113TH CONGRESS
2D SESSION

S. 2007

To amend the Federal Food, Drug, and Cosmetic Act to provide for regulating clinical and health software, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 10, 2014

Mrs. FISCHER (for herself, Mr. KING, and Mr. RUBIO) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for regulating clinical and 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 ''Preventing Regulatory Overreach To Enhance Care Technology Act of 2014'' or the ''PROTECT Act of 2014''.

SEC. 2. FINDINGS; SENSE OF CONGRESS.

(a) FINDINGS.—Congress finds as follows:

(1) The mobile health and mobile application economy was created in the United States and is now being exported globally, with the market expected to exceed $26,000,000,000 by 2017.

(2) The United States mobile application economy is responsible for nearly 500,000 new jobs in the United States.

(3) Consumer health information technologies, including smart phones and tablets, have the potential to transform health care delivery through reduced systemic costs, improved patient safety, and better clinical outcomes.

(4) Clinical and health software innovation cycles evolve and move faster than the existing regulatory approval processes.

(5) Consumers and innovators need a new risk-based framework for the oversight of clinical and health software that improves on the framework of the Food and Drug Administration.

(6) A working group convened jointly by the Food and Drug Administration, the Federal Communications Commission, and the Office of the National Coordinator for Health Information Technology identified in a report that there are several major barriers to the effective regulation of health

information technology that cannot be alleviated without changes to existing law.

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) the President and Congress must intervene to facilitate interagency coordination across regulators that focuses agency efforts on fostering health information technology and mobile health innovation while better protecting patient safety, improving health care, and creating jobs in the United States;

(2) the President and the Congress should work together to develop and enact legislation that establishes a risk-based regulatory framework for such clinical software and health software that reduces regulatory burdens, fosters innovation, and, most importantly, improves patient safety;

(3) The National Institute of Standards and Technology should be the Federal agency that has oversight over technical standards used by clinical software; and

(4) The National Institute of Standards and Technology, in collaboration with the Federal Communications Commission, the National Patient Safety Foundation, and the Office of the National Coordinator for Health Information Technology, should

work on next steps, beyond current oversight efforts, regarding health information technology, such as collaborating with nongovernmental entities to develop certification processes and to promote best practice standards.

SEC. 3. CLINICAL SOFTWARE AND HEALTH SOFTWARE.

(a) DEFINITIONS.—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 'clinical software' means clinical decision support software or other software (including any associated hardware and process dependencies) intended for human or animal use that—

''(A) captures, analyzes, changes, or presents patient or population clinical data or information and may recommend courses of clinical action, but does not directly change the structure or any function of the body of man or other animals; and

''(B) is intended to be marketed for use only by a health care provider in a health care setting.

''(2) The term 'health software' means software (including any associated hardware and process dependencies) that is not clinical software and—

''(A) that captures, analyzes, changes, or presents patient or population clinical data or information;

''(B) that supports administrative or operational aspects of health care and is not used in the direct delivery of patient care; or

''(C) whose primary purpose is to act as a platform for a secondary software, to run or act as a mechanism for connectivity, or to store data.

''(3) The terms 'clinical software' and 'health software' do not include software—

''(A) that is intended to interpret patient-specific device data and directly diagnose a patient or user without the intervention of a health care provider;

''(B) that conducts analysis of radiological or imaging data in order to provide patient-specific diagnostic and treatment advice to a health care provider;

''(C) whose primary purpose is integral to the function of a drug or device; or

''(D) that is a component of a device.''.

(b) PROHIBITION.—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. CLINICAL SOFTWARE AND HEALTH SOFTWARE.

''Clinical software and health software shall not be subject to regulation under this Act.''.

SEC. 4. EXCLUSION FROM DEFINITION OF DEVICE.

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 clinical software or health software.''.

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