

CLIMB

Information Blocking

March 23rd, 2021

Alabama Primary Health Care Association

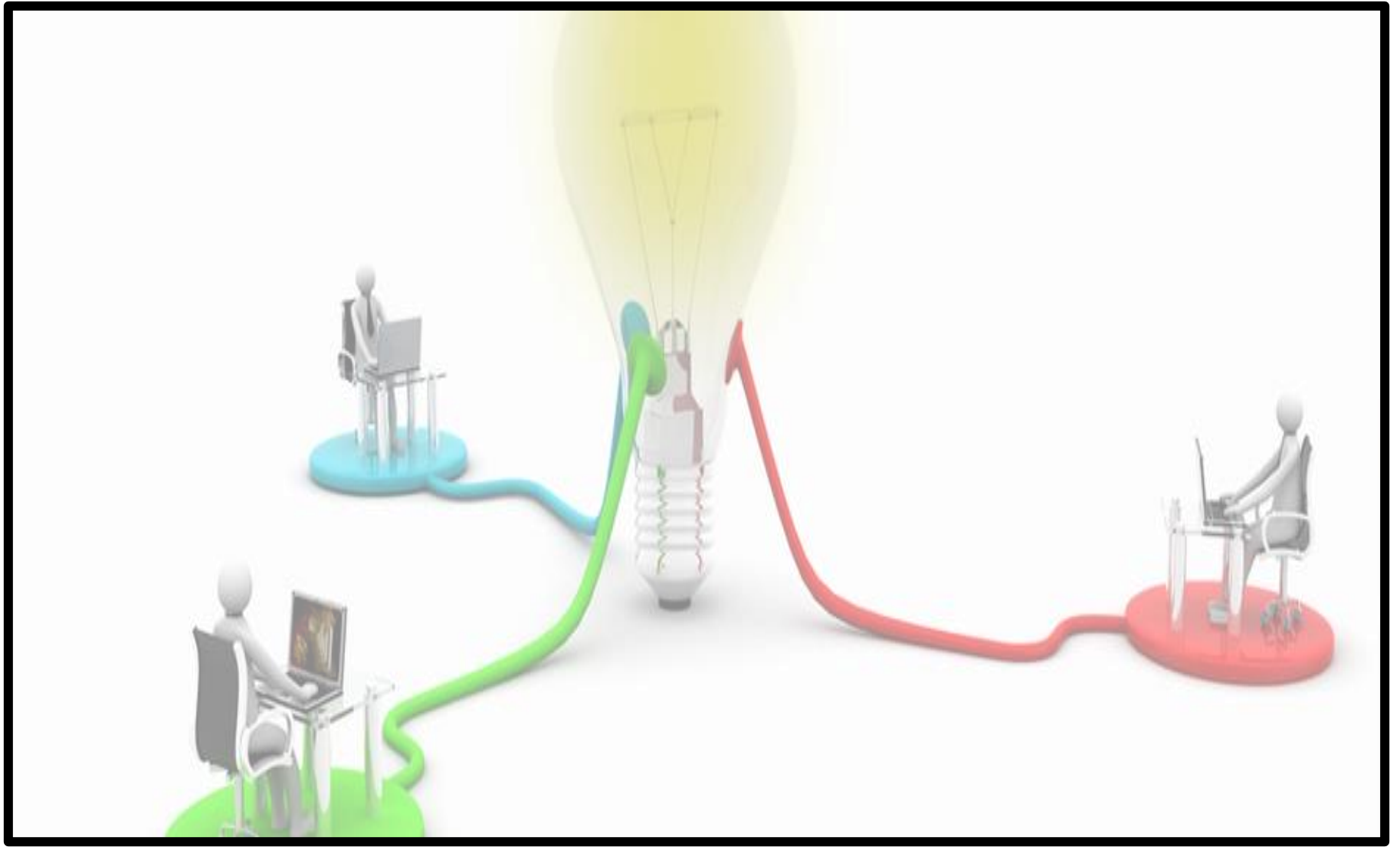


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21st Century Cures ACT: Information Blocking





Agenda

What is the 21st Century Cures Act?

