



Patient Access, 21st Century Cures Act, and Information Blocking

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1

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2

Learning Objectives

- Explore the Cures Act as it relates to Information Blocking and the research environment
- Discuss components of the Information Blocking Rule, including definitions, timelines, and exceptions
- Examine key areas where research compliance professionals can focus efforts to prepare for change

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2020 Cures Act Final Rule

Purpose

To implement certain provisions of the Cures Act that will advance interoperability and support the access, exchange and use of electronic health information (EHI)

Key Provisions

- Conditions and Maintenance of Certification requirements (for certified health IT)
 - Application Programming Interfaces (APIs)
- Information Blocking
 - Reasonable and necessary activities that do not constitute information blocking

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The patient is at the center

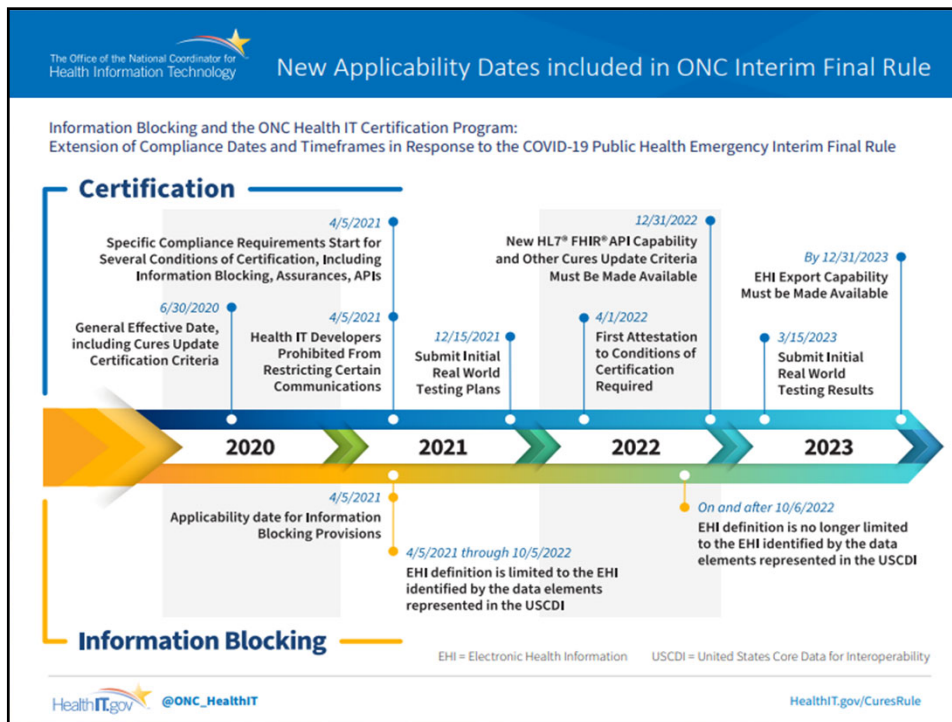


- Puts patients in charge of their health records
- Ease of access to their health records
 - Smartphones, software apps
- Protects patient privacy and security
 - Authentication tools, apps patients authorize
- Promotes the ability to shop for care and manage costs
 - Increased data and transparency

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Information Blocking Definition

Practices by an **Actor** that **likely interfere with**, prevent or materially discourage the **access, exchange, or use** of **electronic health information (EHI)**, except as required by law or covered by an exception

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Actor

Information Blocking Applies To

Yes

No



Health Care Providers



Health IT Developers of Certified Health IT



Health Information Networks or
Health Information Exchanges



Business Associates

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Cures Act Final Rule: Information
Blocking Actors (healthit.gov)

9

Electronic Health Information (EHI)

- ePHI as defined in HIPAA to the extent ePHI is included in the **designated record set (DRS)**. Excludes:
 - Psychotherapy notes
 - Information compiled in reasonable anticipation of, or use in, a civil, criminal or administrative action or proceeding
- April 5, 2021 - October 5, 2022
 - **USCDI** must be available for access, exchange and use
- October 6, 2022 – forward
 - **No longer limited** to USCDI (defined by the DRS)
- Time to fulfill a request
 - Without unnecessary delay

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HIPAA

Designated Record Set § 164.501

(1) A group of records maintained by or for a covered entity that is:

- (i) The medical records and billing records about individuals maintained by or for a covered health care provider;
- (ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or
- (iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.

