

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Final Rule from the Office of the National
Coordinator for Health IT (ONC)

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Acronyms List

EHI Electronic health information

Health IT Health information technology

HHS Department of Health and Human Services

HIE Health information exchange

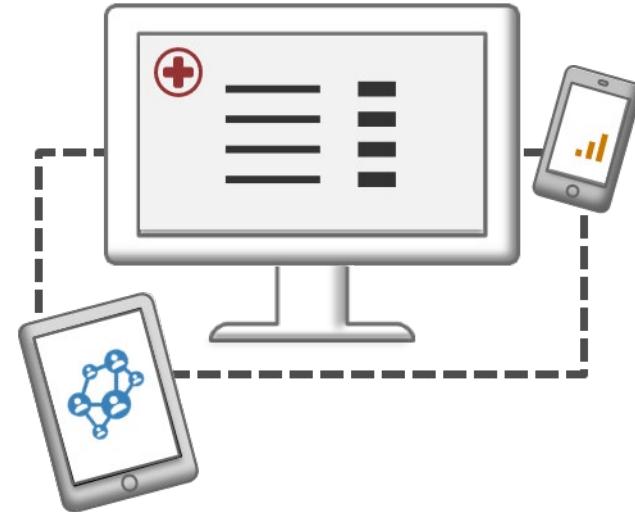
HIN Health information network

ONC Office of the National Coordinator for Health IT

USCDI United States Core Data for Interoperability

ONC's Final Rule

- Advances interoperability and promotes adoption of industry-accepted technical standards through updates to the ONC Health IT Certification Program.
- Addresses occurrences of information blocking and identifies **eight** exceptions for practices that would not be subject to penalties.
- Promotes greater health care choice and competition in the U.S.



Major Themes



Expanding access, exchange, and use of electronic health information (EHI) for patients and providers.



Strengthening interoperability, patient privacy, and security through implementation of technical standards.



Decreasing burden related to development and use of health IT.



Improving transparency of health care costs and quality.

Information Blocking

Information blocking is a practice that, except as required by law or specified by the Department of Health and Human Services (HHS) as a reasonable and necessary activity, is likely to interfere with, prevent, or materially discourage access, exchange, and use of EHI.

Analysis of whether a practice constitutes information blocking will require careful consideration of individual facts and circumstances, including:

1. Whether the practice was required by law.
2. Whether the actor had or should have had requisite knowledge that the practice could be information blocking.
3. Whether an exception applies.

Regulated Actors



Providers

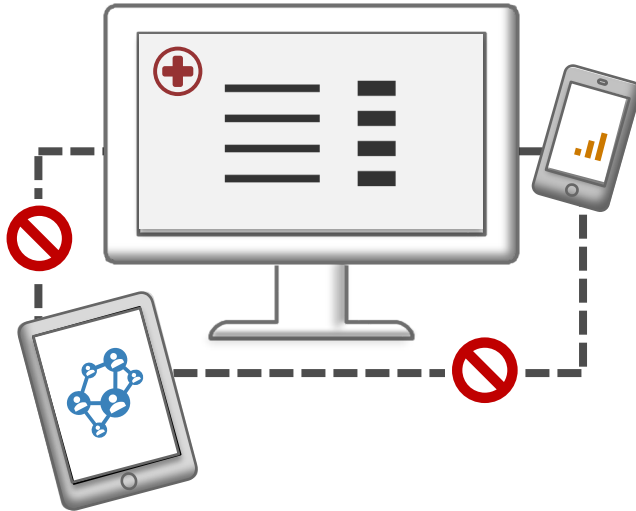


Health IT
Developers



HINs/HIEs

Information Blocking



Section 4004 of the 21st Century Cures Act authorizes HHS to identify reasonable and necessary activities that would not be considered information blocking, referred to as “exceptions.”

- If the actions of a regulated actor satisfy all applicable conditions of an exception at all relevant times, the actor would not be subject to civil penalties or other disincentives.
- Actors have the burden of proof.
- ONC finalized documentation requirements for certain exceptions.
- All exceptions apply to **all** regulated actors, but there are conditions within certain exceptions that apply to one or a subset of actors, as applicable.

