



# Medical Device Nonvisual Accessibility Act

***Issue—Inaccessible digital interfaces prevent blind individuals from independently and safely operating medical devices that are essential to their daily healthcare needs.***

**Medical devices with a digital interface are becoming more prevalent and less accessible for blind Americans.** The rapid proliferation of advanced technology is undeniable. Most new models of medical devices, such as glucose and blood pressure monitors, along with the emergence of in-home devices that offer medical care options, such as chemotherapy treatments and dialysis, require consumers to interact with digital displays or other interfaces. This new technology is constantly being developed and deployed without nonvisual accessibility as an integral part of the design phase, which creates a modern-day barrier. The inaccessibility of these medical devices is not a mere inconvenience; when accessibility for blind consumers is omitted from the medical technology landscape, the health, safety, and independence of blind Americans are in imminent danger.

**Telehealth currently makes up 20 percent of all medical visits, and more healthcare providers are looking to expand telemedicine services.**<sup>1</sup> The National Center for Health Statistics also reported in 2021 that 37 percent of all adults used telehealth.<sup>2</sup> Unfortunately, these visits assume that a person has easy access to accessible medical devices to take their own vital signs. As a result of inaccessibility, blind and low-vision Americans are at a distinct disadvantage when it comes to receiving the same virtual healthcare as their sighted counterparts.

**Nonvisual access is achievable, as demonstrated by several mainstream products.** Apple has incorporated VoiceOver (a screen reading function) into all of its products, making iPhones, Macbooks and Mac desktops, and iPads fully accessible to blind people right out of the box. Virtually all ATMs manufactured in the United States are accessible, and every polling place is required to have a nonvisually accessible voting machine. Frequently, a simple audio output or tactile feature can make a product accessible at little to no additional cost for manufacturers.

**Current disability laws are not able to keep up with advancements due to the expeditious evolution of medical technology and its incorporation into medical devices.** Although the Americans with Disabilities Act and other laws require physical accessibility for people with disabilities (e.g., wheelchair ramps, Braille in public buildings), no laws protect a blind consumer's right to access medical devices. The National Council on Disability concluded that accessibility standards lag behind the rapid pace of technology, which can interfere with technology access.<sup>3</sup> This trend of inaccessibility will continue if accessibility solutions are ignored. Only a fraction of medical device manufacturers have incorporated nonvisual access standards into their product design, while others continue to resist these solutions.

## ***Solution—Medical Device Nonvisual Accessibility Act:***

**Calls on the Food and Drug Administration (FDA) to promulgate nonvisual accessibility regulations for Class II and Class III medical devices.** The FDA will consult with stakeholders with disabilities and manufacturers and issue a notice of proposed rulemaking no later than twelve months after the date of enactment of the act. No later than twenty-four months after the date of enactment of the act, the FDA will publish the final rule including the nonvisual accessibility requirements.

**Requires manufacturers of Class II and Class III medical devices to make their products nonvisually accessible.** Manufacturers will have twelve months following the publication of the final rule to ensure that all the Class II and Class III medical devices they produce are nonvisually accessible.

**Authorizes the FDA to enforce the nonvisual access requirements for Class II and Class III medical devices.** Any manufactured device found to be out of compliance, whether by a public complaint to the FDA or by an independent FDA investigation, will be considered an adulterated product under the Federal Food, Drug, and Cosmetic Act. Manufacturers may file for an exemption for one of two reasons: clear and convincing evidence that making the medical device nonvisually accessible would fundamentally alter the use of the product; or proof that modifying the medical device would create an undue burden for the company.

## **GOAL—END UNEQUAL ACCESS TO MEDICAL DEVICES FOR BLIND AMERICANS.**

### **Sponsor the Medical Device Nonvisual Accessibility Act.**

#### **For more information, contact:**

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<sup>1</sup> See Center for Connected Medicine, *Telehealth utilization settles in at 20% or less of medical appointments*, available at <https://connectedmed.com/resources/post-pandemic-telehealth-utilization-settles-in-at-20-or-less-of-medical-appointments/>

<sup>2</sup> See National Center for Health Statistics, *Telemedicine Used Among Adults: United States, 2021*. Available at <https://www.cdc.gov/nchs/products/databriefs/db445.htm>

<sup>3</sup> See NATIONAL COUNCIL ON DISABILITIES, *National Disability Policy Progress Report: Technology that enables access to the full opportunities of citizenship under the Constitution is a right* at 19 (October 7, 2016), available at <https://ncd.gov/progressreport/2016/progress-report-october-2016>