(2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

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United States Core Data for Interoperability (USCDI v1)

Allergies and Intolerances <ul style="list-style-type: none"> • Substance (Medication) • Substance (Drug Class) • Reaction 	Laboratory <ul style="list-style-type: none"> • Tests • Values/Results 	Smoking Status <ul style="list-style-type: none"> • Smoking Status
Assessment and Plan of Treatment <ul style="list-style-type: none"> • Assessment and Plan of Treatment 	Medications <ul style="list-style-type: none"> • Medications 	Unique Device Identifier(s) for a Patient's Implantable Device(s) <ul style="list-style-type: none"> • Unique Device Identifier(s) for a Patient's Implantable Device(s)
Care Team Members <ul style="list-style-type: none"> • Care Team Members 	Patient Demographics <ul style="list-style-type: none"> • First Name • Last Name • Previous Name • Middle Name (including Middle Initial) • Suffix • Birth Sex • Date of Birth • Race • Ethnicity • Preferred Language • Current Address • Previous Address • Phone Number • Phone Number Type • Email Address 	Vital Signs <ul style="list-style-type: none"> • Diastolic Blood Pressure • Systolic Blood Pressure • Body Height • Body Weight • Heart Rate • Respiratory Rate • Body Temperature • Pulse Oximetry • Inhaled Oxygen Concentration • BMI Percentile (2 - 20 Years) • Weight-for-length Percentile (Birth - 36 Months) • Head Occipital-frontal Circumference Percentile (Birth - 36 Months)
Clinical Notes <ul style="list-style-type: none"> • Consultation Note • Discharge Summary Note • History & Physical • Imaging Narrative • Laboratory Report Narrative • Pathology Report Narrative • Procedure Note • Progress Note 	Problems <ul style="list-style-type: none"> • Problems 	
Goals <ul style="list-style-type: none"> • Patient Goals 	Procedures <ul style="list-style-type: none"> • Procedures 	
Health Concerns <ul style="list-style-type: none"> • Health Concerns 	Provenance <ul style="list-style-type: none"> • Author Time Stamp • Author Organization 	
Immunizations <ul style="list-style-type: none"> • Immunizations 		

12

Open Notes

- Improved patient engagement
- Ability to engage family members
- Promotes patient safety and accurate documentation
- Minimum impact on provider workflow
- Ability per law and exceptions to delay or restrict

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Access, Exchange, Use

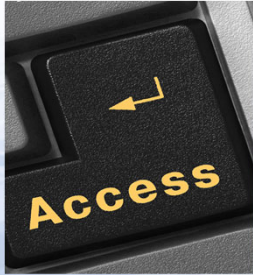
- Access – the ability or means necessary to make EHI available for exchange, use or both
- Exchange – ability for EHI to be transmitted between and among different technologies, systems, platforms or networks
- Use – ability for EHI, once accessed or exchanged, to be understood and acted upon

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Likely Interfere With....



Information blocking will almost always be implicated when a practice likely interferes with:

- Patient access, exchange and use (including charging fees)
- Providers and other authorized individuals having EHI when and where they need it
- Payers and others that purchase health care obtaining information needed
- Health care providers access, exchange and use of EHI for quality improvement and population health management
- Public health and patient safety needs

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Information Blocking Practices

Information Blocking Practices include:

- (1) Restricting access, exchange, or use;
- (2) Limiting or restricting interoperability of health IT;
- (3) Impeding innovations and advancements in access, exchange, or use or health IT-enabled care delivery;
- (4) Rent-seeking and other opportunistic pricing practices;
- (5) Non-standard implementation practices.

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Federal Register :: 21st Century Cures Act:
Interoperability, Information Blocking, and the ONC
Health IT Certification Program (Information Blocking
examples – proposed rule)

16

Information Blocking Examples

- A healthcare provider has the capability to provide same-day access to EHI in a form and format requested by a patient or a patient's healthcare provider but takes several days to respond.
- A health system's internal policies or procedures require staff to obtain an individual's written consent before sharing any of a patient's EHI with unaffiliated providers for treatment purposes even though obtaining an individual's consent is not required by state or federal law.
- A health system incorrectly claims that the HIPAA Rules or other legal requirements preclude it from exchanging EHI with unaffiliated providers.

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Federal Register :: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (Information Blocking examples – proposed rule)

17

Information Blocking Exceptions


PREVENTING HARM EXCEPTION


PRIVACY EXCEPTION


SECURITY EXCEPTION

EXCEPTIONS THAT INVOLVE
not fulfilling requests to access, exchange, or use EHI


INFEASIBILITY EXCEPTION


HEALTH IT PERFORMANCE EXCEPTION

8

EXCEPTIONS TO THE INFORMATION BLOCKING PROVISION


LICENSING EXCEPTION


COSTS EXCEPTION


CONTENT AND MANNER EXCEPTION

EXCEPTIONS THAT INVOLVE
procedures for fulfilling requests to access, exchange, or use EHI

18

Preventing Harm Exception Key Conditions

- Practice must satisfy at least one condition
 - Hold a reasonable belief that the practice will substantially reduce a risk of harm
 - Must be no broader than necessary
 - Must satisfy at least one condition from the following categories:
 - Type of risk
 - Type of harm
 - Implementation basis
 - Must satisfy the condition concerning a patient right to request review of an individualized determination of risk of harm.

