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

Overview

Presented to the NCVHS

March 24, 2020

The Office of the National Coordinator for Health Information Technology

Please Note:

- 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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Overview & 2015 Edition Cures Updates

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Purpose of the Final Rule

- ✓ **Patients**: Right of Access to their Chart, Supporting Patient Privacy and Security, the Ability to Shop for Care and Avoid Bankruptcy
- ✓ **Doctors and Hospitals**: Making Patient's Chart Data Requests Easy and Inexpensive, Allowing Choice of Software, Implementation
- ✓ **Patients, Doctors, and Hospitals**: Improving Patient Safety
- ✓ **Health IT Developers**: Minimizing API Development and Maintenance Costs, Protecting Intellectual Property
- ✓ **American Public**: Maximizing Innovation, Transparency in Health Care

Updates to the 2015 Edition Certification Criteria

Time-Limited and Removed Criteria

- Drug formulary/Drug List Checks
- Patient-Specific Education
- Secure Messaging
- Problem List, Medication List, Med Allergy List
- Smoking Status
- Common Clinical Data Set summary record – create & receive criteria (replaced with USCDI)
- API (replaced with Standardized API criterion)
- Data Export (replaced with EHI export criterion)

Revised Criteria

- Interoperability criteria (C-CDA, VDT, etc.)
  - Updated with USCDI
  - Updated with C-CDA Companion Guide
- ASTM criteria
- Security tags send & receive criteria
- Electronic Prescribing (aligned with CMS)
- CQM – report criterion (aligned with CMS)

New Criteria

- Electronic Health Information (EHI) export
- Standardized API for patient and population services
- Privacy and Security Attestation Criteria

Revised: United States Core Data for Interoperability Standard

The United States Core Data for Interoperability (USCDI) standard will replace the Common Clinical Data Set (CCDS) definition 24 months after publication of this final rule.

USCDI includes the following new required data classes and data elements:

- Provenance
- Clinical Notes
- Pediatric Vital Signs
- Address, Email & Phone Number

Health IT developers need to update their certified health IT to support the USCDI for all certification criteria affected by this change within 24 months after the publication of the final rule.

USCDI Standard Annual Update Schedule

ONC will establish and follow a predictable, transparent, and collaborative process to expand the USCDI, including providing stakeholders with the opportunity to comment on the USCDI's expansion.

Conditions and Maintenance of Certification

The Office of the National Coordinator for Health Information Technology

Conditions and Maintenance of Certification

The 21st Century Cures Act (Section 4002) requires the Secretary of HHS to establish Conditions and Maintenance of Certification requirements for the ONC Health IT Certification Program

The Conditions and Maintenance of Certification express initial requirements and ongoing requirements for health IT developers and their certified Health IT Module(s).

Any noncompliance with the proposed Conditions and Maintenance of Certification requirements would be subject to ONC direct review, corrective action, and enforcement procedures under the ONC Health IT Certification Program.

There are seven Conditions of Certification with accompanying Maintenance of Certification Requirements. They are:

1. **Information Blocking**
2. **Assurances**
3. **Communications**
4. **Application Programming Interfaces (APIs)**
5. **Real World Testing**
6. **Attestations**
7. ***(Future) Electronic Health Record (EHR) Reporting Criteria Submission***

ONC Direct Review of The Conditions And Maintenance Of Certification

ONC will utilize the processes established for ONC direct review of certified health IT.

STEP 1 Initiating Review and Health IT Developer Notice

STEP 2 Records Access

STEP 3 Corrective Action Plan

STEP 4 Certification Ban and/or Termination

STEP 5 Appeal

STEP 6 Public Listing of Certification Ban and/or Terminations

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Information Blocking

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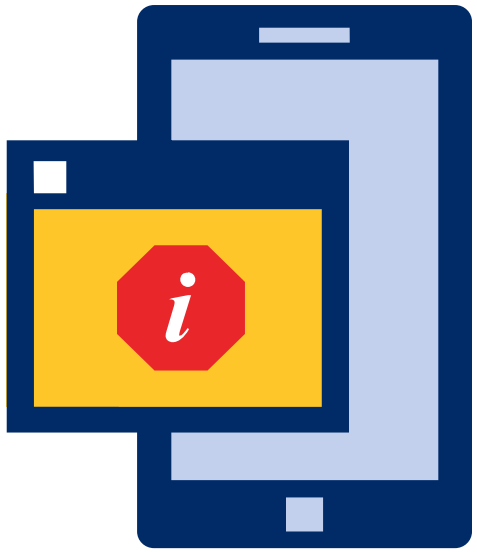
Information Blocking in the 21st Century Cures Act

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



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, prevent, or materially discourage access, exchange, or use of EHI
- ❑ Requisite knowledge by the actor
- ❑ Not required by law
- ❑ Not covered by an exception

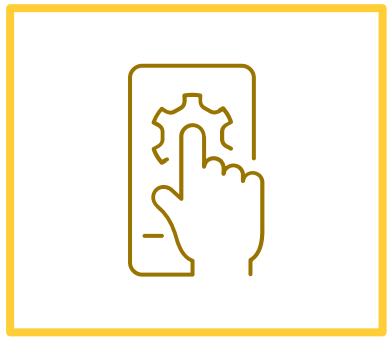
Compliance Timeline

- Actors do **not** have to comply with the information blocking provision until **six months after publication** of the final rule.

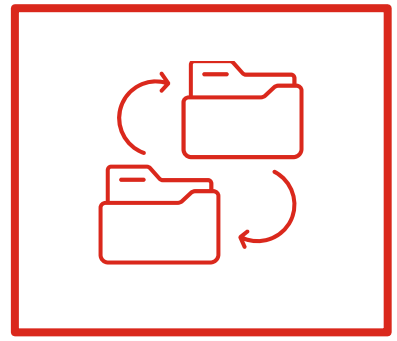
- Enforcement of information blocking civil monetary penalties (CMPs) will not begin until established by future rulemaking by OIG. As a result, actors will not be subject to penalties until the CMP rule is final.
  - *At a minimum*, the timeframe for enforcement will **not** begin sooner than the compliance 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 finale will not be subject to information blocking CMPs.

“Actors” Regulated in the Final Rule

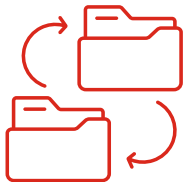
Health Care Providers



Health IT Developers of Certified Health IT



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



Health 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 enable 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.

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

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.

Please visit www.healthit.gov/curesrule

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

The Office of the National Coordinator for Health Information Technology

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