



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

Information Blocking

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- The materials contained in this presentation are based on the provisions contained in 45 C.F.R. Parts 170 and 171. While every effort has been made to ensure the accuracy of this restatement of those provisions, this presentation is not a legal document. The official program requirements are contained in the relevant laws and regulations. Please note that other Federal, state and local laws may also apply.
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Agenda

- A. Background
- B. Framework, Timeline, and Terms
- C. Exceptions
- D. Complaint Process



Information Blocking – Path to the 21st Century Cures Act



In a 2015 report to Congress, ONC provided a definition of information blocking, an analysis of the extent to which the practice exists in the industry, and recommendations to address the issue.



ONC continued to engage with stakeholders and provided ongoing technical assistance to Congress.



In December 2016, the 21st Century Cures Act was signed into law. It included a definition of information blocking and provisions for addressing information blocking.

Information Blocking – Path to the Final Rule



Following the enactment of the Cures Act, ONC continuously met with stakeholders.



ONC listened to and reviewed complaints of information blocking.



ONC consulted with federal agencies, including the HHS OIG, HHS OCR, and the Federal Trade Commission.



After release of the ONC proposed rule on March 4, 2019, ONC received **over 2,000 comment submissions**. ONC met with stakeholders and consulted with federal agencies.



ONC's final rule released on March 9, 2020.

Information Blocking in the 21st Century Cures Act

21st Century Cures Act, Section 4004:

- Defines “information blocking”
- Authorizes the Secretary to identify, through rulemaking, reasonable and necessary activities that do **not** constitute information blocking
- Identifies the HHS Office of Inspector General (OIG) as the HHS office to investigate claims of information blocking and provides referral processes to facilitate coordination with the HHS Office for Civil Rights (OCR)
- Prescribes penalties for information blocking
- Charges ONC with implementing a complaint process for reporting information blocking, and provides confidentiality protections for complaints



Framework, Timeline, and Terms



What Makes an Individual or Entity an Information Blocker?

Elements of information blocking

- ☐ Actor regulated by the information blocking provision
- ☐ Involves electronic health information (EHI)
- ☐ Practice is likely to interfere with, access, exchange, or use of EHI
- ☐ Requisite knowledge by the actor
- ☐ Not required by law
- ☐ Not covered by an exception



Consequences of Being an Information Blocker

- **Cures Act prescribes penalties for information blocking**
 - Health IT developers of certified health IT, health information networks, and health information exchanges → Civil monetary penalties (CMPs) up to \$1 million per violation
 - Health care providers → Appropriate disincentives
- **Certification ban (§ 170.581) for health IT developers in violation of the Conditions of Certification**
 - Information blocking Condition of Certification (§ 170.401)
 - Public listing of certification bans and terminations

Compliance Timeline

- Actors do **not** have to comply with the information blocking provision until **six months after publication** of the final rule.
- Enforcement of information blocking civil monetary penalties (CMPs) will not begin until established by future rulemaking by OIG. As a result, actors will not be subject to penalties until the CMP rule is final.
 - *At a minimum*, the timeframe for enforcement will **not** begin sooner than the compliance date of the ONC final rule and will depend on when the CMP rules are final.
 - Discretion will be exercised such that conduct that occurs before the CMP rule is final will not be subject to information blocking CMPs.

Information Blocking Definition in the Final Rule

(a) Information blocking means a practice that—

- (1) Except as required by law or covered by an exception, is likely to interfere with access, exchange, or use of electronic health information; and
- (2) **If conducted by a health information technology developer, health information network or health information exchange**, such developer, network or exchange knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI; or
- (3) **If conducted by a health care provider**, such provider knows that such practice is unreasonable and is likely to interfere with the access, exchange, or use of EHI.

(b) Until 24 months after the publication date of the final rule, EHI for purposes of paragraph (a) of this section is limited to the EHI identified by the data elements represented in the USCDI standard adopted in § 170.213.

