August 29, 2017

Donald Rucker, MD
National Coordinator
Office of the National Coordinator for Health
Information Technology
Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

Daniel R. Levinson
Inspector General
Department of Health and Human Services
330 Independence Avenue, SW
Room 5527, Cohen Building
Washington, DC 20201

Dear Dr. Rucker and Inspector General Levinson:

Health IT Now convened a diverse group of stakeholders to discuss and make recommendations to address information blocking in the healthcare system. The undersigned organizations write to express our shared goal of ultimately eliminating the harmful business practice of information blocking.

This business practice barrier to interoperability does not just thwart federal and private efforts to more fully share clinical information, it may pose significant risk to patient safety. For instance, information blocking impedes provider access to the most current, accurate, or complete information on their patients. The *21st Century Cures Act* prohibits information blocking and allows for penalties to be placed on vendors and providers who violate the prohibition. The law, if implemented correctly, can facilitate the sharing of information to both enhance personalized care, as well as strengthen the growing population health model of coordinated high-quality care.

We understand that implementing these provisions will require a nuanced approach and believe the best first step for the administration in implementing these provisions is to gain broad stakeholder input.

To that end, we recommend HHS issue a proposed rule that answers the following important questions to provide clarity around the *21st Century Cures* provision:

1. What is information blocking and what is not?
2. What constitutes "special effort" in eliminating blocking and promoting interoperability?
3. How ought "should have known" be defined?
4. How should patient access be measured?
5. How does the law interact with existing laws like HIPAA and medical malpractice?

Additionally, we believe the proposed rule would be greatly enhanced by addressing the following questions and policy considerations:

1. What is standard vs. non-standard implementation?
2. What "reasonable" business practices do not constitute information blocking?
3. The statute institutes penalties on vendors up to $1 million per violation. How should "per violation" be defined?

4. How should active information blocking be differentiated from business conduct such as contract terms?
5. What constitutes a "complete record"?
6. How should the ONC Certification Program be updated to reflect the new requirements?
7. Should there be a mitigation pathway before claims are subjected to OIG investigation and penalties?
8. What data, outside of what is in law, should be collected from the public for reports of info blocking?
9. What flexibilities should be built into a system that can keep up with technology but is sufficiently specific?
10. What are unintended consequences that regulations should avoid?
11. Should there be a reporting mechanism for government information blocking?
12. What, if any, safe harbors will need to be instituted? How will you ensure that if instituted, they do not prevent the enforcement of information blocking prohibitions or deter the benefits of future technology to facilitate information exchange?

We stand ready to assist in the implementation this complex law, and to take the needed steps to put an end to information blocking. We propose a discussion session in September with your team and our stakeholder group to discuss the questions and provide commentary in developing the proposed rule. This is a good way for various stakeholders to show our solidarity in ending this practice that is affecting the healthcare industry at large and placing patient lives at risk. We appreciate your leadership on this important issue.

Sincerely,

American Academy of Family Physicians
American Academy of Ophthalmology
AMIA
athenahealth
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Health IT Now
Healthcare Leadership Council
IBM
ION Solutions
McKesson
National MS Society
National Partnership for Women & Families
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