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The 21st Century Cures Act's Information Blocking Provision

What the new rule means for physicians

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BREAKING NEWS: The ONC just announced today that it is extending the compliance deadline for the information blocking requirements in the 21st Century Cures Act to April 5, 2021. The HHS press release [can be accessed here](#).

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 containing numerous unrelated provisions regulating healthcare. Included in this omnibus act is an “information blocking” provision that imposes penalties for interfering with the lawful sharing of electronic health records. Any physician who 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 U.S. 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. The information blocking requirements of this rule takes effect on November 2, 2020. The Florida Medical Association, along with the medical associations of California, Texas and New York, have formally requested the ONC to delay implementation of the information blocking provisions of the final rule for at least one year so as not to divide physician’s attention from their continued COVID-19 efforts. The American Medical Association and other groups expect forthcoming regulations to delay enforcement. In fact, HHS sent the Office of Management and Budget an interim final rule on Sept. 17, 2000, that revise the timelines. The rule has not been released, but it indicates that an extension of the compliance deadline for the information blocking provisions beyond the November 2nd date is likely. The FMA will, of course, notify our members of any change.





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 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 much 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. In subsequent weeks, the FMA General Counsel’s Office will be publishing an in-depth analysis of various components of the rule along with an explanation of how the rule interacts with other federal acts, such as HIPAA and HITECH.

On Friday, Oct. 30, the FMA will dedicate its noon webinar to a discussion of the information blocking provisions, led by Adam Greene Esq., a partner in the Washington D.C. office of Davis Wright Tremaine and a noted expert on health information security. [Register here for the webinar](#), which is open to FMA members only.

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 4 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 a number of EHR vendors and hospital systems engage in that have made it virtually impossible for some physician practices to switch from one EHR to another. Unfortunately, the provision also will create complicated new regulatory requirements for overburdened physicians 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 healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.





The ONC stressed that EHI is not limited to information that is created or received by a healthcare 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 healthcare 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 that 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 healthcare 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 defining practices that constitute information blocking when engaged in by a health care provider. The Act gave the HHS Secretary 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 eight 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 eight exceptions to the information blocking provision?

The ONC maintains that its eight 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 eight 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.

Where do I go for more information?

The FMA is adding a section to our website dedicated to guiding our members through the information blocking provisions of the 21st Century Cures Act as well as associated rules and regulations. As mentioned, we will be including a series of detailed analyses of the various components of the ONC rule in FMA News over the next several weeks. The Oct. 30 webinar recording will be available online for those who are unable to join the program live, and if needed, additional webinars on this subject will follow.

In addition, the AMA has created a document entitled, "How do I comply with Information Blocking and where do I start?" [which can be accessed here.](#)

As always, FMA members can contact our Legal Department at legal@flmedical.org for more information.

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.





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