

THE INFORMATION BLOCKING PROVISION OF THE 21ST CENTURY CURES ACT: WHAT DOES THE NEW RULE MEAN FOR PHYSICIAN PRACTICES

By Jarrod Fowler, MHA, Director of Health Care Policy and Innovation, Florida Medical Association

As if the byzantine laws and regulations regarding patient medical records and access thereto were not complicated enough, in 2016 Congress passed the 21st Century Cures Act, a 312-page piece of legislation that contains numerous unrelated provisions regulating healthcare. Including in this omnibus act is an “information blocking” provision that imposes penalties for interfering with the lawful sharing of electronic health records. Any physician that maintains an electronic health record system is subject to the prohibition on information blocking.

“Information blocking” is defined as a practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. If the practice is engaged in by a physician¹, it is considered information blocking if the physician knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

This definition is extremely broad and without any guidance it would be virtually impossible for physicians to know what actions (or inactions) would constitute information blocking. To provide guidance, Congress conferred rulemaking authority on the Department of Health and Human Services (HHS) to “identify reasonable and necessary activities that do not constitute information blocking.”

Pursuant to this rulemaking authority, the Office of the National Coordinator for Health Information Technology (ONC) published a final rule on May 1, 2020 implementing provisions of the 21st Century Cures Act related to electronic health information blocking, interoperability and the ONC Health IT Certification Program. Physicians and other “Actors” to whom the bill applies were required to comply with the information blocking requirements of this rule **April 5, 2021**.

Penalties for violation of the information blocking provisions by physicians have not yet been determined by HHS. While HIE/HINs can receive up to \$1 million in civil monetary penalties (CMPs) per violation, the only “disincentives” for physicians currently consist of a potential impact on the Merit-based Incentive Payment System (MIPS) payments for those physicians participating in the Promoting Interoperability Program. Enforcement of information blocking civil monetary penalties will not begin until

¹ https://www.fda.gov/oc/2016/08/01/21st-century-cures-act-information-blocking-provisions

established by future notice and comment rulemaking by the Office of the Inspector General. Physicians will not be subject to penalties until CMP rules are final.

As for the content of the information blocking rules, there is a lot to digest. Rather than attempt to create a single treatise, this piece is meant to provide a brief 30,000-foot summary of the rule. Meanwhile, for practices ready to delve into additional detail, the AMA has created a two-part educational resource to help physicians and their medical practices understand develop an information blocking compliance program. [Part 1](#) outlines what information blocking is, key terms to know, examples of information blocking practices and a summary of exceptions for when physicians may restrict the access, exchange or use of EHI. [Part 2](#) will help physicians start down the path of compliance, including questions to consider, considerations for maintaining a compliance program and next steps.

The AMA has stated that it will add additional resources to its webpage as the federal government [releases new guidance](#). Below are several additional resources to help navigate the regulations:

ONC webinars

<https://www.healthit.gov/curesrule/resources/webinars>

ONC fact sheets

<https://www.healthit.gov/curesrule/resources/fact-sheets>

Information Blocking Resource Center for physicians and other providers

<https://infoblockingcenter.org/>

Information on how to file a complaint on information blocking Actors—EHR vendors or otherwise (Report Information Blocking)

<http://www.healthIT.gov/healthITcomplaints>

Additionally, the FMA will soon be providing an additional webinar to its members, featuring live subject-matter experts that will both discuss the requirements at length and make themselves available to take questions.

WHY DID CONGRESS ENACT THE INFORMATION BLOCKING PROVISION?

The information blocking provision was enacted in response to concerns that some individuals and entities are engaging in practices that unreasonably limit the availability and use of electronic health information (EHI) for authorized and permitted purposes. As stated in the March 4th proposed rule, “these practices undermine public and private sector investments in the nation’s health IT infrastructure and frustrate efforts to use

modern technologies to improve health care quality and efficiency, accelerate research and innovation, and provide greater value and choice to health care consumers.

This provision will benefit physicians by prohibiting some of the practices engaged in by a number of EHR vendors and hospital systems that made it virtually impossible for some physician practices to switch from one EHR to another. Unfortunately, the provision will also add complicated new regulatory requirements that already overburdened physicians will have to navigate.

EXACTLY WHAT INFORMATION DOES THE INFORMATION BLOCKING PROVISION APPLY TO?

The definition of information blocking applies to *electronic health information* (EHI). Since EHI is not specifically defined in the Cures Act, ONC defined it to mean:

- Electronic protected health information; and
- Any other information that:
 - is transmitted by or maintained in electronic media, as defined in 45 CRR 160.103;
 - identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual; and
 - relates to the past, present, or future health or condition of an individual, the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

The ONC stressed that EHI is not limited to information that is created or received by a health care provider, rather the definition provides for an expansive set of EHI, which could include information on an individual's health insurance eligibility and benefits, billing for health care services, and payment information for services to be provided or already provided, which may include price information.