ONC Applicability Dates

New Terms

Definition of Information Blocking

Exceptions

What does this mean to...

Steps for Information Blocking compliance

Protecting Confidential data

FAQs

Take Away



What is the 21st Century Cures Act?

- Office of National Coordinator (ONC) is responsible for the implementation of key provisions in Title IV of the 21st Century Cures Act that are designed to advance interoperability; support the access, exchange, and use of electronic health information (EHI); and address occurrences of information blocking
- Additionally, the final rule modifies the 2015 Edition health IT certification criteria and ONC Health IT Certification Program (Program) in other ways to advance interoperability, enhance health IT certification, and reduce burden and costs.
- the final rule establishes application programming interface (API) requirements, including for patients' access to their health information without special effort.

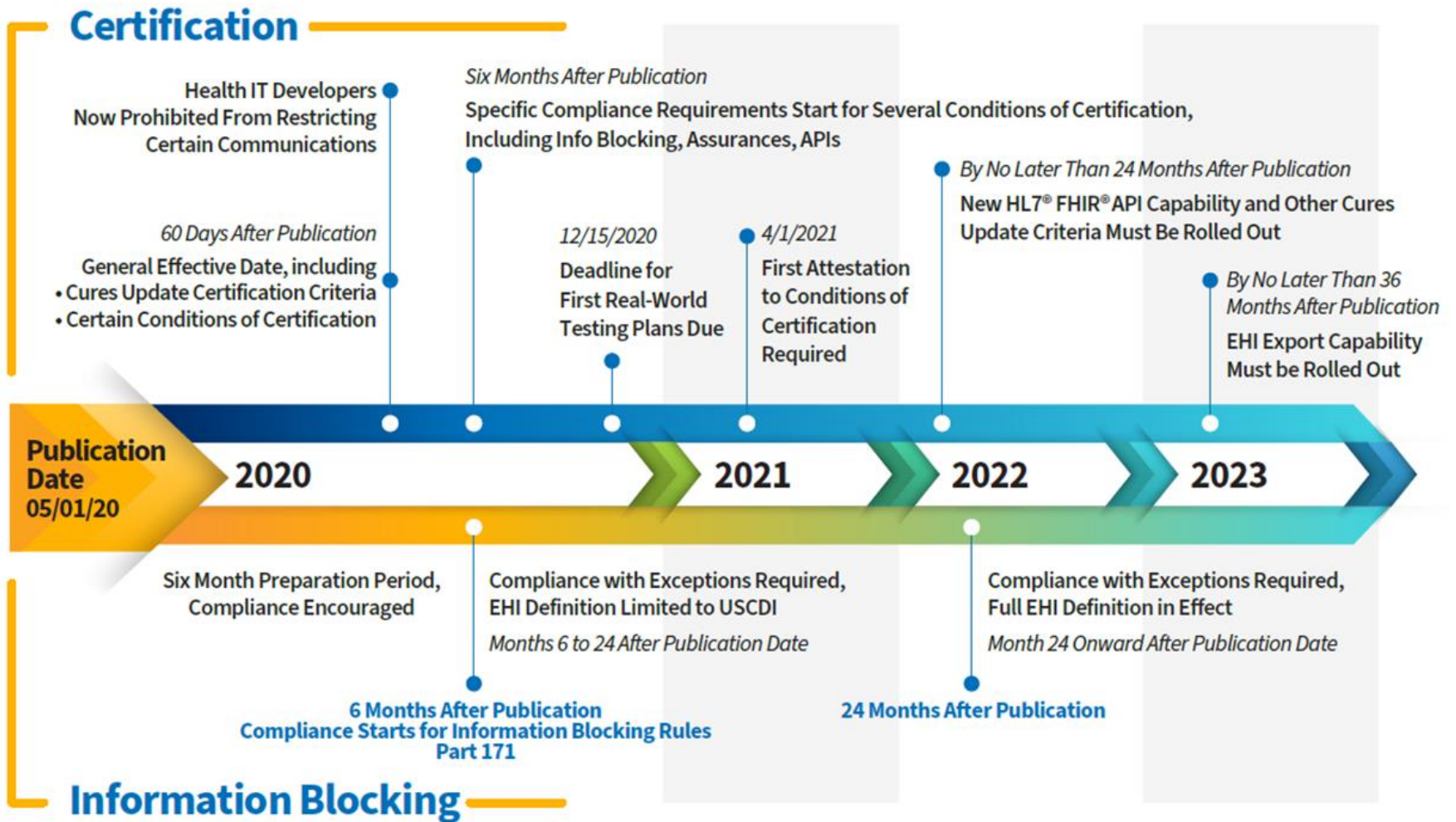
What is the 21st Century Cures Act?

