113TH CONGRESS
2D SESSION

S. 2977

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of patient records and certain decision support software.

IN THE SENATE OF THE UNITED STATES

DECEMBER 4, 2014

Mr. BENNET (for himself and Mr. HATCH) 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 provide for the regulation of patient records and certain decision support software.

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

SEC. 2. REGULATION OF MEDICAL SOFTWARE.

Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

''(o) REGULATION OF PATIENT RECORDS AND CERTAIN DECISION SUPPORT SOFTWARE.—

''(1) IN GENERAL.—The following are not devices within the meaning of section 201(h):

''(A) Software that is intended solely for administrative or operational support of a health care facility or the processing and maintenance of financial records within a health care setting.

''(B) Products that are intended for use in activities unrelated to the clinical treatment of a disease or disorder and that are for the purpose of maintaining health and conditioning.

''(C) Electronic patient records created, stored, transferred, or reviewed by health care professionals or individuals working under supervision of such professionals that functionally represent a medical chart, including patient history records, but excluding diagnostic image data, provided that software designed for use in maintaining such patient records is validated prior to marketing, consistent with the stand-

ards for software validation relied upon by the Secretary in reviewing premarket submissions for devices.

"(D) Software that is intended to format, organize, or otherwise present clinical laboratory test report data prior to analysis, or to otherwise organize and present clinical laboratory test report findings or data and related patient education information.

"(E) Software that is intended to analyze and support the display or printing of patient or other medical information for the purpose of supporting or providing prevention, diagnostic, or treatment recommendations for health care professionals to assist in patient care, and that enables the health care professional to independently review the information on which such recommendations are based such that the intended use of the software is for the health care professional to not rely solely on any specific recommendations or results provided by such software to make a clinical diagnosis or treatment decision, except to the extent that any such software or substantially equivalent product—

"(i) is a component or accessory, or has the same function as a component or accessory, of a device subject to regulation under this Act; or

"(ii) as of the date of enactment of this subsection, is regulated or subject to regulation as a device classified as a class II or class III device or has the same function as a component or accessory of a device subject to regulation under this Act.

"(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as limiting the authority of the Secretary to exercise enforcement discretion as to any device subject to regulation under this Act.".

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