Clarifications from the Proposed Rule

- Defined “interfere with” to include “prevent” and “materially discourage”
- Added paragraph (b)

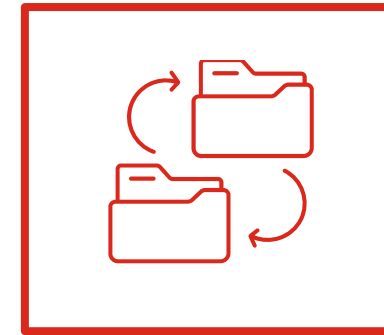
“Actors” Regulated in the Final Rule



**Health Care
Providers**



**Health IT
Developers of
Certified Health IT**



**Health Information
Networks (HIN)/
Health Information
Exchanges (HIE)**



Health Care Providers

Who are they?

- hospital
- skilled nursing facility
- nursing facility
- home health entity or other long term care facility
- health care clinic
- community mental health center
- renal dialysis facility
- blood center
- ambulatory surgical
- emergency medical services provider
- federally qualified health center
- group practice
- pharmacist
- pharmacy
- laboratory
- physician
- practitioner
- rural health clinic
- ambulatory surgical center
- provider operated by, or under contract with, the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization
- “covered entity” under certain statutory provisions
- therapist
- any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary

Finalized as proposed with the the same meaning as “health care provider” in 42 U.S.C. 300jj.



Health IT Developers of Certified Health IT

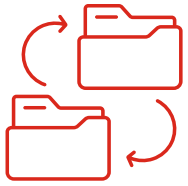
Who are they?

An individual or entity, other than a health care provider that self-develops health IT for its own use, that develops or offers health information technology and which has, **at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules certified** under a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator.

Changes and Clarifications from the Proposed Rule

- Expressly excludes “self-developers” from the definition
- Does not extend beyond the time the developer no longer has health IT certified under the Program





Health Information Networks & Exchanges

Who are they?

An individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of EHI:

1. Among **more than two unaffiliated individuals or entities** (other than the individual or entity to which this definition might apply) **that are able to exchange with each other**; and
2. That is for a **treatment, payment, or health care operations** purpose, as such terms are defined in 45 CFR 164.501 regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164.

Changed in Four Ways

Electronic Health Information

What does it mean?

Electronic protected health information (ePHI) as the term is defined for HIPAA in 45 CFR 160.103 **to the extent that the ePHI would be included in a designated record set (DRS)** as defined in 45 CFR 164.501 (other than psychotherapy notes as defined in 45 CFR 164.501 or information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding), regardless of whether the actor is a covered entity as defined in 45 CFR 160.103.



Changes and Clarifications from the Proposed Rule

- Focused definition on ePHI included in a DRS.
- This definition does not expressly include or exclude price information. To the extent that ePHI includes price information and is included in a DRS, it would be considered EHI.

“Interfere with” or “Interference” What is it?

Interfere with or interference means to prevent, materially discourage, or otherwise inhibit.

- ***Publication of “FHIR service base URLs” (sometimes also referred to as “FHIR endpoints”)*** - A FHIR service base URL cannot be withheld by an actor as it (just like many other technical interfaces) is necessary to enable the access, exchange, and use of EHI.
- ***Delays*** - An actor’s practice of slowing or delaying access, exchange, or use of EHI could constitute an interference and implicate the information blocking provision.
- ***Costs for Electronic Access by Patients/Individuals*** - An actor’s practice of charging an individual, their personal representative, or another person or entity designated by the individual for electronic access to the individual’s EHI would be inherently suspect under an information blocking review.

“Interfere with” or “Interference” What is it not?

Interfere with or interference means to prevent, materially discourage, or otherwise inhibit.