- The final rule was signed into law on December 13, 2016 but the implementation stages have been delayed.
- The ONC notes the final rule:
 - “is designed to give patients and their healthcare providers secure access to health information”.
 - requires “that patients can electronically access all of their electronic health information (EHI), structured and/or unstructured, at no cost”.
 - supports the sharing of EHI between care providers.
 - places new requirements on HIT developers for security, sharing and access to EHI.

**21st Century Cures ACT:
Effective Date April 5th, 2021**



New Applicability Dates included in ONC Interim Final Rule: Certification

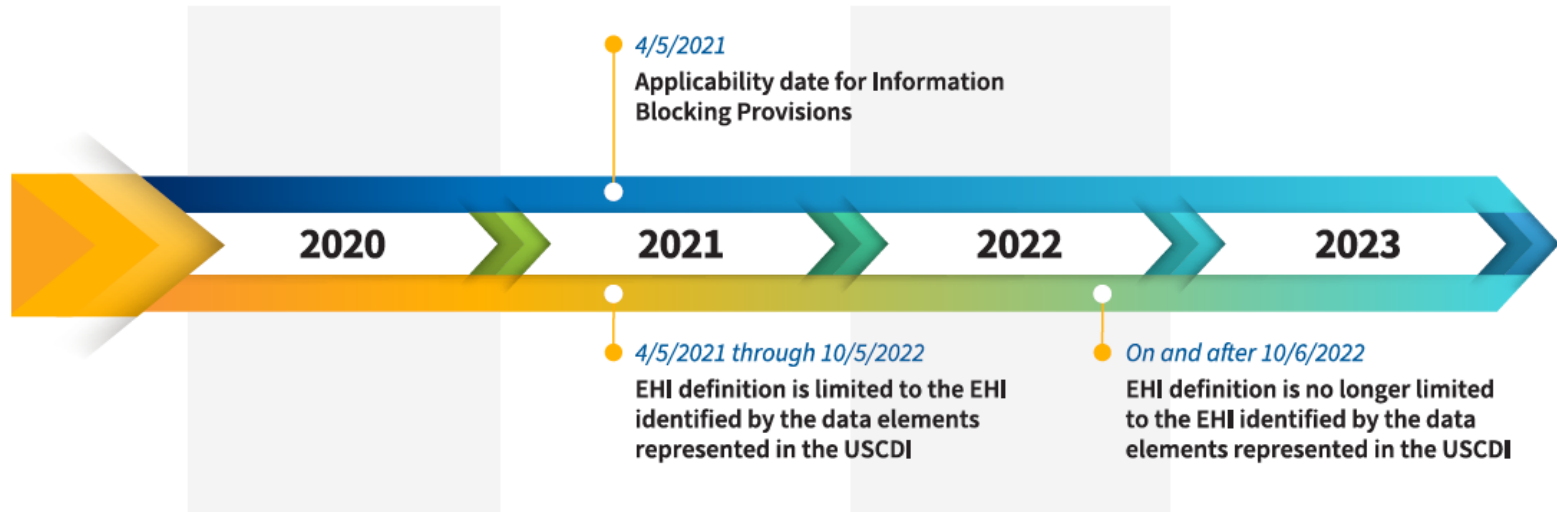


EHI = Electronic Health Information USCDI = United States Core Data for Interoperability

