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114TH CONGRESS
1ST SESSION

H. R. 2396

To amend the Federal Food, Drug, and Cosmetic Act with respect to the regulation of health software, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 18, 2015

Mrs. BLACKBURN (for herself and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the regulation of health software, and for other purposes.

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 ''Sensible Oversight for Technology which Advances Regulatory Efficiency Act'' or the ''SOFTWARE Act''.

SEC. 2. HEALTH SOFTWARE.

Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(ss)(1) The term 'health software' means software that does not, through use of an in vitro diagnostic device or signal acquisition system, acquire, process, or analyze an image or physiological signal, is not an accessory, is not an integral part of a device necessary to support the use of the device, is not used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans, and—

''(A) is intended for use for administrative or operational support or the processing and maintenance of financial records;

''(B) is intended for use in clinical, laboratory, or administrative workflow and related recordkeeping;

''(C)(i) is intended for use solely in the transfer, aggregation, conversion (in accordance with a present specification), storage, management, retrieval, or transmission of data or information;

''(ii) utilizes a connectivity software platform, electronic or electrical hardware, or a physical communications infrastructure; and

''(iii) is not intended for use—

''(I) in active patient monitoring; or

''(II) in controlling or altering the functions or parameters of a device that is connected to such software;

''(D) is intended for use to organize and present information for health or wellness education or for use in maintaining a healthy lifestyle, including medication adherence and health management tools;

''(E) is intended for use to analyze information to provide general health information that does not include patient-specific recommended options to consider in the prevention, diagnosis, treatment, cure, or mitigation of a particular disease or condition; or

''(F) is intended for use to analyze information to provide patient-specific recommended options to consider in the prevention, diagnosis, treatment, cure, or mitigation of a particular disease or condition.

''(2) The term 'accessory' means a product that—

''(A) is intended for use with one or more parent devices;

''(B) is intended to support, supplement, or augment the performance of one or more parent devices; and

''(C) shall be classified by the Secretary—

''(i) according to its intended use; and

''(ii) independently of any classification of any parent device with which it is used.''.

SEC. 3. APPLICABILITY AND INAPPLICABILITY OF REGULATION.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SEC. 524B. HEALTH SOFTWARE.

''(a) INAPPLICABILITY OF REGULATION TO HEALTH SOFTWARE.—Except as provided in subsection (b), health software shall not be subject to regulation under this Act.

''(b) EXCEPTION.—

''(1) IN GENERAL.—Subsection (a) shall not apply with respect to a software product—

''(A) of a type described in subparagraph (F) of section 201(ss)(1); and

''(B) that the Secretary determines poses a significant risk to patient safety.

''(2) CONSIDERATIONS.—In making a determination under subparagraph (B) of paragraph (1) with respect to a product to which such paragraph applies, the Secretary shall consider the following:

''(A) The likelihood and severity of patient harm if the product were to not perform as intended.

''(B) The extent to which the product is intended to support the clinical judgment of a medical professional.

''(C) Whether there is a reasonable opportunity for a medical professional to review the basis of the information or treatment recommendation provided by the product.

''(D) The intended user and user environment, such as whether a medical professional will use a software product of a type described in subparagraph (F) of section 201(ss)(1).

''(c) DELEGATION.—The Secretary shall delegate primary jurisdiction for regulating a software product determined under subsection (b) to be subject to regulation under this Act to the center at the Food and Drug Administration charged with regulating devices.

''(d) REGULATION OF SOFTWARE.—

''(1) IN GENERAL.—The Secretary shall review existing regulations and guidance regarding the regulation of software under this Act. The Secretary may implement a new framework for the regulation of software and shall, as appropriate, modify such

regulations and guidance or issue new regulations or guidance.

''(2) ISSUANCE BY ORDER.—Notwithstanding subchapter II of chapter 5 of title 5, United States Code, the Secretary may modify or issue regulations for the regulation of software under this Act by administrative order published in the Federal Register following the publication of a proposed order.

''(3) AREAS UNDER REVIEW.—The review of existing regulations and guidance under paragraph (1) may include review of the following areas:

''(A) Classification of software.

''(B) Standards for development of software.

''(C) Standards for validation and verification of software.

''(D) Review of software.

''(E) Modifications to software.

''(F) Manufacturing of software.

''(G) Quality systems for software.

''(H) Labeling requirements for software.

''(I) Postmarketing requirements for reporting of adverse events.

''(4) PROCESS FOR ISSUING PROPOSED REGULATIONS, ADMINISTRATIVE ORDER, AND GUID-

ANCE.—Not later than 18 months after the date of enactment of this section, the Secretary shall consult with external stakeholders (including patients, industry, health care providers, academia, and government) to gather input before issuing regulations, an administrative order, and guidance under this subsection.

''(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as providing the Secretary with the authority to regulate under this Act any health software product of the type described in subparagraph (F) of section 201(ss)(1) unless and until the Secretary has made a determination described in subsection (b)(1)(B) with respect to such product.''.

SEC. 4. EXCLUSION FROM DEFINITION OF DEVICE.

Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

(1) in subparagraph (2), by striking ''or'' after ''or other animals,'';

(2) in subparagraph (3), by striking ''and'' and inserting ''or''; and

(3) by inserting after subparagraph (3) the following:

''(4) is not health software (other than software determined to be a risk to patient safety under section 524B(b)), and''.

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