

**Calendar No. 409**114<sup>TH</sup> CONGRESS  
2<sup>D</sup> 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 (for himself and Mr. HATCH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 4, 2016

Reported by Mr. ALEXANDER, with an amendment and an amendment to the title

[Strike out all after the enacting clause and insert the part printed in *italic*]

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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,*

1 **SECTION 1. SHORT TITLE.**

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

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

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

9 “(o) **REGULATION OF MEDICAL AND CERTAIN DECI-**  
10 **SION SUPPORT SOFTWARE.—**

11 “(1) **EXCLUSIONS FROM THE CATEGORY OF DE-**  
12 **VICES.—**The term ‘device’, as defined in section  
13 201(h), shall not include the following:

14 “(A) Software that is intended for admin-  
15 istrative and operational support of a health  
16 care facility or the processing and maintenance  
17 of financial records, appointment schedules,  
18 business analytics, communication, information  
19 about patient populations, and laboratory  
20 workflow processes.

21 “(B) Software that is intended for the pur-  
22 pose of maintaining or encouraging a healthy  
23 lifestyle and are unrelated to the diagnosis,  
24 cure, mitigation, prevention, or treatment of a  
25 disease or disorder.

1           “(C) Except for software intended to inter-  
2           pret or analyze medical image data for the pur-  
3           pose of diagnosis, cure, mitigation, prevention,  
4           or treatment of a disease or condition, elec-  
5           tronic patient records, to the extent that such  
6           records are intended to transfer, store, convert  
7           formats, or display the equivalent of a paper  
8           medical chart, which may include patient his-  
9           tory records if—

10                   “(i) such records were created, stored,  
11                   transferred, or reviewed by health care  
12                   professionals, or by individuals working  
13                   under supervision of such professionals;  
14                   and

15                   “(ii) such records are part of health  
16                   information technology that is certified  
17                   under section 3001(e)(5) of the Public  
18                   Health Service Act as being in compliance  
19                   with applicable certification criteria adopt-  
20                   ed under subtitle A of title XXX of such  
21                   Act.

22           “(D) Except for software intended to inter-  
23           pret or analyze clinical laboratory test data,  
24           software that is intended to transfer, store, con-  
25           vert formats, or display—

1           “(i) clinical laboratory test report  
2           data, results, or findings prior to analysis  
3           or interpretation by a health care profes-  
4           sional; or

5           “(ii) clinical laboratory test report  
6           data, results, or findings, or related patient  
7           education information with respect to such  
8           data, to a patient.

9           “(E) Except for a device accessory and  
10          software that is intended to acquire, process, or  
11          analyze a medical image or a signal from an in  
12          vitro diagnostic device or a pattern or signal  
13          from a signal acquisition system; software  
14          that—

15               “(i) is intended to display, analyze, or  
16               print medical information about a patient  
17               or other medical information (such as peer-  
18               reviewed clinical studies and clinical prac-  
19               tice guidelines);

20               “(ii) is intended to support or provide  
21               recommendations to a health care profes-  
22               sional about prevention, diagnosis, or  
23               treatment; and

24               “(iii) enables the health care profes-  
25               sional to independently review the basis for

1           each recommendation that the software  
2           presents such that it is not the intent that  
3           the health care professional rely solely on  
4           any specific recommendations or results  
5           provided by such software to make a clinical  
6           diagnosis or treatment decision.

7           “(2) MULTIPLE FUNCTIONALITY PRODUCTS.—

8           In the case of a product with multiple functionality  
9           that contains a software function that is excluded  
10          under paragraph (1) from the definition of a device  
11          under section 201(h) and a function that meets the  
12          definition of device under section 201(h), the Secretary  
13          shall not regulate the excluded software function  
14          of the product as a device, but the Secretary  
15          may assess such software function for the purpose of  
16          determining the safety and effectiveness of the device  
17          function of the product.

18          “(3) RULES OF CONSTRUCTION.—Nothing in  
19          this subsection shall be construed as limiting the authority  
20          of the Secretary to—

21                  “(A) exercise enforcement discretion as to  
22                  any device subject to regulation under this Act;  
23                  or

24                  “(B) regulate software devices used in the  
25                  manufacture and transfusion of blood and blood

1 components to assist in the prevention of dis-  
2 ease in humans.”.

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

4 The Secretary of Health and Human Services shall  
5 ensure that software described in subparagraphs (C), (D),  
6 and (E) of subsection (o)(1) of section 520 of the Federal  
7 Food, Drug, and Cosmetic Act (21 U.S.C. 360j) (as  
8 amended by section 3) is consistent with appropriate qual-  
9 ity principles and standards for software development and  
10 validation.

11 **SEC. 4. CLASSIFICATION OF ACCESSORIES.**

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

15 “(9) The Secretary shall classify an accessory  
16 under this section based on the intended use of the  
17 accessory, notwithstanding the classification of any  
18 other device with which such accessory is intended to  
19 be used.”.