Information Blocking Exceptions

Permit actors to not share all or a subset of the requested EHI

1. Preventing Harm Exception (§ 171.201)
2. Privacy Exception (§ 171.202)
3. Security Exception (§ 171.203)
4. Infeasibility Exception (§ 171.204)
5. Health IT Performance Exception (§ 171.205)

Involve fulfilling requests to access, exchange, or use electronic health information

6. **Content and Manner Exception (§ 171.301)**
7. Fees Exception (§ 171.302)
8. Licensing Exception (§ 171.303)

Exceptions that permit actors to not share all or a subset of the requested EHI

Objective

Preventing Harm Exception § 171.201	Applies to certain practices that are reasonable and necessary to prevent harm to a patient or another person.
Privacy Exception § 171.202	Applies to practices that are reasonable and necessary to protect the privacy of an individual's EHI.
Security Exception § 171.203	Applies to practices that are reasonable and necessary to promote the security of EHI.
Infeasibility Exception § 171.204	Permit an actor to decline to provide access, exchange, or use of EHI in a manner that is infeasible.
Health IT Performance Exception § 171.205	Applies to practices that are reasonable and necessary to maintain and improve the overall performance of health IT, including unavailability of health IT due to planned or unplanned maintenance and improvement.

Exceptions involving procedures for fulfilling requests to access, exchange, or use EHI

Objective

Content and Manner Exception
§ 171.301

Provides flexibility to actors concerning the required scope of EHI sent to fulfill a request, and the way the actor may fulfill the request.

Fees Exception
§ 171.302

Enables actors to charge fees related to the development of technologies and provision of services that enhance interoperability, while not protecting rent-seeking, opportunistic fees, and exclusionary practices that interfere with access, exchange, or use of EHI.

Licensing Exception
§ 171.303

Allows actors to protect the value of their innovations and charge reasonable royalties to earn returns on the investments they have made to develop, maintain, and update those innovations.

New: Content and Manner Exception





Content Condition

1. Up to 24 months after the publication date of the Cures Act final rule, an actor must respond to a request to access, exchange, or use EHI with, at a minimum, the EHI identified by the data elements represented in the United States Core Data for Interoperability (USCDI).
2. On and after 24 months after the publication date of the Cures Act final rule, an actor must respond to a request to access, exchange, or use EHI with EHI as defined in §171.102.

Manner Condition

1. An actor may need to fulfill a request in an alternative manner when the actor is:
 - Technically unable to fulfill the request in any manner requested or
 - Cannot reach agreeable terms with the requestor to fulfill the request.
2. If an actor fulfills a request in an alternative manner, such fulfillment must comply with the order of priority described in the manner condition and must satisfy the Fees Exception and Licensing Exception, as applicable.

New: Content and Manner Exception

Concern in Comments on Proposed Rule	How New Exception Addresses Concern
 <p>Breadth of the proposed EHI definition and requesting flexibility in the implementation of the information blocking provision.</p>	 <p>Content Condition: Establishes the content an actor must provide in response to a request to access, exchange, or use EHI in order to satisfy the exception.</p>
 <p>Providing a reasonable alternative means of accessing, exchanging or using the EHI as proposed in Infeasibility Exception.</p>	 <p>Manner Condition: Establishes the way an actor must fulfill a request to access, exchange, or use EHI in order to satisfy this exception.</p> <ul style="list-style-type: none"> Removed “reasonable alternative” requirement from the Infeasibility Exception and incorporated the general concept into the Content and Manner Exception.

02 Key Information Blocking Provisions and Updates

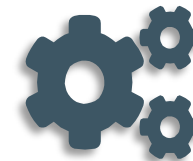
New: Content and Manner Exception

Exception gives actors an additional 18 months to gain experience applying the exceptions with just the EHI identified by the data elements represented in the USCDI, as compared to the full scope of EHI that would apply thereafter.



Fees and licensing royalties are allowed for the manners used in the content and manner exception, if they meet conditions.

An actor must try to enable access, exchange, or use of EHI in one of the ways described in the content and manner exception before they move to the infeasibility exception.



Infeasibility exception should be a last resort and is only available if the actor absolutely cannot provide the EHI in any way.

03 | Preparing for Compliance

**Date of
Publication**



Actors have six months to prepare for compliance with information blocking rules.

**6
Months**



Actors are required to comply with exceptions, with EHI definition limited to USCDI.

**24
Months
and On**



Actors are required to comply with exceptions, with full EHI definition in place.

Immediate Activities: Months 1-2



- Review Final Rule, fact sheets and other resources from ONC.
- Identify affected teams and personnel at organization.
- Designate an information blocking champion/leader.
- Develop compliance strategy and plan.
- Educate leadership and staff on the Rule and its components.

Short-term Activities: Months 3-6



- Review existing policies and processes for data access.
- Review all new and existing agreements and pricing for health IT.
- Identify changes to contracts, agreements, and licenses.
- Update policies and procedures to support access, exchange, and use of EHI.
- Train staff on updated policies and procedures.
- Implement new documentation practices that align to information blocking exceptions.

Long-term Activities: Month 6 and on



- Perform quality assurance and monitor compliance plan for effectiveness.
- Implement regular education and training for staff.
- Investigate and remediate problems.

03 | Preparing for Compliance



If you are interested in learning about Discern's health IT capabilities, please contact:

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