

S 3621

Medical Device Nonvisual Accessibility Act of 2024

Congress: 118 (2023–2025, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Jan 18, 2024

Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Jan 18, 2024)

Official Text: <https://www.congress.gov/bill/118th-congress/senate-bill/3621>

Sponsor

Name: Sen. Hassan, Margaret Wood [D-NH]

Party: Democratic • **State:** NH • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Braun, Mike [R-IN]	R · IN		Jan 18, 2024

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Jan 18, 2024

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
118 HR 1328	Related bill	Mar 10, 2023: Referred to the Subcommittee on Health.

Medical Device Nonvisual Accessibility Act of 2024

This bill requires certain medical devices with a digital interface to meet nonvisual accessibility standards established by the Food and Drug Administration (FDA).

Specifically, the FDA must establish regulations to require a Class II or Class III medical device with a digital interface to provide a blind or low-vision user access to the same services and information, and generally the same ease of use, as provided to a user who is not low-vision or blind. (The FDA classifies medical devices in three classes. Class I devices are low-risk, Class II devices are moderate-risk, and Class III devices are high-risk.)

A Class II or Class III medical device that does not meet the nonvisual accessibility standards established under this bill may not be sold. However, the FDA may waive the bill's requirements for a device upon a showing that applying the standards would fundamentally alter the nature of the device or create an undue hardship for the manufacturer. The bill also does not apply to devices that are intended solely for use by a health care provider or in a setting outside the home.

Actions Timeline

- **Jan 18, 2024:** Introduced in Senate
- **Jan 18, 2024:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.