

114TH CONGRESS  
1ST SESSION

# S. 1101

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

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IN THE SENATE OF THE UNITED STATES

APRIL 27, 2015

Mr. BENNET 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.

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”.

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

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

1       “(o) REGULATION OF MEDICAL AND CERTAIN DECI-  
2       SION SUPPORT SOFTWARE.—

3               “(1) EXCLUSIONS FROM THE CATEGORY OF DE-  
4       VICES.—The term ‘device’, as defined in section  
5       201(h), shall not include the following:

6               “(A) Software that is intended for admin-  
7       istrative and operational support of a health  
8       care facility or the processing and maintenance  
9       of financial records, appointment schedules,  
10      business analytics, communication, information  
11      about patient populations, and laboratory  
12      workflow processes.

13              “(B) Software that is intended for the pur-  
14      pose of maintaining or encouraging a healthy  
15      lifestyle and are unrelated to the diagnosis,  
16      cure, mitigation, prevention, or treatment of a  
17      disease or disorder.

18              “(C) Except for software intended to inter-  
19      pret or analyze medical image data for the pur-  
20      pose of diagnosis, cure, mitigation, prevention,  
21      or treatment of a disease or condition, elec-  
22      tronic patient records, to the extent that such  
23      records are intended to transfer, store, convert  
24      formats, or display the equivalent of a paper

1 medical chart, which may include patient his-  
2 tory records if—

3 “(i) such records were created, stored,  
4 transferred, or reviewed by health care  
5 professionals, or by individuals working  
6 under supervision of such professionals;  
7 and

8 “(ii) such records are part of health  
9 information technology that is certified  
10 under section 3001(c)(5) of the Public  
11 Health Service Act as being in compliance  
12 with applicable certification criteria adopt-  
13 ed under subtitle A of title XXX of such  
14 Act.

15 “(D) Except for software intended to inter-  
16 pret or analyze clinical laboratory test data,  
17 software that is intended to transfer, store, con-  
18 vert formats, or display—

19 “(i) clinical laboratory test report  
20 data, results, or findings prior to analysis  
21 or interpretation by a health care profes-  
22 sional; or

23 “(ii) clinical laboratory test report  
24 data, results, or findings, or related patient

1 education information with respect to such  
2 data, to a patient.

3 “(E) Except for a device accessory and  
4 software that is intended to acquire, process, or  
5 analyze a medical image or a signal from an in  
6 vitro diagnostic device or a pattern or signal  
7 from a signal acquisition system, software  
8 that—

9 “(i) is intended to display, analyze, or  
10 print medical information about a patient  
11 or other medical information (such as peer-  
12 reviewed clinical studies and clinical prac-  
13 tice guidelines);

14 “(ii) is intended to support or provide  
15 recommendations to a health care profes-  
16 sional about prevention, diagnosis, or  
17 treatment; and

18 “(iii) enables the health care profes-  
19 sional to independently review the basis for  
20 each recommendation that the software  
21 presents such that it is not the intent that  
22 the health care professional rely solely on  
23 any specific recommendations or results  
24 provided by such software to make a clin-  
25 ical diagnosis or treatment decision.

1           “(2) MULTIPLE FUNCTIONALITY PRODUCTS.—

2           In the case of a product with multiple functionality  
3           that contains a software function that is excluded  
4           under paragraph (1) from the definition of a device  
5           under section 201(h) and a function that meets the  
6           definition of device under section 201(h), the Sec-  
7           retary shall not regulate the excluded software func-  
8           tion of the product as a device, but the Secretary  
9           may assess such software function for the purpose of  
10          determining the safety and effectiveness of the de-  
11          vice function of the product.

12          “(3) RULES OF CONSTRUCTION.—Nothing in  
13          this subsection shall be construed as limiting the au-  
14          thority of the Secretary to—

15                 “(A) exercise enforcement discretion as to  
16                 any device subject to regulation under this Act;  
17                 or

18                 “(B) regulate software devices used in the  
19                 manufacture and transfusion of blood and blood  
20                 components to assist in the prevention of dis-  
21                 ease in humans.”.

22 **SEC. 3. QUALITY AND STANDARDS.**

23          The Secretary of Health and Human Services shall  
24          ensure that software described in subparagraphs (C), (D),  
25          and (E) of subsection (o)(1) of section 520 of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C. 360j) (as  
2 amended by section 3) is consistent with appropriate qual-  
3 ity principles and standards for software development and  
4 validation.

5 **SEC. 4. CLASSIFICATION OF ACCESSORIES.**

6 Subsection 513(b) of the Federal Food, Drug, and  
7 Cosmetic Act (21 U.S.C. 360c(b)) is amended by adding  
8 at the end the following:

9 “(9) The Secretary shall classify an accessory  
10 under this section based on the intended use of the  
11 accessory, notwithstanding the classification of any  
12 other device with which such accessory is intended to  
13 be used.”.

14 **SEC. 5. CONFORMING AMENDMENT.**

15 Section 201(h) of the Federal Food, Drug, and Cos-  
16 metic Act (21 U.S.C. 321(h)) is amended by adding at  
17 the end “The term ‘device’ does not include medical and  
18 decision support software described in section 520(o).”.

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