20 **SEC. 5. CONFORMING AMENDMENT.**

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

1 **SECTION 1. SHORT TITLE.**

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

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

6 *(a) IN GENERAL.—Section 520 of the Federal Food,*  
 7 *Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by*  
 8 *adding at the end the following:*

9 *“(o) REGULATION OF MEDICAL AND CERTAIN DECI-*  
 10 *SIONS SUPPORT SOFTWARE.—*

11 *“(1) REGULATION OF CERTAIN SOFTWARE.—The*  
 12 *term ‘device’, as defined in section 201(h), shall not*  
 13 *include a software function that is intended—*

14 *“(A) for administrative support of a health*  
 15 *care facility, including the processing and main-*  
 16 *tenance of financial records, claims or billing in-*  
 17 *formation, appointment schedules, business ana-*  
 18 *lytics, information about patient populations,*  
 19 *admissions, practice and inventory management,*  
 20 *analysis of historical claims data to predict fu-*  
 21 *ture utilization or cost-effectiveness, determina-*  
 22 *tion of health benefit eligibility, population*  
 23 *health management, and laboratory workflow;*

24 *“(B) for maintaining or encouraging a*  
 25 *healthy lifestyle and is unrelated to the diag-*

1            *nosis, cure, mitigation, prevention, or treatment*  
2            *of a disease or condition;*

3            *“(C) to serve as electronic patient records,*  
4            *including patient-provided information, to the*  
5            *extent that such records are intended to transfer,*  
6            *store, convert formats, or display the equivalent*  
7            *of a paper medical chart, so long as—*

8            *“(i) such records were created, stored,*  
9            *transferred, or reviewed by health care pro-*  
10           *essionals, or by individuals working under*  
11           *supervision of such professionals;*

12           *“(ii) such records are part of health in-*  
13           *formation technology that is certified under*  
14           *section 3001(c)(5) of the Public Health*  
15           *Service Act as being in compliance with ap-*  
16           *plicable certification criteria adopted under*  
17           *subtitle A of title XXX of such Act; and*

18           *“(iii) such function is not intended to*  
19           *interpret or analyze patient records, includ-*  
20           *ing medical image data, for the purpose of*  
21           *the diagnosis, cure, mitigation, prevention,*  
22           *or treatment of a disease or condition;*

23           *“(D) for transferring, storing, converting*  
24           *formats, or displaying clinical laboratory test or*  
25           *other device data and results, findings by a*



1           *health care professional with respect to such data*  
2           *and results, general information about such find-*  
3           *ings, and general background information about*  
4           *such laboratory test or other device, unless such*  
5           *function is intended to interpret or analyze clin-*  
6           *ical laboratory test or other device data, results,*  
7           *and findings; or*

8           “(E) for the purpose of—

9           “(i) displaying, analyzing, or printing  
10           *medical information about a patient or*  
11           *other medical information (such as peer-re-*  
12           *viewed clinical studies and clinical practice*  
13           *guidelines);*

14           “(ii) supporting or providing rec-  
15           *ommendations to a health care professional*  
16           *about prevention, diagnosis, or treatment of*  
17           *a disease or condition; and*

18           “(iii) enabling such health care profes-  
19           *sional to independently review the basis for*  
20           *such recommendations that such software*  
21           *presents so that it is not the intent that*  
22           *such health care professional rely primarily*  
23           *on any of such recommendations to make a*  
24           *clinical diagnosis or treatment decision re-*  
25           *garding an individual patient;*

1           *unless a function described in subparagraph (E)*  
2           *is intended to acquire, process, or analyze a*  
3           *medical image or a signal from an in vitro diag-*  
4           *nostic device or a pattern or signal from a signal*  
5           *acquisition system.*

6           “(2) *MULTIPLE FUNCTIONALITY PRODUCTS.—In*  
7           *the case of a product with multiple functions that*  
8           *contains—*

9                   “(A) *at least one software function that*  
10                   *meets the criteria under paragraph (1) or that*  
11                   *otherwise does not meet the definition of ‘device’*  
12                   *under section 201(h); and*

13                   “(B) *at least one function that does not*  
14                   *meet the criteria under paragraph (1) and that*  
15                   *otherwise meets the definition of a ‘device’ under*  
16                   *section 201(h),*

17           *the Secretary shall not regulate the software function*  
18           *of such product described in subparagraph (A) as a*  
19           *device. Notwithstanding the preceding sentence, when*  
20           *assessing the safety and effectiveness of the device*  
21           *function or functions of such product described in*  
22           *subparagraph (B), the Secretary may assess the im-*  
23           *portance that the software function or functions described*  
24           *in subparagraph (A) have on such device function or*  
25           *functions.*

1           “(3) *EXCEPTION.*—

2                   “(A) *IN GENERAL.*—*Notwithstanding para-*  
3 *graph (1), a software function shall not be ex-*  
4 *cluded from the definition of ‘device’ under sec-*  
5 *tion 201(h) if—*

