S 1101

MEDTECH Act

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Apr 27, 2015
Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 409.
Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 409. (Apr 4, 2016)
Official Text: https://www.congress.gov/bill/114th-congress/senate-bill/1101

Sponsor

Name: Sen. Bennet, Michael F. [D-CO]
Party: Democratic • **State:** CO • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Hatch, Orrin G. [R-UT]	R · UT		May 14, 2015

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Apr 4, 2016

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Apr 4, 2016)

Medical Electronic Data Technology Enhancement for Consumers' Health Act or the MEDTECH Act

(Sec. 2) This bill amends the Federal Food, Drug, and Cosmetic Act to exempt certain software from requirements for medical devices. The exemption applies to:

- administrative software used in health care facilities;
- software for maintaining or encouraging a healthy lifestyle unrelated to medical care;
- electronic patient records that are part of certified health information technology;
- software for transferring, storing, converting, or displaying medical information; and
- software that provides medical recommendations and the basis for those recommendations to health care professionals.

Software remains subject to regulation as a medical device if: (1) the software acquires, processes, analyzes, or interprets medical information; or (2) the Food and Drug Administration (FDA) identifies use of the software as reasonably likely to have serious adverse health consequences.

When assessing a medical device that includes a software function exempted from medical device requirements, the FDA may assess the impact of the software on the functioning of the device.

The Department of Health and Human Services must report on the health risks and benefits associated with exempted software.

The FDA must classify a medical device accessory based on its intended function, not based on the classification of the medical device with which it is used.

Actions Timeline

- **Apr 4, 2016:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Alexander with an amendment in the nature of a substitute and an amendment to the title. Without written report.
- **Apr 4, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 409.
- **Mar 9, 2016:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Apr 27, 2015:** Introduced in Senate
- **Apr 27, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.