Calendar No. 409

114TH CONGRESS
2D 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.

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]

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 MEDICAL AND CERTAIN DECISION SUPPORT SOFTWARE.—

''(1) EXCLUSIONS FROM THE CATEGORY OF DEVICES.—The term 'device', as defined in section 201(h), shall not include the following:

''(A) Software that is intended for administrative and operational support of a health care facility or the processing and maintenance of financial records, appointment schedules, business analytics, communication, information about patient populations, and laboratory workflow processes.

''(B) Software that is intended for the purpose of maintaining or encouraging a healthy lifestyle and are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or disorder.

"(C) Except for software intended to interpret or analyze medical image data for the purpose of diagnosis, cure, mitigation, prevention, or treatment of a disease or condition, electronic patient records, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, which may include patient history records if—

"(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals; and

"(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act as being in compliance with applicable certification criteria adopted under subtitle A of title XXX of such Act.

"(D) Except for software intended to interpret or analyze clinical laboratory test data, software that is intended to transfer, store, convert formats, or display—

''(i) clinical laboratory test report data, results, or findings prior to analysis or interpretation by a health care professional; or

''(ii) clinical laboratory test report data, results, or findings, or related patient education information with respect to such data, to a patient.

''(E) Except for a device accessory and software that is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, software that—

''(i) is intended to display, analyze, or print medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

''(ii) is intended to support or provide recommendations to a health care professional about prevention, diagnosis, or treatment; and

''(iii) enables the health care professional to independently review the basis for

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

''(2) MULTIPLE FUNCTIONALITY PRODUCTS.—In the case of a product with multiple functionality that contains a software function that is excluded under paragraph (1) from the definition of a device under section 201(h) and a function that meets the definition of device under section 201(h), the Secretary shall not regulate the excluded software function of the product as a device, but the Secretary may assess such software function for the purpose of determining the safety and effectiveness of the device function of the product.

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

''(A) exercise enforcement discretion as to any device subject to regulation under this Act; or

''(B) regulate software devices used in the manufacture and transfusion of blood and blood

components to assist in the prevention of disease in humans.''.

SEC. 3. QUALITY AND STANDARDS.

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

SEC. 4. CLASSIFICATION OF ACCESSORIES.

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

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

SEC. 5. CONFORMING AMENDMENT.

Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended by adding at the end ''The term 'device' does not include medical and decision support software described in section 520(o).''.

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.

(a) IN GENERAL.—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 MEDICAL AND CERTAIN DECISIONS SUPPORT SOFTWARE.—

"(1) REGULATION OF CERTAIN SOFTWARE.—The term 'device', as defined in section 201(h), shall not include a software function that is intended—

"(A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

"(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diag-

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

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

"(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

"(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act as being in compliance with applicable certification criteria adopted under subtitle A of title XXX of such Act; and

"(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

"(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a

health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or

"(E) for the purpose of—

"(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

"(ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

"(iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient;

unless a function described in subparagraph (E) is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system.

"(2) MULTIPLE FUNCTIONALITY PRODUCTS.—In the case of a product with multiple functions that contains—

"(A) at least one software function that meets the criteria under paragraph (1) or that otherwise does not meet the definition of 'device' under section 201(h); and

"(B) at least one function that does not meet the criteria under paragraph (1) and that otherwise meets the definition of a 'device' under section 201(h),

the Secretary shall not regulate the software function of such product described in subparagraph (A) as a device. Notwithstanding the preceding sentence, when assessing the safety and effectiveness of the device function or functions of such product described in subparagraph (B), the Secretary may assess the impact that the software function or functions described in subparagraph (A) have on such device function or functions.

"(3) EXCEPTION.—

"(A) IN GENERAL.—Notwithstanding paragraph (1), a software function shall not be excluded from the definition of 'device' under section 201(h) if—

"(i) the Secretary determines that the software function meets the criteria under subparagraph (C), (D), or (E) of paragraph (1);

"(ii) the Secretary makes a finding that use of such software function would be reasonably likely to have serious adverse health consequences; and

"(iii) the software function has been identified in a final order issued by the Secretary under subparagraph (B).

"(B) PROCEDURES.—Subparagraph (A) shall apply only if the Secretary—

"(i) publishes a notification and proposed order in the Federal Register;

"(ii) includes in such notification the Secretary's finding, including the rationale and identification of the evidence on which such finding was based, as described in subparagraph (A)(ii); and

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

"(C) CONSIDERATIONS.—In making a finding under subparagraph (A)(ii) with respect to a software function, the Secretary shall consider the following:

"(i) The likelihood and severity of patient harm if the software function were to not perform as intended.

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

"(iii) Whether there is a reasonable opportunity for a health care professional to review the basis of the information or treatment recommendation provided by the software function.

"(iv) The intended user and user environment, such as whether a health care professional will use a software function of a type described in subparagraph (E) of paragraph (1).

"(4) RULES OF CONSTRUCTION.—Nothing in this subsection shall be construed as limiting the authority of the Secretary to—

"(A) exercise enforcement discretion as to any device subject to regulation under this Act;

"(B) regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or

"(C) regulate software as a device under this Act if such software meets the criteria in section 513(a)(1)(C).".

(b) REPORT.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary"), after consultation with agencies and offices of the Department of Health and Human Services involved in health information technology, shall publish a report, every 2 years beginning after the date of enactment of this Act, that—

(1) includes input from outside experts, such as representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employ-

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

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

(3) summarizes findings regarding the impact of such software functions on patient safety, including best practices to promote safety, education, and competency related to such functions.

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

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

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

'device' does not include software functions excluded pursuant 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.''.

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