



American Hospital  
Association®

800 10th Street, NW  
Two CityCenter, Suite 400  
Washington, DC 20001-4956  
(202) 638-1100 Phone  
[www.aha.org](http://www.aha.org)

July 10, 2015

The Honorable Fred Upton  
Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Frank Pallone Jr.  
Ranking Member  
Committee on Energy and Commerce  
U.S. House of Representatives  
2322-A Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Upton and Ranking Member Pallone:

I am writing on behalf of the nearly 5,000 member hospitals, health systems and other health care organizations, and 43,000 individual members of the American Hospital Association (AHA) regarding H.R. 6, the 21<sup>st</sup> Century Cures Act. We commend the committee for its efforts to find better ways to accelerate the discovery of new cures and improve innovation. The AHA favors the National Institutes of Health mandatory funding included in the bill because it will help advance efforts to promote healthy communities across the nation, where each individual reaches their highest potential for health. However, we have concerns regarding the problematic interoperability enforcement provisions included in Section 3001.

While we appreciate the positive changes made to the interoperability provisions and elsewhere in this legislation, the enforcement provisions in Section 3001 still rely on fraud and abuse mechanisms that will result in unfair sanctions to hospitals and other providers. The bill also includes an overly broad definition of “information blocking” that would result in penalties for providers’ reasonable business practices and beneficial modifications to information technology (IT) systems that improve patient care.

**“Information Blocking” Sanctions.** The bill requires investigations by the Department of Health and Human Services (HHS) Office of Inspector General (OIG) and imposition of civil monetary penalties on providers that engage in “information blocking.” Section 3001 gives the Secretary broad authority to set the amount of the civil monetary penalties and allows the OIG to keep all amounts recovered, creating a financial incentive for the Secretary and the OIG to establish and impose large penalties, similar to the current Recovery Audit Contractor (RAC) program. Section 3001 replaces current law, which requires an attestation that a hospital has not interfered with the interoperability of its electronic health record (EHR), with an attestation that a hospital has not engaged in “information blocking.”



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The AHA strongly opposes any sanctions on providers beyond the existing EHR Incentive Programs. For hospitals and other care providers, Medicare fraud and abuse mechanisms, such as OIG investigations or imposition of civil monetary penalties, to address concerns about “information blocking” are unnecessary and duplicative.

The AHA recommends the use of the existing structures of the Medicare and Medicaid EHR Incentive Programs to promote information sharing. The programs already include specific requirements for providers to share health information. In addition, current law includes provisions requiring health care providers to make an affirmative attestation to the government that they have not taken steps to limit the interoperability of their EHRs as part of the requirements of meaningful use. Penalties for failing to meet meaningful use are significant, and grow larger over time. We do not believe the penalties contained in H.R. 6 are needed. The EHR Incentive Programs are the logical placement for sanctions.

**Broad Definition of “Information Blocking.”** Section 3001 applies the same definition of “information blocking” to both providers and vendors. At its core, the definition encompasses “business, technical and organizational practices” that “prevent or materially discourage the access, exchange, or use of electronic health information.” Such practices describe virtually every aspect of a provider’s information sharing activity.

Instead of this broad definition applied to all parties, the AHA recommends that vendors and providers have separate definitions of “information blocking” because their roles in information sharing are unique. Vendors establish the software and exchange infrastructure. Unlike providers, vendors do not have an existing obligation to demonstrate that they have not limited the interoperability of their product. Therefore, the provisions in Section 3001 could help hold vendors accountable for the design and marketing of interoperable products.

In contrast, providers use the technical infrastructures created by vendors to provide care and engage patients. Information must be shared for those purposes, as consistent with existing privacy and security regulations. However, the infrastructure may not yet exist for a provider to do so electronically.

Therefore, we recommend a definition of information blocking specific to providers that focuses on deliberate actions to:

- (1) Limit or restrict electronic sharing, through certified EHRs, of patient information necessary for the care of the patient that is permissible to be shared under relevant federal and state privacy laws, insofar as the technology and supporting infrastructure have the capability to carry out such electronic sharing; or
- (2) Limit or restrict patients’ access to their electronic records, as specified in existing federal and state privacy laws, insofar as the provider has current capability to efficiently and effectively share the data electronically.

The definition of “information blocking” for providers also should recognize that a provider may not be able to share information electronically when doing so would involve an excessive burden

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due to technological limitations or to high costs or fees imposed by a certified EHR technology vendor for such electronic sharing or access. Connecting systems today often requires significant financial and human resources. Given this reality and limited resources, a provider may not be able to accommodate all types of electronic information exchange. Under this far-reaching definition, a hospital that cannot afford to pay for new interfaces or new exchange mechanisms to support any given instance of electronic information sharing could be unfairly sanctioned for information blocking.

**Health IT Standards Committee.** Section 3001 also eliminates the Health IT Standards Committee. The AHA believes the committee should be maintained as it provides an important vehicle to engage a diverse set of experts with real-world experience in the process of setting standards and developing implementation guidance.

Hospitals and health systems across the country are actively engaged in building their IT systems and view information exchange as vital to care improvement, as well as to successful implementation of new models of care. In doing so, they are committed to sharing health information to improve patient care and engage individuals in their health care. While progress is being made in some areas, the certified EHRs and related infrastructure that providers must rely on do not yet support efficient and effective electronic information exchange. There are positive steps that would further our shared goals, such as federal support for more robust testing of health IT products and greater commitment to developing and maturing data standards. We look forward to working with Congress to explore such positive, rather than punitive, approaches to making progress.

Thank you in advance for your consideration of these issues. If you have any questions, please contact Aimee Kuhlman, senior associate director for federal relations, at 202-626-2291 or [akuhlman@aha.org](mailto:akuhlman@aha.org).

Sincerely,

Rick Pollack  
Executive Vice President