HR 2396

SOFTWARE Act

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: May 18, 2015
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (May 22, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/2396

Sponsor

Name: Rep. Blackburn, Marsha [R-TN-7]
Party: Republican • **State:** TN • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Green, Gene [D-TX-29]	D · TX		May 18, 2015

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 22, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 HR 6	Related bill	**Jul 13, 2015:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of May 18, 2015)

Sensible Oversight for Technology which Advances Regulatory Efficiency Act or the SOFTWARE Act

This bill amends the Federal Food, Drug, and Cosmetic Act to define health software as software that does not acquire, process, or analyze data from an in vitro diagnostic device or signal acquisition system, is not an accessory or part of a medical device, is not used to prevent disease in the transfusion of blood and blood components, and is for:

- administrative or operational support or the processing and maintenance of financial records;
- use in clinical, laboratory, or administrative workflow and recordkeeping;
- managing data but not for active patient monitoring or controlling the functions of a connected medical device;
- organizing and presenting information for health or wellness education or maintaining a healthy lifestyle; or
- analyzing information to provide general health information or patient-specific recommendations.

The FDA must classify an accessory of a medical device independently from the medical device with which it is used.

Health software is exempted from regulation by the FDA (including as a medical device), except for software that provides patient-specific recommendations and poses a significant risk to patient safety.
The FDA must review existing regulations and guidance regarding the regulation of health software.

Actions Timeline

- **May 22, 2015:** Referred to the Subcommittee on Health.
- **May 18, 2015:** Introduced in House
- **May 18, 2015:** Referred to the House Committee on Energy and Commerce.

LegiList

CONGRESS, MADE CLEAR.

Search Every Federal Bill, Law, and Vote

LegiList is the fastest way to research Congress. Track any bill from introduction to enactment, see how every legislator voted, follow committee activity, and read the full text of every bill — all in one place, always up to date.

legilist.com

Free Course: Learn How Congress Actually Works

LegiList Learn is a free, self-paced course that walks through the entire legislative process — from drafting a bill to a presidential signature. Seven modules, plain language, no politics. Earn a certificate when you finish.

legilist.com/learn

Developer API: Build Apps on Legislative Data

The LegiList API gives developers direct access to bills, votes, legislators, committees, and more. Start free with 1,000 requests per day — no credit card required. Upgrade to Pro when you need to scale.

legilist.com/api

Public data belongs to the public. — legilist.com