



(Original Signature of Member)

114TH CONGRESS
1ST SESSION

H. R. _____

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

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

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”.

1 **SEC. 2. HEALTH SOFTWARE.**

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

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

13 “(A) is intended for use for administrative
14 or operational support or the processing and
15 maintenance of financial records;

16 “(B) is intended for use in clinical, labora-
17 tory, or administrative workflow and related
18 recordkeeping;

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

24 “(ii) utilizes a connectivity software plat-
25 form, electronic or electrical hardware, or a
26 physical communications infrastructure; and

1 “(iii) is not intended for use—
2 “(I) in active patient monitoring; or
3 “(II) in controlling or altering the
4 functions or parameters of a device that is
5 connected to such software;
6 “(D) is intended for use to organize and
7 present information for health or wellness edu-
8 cation or for use in maintaining a healthy life-
9 style, including medication adherence and
10 health management tools;
11 “(E) is intended for use to analyze infor-
12 mation to provide general health information
13 that does not include patient-specific rec-
14 ommended options to consider in the preven-
15 tion, diagnosis, treatment, cure, or mitigation of
16 a particular disease or condition; or
17 “(F) is intended for use to analyze infor-
18 mation to provide patient-specific recommended
19 options to consider in the prevention, diagnosis,
20 treatment, cure, or mitigation of a particular
21 disease or condition.
22 “(2) The term ‘accessory’ means a product that—
23 “(A) is intended for use with one or more par-
24 ent devices;

1 “(B) is intended to support, supplement, or
2 augment the performance of one or more parent de-
3 vices; and

4 “(C) shall be classified by the Secretary—

5 “(i) according to its intended use; and

6 “(ii) independently of any classification of
7 any parent device with which it is used.”.

8 **SEC. 3. APPLICABILITY AND INAPPLICABILITY OF REGULA-**
9 **TION.**

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

13 **“SEC. 524B. HEALTH SOFTWARE.**

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

17 “(b) **EXCEPTION.**—

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

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

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

24 “(2) **CONSIDERATIONS.**—In making a deter-
25 mination under subparagraph (B) of paragraph (1)

1 with respect to a product to which such paragraph
2 applies, the Secretary shall consider the following:

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

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

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

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

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

22 “(d) REGULATION OF SOFTWARE.—

23 “(1) IN GENERAL.—The Secretary shall review
24 existing regulations and guidance regarding the reg-
25 ulation of software under this Act. The Secretary

1 may implement a new framework for the regulation
2 of software and shall, as appropriate, modify such
3 regulations and guidance or issue new regulations or
4 guidance.

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

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

14 “(A) Classification of software.

15 “(B) Standards for development of soft-
16 ware.

17 “(C) Standards for validation and
18 verification of software.

19 “(D) Review of software.

20 “(E) Modifications to software.

21 “(F) Manufacturing of software.

22 “(G) Quality systems for software.

23 “(H) Labeling requirements for software.

24 “(I) Postmarketing requirements for re-
25 porting of adverse events.

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“(4) PROCESS FOR ISSUING PROPOSED REGULATIONS, ADMINISTRATIVE ORDER, AND GUIDANCE.—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.

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“(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.”.

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

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

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

22 (2) in subparagraph (3), by striking “and” and
23 inserting “or”; and

24 (3) by inserting after subparagraph (3) the following:
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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”.