



March 29, 2018

The Honorable Lamar Alexander  
Chairman  
U.S. Senate Committee on Health, Education,  
Labor, and Pensions  
Washington, D.C. 20510

The Honorable Patty Murray  
Ranking Member  
U.S. Senate Committee on Health, Education,  
Labor, and Pensions  
Washington, D.C. 20510

Dear Chairman Alexander and Ranking Member Murray:

The Confidentiality Coalition appreciates the opportunity to comment on H.R. 4613, "The Ensuring Patient Access to Healthcare Records Act of 2017."

The Confidentiality Coalition is a broad group of organizations working to ensure that policies are implemented to appropriately balance the protection of confidential health information with the efficient and interoperable systems needed to provide high quality healthcare. Access to timely and accurate patient information leads to both improvements in quality and safety and the development of new lifesaving and life-enhancing medical interventions.

The Confidentiality Coalition is comprised of hospitals, medical teaching colleges, health plans, pharmacies, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, employers, health product distributors, pharmacy benefit managers, health information and research organizations, clinical laboratories, and others. Through this diversity, we develop a nuanced perspective on the impact of any legislation or regulation affecting the privacy and security of health consumers.

The Confidentiality Coalition supports the House Energy and Commerce and Ways and Means Committees' intent to ensure access to patient health data to support medical care and innovative payment models that lower healthcare costs. However, coalition members are concerned that H.R. 4613 would eliminate important privacy protections and patient-centered business practices that are regulated through the Health Insurance Portability and Accountability Act (HIPAA) privacy rule without providing meaningful benefits for patients.

As we read the bill, it would authorize disclosure of protected health information (PHI) beyond today's HIPAA rules without any new protections for this data, and in some circumstances, with weakened protections for this information, as it would permit the use and disclosure of protected PHI by clearinghouses without patient knowledge of clearinghouse existence and/or clearinghouse data use activity. The coalition has the following concerns about H.R. 4613:

- Some of HIPAA's privacy protections for PHI and individuals would be eliminated under H.R. 4613.
  - The bill would invalidate existing business associate agreements between clearinghouses and healthcare providers, plans and other entities that establish protections for PHI. Further, it would permit clearinghouses to engage in the full range of treatment, payment and operations activities even though clearinghouses do not have a relationship with patients.

- If a clearinghouse does not have “direct interaction” with an individual the clearinghouse would not have to follow HIPAA regulations that grant individual rights. And most clearinghouses would not have a direct relationship with an individual.
- The bill requires clearinghouses to post a website notice of privacy practices, but most patients will not have any direct interaction with the clearinghouse and therefore will have no basis to know that the clearinghouse is using their information or that a notice of privacy practices is available.
- While the bill would grant clearinghouse broad new rights to use and disclose patient data, it would not provide appropriate protections to individuals if the clearinghouse has a security breach.
  - Clearinghouses would have to provide breach notification to affected individuals only in limited situations where they are in “direct interaction” with individuals. Since clearinghouses typically do not perform functions for individuals, the clearinghouses almost never interact with individuals.
  - There is a fallback provision that would require covered entities (with a direct patient relationship) to provide notice, but this would be in situations where the covered entities did nothing wrong at all and where there is no business associate agreement (because of this legislation) to protect the covered entities.
- The bill also permits clearinghouses to charge fees to patients for their records that could be far higher than the fees set by HIPAA regulations and guidance. Under the bill, clearinghouses may purchase PHI from other clearinghouses, create longitudinal patient records, and then charge fair market value for the longitudinal record.
  - Only clearinghouses would be able to buy and sell PHI amongst each other to prepare record requests.

We are also concerned about ambiguities or inconsistent provisions in this bill. There are references to expanding the role of covered entities as well as the role of clearinghouses and genetic information privacy, but the impact of expanding covered entity authority is not well defined.

Lastly, in light of recently announced and/or implemented government initiatives that aim to improve the flow of health data and patient access to health, such as the HHS Office of National Coordinator’s Trusted Exchange Framework and Common Agreement (TEFCA); HHS’ MyHealthEDData Initiative, including Blue Button 2.0; the forthcoming notice of proposed rulemaking on information blocking; as well as the ongoing work of Qualified Entities under CMS’ Qualified Entity Certification Program, we urge Congress to allow these initiatives to develop and mature, rather than substantially re-write HIPAA, which has served patients well since its implementation.

For these reasons, members of the Confidentiality Coalition oppose H.R. 4613. While we applaud the intent of H.R. 4613, we respectfully request the Senate HELP Committee consider alternative approaches to data that support medical care and improve healthcare payment models. Members of the Confidentiality Coalition stand ready to engage with the committee to examine proposed approaches that will appropriately enable healthcare data flow, protect patient information and privacy, and are equitable among all stakeholders. Please contact Tina Grande, Senior Vice President for Policy at the Healthcare Leadership Council on behalf of the

Confidentiality Coalition at [tgrande@hlc.org](mailto:tgrande@hlc.org) or at (202) 449-3433 if there are any comments or questions about the comments in this letter.

Sincerely,

A handwritten signature in black ink that reads "Tina O. Grande". The signature is written in a cursive style with a large, looped initial "T".

Tina Grande  
Healthcare Leadership Council on behalf of the Confidentiality Coalition