1) NOTIFICATIONS TO THE SECRETARY.—

22 “(A) IN GENERAL.—Beginning 180 days
23 after the Secretary establishes the form and
24 manner for recall notifications under subsection
25 (a), a manufacturer or importer of a device

1 shall submit notifications required under section
2 519(g) to the Secretary through the electronic
3 notification format established under subsection
4 (a).

5 “(B) REVIEW REQUIREMENT.—

6 “(i) INITIAL REVIEW.—Not later than
7 2 business days after receipt of a notifica-
8 tion described in subparagraph (A), the
9 Secretary shall conduct an initial review of
10 such notification.

11 “(ii) RESPONSE OF THE SEC-
12 RETARY.—Not later than 3 business days
13 after the completion of such review, the
14 Secretary shall inform the manufacturer or
15 importer of the information the Secretary
16 determines, through the initial review
17 under clause (i), should be shared with de-
18 vice user facilities and health professionals.

19 “(2) NOTIFICATIONS TO DEVICE USER FACILI-
20 TIES AND HEALTH PROFESSIONALS.—

21 “(A) INITIAL NOTIFICATIONS.—A manu-
22 facturer or importer shall submit notifications
23 to device user facilities and health professionals
24 through the electronic notification format estab-
25 lished under subsection (a) after an initial re-

1 view by the Secretary is completed under para-
2 graph (1)(B)(i).

3 “(B) SUBSEQUENT NOTIFICATIONS.—A
4 manufacturer or importer shall provide notifica-
5 tions in addition to those described in subpara-
6 graph (A), as necessary, to device user facilities
7 or health professionals through the electronic
8 notification format established under subsection
9 (a).

10 “(c) ELECTRONIC DATABASE.—The Secretary shall
11 maintain an electronic database that is publicly accessible,
12 downloadable, and populated with information regarding
13 device notifications made under this section.

14 “(d) DEFINITIONS.—In this section and in section
15 518C—

16 “(1) the term ‘device user facility’ has the
17 meaning given such term in section 519(b)(6); and

18 “(2) the term ‘recall’ has the meaning given
19 such term in section 518A.

20 “(e) AUTHORIZATION OF APPROPRIATIONS.—For
21 purposes of conducting activities under this section and
22 hiring personnel to conduct such activities, there is au-
23 thorized to be appropriated \$6,700,000 for fiscal year
24 2026, \$1,700,000 for fiscal year 2027, and \$1,000,000

1 for each of fiscal years 2028 through 2030, to remain
 2 available until expended, without fiscal year limitation.

3 **“SEC. 518C. PATIENT NOTIFICATION.**

4 “(a) IN GENERAL.—The Secretary shall require that
 5 any recall strategy under section 519(g) provides for no-
 6 tice to patients whom device user facilities and health pro-
 7 fessionals treated with the device.

8 “(b) COMPLIANCE.—In accordance with subsection
 9 (a), the Secretary shall require recall notifications sent
 10 from the manufacturer or importer of the device to—

11 “(1) include information for device user facili-
 12 ties and health professionals about the risks pre-
 13 sented by the device to patients whom device user
 14 facilities and health professionals treated with the
 15 device; and

16 “(2) instruct such device user facilities and
 17 health professionals to share information under
 18 paragraph (1) with patients whom device user facili-
 19 ties and health professionals treated with the device.

20 “(c) AFFECTED DEVICES.—Subsection (a) shall
 21 apply with respect to any class I or class II recall for a
 22 class II or class III device that is used outside of device
 23 user facilities and—

24 “(1) implanted in the human body;

25 “(2) life-sustaining;

1 “(3) life-supporting; or

2 “(4) used significantly in pediatric populations.

3 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
 4 tion shall be construed to require device user facilities or
 5 health professionals to provide patient information to the
 6 manufacturer or importer of the device.”.

7 **SEC. 3. PROHIBITED ACTS.**

8 Section 301 of the Federal Food, Drug, and Cosmetic
 9 Act (21 U.S.C. 331) is amended by adding at the end the
 10 following:

11 “(jjj) The refusal or failure to submit notifications
 12 in accordance with paragraphs (1) and (2) of section
 13 518B(b).

14 “(kkk) The refusal or failure to provide notice in ac-
 15 cordance with section 518C.”.

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