- ***Business Associate Agreements (BAAs)*** – Actors are not required to violate BAAs or associated service level agreements. *However*, a BAA or its associated service level agreements must not be used in a discriminatory manner by an actor to forbid or limit disclosures that otherwise would be permitted by the Privacy Rule.
- ***Educate Patients about Privacy and Security Risks of Apps and 3rd Parties*** – Actors may provide patients with information that:
 - Focuses on any current privacy and/or security risks posed by the technology or the third-party developer of the technology;
 - Is factually accurate, unbiased, objective, and not unfair or deceptive; and
 - Is provided in a non-discriminatory manner.

Knowledge Standard

Health Care Providers

“...**knows** that such practice is **unreasonable** and is likely to interfere with, prevent, or materially discourage the access, exchange or use of electronic health information....”

Health IT Developers of Certified Health IT and HINs/HIEs

“...**knows, or should know**, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange or use of electronic health information....”

Required by Law

What does it mean?

- Refers specifically to interferences with access, exchange, or use of EHI that are explicitly required by state or federal law.
- Distinguishes between interferences that are “required by law” and those engaged in pursuant to a privacy law, but which are not “required by law.”

Clarification from the Proposed Rule

Federal and state law includes:

- Statutes, regulations, court orders, and binding administrative decisions or settlements, such as (at the Federal level) those from the FTC or the Equal Employment Opportunity Commission (EEOC)
- Tribal laws, as applicable

Exceptions

Overview of the Exceptions

- On behalf of HHS, ONC has defined **eight** exceptions that offer actors **certainty** that, when their practices with respect to accessing, exchanging, or using EHI meet the conditions of one or more exceptions, such practices will **not** be considered information blocking.
- 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.



Overview of the Exceptions

The **eight exceptions** are divided into **two categories**:

Exceptions for *not fulfilling* requests to
access, exchange, or use EHI



1. Preventing Harm



2. Privacy



3. Security



4. Infeasibility



5. Health IT Performance

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



6. Content and Manner



7. Fees



8. Licensing



Preventing Harm Exception

Overview

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

To satisfy this exception:

The actor must hold a reasonable belief that the practice will substantially reduce a risk of harm *and* the practice must be no broader than necessary

+

The practice must satisfy at least one condition from each category: type of risk, type of harm, *and* implementation basis

+

The practice must satisfy the condition concerning a patient right to request review of an individualized determination of risk of harm

Objective

This exception recognizes that the public interest in protecting patients and other persons against unreasonable risks of harm can justify practices that are likely to interfere with access, exchange, or use of EHI.



Privacy Exception

Overview

It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI in order to protect an individual's privacy, provided certain conditions are met.

**To satisfy this exception,
an actor's privacy-protective practice must:**

Satisfy at least one sub-exception

+

**Meet all conditions applicable
to a sub-exception being relied upon**

Objective

This exception recognizes that if an actor is permitted to provide access, exchange, or use of EHI under a privacy law, then the actor should provide that access, exchange, or use. However, an actor should not be required to use or disclose EHI in a way that is prohibited under state or federal privacy laws.



Security Exception

Overview

It will not be information blocking for an actor to interfere with the access, exchange, or use of EHI in order to protect the security of EHI, provided certain conditions are met.

To satisfy this exception,
an actor's security-related practice must:

Satisfy threshold conditions

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Implement a Qualifying
Organizational Security Policy

OR

Implement a Qualifying
Security Determination

Objective

This exception is intended to cover all legitimate security practices by actors, but does not prescribe a maximum level of security or dictate a one-size-fits-all approach.



Infeasibility Exception

Overview

It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI due to the infeasibility of the request, provided certain conditions are met.

To satisfy this exception, an actor must:

Demonstrate that the practice meets one of the conditions for uncontrollable events, segmentation, *or* infeasibility under the circumstances

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Provide written response, within 10 business days of receipt of the request, with the reason(s) why the request is infeasible

Objective

This exception recognizes that legitimate practical challenges may limit an actor's ability to comply with requests for access, exchange, or use of EHI. An actor may not have—and may be unable to obtain—the requisite technological capabilities, legal rights, or other means necessary to enable access, exchange, or use.



Health IT Performance Exception

Overview

It will not be information blocking for an actor 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.

