S 3477

PREVENT Medical Device Shortages Act of 2022

Congress: 117 (2021–2023, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Jan 11, 2022
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 11, 2022)
Official Text: https://www.congress.gov/bill/117th-congress/senate-bill/3477

Sponsor

Name: Sen. Casey, Robert P., Jr. [D-PA]
Party: Democratic • **State:** PA • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Collins, Susan M. [R-ME]	R · ME		Jan 11, 2022

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Jan 11, 2022

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
117 S 3799	Related bill	**Mar 15, 2022:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
117 S 3834	Related bill	**Mar 14, 2022:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Jan 11, 2022)

Planning, Reporting, and Enabling Voluntary Expansion of Notifications Targeting Medical Device Shortages Act of 2022 or the PREVENT Medical Device Shortages Act of 2022

This bill expands existing requirements for manufacturers of certain medical devices to alert the Food and Drug Administration (FDA) of supply disruptions and addresses related issues.

Under this bill, a manufacturer of a medical device that is critical to public health during a declared public health emergency must notify the FDA as soon as practicable of any circumstance that is likely to lead to a meaningful disruption to the supply of the device in the United States. Currently, the manufacturer is only required to notify the FDA of supply disruptions stemming from manufacturing issues.

The bill also authorizes the FDA to receive notifications from manufacturers of medical devices that are critical to public health about manufacturing issues that are likely to lead to a meaningful disruption to the U.S. supply of the device.

Each manufacturer of a medical device that is critical to the public health must develop and implement a redundancy risk management plan in each manufacturing facility for the device. Such a plan shall be subject to FDA inspection.

Actions Timeline

- **Jan 11, 2022:** Introduced in Senate
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