



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

**Testimony Before the United States Senate Committee on
Health, Education, Labor, and Pensions**

**“Implementation of the 21st Century Cures Act:
Achieving the Promise of Health Information Technology”**

Testimony of:

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Good afternoon, Chairman Alexander, Ranking Member Murray, and other distinguished Members of the Committee. I am James Cannatti, Senior Counselor for Health Information Technology for the Office of Inspector General (OIG), U.S. Department of Health and Human Services (HHS or Department). Thank you for the opportunity to appear before you to discuss OIG's role in the implementation of the health information technology (health IT) provisions of the 21st Century Cures Act (the Cures Act). My testimony today will focus on our new information blocking investigative and enforcement authorities provided under Section 4004 of the Cures Act.

Information Blocking Harms Patient Care and Our Health Care System

In general terms, information blocking is a practice that inappropriately impedes the flow or use of information.¹ The availability of information when and where it is needed is a critical element of a high-functioning health care system.

OIG has long acknowledged the importance of the appropriate flow of information, subject, of course, to privacy and security protections. In fact, OIG has highlighted the issue for the past several years in our annual list of Top Management and Performance Challenges facing the Department.² Addressing the negative impacts of information blocking is consistent with OIG's mission to protect the integrity of HHS programs, as well as the health and welfare of program beneficiaries.

Information blocking can pose a threat to patient safety and undermine efforts by providers, payors, and others to make our health care system more efficient and effective. For example, when pertinent information is not available in a patient's record, a physician may inadvertently prescribe a contraindicated drug causing the patient to become ill. Further, when results are not shared between providers, patients may be subjected to duplicate tests. Beyond unnecessarily exposing patients to risks associated with the tests,³ payors and patients incur unnecessary costs for the duplicative services. Information blocking also threatens the significant investment taxpayers have made in encouraging the adoption and use of technologies like electronic health records (EHRs).

¹ Section 4004 of the Cures Act added a specific definition of information blocking for purposes of the statute. That definition is codified at Section 3022(a) of the Public Health Services Act, 42 U.S.C. § 300jj-52(a).

² For 2016, OIG identified 10 top management and performance challenges, including one entitled "Health Information Technology and the Meaningful and Secure Exchange and Use of Electronic Information." OIG's 2016 Top Management and Performance Challenges Facing HHS is available at <https://oig.hhs.gov/reports-and-publications/top-challenges/2016/>.

³ Some tests pose greater risks than others; for example, some tests may be more invasive or expose the patient to higher levels of radiation than other tests.

OIG’s Approach to Information Blocking Before the Cures Act

Historically, OIG had no authority to investigate or take enforcement action based solely on acts of information blocking. Rather, the concept arose for us in the context of the application of the Federal anti-kickback statute (the Anti-Kickback Statute)⁴ to arrangements in which one party, such as a hospital, provides an EHR system to another party, such as a physician group practice. These “donation” arrangements were designed to facilitate and promote broad adoption of EHRs. Questions arose about the need for safe harbor protection for some of these donation arrangements. In 2006, OIG issued a final rule establishing a safe harbor that protected certain EHR donation arrangements and required, among other conditions, that donated EHR software be interoperable (the EHR safe harbor).⁵ Our goal was to “promot[e] the adoption of interoperable [EHR] technology that benefits patient care while reducing the likelihood that the safe harbor [would] be misused by donors to secure referrals” from those receiving the technology.⁶ As with all safe harbors, we attempted to strike a balance—endeavoring to include safeguards that minimize potential fraud and abuse risks, without impacting the positive benefits of the underlying arrangements. In the case of the EHR safe harbor, one of the key safeguards prohibited donors and certain other parties from taking actions to limit or restrict the use, compatibility, or interoperability of donated EHR systems.

