118TH CONGRESS
2D SESSION

S. 3621

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 SENATE OF THE UNITED STATES

JANUARY 18, 2024

Ms. HASSAN (for herself and Mr. BRAUN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medical Device Nonvisual Accessibility Act of 2024''.

SEC. 2. FINDINGS.

Congress finds the following:

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

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

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

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

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

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

(6) Many technology companies have incorporated screen access technology functions, such as text to speech software, into products developed and sold by such companies.

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

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

(9) Devices can be designed to work with nonvisual access technology used by individuals who are blind or have low-vision, at little or no extra cost, as long as such compatibility is taken into consideration at the beginning of the design process.

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

SEC. 3. NONVISUAL ACCESSIBILITY STANDARDS FOR CERTAIN DEVICES.

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

''(k)(1) Beginning on the effective date specified in section 515D(d)(2), if it is a covered device, unless the device meets the nonvisual accessibility standard specified under section 515D or the Secretary issues a waiver with respect to the device under subparagraph (2).

''(2) The Secretary may waive the application of subparagraph (1) with respect to a covered device if, based on clear and convincing evidence (as determined by the Secretary) provided by the manufacturer involved, the Secretary determines that the application of such subparagraph to the device would result in a fundamental alteration to the nature of the product or an undue hardship for the manufacturer.

''(3) In this paragraph:

''(A) The term 'covered device' means a device that—

''(i) is classified under section 513 into class II or III;

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

''(iii) has a user interface; and

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

''(B) The term 'fundamental alteration' means an alteration to the nature of a covered device that

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

''(C)(i) The term 'undue hardship' means an action requiring significant difficulty or expense, when considered in light of the factors set forth in subclause (ii).

''(ii) In determining whether application of subparagraph (1) would impose an undue hardship on a manufacturer of a covered device, factors to be considered may include—

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

''(II) the overall financial resources of the manufacturer of a covered device.

''(D) The term 'user interface' means a screen or mobile application through which a human user interacts or communicates with the device by inputting or receiving information.''.

(b) RECOGNITION OF STANDARD.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 515C (21 U.S.C. 360e–4) the following:

''SEC. 515D. NONVISUAL ACCESSIBILITY STANDARDS FOR CERTAIN DEVICES.

''(a) STANDARD.—The nonvisual accessibility standard specified in this section is, with respect to a user inter-

face of a device described in section 501(k), that the user interface is as effective in allowing blind or low-vision individuals to access information, engage in interactions, and enjoy services with the same privacy, independence, and ease of use as the user interface of the device enables individuals who do not have low-vision or are not blind.

''(b) TRAINING.—The Secretary shall conduct training to educate manufacturers of a user interface of a device described in section 501(k) or of a device described in such section on the standards developed under subsection (a) and how to comply with such standard.

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

''(1) the Architectural and Transportation Barriers Compliance Board established under section 502 of the Rehabilitation Act of 1973; and

''(2) individuals who are blind or who have low-vision.

''(d) REGULATIONS.—

''(1) IN GENERAL.—The Secretary shall, in consultation with the Architectural and Transportation Barriers Compliance Board referred to in subsection (c)(1)—

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

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

"(2) EFFECTIVE DATE.—The final rule published under paragraph (1)(B) shall take effect on the date that is 1 year after the date on which such rule is published.".

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