

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Electronic
5 Data Technology Enhancement for Consumers’ Health
6 Act” or the “MEDTECH Act”.

1 **SEC. 2. REGULATION OF MEDICAL SOFTWARE.**

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

5 “(o) REGULATION OF PATIENT RECORDS AND CER-
6 TAIN DECISION SUPPORT SOFTWARE.—

7 “(1) IN GENERAL.—The following are not de-
8 vices within the meaning of section 201(h):

9 “(A) Software that is intended solely for
10 administrative or operational support of a
11 health care facility or the processing and main-
12 tenance of financial records within a health care
13 setting.

14 “(B) Products that are intended for use in
15 activities unrelated to the clinical treatment of
16 a disease or disorder and that are for the pur-
17 pose of maintaining health and conditioning.

18 “(C) Electronic patient records created,
19 stored, transferred, or reviewed by health care
20 professionals or individuals working under su-
21 pervision of such professionals that functionally
22 represent a medical chart, including patient his-
23 tory records, but excluding diagnostic image
24 data, provided that software designed for use in
25 maintaining such patient records is validated
26 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 labora-
tory test report data prior to analysis, or to
otherwise organize and present clinical labora-
tory test report findings or data and related pa-
tient 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 inde-
pendently review the information on which such
recommendations are based such that the in-
tended 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 treat-
ment decision, except to the extent that any
such software or substantially equivalent prod-
uct—

1 “(i) is a component or accessory, or
2 has the same function as a component or
3 accessory, of a device subject to regulation
4 under this Act; or

5 “(ii) as of the date of enactment of
6 this subsection, is regulated or subject to
7 regulation as a device classified as a class
8 II or class III device or has the same func-
9 tion as a component or accessory of a de-
10 vice subject to regulation under this Act.

11 “(2) RULE OF CONSTRUCTION.—Nothing in
12 this subsection shall be construed as limiting the au-
13 thority of the Secretary to exercise enforcement dis-
14 cretion as to any device subject to regulation under
15 this Act.”.

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