6                           “(i) *the Secretary determines that the*  
7 *software function meets the criteria under*  
8 *subparagraph (C), (D), or (E) of paragraph*  
9 *(1);*

10                           “(ii) *the Secretary makes a finding*  
11 *that use of such software function would be*  
12 *reasonably likely to have serious adverse*  
13 *health consequences; and*

14                           “(iii) *the software function has been*  
15 *identified in a final order issued by the Sec-*  
16 *retary under subparagraph (B).*

17                   “(B) *PROCEDURES.*—*Subparagraph (A)*  
18 *shall apply only if the Secretary—*

19                           “(i) *publishes a notification and pro-*  
20 *posed order in the Federal Register;*

21                           “(ii) *includes in such notification the*  
22 *Secretary’s finding, including the rationale*  
23 *and identification of the evidence on which*  
24 *such finding was based, as described in sub-*  
25 *paragraph (A)(ii); and*

1           “(iii) provides for a period of not less  
2           than 30 calendar days for public comments  
3           before issuing a final order or withdrawing  
4           such proposed order.

5           “(C) CONSIDERATIONS.—In making a find-  
6           ing under subparagraph (A)(ii) with respect to  
7           a software function, the Secretary shall consider  
8           the following:

9           “(i) The likelihood and severity of pa-  
10          tient harm if the software function were to  
11          not perform as intended.

12          “(ii) The extent to which the software  
13          function is intended to support the clinical  
14          judgment of a health care professional.

15          “(iii) Whether there is a reasonable op-  
16          portunity for a health care professional to  
17          review the basis of the information or treat-  
18          ment recommendation provided by the soft-  
19          ware function.

20          “(iv) The intended user and user envi-  
21          ronment, such as whether a health care pro-  
22          fessional will use a software function of a  
23          type described in subparagraph (E) of  
24          paragraph (1).

1           “(4) *RULES OF CONSTRUCTION.*—*Nothing in this*  
 2           *subsection shall be construed as limiting the authority*  
 3           *of the Secretary to—*

4                   “(A) *exercise enforcement discretion as to*  
 5                   *any device subject to regulation under this Act;*

6                   “(B) *regulate software used in the manufac-*  
 7                   *ture and transfusion of blood and blood compo-*  
 8                   *nents to assist in the prevention of disease in hu-*  
 9                   *mans; or*

10                   “(C) *regulate software as a device under*  
 11                   *this Act if such software meets the criteria in*  
 12                   *section 513(a)(1)(C).”.*

13           (b) *REPORT.*—*The Secretary of Health and Human*  
 14           *Services (referred to in this subsection as the “Secretary”),*  
 15           *after consultation with agencies and offices of the Depart-*  
 16           *ment of Health and Human Services involved in health in-*  
 17           *formation technology, shall publish a report, every 2 years*  
 18           *beginning after the date of enactment of this Act, that—*

19                   (1) *includes input from outside experts, such as*  
 20                   *representatives of patients, consumers, health care*  
 21                   *providers, startup companies, health plans or other*  
 22                   *third-party payers, venture capital investors, infor-*  
 23                   *mation technology vendors, health information tech-*  
 24                   *nology vendors, small businesses, purchasers, employ-*

1        *ers, and other stakeholders with relevant expertise, as*  
2        *determined by the Secretary;*

3            *(2) examines information available to the Sec-*  
4        *retary on any risks and benefits to health associated*  
5        *with software functions described in section 520(o)(1)*  
6        *of the Federal Food, Drug, and Cosmetic Act (21*  
7        *U.S.C. 360j) (as amended by subsection (a) of this*  
8        *Act); and*

9            *(3) summarizes findings regarding the impact of*  
10       *such software functions on patient safety, including*  
11       *best practices to promote safety, education, and com-*  
12       *petency related to such functions.*

13        *(c) CLASSIFICATION OF ACCESSORIES.—Subsection*  
14       *513(b) of the Federal Food, Drug, and Cosmetic Act (21*  
15       *U.S.C. 360c(b)) is amended by adding at the end the fol-*  
16       *lowing:*

17            *“(9) The Secretary shall classify an accessory*  
18        *under this section based on the intended use of the ac-*  
19        *cessory, notwithstanding the classification of any*  
20        *other device with which such accessory is intended to*  
21        *be used.”.*

22        *(d) CONFORMING AMENDMENT.—Section 201(h) of the*  
23       *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))*  
24       *is amended by adding at the end the following: “The term*

- 1 *'device' does not include software functions excluded pursu-*
- 2 *ant to section 520(o).'*

Amend the title so as to read: “A bill to amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of patient records and certain decision support software.”.

**Calendar No. 409**

114<sup>TH</sup> CONGRESS  
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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.

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APRIL 4, 2016

Reported with an amendment and an amendment to the title