De-identified data is excluded from the definition of EHI. EHI also does not include psychotherapy notes, or information compiled in reasonable anticipation of, or for use in, civil, criminal or administrative actions or proceedings.

Initially, ONC will define EHI as the data elements in the United States Core Data for Interoperability (USCDI) standard. Almost all USCDI data elements are already captured in 2015 Edition certified EHRs today – which means that the information blocking policies will apply to the information that is likely available on a physician practice's system. However, under ONC's rule, the definition of EHI will eventually expand beyond the USCDI. Starting May 2022, the EHI definition will include the full HIPAA electronic designated data set.

WHAT PRACTICES IMPLICATE THE INFORMATION BLOCKING PROVISION?

To meet the definition of information blocking under the Cures Act, a practice must be likely to interfere with, prevent or materially discourage the access, exchange, or use of EHI. The ONC noted in the final rule because information blocking may take many forms, it is not possible to anticipate or catalog all potential types of practices that may raise information blocking concerns. The ONC emphasized that any analysis of information blocking necessarily requires a careful consideration of the individual facts and circumstances, including whether the practice was required by law, whether the actor had the requisite knowledge, and whether an exception applies. The ONC also pointed out that to *implicate* the information blocking provision is not necessarily to violate it.

There are a number of examples in the proposed rule as to what would be considered information blocking. To give one example, the information blocking provision would be implicated if a physician's practice has the capability to provide same-day access to EHI in a form and format requested by a patient or a patient's health care provider, but takes several days to respond to the request.

This subject will be dealt with extensively in the next few weeks.

WHAT DOES THE INFORMATION BLOCKING RULE DO?

Section 4004 of the Cures Act added language to the Public Health Services Act that defined practices that constitute information blocking when engaged in by a health care provider. The Act gave the HHS Secretary the authority to identify, through rulemaking, reasonable and necessary activities that do not constitute information blocking as defined in the Act. The ONC's final rule does exactly that – it establishes 8 exceptions to the information blocking provision that define certain activities that would not constitute information blocking as defined in the Cures Act.

WHAT ARE THE 8 EXCEPTIONS TO THE INFORMATION BLOCKING PROVISION?

The ONC maintains that their 8 exceptions will support seamless and secure access, exchange, and use of EHI and offer physicians certainty that practices that meet the conditions of an exception will not be considered information blocking.

The 8 exceptions are divided into two classes as set forth below:

➤ **Exceptions that involve not fulfilling requests to access, exchange or use EHI:**

1. Preventing Harm Exception. It will not be information blocking for a physician to engage in practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain conditions are met.

2. Privacy Exception. It will not be information blocking if a physician does not fulfill a request to access, exchange or use EHI to protect an individual's privacy, provided certain conditions are met.
3. Security Exception. It will not be information blocking for a physician to interfere with the access, exchange or use of EHI to protect the security of EHI, provided certain condition are met.
4. Infeasibility Exception. It will not be information blocking if a physician does not fulfill a request to access, exchange or use EHI due to the infeasibility of the request, provided certain conditions are met.
5. Health IT Performance Exception. It will not be information blocking for a physician to take reasonable and necessary measures to make health IT temporarily unavailable or to degrade the health IT's performance for the benefit of the overall performance of the health IT, provided certain conditions are met.

➤ **Exceptions that involve procedures for fulfilling requests to access, exchange or use EHI:**

6. Content and Manner Exception. It will not be information blocking for a physician to limit the content of its response to a request to access, exchange or use EHI or how it fulfills a request to access, exchange or use EHI, provided certain conditions are met.
7. Fees Exception. It will not be information blocking for a physician to charge fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI, provided certain conditions are met.
8. Licensing Exception. It will not be information blocking for an actor to license interoperability elements for EHI to be accessed, exchanged, or used, provided certain conditions are met.

WHO CAN I CONTACT FOR ADDITIONAL HELP OR INFORMATION?

Please contact us at membership@flmedical.org with any additional questions you may have.

¹ The information blocking provisions are applicable to health information technology developers (HITs), health information exchanges (HIEs), health information networks (HINs) and health care providers. Physicians are included in the definition of “health care provider.” Physicians, if they engage in certain practices, can be considered HITs, HIEs or HINs for purpose of the Act. For purposes of this article, the focus will be on the effects of the information blocking provisions on physician practices and not on the requirements applicable to HITs, HIEs or HINs.
