

HR 3303

SOFTWARE Act of 2013

Congress: 113 (2013–2015, Ended)

Chamber: House

Policy Area: Health

Introduced: Oct 22, 2013

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Oct 25, 2013)

Official Text: <https://www.congress.gov/bill/113th-congress/house-bill/3303>

Sponsor

Name: Rep. Blackburn, Marsha [R-TN-7]

Party: Republican • **State:** TN • **Chamber:** Senate

Cosponsors (38 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Butterfield, G. K. [D-NC-1]	D · NC		Oct 22, 2013
Rep. DeGette, Diana [D-CO-1]	D · CO		Oct 22, 2013
Rep. Gingrey, Phil [R-GA-11]	R · GA		Oct 22, 2013
Rep. Green, Gene [D-TX-29]	D · TX		Oct 22, 2013
Rep. Walden, Greg [R-OR-2]	R · OR		Oct 22, 2013
Rep. Burgess, Michael C. [R-TX-26]	R · TX		Nov 14, 2013
Rep. Vargas, Juan [D-CA-51]	D · CA		Nov 15, 2013
Rep. Bilirakis, Gus M. [R-FL-12]	R · FL		Nov 19, 2013
Rep. Ellmers, Renee L. [R-NC-2]	R · NC		Nov 20, 2013
Rep. Latta, Robert E. [R-OH-5]	R · OH		Nov 20, 2013
Rep. Fincher, Stephen Lee [R-TN-8]	R · TN		Nov 21, 2013
Rep. Gardner, Cory [R-CO-4]	R · CO		Nov 21, 2013
Rep. Westmoreland, Lynn A. [R-GA-3]	R · GA		Nov 21, 2013
Rep. McKinley, David B. [R-WV-1]	R · WV		Dec 2, 2013
Rep. Bera, Ami [D-CA-7]	D · CA		Dec 3, 2013
Rep. Tsongas, Niki [D-MA-3]	D · MA		Dec 5, 2013
Rep. Griffith, H. Morgan [R-VA-9]	R · VA		Dec 12, 2013
Rep. Hanna, Richard L. [R-NY-22]	R · NY		Dec 19, 2013
Rep. Matheson, Jim [D-UT-4]	D · UT		Jan 9, 2014
Rep. Kilmer, Derek [D-WA-6]	D · WA		Jan 14, 2014
Rep. Johnson, Bill [R-OH-6]	R · OH		Jan 27, 2014
Rep. Guthrie, Brett [R-KY-2]	R · KY		Jan 28, 2014
Rep. Swalwell, Eric [D-CA-15]	D · CA		Jan 28, 2014
Rep. Collins, Chris [R-NY-27]	R · NY		Feb 4, 2014
Rep. Tiberi, Patrick J. [R-OH-12]	R · OH		Feb 5, 2014
Rep. Roe, David P. [R-TN-1]	R · TN		Mar 4, 2014
Rep. Olson, Pete [R-TX-22]	R · TX		Mar 24, 2014
Rep. Rangel, Charles B. [D-NY-13]	D · NY		Mar 24, 2014
Rep. Jenkins, Lynn [R-KS-2]	R · KS		Apr 1, 2014
Rep. Ross, Dennis A. [R-FL-15]	R · FL		Apr 1, 2014
Rep. Lowey, Nita M. [D-NY-17]	D · NY		Apr 28, 2014
Rep. Jeffries, Hakeem S. [D-NY-8]	D · NY		May 20, 2014
Rep. Scott, Austin [R-GA-8]	R · GA		May 20, 2014
Rep. Peters, Scott H. [D-CA-52]	D · CA		May 23, 2014
Rep. Herrera Beutler, Jaime [R-WA-3]	R · WA		Jun 10, 2014
Rep. Heck, Joseph J. [R-NV-3]	R · NV		Jun 20, 2014
Rep. Heck, Denny [D-WA-10]	D · WA		Jun 30, 2014
Rep. Schock, Aaron [R-IL-18]	R · IL		Jul 29, 2014

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Oct 25, 2013

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Oct 22, 2013)

Sensible Oversight for Technology which Advances Regulatory Efficiency Act of 2013 or the SOFTWARE Act of 2013 - Amends the Federal Food, Drug, and Cosmetic Act (FDCA) to apply it to medical software to the same extent and in the same manner as it applies to devices. Defines "medical software" as software that is intended to be marketed:

- to directly change the structure or any function of the body of man or other animals; or
- for use by consumers and makes recommendations for clinical action that includes the use of a drug, device, or procedure to cure or treat a disease or other condition without requiring the involvement of a health care provider and which, if followed, would change the structure or any function of the body of man or other animals. Excludes from such definition software whose primary purpose is integral to the functioning of a drug or device and is not a component of a device.

Excludes clinical software and health software (defined as follows) from FDCA regulation.

Defines "clinical software" as software 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 for use only by a health care provider in a health care setting.

Defines "health software" as software that is not medical software or clinical software and that: (1) captures, analyzes, changes, or presents patient or population clinical data or information or supports administrative or operational aspects of health care and is not used in the direct delivery of care; or (2) has as its primary purpose to act as a platform for a secondary software, to run or act as a mechanism for connectivity, or to store data.

Expresses the sense of Congress concerning the value of clinical software and health software to health care quality and efficacy and the need for legislation that establishes a risk-based regulatory framework that reduces regulatory burdens, promotes patient safety, and fosters innovation.

Excludes medical software, clinical software, and health software from the FDCA definition of "device."

Actions Timeline

- **Oct 25, 2013:** Referred to the Subcommittee on Health.
- **Oct 22, 2013:** Introduced in House
- **Oct 22, 2013:** Referred to the House Committee on Energy and Commerce.