Although we did not use the term “information blocking” at the time, the EHR safe harbor conditions included concepts that align closely with the Cures Act prohibition on information blocking. We were concerned that information blocking would serve as a method of locking in or steering referrals, conduct prohibited by the Anti-Kickback Statute. Over time, our concerns about this risk grew. Moreover, Congress, HHS, and other stakeholders began raising additional concerns about information blocking. Accordingly, we issued a policy reminder in 2015 to again warn the industry about the impact of information blocking on potential safe harbor protection, and we went so far as to restate our position that EHR donation arrangements involving information blocking would be suspect under the Anti-Kickback Statute.⁷

The Cures Act Empowers OIG to Directly Address Information Blocking

With the passage of the Cures Act in December 2016, Congress gave OIG new authorities that will allow us to address the issue of information blocking more directly—beyond those limited circumstances in which the conduct is a part of a larger kickback scheme. The Cures Act added section 3022(b)(1) of the Public Health Services Act,⁸ which granted OIG specific authority to investigate claims that certain parties (health information technology developers, health care providers, and others) engaged in information blocking as defined in section 3022(a). Further, subsection (b)(2) established penalties for those engaged in information blocking. For developers and certain other parties, the penalties take the form of civil monetary penalties not to

⁴ 42 U.S.C. § 1320a-7b(b).

⁵ 71 Fed. Reg. 45110 (Aug. 8, 2006); 42 C.F.R. § 1001.952(y). We most recently modified the EHR safe harbor at the end of 2013. 78 Fed. Reg. 79208 (Dec. 27, 2013).

⁶ 78 Fed. Reg. 79208 (Dec. 27, 2013).

⁷ OIG Alert, OIG Policy Reminder: Information Blocking and the Federal Anti-Kickback Statute (Oct. 6, 2015), available at <https://oig.hhs.gov/compliance/alerts/guidance/policy-reminder-100615.pdf>.

⁸ 42 U.S.C. § 300jj-52.

exceed \$1 million per violation.⁹ For health care providers, the Cures Act directs OIG to refer such parties to “the appropriate agency to be subject to appropriate disincentives. . . .”¹⁰

OIG’s information blocking authorities under the statute are directly tied to the definition of information blocking in Section 3022(a). That definition contemplates rulemaking to identify “reasonable and necessary” activities that would not constitute information blocking for purposes of the Cures Act. Within the Department, our colleagues at the Office of the National Coordinator for Health Information Technology (ONC) have been tasked with that rulemaking, which will address the definition of information blocking within the meaning of Section 3022 and will provide the legal basis that OIG will use to assess conduct during our investigations and enforcement actions.

OIG Is Preparing for Effective, Efficient, and Fair Enforcement

OIG has been readying for effective, efficient, and fair enforcement. Our goal is to protect patients and the health care system by stopping information blocking. We aim to leverage our new authorities to change behaviors in the industry. We believe this can best be accomplished through a combination of clear rules of the road for those who want to comply with the law and targeted enforcement against those who choose to break it.

The Cures Act information blocking prohibition covers a broad spectrum of conduct and arrangements. It covers everyone from large electronic health IT developers to individual physicians. And the information blocking landscape is complex. It combines highly technical issues and a breadth of business arrangements and scenarios. Stakeholder engagement is critical to developing a deep understanding of this complex landscape. That is why we began engaging with industry and other private stakeholders that expressed an interest in sharing their unique perspectives on information blocking. To date, we have held more than a dozen stakeholder meetings with representatives from a wide cross-section of the health care and technology communities. We have included our colleagues from ONC in these meetings to further coordination on this topic within HHS. The insights gained from stakeholders will help us as we implement an effective, efficient, and fair enforcement approach to the issue of information blocking.

We have also engaged with our Federal partners, including ONC, the Centers for Medicare & Medicaid Services, the HHS Office for Civil Rights, and the Federal Trade Commission. For example, we have provided technical assistance to ONC on enforcement-related issues in order to inform its policy formulation efforts. Additionally, we are working to formalize processes for sharing complaints, referrals, and other information relevant to information blocking enforcement efforts within HHS that build on existing efforts, where possible. These efforts are intended to ensure that we are prepared to leverage the new tools to curb information blocking.

⁹ Section 3022(b)(2)(A) of the Public Health Services Act, 42 U.S.C. § 300jj-52(b)(2)(A).

¹⁰ Section 3022(b)(2)(B) of the Public Health Services Act, 42 U.S.C. § 300jj-52(b)(2)(B).

Conclusion

Stopping information blocking is important for patients and the broader health care system. The Cures Act provides important new authorities that enhance the Government's ability to address this problem. OIG is working diligently, alongside our HHS partners and with substantial input from private stakeholders, to implement an enforcement approach that deters information blocking, holds wrongdoers accountable, promotes the integrity of HHS programs, helps protect the health and welfare of program beneficiaries, and benefits the American public.

Thank you for the opportunity to testify on this important issue. I look forward to answering questions.