Practice Management Center

# 21st Century Cures Act: Interoperability, Information Blocking Rule Information

## Information Blocking Rule & Patient Access Overview FAQs

** The Academy is able to share the resources that link from this document on an informational basis only. This does not represent an endorsement by the Academy. Please compare, evaluate, and consider which resources best meet your needs.*

**Important dates to know:**
Date of mandated compliance: April 5, 2021

**What is the information blocking rule?**
Congress passed the 21st Century Cures law and one of the provisions is making the blocking of health information illegal. CMS has published regulations (the Information Blocking Rule) that implements this provision. Under HIPAA, covered entities CAN share protected health information for treatment, payment, or operations, but it was not REQUIRED. Under Information Blocking health care providers MUST share protected health information to other Covered Entities and other entities as directed by the patient. The Information Blocking Rule also lays out a set of exceptions (such as protecting patient privacy) where it is considered okay to not share information.

*For more information regarding the exceptions that may apply to you and your practice, please speak directly with your attorney.*

**What makes an individual or entity an Information Blocker?**
There are many elements of information blocking. This includes: an actor regulated by the information blocking process, involving Electronic Health Information (EHI), a practice likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI, not required by law, and not covered by an exception.

**Who are the actors regulated in the final rule?**

- Healthcare providers
- Health IT Developers of Certified HIT
- Health Information Networks (HIN) or Health Information Exchange (HIE)

**Am I a covered Actor?**
Review the terms and definitions available in the Heath Care Provider Fact sheet and IB Actors fact sheet.

**What information must be shared?**
The official term in the Information Blocking Rule is Electronic Health Information (EHI). EHI is defined to mean Electronic Protected Health Information (ePHI) to the extent that the ePHI is included in a Designated Record Set (DRS), as defined for HIPAA. That is legalese to say the patient's medical record. However, the rule does limit the definition for the first 24 months to only a core set of patient data. This core data is the data elements that make up the United States Core Data for Interoperability (USCDI). View the information on USCDI.

Learn more about information blocking exceptions. An actor's practice that does not meet the conditions of an exception will not automatically constitute information blocking. Instead such practices will be evaluated on a case-by-case basis to determine whether information blocking has occurred.

**When is it okay *not* to share patient information?**
The Information Blocking Rule is designed to require for all covered actors to share all electronic health information (see "What Information must be Shared") unless an exception can be applied. The rule lays out a set of exceptions that can be applied. These exceptions cover preventing harm, protecting privacy, security issues, feasibility of sharing, and problems with software. You can read about the exception in this ONC factsheet.

**When would a delay in fulfilling a request for access, exchange, or use of EHI be considered an interference under the information blocking regulation? *3/19/2021***

A determination as to whether a delay would be an interference that implicates the information blocking regulation would require a fact-based, case-by-case assessment of the circumstances. That assessment would also determine whether the interference is with the legally permissible access, exchange, or use of EHI; whether the actor engaged in the practice with the requisite intent; and whether the practice satisfied the conditions of an exception. Please see 45 CFR 171.103 regarding the elements of information blocking.

***Unlikely** to be an Interference:* If the delay is *necessary* to enable the access, exchange, or use of EHI, it is ***unlikely*** to be considered an interference under the definition of information blocking (85 FR 25813). You can read more about tan unlikely situation in this ONC factsheet.

***Likely** to be an Interference:* It would ***likely*** be considered an interference for purposes of information blocking if a health care provider established an organizational policy that, for example, imposed delays on the release of lab results for any period of time in order to allow an ordering clinician to review the results or in order to personally inform the patient of the results before a patient can electronically access such results (*see also* 85 FR 25842 specifying that such a practice does not qualify for the "Preventing Harm" Exception). You can read more about a likely situation in this ONC factsheet.

**Where do I begin with info blocking?**
According to the AMA, "Physicians should strike a balance between strict regulatory compliance and exercising his/her independent professional judgment — guided by personal and professional beliefs — as to what is in the best interests of patients, the profession, and the community[1]."