New Applicability Dates included in ONC Interim Final Rule: Information Blocking

Information Blocking and the ONC Health IT Certification Program:
Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency Interim Final Rule

Information Blocking



NEW Terms

ONC 21st Century Cures Act Final Rule

Information Blocking

EHI – Electronic Health Information

Actors –

- Health Care Provider
- Health Information Network/Health Information Exchange
- Health IT Developer of Certified Health IT

USCDI - United States Core Data for Interoperability



USCDI Data Elements



The USCDI is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.

A USCDI “Data Class” is an aggregation of various Data Elements by a common theme or use case

A USCDI “Data Element” is the most granular level at which a piece of data is represented in the USCDI for exchange.



USCDI v1 Data Elements

Allergies and Intolerances

Assessment or Plan of Treatment

Care Team Members

Clinical Notes

- Progress Note
- D/C Summary Note
- Consultation Note

Patient Goals

Health Concerns

Immunizations

Laboratory

- Tests and Results

Medications

Patient Demographics

Problems List

Procedures

Provenance

- Author Organization
- Author Timestamp

Smoking Status

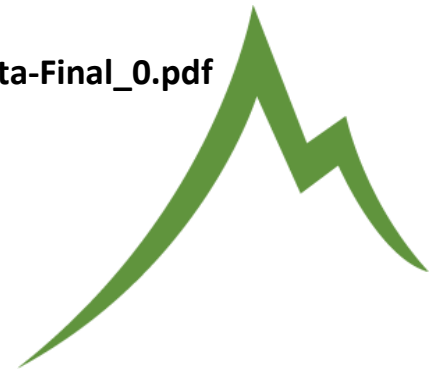
Implantable Device Identifiers

Vital Signs

- BP, Height, Weight, Temp, BMI

Source:

https://www.healthit.gov/isa/sites/isa/files/2020-10/USCDI-Version-1-July-2020-Errata-Final_0.pdf





Information Blocking Definition

Information Blocking Definition

Information blocking means a practice that:

- Except as required by law or covered by an exception, is likely to interfere with access, exchange, or use of electronic health information (EHI); and
- 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 access, exchange, or use of EHI; or
- 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.

Until date specified in 45 CFR 171.103(b), EHI for purposes of §171.103(a) is limited to the EHI identified by the data elements represented in the USCDI standard adopted in §170.213.



Information Blocking Exceptions



Exceptions:

- Eight “reasonable and necessary” activities that “actors” (health care providers, health IT developers of certified health IT, health Information exchanges, and health information networks) may engage in that could limit access to EHI.
- Only one exception needs to be met in order to avoid penalties for information blocking, but that exception must be “met at all relevant times,” not just as a one-off occurrence.
- The practice that fails to meet all of the conditions of an exception will be evaluated on a case-by-case basis to assess the specific facts and circumstances to determine whether information blocking has occurred.

Exceptions

Preventing Harm

Privacy Exception

Security Exception

Infeasibility Exception

Health IT Performance Exception

Content and Manner Exception

Fees Exception

Licensing Exception



Preventing Harm Exception

- The actor must hold a reasonable belief that the practice will substantially reduce a risk of harm;
- The actor's practice must be no broader than necessary;
- The actor's practice must satisfy at least one condition from each of the following categories: 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.



