

117TH CONGRESS
1ST SESSION

H. R. 4853

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

JULY 29, 2021

Ms. SCHAKOWSKY 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 2021”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) Rapid advances in digital technology have
9 led to increasingly complex user interfaces for every-

1 day products, such as life-sustaining medical devices
2 and technologies.

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

8 (3) Medical devices designed for use in the
9 home are being increasingly utilized to lessen the
10 cost of inpatient care for consumers.

11 (4) Devices such as blood pressure monitors,
12 sleep apnea machines, and in-home chemotherapy
13 treatments generally lack nonvisual accessibility.

14 (5) If a medical device is not accessible in a
15 nonvisual manner, a blind or low-vision individual
16 cannot use it safely.

17 (6) Many technology companies have incor-
18 porated screen access technology functions into
19 products developed and sold by such companies.

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

23 (8) Tactile markings, audible tones, or cost ef-
24 fective and widely available text-to-speech technology

1 may be sufficient to make such devices fully acces-
2 sible.

3 (9) Devices that utilize these mechanisms will
4 be more user-friendly in general by increasing meth-
5 ods for confirmation of readings, which has the po-
6 tential to lead to less waste and fewer mistakes.

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

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

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

19 (a) IN GENERAL.—Section 501 of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 351) is amended by
21 inserting after subsection (j) the following:

22 “(k) If it is a device classified under section 513 into
23 class II or III, unless the device meets the nonvisual acces-
24 sibility standards specified under section 515C.”.

1 (b) RECOGNITION OF STANDARD.—The Federal
2 Food, Drug, and Cosmetic Act is amended by inserting
3 after section 515B (21 U.S.C. 360e–3) the following:

4 **“SEC. 515C. NONVISUAL ACCESSIBILITY STANDARDS FOR**
5 **CERTAIN DEVICES.**

6 “(a) STANDARD.—The nonvisual accessibility stand-
7 ard specified in this section is, with respect to a digital
8 interface of a device described in section 501(k), that the
9 digital interface allows for blind or low-vision individuals
10 to access the same information, engage in the same inter-
11 actions, and to enjoy the same services with the same pri-
12 vacy, independence, and ease of use offered to individuals
13 who do not have low-vision or are not blind.

14 “(b) TRAINING.—The Secretary shall, in consultation
15 with the Architectural and Transportation Barriers Com-
16 pliance Board (established under section 504 of the Reha-
17 bilitation Act of 1973), conduct training to educate manu-
18 facturers of a digital interface of a device described in sec-
19 tion 501(k) or of a device described in such section on
20 the standards developed under subsection (a).

21 “(c) REGULATIONS.—The Secretary shall, in con-
22 sultation with the Architectural and Transportation Bar-
23 riers Compliance Board—

24 “(1) not later than 1 year after the date of the
25 enactment of this section, issue proposed regulations

1 to implement the standard specified under sub-
2 section (a); and

3 “(2) not later than 2 years after the date of the
4 enactment of this section, publish a final rule with
5 respect to such proposed regulations.

6 “(d) EFFECTIVE DATE.—A final rule published
7 under subsection (c)(2) shall take effect 1 year after the
8 publication of such rule.

9 “(e) DIGITAL INTERFACE DEFINED.—In this section,
10 the term ‘digital interface’ means a means by which
11 human users interact or communicate with electronic de-
12 vices, including computerized devices.

13 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
14 is authorized to be appropriated to carry out this section
15 \$1,500,000 fiscal years 2023 through 2024.”.

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