Ensure that your practice has a compliance program and find out if it has begun work on including information on info blocking compliance. If it has not, it is critical that your medical practice focus on updating your HIPAA policies and procedures to address the info blocking rule. View information on how you would comply with information blocking (PDF download).

**What about making office notes, lab results, and other diagnostic reports available to patients?**
These should be available to patients *as soon* as the physician's office receives the electronic copy in their hands. It is likely that your practice or organization already has protocols set up for releasing information. The Academy recommends members to reach out to their Risk Managers or General Council to make sure policies on patient access are updated appropriately. View information on releasing lab results (PDF download).

**Would the Preventing Harm Exception cover a "blanket" several day delay on the release of laboratory or other test results to patients so an ordering clinician can evaluate each result for potential risk of harm associated with the release? *1/15/2021***

The ONC has noted that the Preventing Harm Exception would not cover a "blanket" several day delay on the release of lab test results or other results and so developing policies to meet these standards regarding sharing test results with patients should be done on an individualized basis. Such individualized determinations made in good faith by an ordering clinician, in the exercise of their professional judgment and in the context of the treatment relationship within which they order the test, would satisfy the *type of risk* and *type of harm* conditions of the Preventing Harm Exception. View more information on Information Blocking FAQs.

1. https://www.ama-assn.org/system/files/2020-11/info-blocking-compliance.pdf

**What is a digital contact? What should we know about updating our digital contact information? Specifically, where do providers find information on how to enter or update digital contact information associated with their National Provider Identifier (NPI) in the National Plan and Provider Enumeration System (NPPES) and what fields are required to complete their entry for digital contact?**

Digital contact information, also known as endpoints, provide a secure way for health care entities, including providers and hospitals, to send authenticated, encrypted health information directly to known, trusted recipients over the internet.

Health care organizations seeking to engage in electronic health information exchange need accurate information about the electronic addresses (for example, Direct address, FHIR server URL, query endpoint, or other digital contact information) of potential exchange partners to facilitate this information exchange. NPPES can now capture information about a wide range of endpoints that providers can use to facilitate secure exchange of health information (85 FR 25581).

CMS will begin publicly reporting providers who do not list or update their digital contact information in the National Plan and Provider Enumeration System (NPPES) **by the end of 2021** *(date subject to change)*. This includes providing digital contact information such as secure digital endpoints like a Direct Address and/or a Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (API) endpoint. Making the list of providers who do not provide this digital contact information public will encourage providers to make this valuable, secure contact information necessary to facilitate care coordination and data exchange easily accessible.

Be sure to update your NPPES digital contact information.

**What should we know about public reporting and information blocking related to the MIPS Promoting Interoperability (PI) section of the Quality Payment Program (QPP)?**

For the MIPS PI section of the QPP, there are three statements to attest to targeting late 2020/early *2021 (date subject to change)*. The three attestation statements can be found on the 2019 PI Information Blocking factsheet. If a physician does not attest to these by the expected date, CMS will report it on the Physician Compare website, with 30 days advance notice.

**What are the penalties?**
The Academy understands that HHS has yet to propose a specific enforcement mechanism or has not implemented any penalties or rules for physicians or healthcare organizations. The OIG's recent proposed rule mainly applies to HIT/EHR technology developers/vendor. The OIG will issue future rulemaking on covering physicians and what enforcement action and violations will apply. When that occurs, the Academy will be sure to let members know.

On September 15, 2021, CMS published three FAQs which explain that CMS will not take enforcement action against certain payers for the payer-to-payer data exchange provision of the May 2020 Interoperability and Patient Access final rule until future rulemaking is finalized. CMS' decision to exercise enforcement discretion for the payer-to-payer policy until future rulemaking occurs does not affect any other existing regulatory requirements and implementation timelines outlined in the final rule. Please review the relevant FAQs for details.

*As the Academy develops more information on the rule, this document will be updated accordingly.*

**Updated:** September 22, 2021

1. https://www.ama-assn.org/system/files/2020-11/info-blocking-compliance.pdf