

21st Century Cures Act Update

July 10, 2015

On Friday, following votes on amendments, the House of Representatives passed the 21st Century Cures Act by a vote of 344-77. Republicans voted 170-70 in favor of the bill; Democrats voted 174-7 in favor. The full [roll call vote is here](#).

The “21st Century Cures Act” (H.R.6) is the latest attempt by Congress to accelerate the discovery, development, and delivery of 21st century cures. The largely bipartisan legislation was not without controversy, however. House Republicans took issue with the bill’s price tag and the increase to mandatory spending, as demonstrated by Dave Brat’s (R-VA) amendment to change the mandatory spending in the bill to discretionary spending. Brat’s amendment was defeated by a vote of 141-281. Democrats protested the decreased funding for the National Institutes of Health and policy riders affecting abortion. Barbara Lee (D-CA) offered an amendment to remove limits on NIH and FDA funding, but that amendment also failed by a vote of 176-245.

The legislation will now be sent to the Senate, although its prospects for consideration in the upper chamber remain unclear at this time. The Senate HELP Committee, chaired by Senator Lamar Alexander (R-TN), will likely take up the issue after September, once the chamber finishes consideration on education related policy. Alexander is, however, calling hearings, meetings, and working on related legislation to the Cures bill. The HELP Committee will hold additional hearings on electronic health records in the coming months, including one on “Information Blocking” on July 23.

To recap, H.R. 6 authorizes and appropriates \$1.86 billion annually for fiscal years 2016-2020 for the “NIH and Cures Innovation Fund”. The 21st Century Cures Act also contains the SOFTWARE Act, a bill designed by Marsha Blackburn (R-TN) which clarifies the FDA’s role in regulating health information technology. Additionally, the bill contains telehealth language designed to allow health care providers the ability to use technology to communicate with their patients. Finally, the latest version of the bill, first released on July 2, contains, but is not limited to, the following interoperability provisions (portions differing from the last version are in *italics*):

H.R. 6, Title III, Subtitle A - Interoperability

SEC. 3010 – Ensuring Interoperability of Health Information Technology

- Includes criteria for interoperability; must include the secure transfer of health information, complete access to health information, and ensure that the technology does not engage in information blocking.
 - *Additional criteria for querying and requesting health information for access, exchanged, and use.*

SEC. 3003A – Recommendations for Standards Through Contracts with Standards Development Organizations

- Authorizes the Secretary of HHS to enter into contracts with health care standards development organizations accredited by the American National Standards Institute, *or with the ANSI itself.*
 - *Entities must recommend methods to test HIT compatibility with standards.*
 - *Entities must submit recommendations to, and may also consult with, the National Institute of Standards and Technology.*
- *The Secretary is authorized to modify implementation specifications after a period of public comment.*
- *Vendors of HIT may use additional standards beyond the baseline standards to allow flexibility, so long as the additional standards are satisfy the baseline adopted standards.*
- *Eliminates the follow up report of the Secretary for December 31, 2019 (SEC. 3003A in the previous version).*
- *The Secretary must provide a method and process by which a vendor may demonstrate it is compatible with standards and implementation specifications on or after January 1, 2018.*

SEC. 3010A – Enforcement Mechanisms

- *Vendors found in violation of an attestation will be subject to a “civil monetary penalty in such an amount as determined appropriate by the Secretary through rulemaking.*
- *The bill also includes an extended “sense of Congress” section that states patients, individuals, and other authorized representatives have the right to access the entirety of their health information and without cost.*
 - *Including that health care providers should not have the ability to deny a request of the individual access to the information.*
 - *Mechanisms should be utilized for the bidirectional exchange of information (such as through web portals).*