To satisfy this exception, the practice must meet one of the following conditions:

Maintenance and improvements

OR

Assured level of performance

OR

Practices that prevent harm / security-related practices

Objective

This exception recognizes that for health IT to perform properly and efficiently, it must be maintained, and in some instances improved, which may require that health IT be taken offline temporarily. Actors should not be deterred from taking 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 health IT.



Content and Manner Exception

Overview

It will not be information blocking for an actor to limit the content of its response to a request to access, exchange, or use EHI or the manner in which it fulfills a request, provided certain conditions are met.

To satisfy this exception,
an actor must meet both of these conditions:

Content condition

+

Manner condition

Objective

This exception provides clarity and flexibility to actors concerning the required content of an actor's response to a request to access, exchange, or use EHI and the manner in which the actor may fulfill the request. It supports innovation and competition by allowing actors to first attempt to reach and maintain market negotiated terms for the access, exchange, and use of EHI.



Content and Manner Exception

Content Condition

1. **Up to 24 months** after the publication date of the 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 USCDI standard**.
2. **On and after 24 months** after the publication date of the final rule, an actor must respond to a request to access, exchange, or use EHI with **EHI as defined in § 171.102**.



Content and Manner Exception

Manner Condition – Any Manner Requested

- An actor must fulfill a request **in any manner** requested *unless* the actor is:
 1. Technically unable to fulfill the request in a manner requested; **or**
 2. Cannot reach agreeable terms with the requestor to fulfill the request.
- If an actor fulfills a request in **any manner requested**, the actor is **not** required to comply with the Fees or Licensing Exception.



Content and Manner Exception

Manner Condition – Alternative Manner

- If an actor responds in an **alternative manner**, the actor must fulfill the request **without unnecessary delay** in the **following order of priority**, only proceeding to the next consecutive paragraph if **technically unable** to fulfill the request in that manner:
 1. Using technology certified to standard(s) adopted in Part 170 that is specified by the requestor.
 2. Using content and transport standards specified by the requestor and published by:
 - Federal Government; or
 - Standards developing organization accredited by the American National Standards Institute.
 3. Using an alternative machine-readable format, including the means to interpret the EHI, agreed upon with the requestor.



Fees Exception

Overview

It will not be information blocking for an actor to charge fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI, provided certain conditions are met.

To satisfy this exception, the practice must:

Meet basis for fees condition

+

Not be specifically excluded

+

Comply with Assurances and/or API Conditions of Certification, as applicable



Objective

This exception 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

Overview

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.

To satisfy this exception, the practice must:

Meet the negotiating a license conditions

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Meet the licensing conditions

+

Meet the additional conditions relating to the provision of interoperability elements

Objective

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



Complaint Process

Complaint Process

- The Cures Act directs the National Coordinator to implement a standardized process for the public to submit reports on claims of information blocking.
- We will **implement and evolve** the complaint process by building on existing mechanisms, including the process for providing feedback and expressing concerns about health IT that is currently available at www.healthit.gov/healthit-feedback.
- For additional information about submitting an information blocking complaint or about information blocking general, please see our final rule website and materials at www.healthit.gov/curesrule.

Protection from Disclosure of Information

Any information received by
ONC in connection with a
claim or suggestion of
possible information
blocking and that could
reasonably be expected to
facilitate identification of the
source of the information
would fall under protections
in section 3022(d)(2) of the
Public Health Service Act.

Excerpt from 21st Century Cures Act

SEC. 4004. INFORMATION BLOCKING.

Subtitle C of title XXX of the Public Health Service Act ([42 U.S.C. 300jj–51 et seq.](#)) is amended by adding at the end the following:

‘SEC. 3022. INFORMATION BLOCKING.

“(d) ADDITIONAL PROVISIONS

...

