

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

A BILL

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

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 “Sensible Oversight for
5 Technology which Advances Regulatory Efficiency Act” or
6 the “SOFTWARE Act”.

7 **SEC. 2. HEALTH SOFTWARE.**

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

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

9 “(A) is intended for use for administrative
10 or operational support or the processing and
11 maintenance of financial records;

12 “(B) is intended for use in clinical, labora-
13 tory, or administrative workflow and related
14 recordkeeping;

15 “(C)(i) is intended for use solely in the
16 transfer, aggregation, conversion (in accordance
17 with a present specification), storage, manage-
18 ment, retrieval, or transmission of data or in-
19 formation;

20 “(ii) utilizes a connectivity software plat-
21 form, electronic or electrical hardware, or a
22 physical communications infrastructure; and

23 “(iii) is not intended for use—

24 “(I) in active patient monitoring; or

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

4 “(D) is intended for use to organize and
5 present information for health or wellness edu-
6 cation or for use in maintaining a healthy life-
7 style, including medication adherence and
8 health management tools;

9 “(E) is intended for use to analyze infor-
10 mation to provide general health information
11 that does not include patient-specific rec-
12 ommended options to consider in the preven-
13 tion, diagnosis, treatment, cure, or mitigation of
14 a particular disease or condition; or

15 “(F) is intended for use to analyze infor-
16 mation to provide patient-specific recommended
17 options to consider in the prevention, diagnosis,
18 treatment, cure, or mitigation of a particular
19 disease or condition.

20 “(2) The term ‘accessory’ means a product that—

21 “(A) is intended for use with one or more par-
22 ent devices;

23 “(B) is intended to support, supplement, or
24 augment the performance of one or more parent de-
25 vices; and

1 “(C) shall be classified by the Secretary—
2 “(i) according to its intended use; and
3 “(ii) independently of any classification of
4 any parent device with which it is used.”.

5 **SEC. 3. APPLICABILITY AND INAPPLICABILITY OF REGULA-**
6 **TION.**

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

10 **“SEC. 524B. HEALTH SOFTWARE.**

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

14 “(b) **EXCEPTION.**—

15 “(1) **IN GENERAL.**—Subsection (a) shall not
16 apply with respect to a software product—

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

19 “(B) that the Secretary determines poses a
20 significant risk to patient safety.

21 “(2) **CONSIDERATIONS.**—In making a deter-
22 mination under subparagraph (B) of paragraph (1)
23 with respect to a product to which such paragraph
24 applies, the Secretary shall consider the following:

1 “(A) The likelihood and severity of patient
2 harm if the product were to not perform as in-
3 tended.

4 “(B) The extent to which the product is
5 intended to support the clinical judgment of a
6 medical professional.

7 “(C) Whether there is a reasonable oppor-
8 tunity for a medical professional to review the
9 basis of the information or treatment rec-
10 ommendation provided by the product.

11 “(D) The intended user and user environ-
12 ment, such as whether a medical professional
13 will use a software product of a type described
14 in subparagraph (F) of section 201(ss)(1).

15 “(c) DELEGATION.—The Secretary shall delegate pri-
16 mary jurisdiction for regulating a software product deter-
17 mined under subsection (b) to be subject to regulation
18 under this Act to the center at the Food and Drug Admin-
19 istration charged with regulating devices.

20 “(d) REGULATION OF SOFTWARE.—

21 “(1) IN GENERAL.—The Secretary shall review
22 existing regulations and guidance regarding the reg-
23 ulation of software under this Act. The Secretary
24 may implement a new framework for the regulation
25 of software and shall, as appropriate, modify such

1 regulations and guidance or issue new regulations or
2 guidance.

3 “(2) ISSUANCE BY ORDER.—Notwithstanding
4 subchapter II of chapter 5 of title 5, United States
5 Code, the Secretary may modify or issue regulations
6 for the regulation of software under this Act by ad-
7 ministrative order published in the Federal Register
8 following the publication of a proposed order.

9 “(3) AREAS UNDER REVIEW.—The review of ex-
10 isting regulations and guidance under paragraph (1)
11 may include review of the following areas:

12 “(A) Classification of software.

13 “(B) Standards for development of soft-
14 ware.

15 “(C) Standards for validation and
16 verification of software.

17 “(D) Review of software.

18 “(E) Modifications to software.

19 “(F) Manufacturing of software.

20 “(G) Quality systems for software.

21 “(H) Labeling requirements for software.

22 “(I) Postmarketing requirements for re-
23 porting of adverse events.

24 “(4) PROCESS FOR ISSUING PROPOSED REGU-
25 LATIONS, ADMINISTRATIVE ORDER, AND GUID-

1 ANCE.—Not later than 18 months after the date of
2 enactment of this section, the Secretary shall consult
3 with external stakeholders (including patients, indus-
4 try, health care providers, academia, and govern-
5 ment) to gather input before issuing regulations, an
6 administrative order, and guidance under this sub-
7 section.

8 “(e) **RULE OF CONSTRUCTION.**—Nothing in this sec-
9 tion shall be construed as providing the Secretary with the
10 authority to regulate under this Act any health software
11 product of the type described in subparagraph (F) of sec-
12 tion 201(ss)(1) unless and until the Secretary has made
13 a determination described in subsection (b)(1)(B) with re-
14 spect to such product.”.

15 **SEC. 4. EXCLUSION FROM DEFINITION OF DEVICE.**

16 Section 201(h) of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 321) is amended—

18 (1) in subparagraph (2), by striking “or” after
19 “or other animals,”;

20 (2) in subparagraph (3), by striking “and” and
21 inserting “or”; and

22 (3) by inserting after subparagraph (3) the fol-
23 lowing:

1 “(4) is not health software (other than software
2 determined to be a risk to patient safety under sec-
3 tion 524B(b)), and”.

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