Center for Connected Health Policy
The National Telehealth Policy Resource Center

HR 3303 - Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act of 2013

Reps. Marsha Blackburn (R-TN), G.K. Butterfield (D-NC), Diana DeGette (D-CO), Phil Gingrey (R-GA), Gene Green (D-TX), Greg Walden (R-OR)

Author Intent: To amend the Federal Food, Drug, and Cosmetic Act to provide for regulating medical software, and for other purposes.

BILL DRAFT	CURRENT LAW
'Medical software' is defined as, "software that is intended for human or animal use, and: 1. Is intended to be marketed to directly change the structure or any function of the body of man or other animal; or is intended to be marketed for use by consumers and make recommendations for clinical action that includes the use of drug, device, or procedure to cure or treat a disease or other condition without requiring the involvement of a health care provider, and, if followed, would change the structure or any function of the body of man or other animal; 2. Is not software whose primary purpose is integral to the functioning of a drug or device; and 3. Is not a component of a device."	N/A
All of the provisions of the Federal Food, Drug, and Cosmetic Act which apply to 'devices' will also apply to 'medical software.' The Food and Drug Administration is charged with regulating medical software.	The Food and Drug Administration is charged with regulating 'devices,' according to the provisions in the Federal Food, Drug, and Cosmetic Act.

BILL DRAFT	CURRENT LAW
'Clinical software' is defined as, "clinical decision support software or other software (including any associated hardware and process dependencies) intended for human or animal use that: 1. 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 2. Is intended to be marketed for use only by a health care provider in a health care setting."	N/A
`Health software' is defined as, "software (including any associated hardware and process dependencies) that is not medical software or clinical software, and: 1. That captures, analyzes, changes, or presents patient or population clinical data or information; 2. That supports administrative or operational aspects of health care, and is not used in the direct delivery of patient care; or 3. 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."	N/A
Clinical software and health software are not subject to regulation under the Federal Food, Drug, and Cosmetic Act.	N/A
Encourages President and Congress to 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, promotes patient safety, and fosters innovation.	N/A
Clarifies that the term 'device' does not include medical software, clinical software, or health software.	The term 'device' means, "an instrument, apparatus, implement, machine contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: 1. Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; 2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals; or 3. Intended to affect the structure or any function of the body of man or other animals; and 4. Which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals, and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

Impact and Analysis

HR 3303 would divide software intended for health-related purposes into three categories: medical software, clinical software, and health software. Only medical software, which the bill defines as, "software intended to change or make clinical recommendations that would affect the structure or function of a man or animal's body," would be regulated by the FDA under the Federal Food, Drug, and Cosmetic Act. The FDA would not regulate clinical or health software, both of which do not directly change the structure or any function of the body of man or animal.

In guidance released in September 2013, the FDA details how it intends to apply its regulatory authority to select software applications intended for use on mobile platforms. In the guidance, the FDA distinguishes between mobile medical apps that could pose a risk to a patient's safety if it didn't perform as intended, which the FDA intends to regulate, and all other mobile medical apps, to which they intend to exercise "enforcement discretion." The approach in HR 3303 of securing FDA regulation only for medical software (as opposed to clinical and health software) aligns with the FDA's approach toward mobile medical apps of reserving their regulatory authority for products that pose the greatest risk to the body's structure and function. However, under the FDA guidance, it retains the right to regulate any mobile medical app. Under HR 3303, the FDA would have no authority to regulate clinical and health software.

The bill suggests, but in no way requires, the President and Congress to work together to develop and enact legislation that establishes a risk-based regulatory framework for such clinical software and health software. It is possible that no such framework would be in place at the time this bill would go into effect, leaving "clinical software" and "health software" unregulated.