Privacy Exception

- Precondition not satisfied: If an actor is required by a state or federal law to satisfy a precondition (such as a patient consent or authorization) prior to providing access, exchange, or use of EHI, the actor may choose not to provide access, exchange, or use of such EHI if the precondition has not been satisfied under certain circumstances.
- Health IT developer of certified health IT not covered by HIPAA: If an actor is a Health IT developer of certified health IT that is not required to comply with the HIPAA Privacy Rule, the actor may choose to interfere with the access, exchange, or use of EHI for a privacy-protective purpose if certain conditions are met.
- Denial of an individual's request for their EHI consistent with 45 CFR 164.524(a)(1) and (2): An actor that is a covered entity or business associate may deny an individual's request for access to his or her EHI in the circumstances provided under 45 CFR 164.524(a)(1) and (2) of the HIPAA Privacy Rule. (Psychotherapy notes / legal hold)
- Respecting an individual's request not to share information: An actor may choose not to provide access, exchange, or use of an individual's EHI if doing so fulfills the wishes of the individual, provided certain conditions are met.

Security Exception

The practice must be:

- Directly related to safeguarding the confidentiality, integrity, and availability of EHI;
- Tailored to specific security risks; and
- Implemented in a consistent and non-discriminatory manner.

The practice must either implement a qualifying organizational security policy or implement a qualifying security determination.



Infeasibility Exception

The practice **must meet one** of the following conditions:

- Uncontrollable events: The actor cannot fulfill the request for access, exchange, or use of electronic health information due to a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority.
- Segmentation: The actor cannot fulfill the request for access, exchange, or use of EHI because the actor cannot unambiguously segment the requested EHI.
- Infeasibility under the circumstances: The actor demonstrates through a contemporaneous written record or other documentation its consistent and non-discriminatory consideration of certain factors that led to its determination that complying with the request would be infeasible under the circumstances.

The actor **must provide a written response to the requestor within 10 business days of receipt of the request with the reason(s) why the request is infeasible.**

Health IT Performance Exception

The practice must:

- Be implemented for a period of time no longer than necessary to achieve the maintenance or improvements for which the health IT was made unavailable or the health IT's performance degraded;
- Be implemented in a consistent and non-discriminatory manner; and
- Meet certain requirements if the unavailability or degradation is initiated by a health IT developer of certified health IT, HIE, or HIN.

An actor may take action against a third-party app that is negatively impacting the health IT's performance, provided that the practice is:

- For a period of time no longer than necessary to resolve any negative impacts;
- Implemented in a consistent and non-discriminatory manner; and
- Consistent with existing service level agreements, where applicable.

If the unavailability is in response to a risk of harm or security risk, the actor must only comply with the Preventing Harm or Security Exception, as applicable.

Content and Manner Exception

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.

- 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) standard.
- 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: Establishes the manner in which an actor must fulfill a request to access, exchange, or use EHI in order to satisfy this exception.

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.

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.

Fees Exception

Meet the basis for fees condition.

For instance, the fees an actor charges must:

- Be based on objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons or entities and requests.
- Be reasonably related to the actor's costs of providing the type of access, exchange, or use of EHI.
- Not be based on whether the requestor or other person is a competitor, potential competitor, or will be using the EHI in a way that facilitates competition with the actor.

Not be specifically excluded.

For instance, the exception does not apply to:

- A fee based in any part on the electronic access by an individual, their personal representative, or another person or entity designated by the individual to access the individual's EHI.
- A fee to perform an export of electronic health information via the capability of health IT certified to § 170.315(b)(10).

Comply with Conditions of Certification in § 170.402(a)(4) (Assurances – certification to “EHI Export” criterion) or § 170.404 (API).

Providers should maintain documentation of costs incurred and objective criteria justifying the fees they charge in connection with providing EHI to defend against allegations the Provider's fees constitute information blocking.

Licensing Exception

The negotiating a license conditions: An actor must begin license negotiations with the requestor within 10 business days from receipt of the request and negotiate a license within 30 business days from receipt of the request.

The licensing conditions:

- Scope of rights
- Reasonable royalty
- Non-discriminatory terms
- Collateral terms
- Non-disclosure agreement

Additional conditions relating to the provision of interoperability elements.



