

119TH CONGRESS
1ST SESSION

H. R. 6117

To amend the Federal Food, Drug, and Cosmetic Act to authorize requiring the manufacturers of a covered device to disclose to a patient all patient-specific data that is recorded or transmitted by the device and accessible to the manufacturer, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 18, 2025

Ms. SHERRILL 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 authorize requiring the manufacturers of a covered device to disclose to a patient all patient-specific data that is recorded or transmitted by the device and accessible to the manufacturer, 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 “Patient Device Data
5 Access Act of 2025”.

1 **SEC. 2. SHARING OF PATIENT-SPECIFIC DATA BY DEVICE**
2 **MANUFACTURERS.**

3 (a) IN GENERAL.—Subchapter A of chapter V of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
5 et seq.) is amended by adding at the end the following:

6 **“SEC. 524C. SHARING OF PATIENT-SPECIFIC DATA BY DE-**
7 **VICE MANUFACTURERS.**

8 “(a) REQUIREMENT AUTHORIZED.—The Secretary
9 may require the manufacturer of a covered device, at the
10 request of a patient who is using or has used such covered
11 device, to disclose all patient-specific data that is—

12 “(1) recorded or transmitted by such device;

13 and

14 “(2) accessible to the manufacturer.

15 “(b) REGULATIONS.—

16 “(1) ISSUANCE.—Any requirement imposed on
17 manufacturers under subsection (a) shall be by regu-
18 lation.

19 “(2) APPLICABILITY TO ALL MANUFACTURERS
20 OF COVERED DEVICES.—Any requirement imposed
21 under subsection (a) shall be applicable with respect
22 to all manufacturers of covered devices.

23 “(3) CONSIDERATION.—In issuing any regula-
24 tion under paragraph (1), the Secretary shall take
25 into consideration the guidance issued in October
26 2017 by the Food and Drug Administration titled

1 ‘Manufacturers Sharing Patient-Specific Information
2 from Medical Devices with Patients Upon Request’.

3 “(4) CONTENTS.—If the Secretary issues regu-
4 lations under paragraph (1), the Secretary may in-
5 clude in such regulations provisions requiring the
6 manufacturer of a covered device to do the following:

7 “(A) At the request of a patient, disclose
8 patient-specific data referred to in subsection
9 (a), where possible—

10 “(i) in a format that is understand-
11 able to the patient; and

12 “(ii) to the extent practicable, in a
13 format preferred by the patient.

14 “(B) Publish on the public website of the
15 manufacturer of a covered device—

16 “(i) an indication that such device is
17 a covered device subject to regulation
18 under this section;

19 “(ii) what types of patient-specific
20 data, if any, are—

21 “(I) being recorded or trans-
22 mitted by the covered device; and

23 “(II) accessible to the manufac-
24 turer; and

1 “(iii) whether and how the manufac-
2 turer utilizes patient data, not including
3 any proprietary information of the manu-
4 facturer.

5 “(C) Make publicly available, by posting on
6 the manufacturer’s website, the method by
7 which patients who are using or have used the
8 covered device may request their own patient-
9 specific data described in subsection (a).

10 “(D) Notify, where possible, patients who
11 are using or have used the covered device about
12 how they can access patient-specific data de-
13 scribed in subsection (a).

14 “(E) Notify patients if their covered device
15 is subject to a recall, has a software update, or
16 has generated an error message.

17 “(c) EXCEPTIONS.—This section does not authorize
18 the Secretary to require the manufacturer of a covered de-
19 vice—

20 “(1) to disclose data that is—

21 “(A) recorded, transmitted, and retained in
22 a closed system; and

23 “(B) inaccessible to the manufacturer;

24 “(2) to redesign the covered device to enable
25 disclosure of patient-specific data; or

1 “(3) to disclose patient-specific data that is in-
2 accessible to the manufacturer.

3 “(d) DEFINITIONS.—In this section:

4 “(1) The term ‘covered device’ means any elec-
5 tronic device that is—

6 “(A) intended for use in the diagnosis,
7 cure, mitigation, treatment, or prevention of
8 disease;

9 “(B) implanted into a patient’s body;

10 “(C) used for the purposes of remote moni-
11 toring; and

12 “(D) capable of recording or transmitting
13 patient data.

14 “(2) The term ‘patient-specific data’—

15 “(A) means data unique to an individual
16 patient or unique to the patient’s treatment or
17 diagnosis that is recorded or transmitted by a
18 covered device;

19 “(B) includes data described in subpara-
20 graph (A) irrespective of whether such data, ab-
21 sent regulation under this section, would other-
22 wise be required by law to be disclosed to the
23 patient or their physician; and

24 “(C) shall include—

1 “(i) information recorded by a covered
2 device regarding usage, alarms, or outputs;
3 and

4 “(ii) pulse oximetry data, heart elec-
5 trical activity data, and data on rhythms
6 as monitored by a pace maker.

7 “(3) The term ‘inaccessible to the manufac-
8 turer’ means data that is not reasonably acces-
9 sible.”.

10 (b) CIVIL PENALTIES.—Section 303(f)(1)(A) of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 333(f)(1)(A)) is amended by inserting “, including any
13 such requirement under section 524C,” after “a require-
14 ment of this Act which relates to devices”.

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