(2) PROTECTION FROM DISCLOSURE OF INFORMATION.—Any information that is received by the National Coordinator in connection with a claim or suggestion of possible information blocking and that could reasonably be expected to facilitate identification of the source of the information—

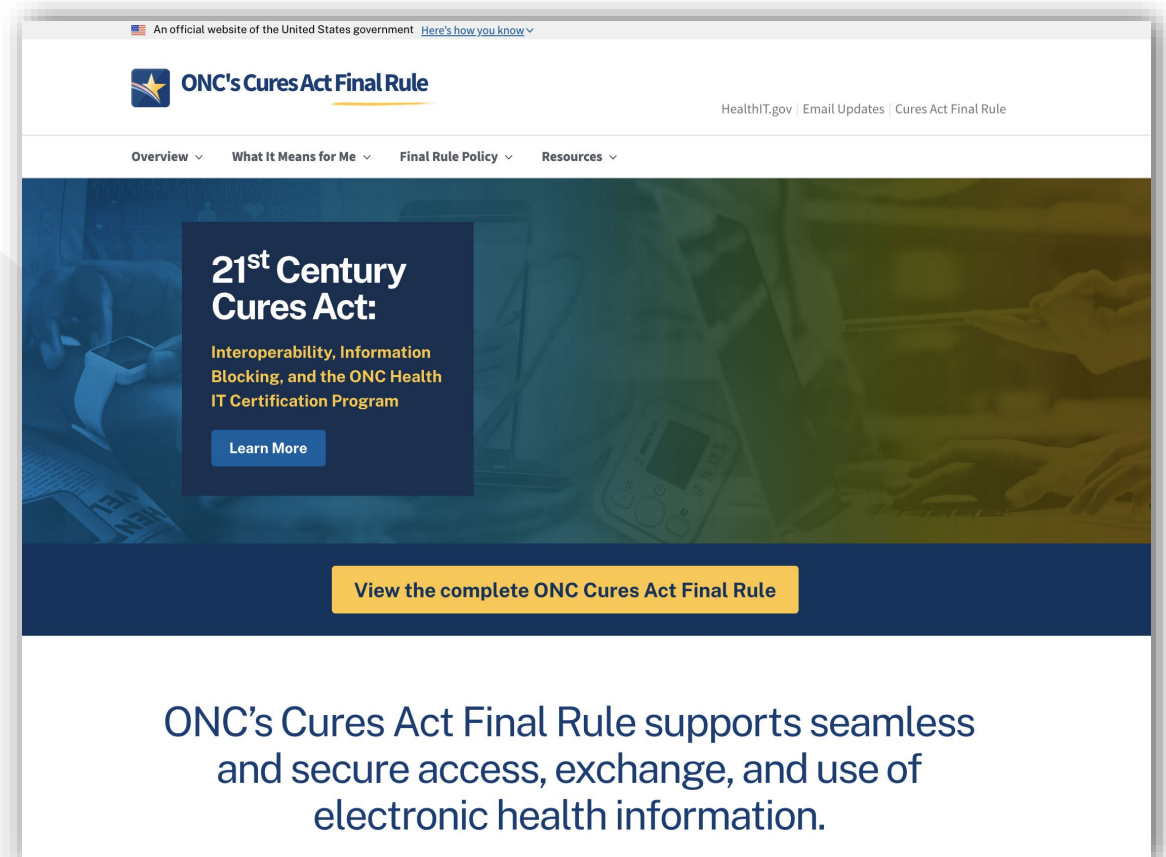
“(A) shall not be disclosed by the National Coordinator except as may be necessary to carry out the purpose of this section;

“(B) shall be exempt from mandatory disclosure under section 552 of title 5, United States Code, as provided by subsection (b)(3) of such section; and

“(C) may be used by the Inspector General or Federal Trade Commission for reporting purposes to the extent that such information could not reasonably be expected to facilitate identification of the source of such information.

Please visit www.healthit.gov/curesrule

- View the Final Rule
- Fact Sheets
- Upcoming Webinar Schedule
- Previously Recorded Webinars
- Additional Resources





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Health Information Technology

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