Information Blocking Effects

What it means for...Patients

Ease of Access to Their Records

- Increasing patient safety
- Increasing patient compliance
- Improved understanding of their health and medical conditions
- New access methods

Protecting Patient Privacy and Security

Promoting the Ability to Shop for Care and Manage Costs

What it means for...Clinicians

ONC lists four main areas of focus clinicians should follow to maintain compliance with the Cure Act Final Rule:

- Make patient data requests easy and inexpensive
- Allow choice of apps patients can use to access their medical information
- Implement practices that are considered reasonable and necessary activities that do not constitute information blocking
- Improve patient safety by balancing transparency of patient data while protecting the security of health IT



What it means for...HIT Developers

Additional Certification Requirements

- EHI Export
- Standardized API for Patient and Population Services
- Encrypt Authentication Credentials
- Multi-factor Authentication

Revised Certification Criteria

- E-Prescribing
- Security tags for Summary of Care send/receive
- CQMs Report
- Adjustable Events and Tamper-Resistance
- Audit Reports
- Auditing Actions on Health Information

Updated Interoperability standards for Clinical Data



Information Blocking Compliance

Steps for Information Blocking Compliance

Fully utilize your Patient Portal by publishing

- Visit Summary
 - All sections
 - All visit types
- Patient Education material
- Alerts and reminders
- Referrals
- Immunization History
- Personal Health Record (CCDA)





Psychotherapy Notes

The ONC has established that

...all notes that are ‘psychotherapy notes’ for purposes of the HIPAA Rules are also ‘psychotherapy notes’ for the purposes of the information blocking regulations in 45 CFR part 171 and are therefore excluded from the definition of EHI for the purposes of the information blocking regulations.

Source:

<https://www.healthit.gov/curesrule/resources/information-blocking-faqs>

Family Planning

The Privacy Exception (171.202), sub-exception (e)(1) for respecting an individual's request not to share information states unless otherwise required by law, an actor may elect not to provide access, exchange, or use of an individual's EHI if

...the individual requests that the actor not provide such access, exchange, or use of electronic health information without any improper encouragement or inducement of the request by the actor;

Source: <https://www.healthit.gov/condition-ccg/information-blocking>



Take Away

Information must be made accessible to the patient in a timely manner

- Have a procedure to timely respond or process patient requests

Not publishing data should only be done on a case-by-case basis

- No more publishing only specific lab results or requiring provider review prior

Use of the Patient Portal is not required but is the easiest method for providing access

- Also improves Patient Engagement targets

Understand from your EHR vendor the areas where confidential information can be documented

Reporting Claims of Information Blocking

Anyone who believes they may have experienced or observed information blocking by [any health care provider, health IT developer of certified health IT, or health information network or health information exchange](#) is encouraged to share their concerns with us through the Information Blocking Portal on ONC's website, HealthIT.gov.

Please note that we have not yet reached the applicability date for the information blocking regulations in 45 CFR part 171. The applicability date was established in the ONC Cures Act Final Rule and was subsequently adjusted in the ONC Interim Final Rule. [The Interim Final Rule moved the applicability date from November 2, 2002 to April 5, 2021.](#)

The most up-to-date information regarding the timing for applicability, compliance, and enforcement can be found on the ONC website at [HealthIT.gov/CuresRule](https://www.healthit.gov/CuresRule). We have also posted fact sheets, webinars, and other resources you may find helpful.

Investigations and Penalties/ Disincentives

- Actors that are subject to the information blocking regulations may be investigated by the HHS Office of Inspector General if they are the subject of a claim of information blocking.
- Further, actors found to have committed information blocking are subject to penalties:
 - 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 to be established by the Secretary

References

ONC's Cures Act webinars

<https://www.healthit.gov/curesrule/resources/webinars>

US Core Data for Interoperability

<https://www.healthit.gov/isa/united-states-core-data-interopability-uscdi>

Federal Register

<https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interopability-information-blocking-and-the-onc-health-it-certification>

OpenNotes.org

<https://www.opennotes.org/>





Questions & Answers

Upcoming Events:
Networking Forum Bootcamp May 11th, 2021
HITEQ: Information Blocking, CFR 42, Privacy/Security

CLIMB Meetings 2021:

March 23rd

June 23rd

September 8th



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