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Privacy Exception Key Conditions

- Practice must meet at least one of the four sub-exceptions
 - Precondition not satisfied
 - Health IT developer of certified health IT not covered by HIPAA
 - Denial of an individual's request for their EHI consistent with 45 CFR 164.524(a)
 - Respecting an individual's request not to share information

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Security Exception Key Conditions

- 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

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Infeasibility Exception Key Conditions

- A 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.

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Health IT Performance Key Conditions

- 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.

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Content and Manner Key Conditions

- **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.

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Content and Manner Key Conditions

- **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.

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Fees Exception Key Conditions

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).

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Licensing Exception Key Conditions

The practice must meet:

- 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 must include:
 - Scope of rights
 - Reasonable royalty
 - Non-discriminatory terms
 - Collateral terms
 - Non-disclosure agreement
- Additional conditions relating to the provision of Interoperability elements

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Risk Mitigation Strategies and Actions

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Start at the Beginning

- Review the ONC and CMS Rules
- Become familiar with Part 171 ONC IB rules and the 8 exceptions
- Determine whether you are an Actor
- Identify how your organization will be impacted
- Connect with your Health IT Vendor to determine their readiness plans



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Evaluate Compliance and System Infrastructure

- Review Notice of Privacy Practice (NPP)
- Review business associate agreements (BAAs) to determine any revisions necessary to contracts, agreements, and licenses related to information blocking and interoperability.
- Plan and/or implement appropriate HL7 Fast Healthcare Interoperability Resources (FHIR)-based interfaces to meet the demands of the rules for patient access to their own data through publicly accessible and published APIs.

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Intent to Improve Access for Research

- Sharing data is essential in biomedical research
- Common Rule harmonizes with the Cures Act
- Prior constraints for the National Institutes of Health
- Significant advances in research privacy protections.
- Certificates of confidentiality provided to all NIH-funded scientists conducting research
- Potential increase in consumer demand

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Evaluate Other Regulations

- Evaluate other privacy and security rules such as:
 - [Federal Trade Commission \(FTC\) Act](#),
 - [California Consumer Privacy Act \(CCPA\)](#)
 - State privacy laws for compliance in conjunction with the information blocking and interoperability rules.
 - Common Rule/HIPAA

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Education Workforce

- Workforce and Providers
 - Develop education plans and timeline
 - Ensure education is developed and delivered based upon the audience
 - Develop education tools
 - Incorporated into new hire orientation, annual update
 - Evaluate how annual HIPAA training will need to be updated
 - Deliver education
 - Use various formats, videos, reminders on video screens, web-based, etc.
 - Incorporate IB compliance into performance evaluations

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Education Patients/Consumers

- Patients/Consumers--APIs
 - Develop plans for EHI availability via APIs
 - Develop processes to verify Apps privacy/security policies
 - Develop and deliver patient education of Apps (privacy and security)

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Develop Plans Update Policies and Procedures

- For public reporting of providers for information blocking.
- To ensure compliance and business actions related to information blocking/interoperability.
- To address patient requests of EHI via an app.
- Review and revise ROI P&Ps as necessary to meet the information blocking requirements.

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Develop Plans Update Policies and Procedures

- Develop policies and procedures for the exceptions to the information blocking rules.
- Develop an information blocking/interoperability and patient access incident management policy and procedure that includes data collection, reporting and forms.
- Review, update, and implement patient access, interoperability, API, and information blocking related patient request workflows, policies, procedure, and forms.
- Develop policies and procedures to monitor effectiveness of information blocking/interoperability compliance.

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Develop Plans Update Policies and Procedures

- Update and/or develop any applicable HR policies, procedures, documentation, and systems to provide for discipline for information blocking/interoperability compliance violations by workforce members.
- Develop education and training materials as well as competency tests on information blocking/interoperability.
- Develop patient education plans regarding information blocking and the risks associated with using non-certified third-party applications.

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Questions/Thoughts/Additional Comments



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38

Resources

- [Cures Act Final Rule: Federal Register](#)
- [ONC's Cures Act Final Rule page](#)
- [AHIMA webinar on Information Blocking Journal of AHIMA](#)
- [AHIMA Advocacy](#)
- [Information Blocking FAQs \(healthit.gov\)](#)
- [Federal Register: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program](#) (Information Blocking examples – proposed rule)
- [Home - The Sequoia Project](#)
- [AHIOS – AHIOS INSTITUTE](#)
- [Cures | National Institutes of Health \(NIH\)](#)
- [Cures Act Research FAQ | Office of Clinical Research | Perelman School of Medicine at the University of Pennsylvania \(upenn.edu\)](#)
- <https://fpf.org/blog/21st-century-cures-act-final-rule-key-health-data-privacy-considerations/>
- [OpenNotes – Patients and clinicians on the same page](#)

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