

119TH CONGRESS
2D SESSION

S. 4519

To amend the Federal Food, Drug, and Cosmetic Act to expand the types of devices for which required labeling may be made available solely by electronic means, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 13, 2026

Mr. BANKS (for himself and Mr. HICKENLOOPER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to expand the types of devices for which required labeling may be made available solely by electronic means, 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 Elec-
5 tronic Labeling Act”.

1 **SEC. 2. ALLOWING REQUIRED LABELING OF DEVICES TO**
2 **BE MADE AVAILABLE SOLELY BY ELEC-**
3 **TRONIC MEANS.**

4 Section 502(f) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 352(f)) is amended to read as fol-
6 lows:

7 “(f)(1) Unless its labeling bears (A) adequate direc-
8 tions for use; and (B) such adequate warnings against use
9 in those pathological conditions or by children where its
10 use may be dangerous to health, or against unsafe dosage
11 or methods or duration of administration or application,
12 in such manner and form, as are necessary for the protec-
13 tion of users, except that where any requirement of clause
14 (A) of this subparagraph, as applied to any drug or device,
15 is not necessary for the protection of the public health,
16 the Secretary shall promulgate regulations exempting such
17 drug or device from such requirement.

18 “(2) Subject to subparagraph (3), required labeling
19 for devices (including in vitro diagnostic devices) may be
20 made available solely by electronic means, provided that—

21 “(A) such required labeling complies with all
22 applicable requirements of law and the manufacturer
23 provides intended users of such devices with easy
24 and user-friendly access to such labeling;

25 “(B) the manufacturer affords intended users
26 of such devices the opportunity to request, through

1 easily accessible mechanisms for making such re-
2 quest, the required labeling in paper form, and upon
3 such request, promptly provides the requested infor-
4 mation in paper form without additional cost; and

5 “(C) the label affixed to the device or its imme-
6 diate container includes all information in compli-
7 ance with this Act and the regulations thereunder or
8 any applicable order of the Secretary under subpara-
9 graph (3)(A).

10 “(3)(A) The Secretary may issue an order estab-
11 lishing requirements in addition to, or exceptions from, the
12 requirements under subparagraph (2) for the label affixed
13 to a device.

14 “(B) An order under clause (A) establishing a re-
15 quirement in addition to the requirements under subpara-
16 graph (2) may be issued if the Secretary determines
17 that—

18 “(i) such additional requirement is necessary to
19 ensure that the label of a device intended for use by
20 patients without provider supervision contains cer-
21 tain information or complies with certain conditions;
22 or

23 “(ii) making labeling available solely by elec-
24 tronic means would not be sufficient to provide a

1 reasonable assurance of the safety and effectiveness
2 of the device.

3 “(C) An order under clause (A) establishing an ex-
4 ception from the requirements under subparagraph (2)
5 shall contain a detailed description of which requirement
6 the exception applies to and the justification for the excep-
7 tion.

8 “(D) Notwithstanding subchapter II of chapter 5 of
9 title 5, United States Code, an order under this subpara-
10 graph shall be published in the Federal Register, following
11 publication of a proposed order in the Federal Register
12 and consideration of comments to a public docket.”.

13 **SEC. 3. REQUEST FOR INFORMATION AND PUBLIC COM-**
14 **MENT.**

15 Not later than 2 years after the date of enactment
16 of this Act, the Secretary of Health and Human Services,
17 acting through the Commissioner of Food and Drugs,
18 shall post a request for information including a public
19 docket in the Federal Register and on a publicly accessible
20 website of the Department of Health and Human Services
21 enabling stakeholders to submit comments on how to con-
22 tinue to optimize the format, accessibility, and usability
23 of electronic labeling of devices other than prescription de-
24 vices intended for use in health care facilities or by a
25 health care professional and in vitro diagnostic devices in-

- 1 tended for use by health care professionals or in blood es-
- 2 tablishments.

