

118TH CONGRESS
1ST SESSION

H. R. 1328

To amend the Federal Food, Drug, and Cosmetic Act to establish nonvisual accessibility standards for certain devices with digital interfaces, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 1, 2023

Ms. SCHAKOWSKY (for herself, Mr. TRONE, Mr. VEASEY, Mr. BISHOP of Georgia, Mr. PANETTA, Mr. SARBANES, Mr. POCAN, Mr. QUIGLEY, Mr. SMITH of Washington, Mr. RUPPERSBERGER, Ms. BUSH, Mr. SESSIONS, Mr. LARSON of Connecticut, Ms. LEE of California, Mr. GRIJALVA, Mr. CASTEN, Mr. GARCÍA of Illinois, Mr. RUTHERFORD, Mr. LYNCH, Ms. TITUS, Ms. BLUNT ROCHESTER, Mrs. CHERFILUS-McCORMICK, Mr. CONNOLLY, Mr. CASE, Mr. KEATING, Mr. FITZPATRICK, Mr. DAVIS of Illinois, Ms. TLAIB, Ms. CRAIG, Ms. SEWELL, Mrs. HAYES, Mr. KILDEE, and Ms. KUSTER) 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 establish nonvisual accessibility standards for certain devices with digital interfaces, 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 Non-
5 visual Accessibility Act of 2023”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) Rapid advances in digital technology have
4 led to increasingly complex user interfaces for every-
5 day products, such as life-sustaining medical devices
6 and technologies.

7 (2) Many of these new devices utilize displays
8 that can only be operated visually and require user
9 interaction with on-screen menus and other inter-
10 faces that are inaccessible to consumers who are
11 blind or have low-vision.

12 (3) Medical devices designed for use in the
13 home are being increasingly utilized to lessen the
14 cost of inpatient care for consumers.

15 (4) Devices such as blood pressure monitors,
16 sleep apnea machines, in-home chemotherapy treat-
17 ments, and many others generally lack nonvisual ac-
18 cessibility.

19 (5) If a medical device is not accessible in a
20 nonvisual manner, a blind or low-vision individual is
21 unable to use it privately, independently, and safely.

22 (6) Many technology companies have incor-
23 porated screen access technology functions, such as
24 text to speech software, into products developed and
25 sold by such companies.

1 (7) Screen access technology is not the only
2 mechanism by which medical devices can be made
3 accessible to blind or low-vision consumers.

4 (8) Devices that utilize these mechanisms will
5 be more user-friendly in general by including mul-
6 tiple methods to confirm readings and other data,
7 leading to less waste and fewer mistakes.

8 (9) Devices can be designed to work with non-
9 visual access technology used by individuals who are
10 blind or have low-vision at little or no extra cost as
11 long as such compatibility is taken into consider-
12 ation at the beginning of the design process.

13 (10) Consumers who are blind or have low-vi-
14 sion must be able to operate medical devices in an
15 equally effective and equally integrated manner and
16 with equivalent ease of use as consumers without
17 disabilities.

18 **SEC. 3. NONVISUAL ACCESSIBILITY STANDARDS FOR CER-**
19 **TAIN DEVICES.**

20 (a) IN GENERAL.—Section 501 of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 351) is amended by
22 adding at the end the following:

23 “(k)(1) Beginning on the effective date specified in
24 section 515D(d), if it is a covered device, unless the device
25 meets the nonvisual accessibility standard specified under

1 section 515D or the Secretary issues a waiver with respect
2 to the device under subparagraph (2).

3 “(2) The Secretary may waive the application of sub-
4 paragraph (1) with respect to a covered device if, based
5 on clear and convincing evidence (as determined by the
6 Secretary) provided by the manufacturer involved, the
7 Secretary determines that the application of such subpara-
8 graph to the device would result in a fundamental alter-
9 ation to the nature of the product or an undue hardship
10 for the manufacturer.

11 “(3) In this paragraph:

12 “(A) The term ‘covered device’ means a device
13 that—

14 “(i) is classified under section 513 into
15 class II or III;

16 “(ii) is cleared under section 510(k),
17 granted marketing authorization under section
18 513(f)(2), or approved under section 515 after
19 the effective date specified in section 515D(d);

20 “(iii) has a user interface; and

21 “(iv) is not intended solely for use by a
22 health care provider or in a setting outside the
23 home.

24 “(B) The term ‘fundamental alteration’ means
25 an alteration to the nature of a covered device that

1 would render it unusable or incapable of performing
2 an essential function.

3 “(C)(i) The term ‘undue hardship’ means an
4 action requiring significant difficulty or expense,
5 when considered in light of the factors set forth in
6 clause (ii).

7 “(ii) In determining whether application of this
8 subparagraph would impose an undue hardship on a
9 manufacturer of a covered device, factors to be con-
10 sidered may include—

11 “(I) the nature and cost of compliance
12 with the standard under section 515D; and

13 “(II) the overall financial resources of the
14 manufacturer of a covered device.

15 “(D) The term ‘user interface’ means a screen
16 or mobile application through which a human user
17 interacts or communicates with the device by
18 inputting or receiving information.”.

19 (b) RECOGNITION OF STANDARD.—The Federal
20 Food, Drug, and Cosmetic Act is amended by inserting
21 after section 515C (as added by Public Law 117–328) the
22 following:

1 **“SEC. 515D. NONVISUAL ACCESSIBILITY STANDARDS FOR**
2 **CERTAIN DEVICES.**

3 “(a) STANDARD.—The nonvisual accessibility stand-
4 ard specified in this section is, with respect to a user inter-
5 face of a device described in section 501(k), that the user
6 interface is as effective in allowing blind or low-vision indi-
7 viduals to access information, engage in interactions, and
8 enjoy services with the same privacy, independence, and
9 ease of use as the user interface of the device enables indi-
10 viduals who do not have low-vision or are not blind.

11 “(b) TRAINING.—The Secretary shall conduct train-
12 ing to educate manufacturers of a user interface of a de-
13 vice described in section 501(k) or of a device described
14 in such section on the standards developed under sub-
15 section (a) and how to comply with such standard.

16 “(c) STAKEHOLDERS.—In developing the standard
17 under subsection (a) and the training to be conducted
18 under subsection (b), the Secretary shall consult with—

19 “(1) the Architectural and Transportation Bar-
20 riers Compliance Board established under section
21 504 of the Rehabilitation Act of 1973; and

22 “(2) individuals who are blind or who have low-
23 vision.

24 “(d) REGULATIONS.—

25 “(1) IN GENERAL.—The Secretary shall, in con-
26 sultation with the Architectural and Transportation

1 Barriers Compliance Board referred to in subsection
2 (b)—

3 “(A) not later than 1 year after the date
4 of the enactment of this section, issue proposed
5 regulations to implement the standard specified
6 under subsection (a); and

7 “(B) not later than 2 years after the date
8 of the enactment of this section, publish a final
9 rule with respect to such proposed regulations.

10 “(2) EFFECTIVE DATE.—The final rule pub-
11 lished under paragraph (1)(B) shall take effect on
12 the date that is 1 year after the date on which such
13 rule is published.

14 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
15 is authorized to be appropriated to carry out this section
16 \$1,500,000 the period of fiscal years 2024 through
17 2025.”.

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