

Information Blocking Basics

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Overview

- A Paradigm Shift
- What is information blocking?
- Who and what is subject to information blocking?
- When does information blocking apply?
- How do you avoid information blocking?
- What do you do now?

A Paradigm Shift

“Give patients electronic modern software control of their medical care, of their chart and of their information.”

"The patients have a right to that data."

"Give patients the consumer power that they have in the rest of their lives."

“Give the patient agency”

"I believe an entire ecosystem will build out of that."

"It is the patient's data for the patient to control and move as they desire rather than to be purely in the control of providers and payors."

Don Rucker, M.D.
National Coordinator for Health Information Technology
May 13, 2020, 2020 HIMSS Conference

A Paradigm Shift

- HIPAA established restrictions on uses and disclosure of Protected Health Information (“PHI”)
- HIPAA made most uses and disclosures permissive at the option of the covered entity holding the PHI
- Information blocking requires disclosures of Electronic Health Information when disclosure is permissive

Related Regulations

- **ONC, Final Rules. 21st Century Cures Act: Interoperability, Information Blocking and the ONC Health IT Certification Program** - 45 CFR parts 170 and 171 ([May 1, 2020, 85 FR 25642](#)) “Information Blocking Regs.”
- **ONC, Interim Final Rule. Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency** – ([November 4, 2020, 85 Fed. Reg. 70064](#)) “Extension Reg.”
- **OIG, Proposed Rules. Grants, Contracts and other Agreements: Fraud and Abuse; Information Blocking Office of inspector General’s Civil Monetary Penalty Rules.** 42 CFR parts 1003 and 1005 ([April 24, 2020, 85 FR 22979](#)) “Enforcement Rule.”
- **CMS, Final Rules, Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally- Facilitated Exchanges, and Health Care Providers.** 45 CFR Part 156, amending 42 CFR Part 482 and 485, ([May 1, 2020, 85 FR 25510](#)) “Patient Access Rule.”

What is Information Blocking?

“Information Blocking” means a practice that:

- A. except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is **likely to interfere with, prevent or materially discourage access, exchange or use of electronic health information**; and
- B. (i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network **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; or
(ii) If conducted by a health care provider, such provider **knows that such practice is unreasonable** and is likely to interfere with, prevent, or materially discourage access, exchange or use of electronic health information .

Who--Actors

Health Care Provider

A health care provider is a: 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 center; emergency medical services provider; federally qualified health center; group practice; pharmacist; pharmacy; laboratory; physician; practitioner; provider operated by or under contract with the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization; rural health clinic; covered entity under 42 U.S.C. 256b; ambulatory surgical center; therapist; and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the HHS Secretary.

Who--Actors

Health Information Network or Health Information Exchange

Health information network or health information exchange means 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 electronic health information:

1. **Among more than two unaffiliated individuals or entities** (other than the individual or entity to which this definition might apply) that are enabled 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.

Who--Actors

Health IT Developer of Certified Health IT

Health IT developer of certified health IT means 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** (as that term is defined in 42 U.S.C. 300jj(5)) 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 pursuant to 42 U.S.C. 300jj-11(c)(5) (ONC Health IT Certification Program).

What—Electronic Health Information

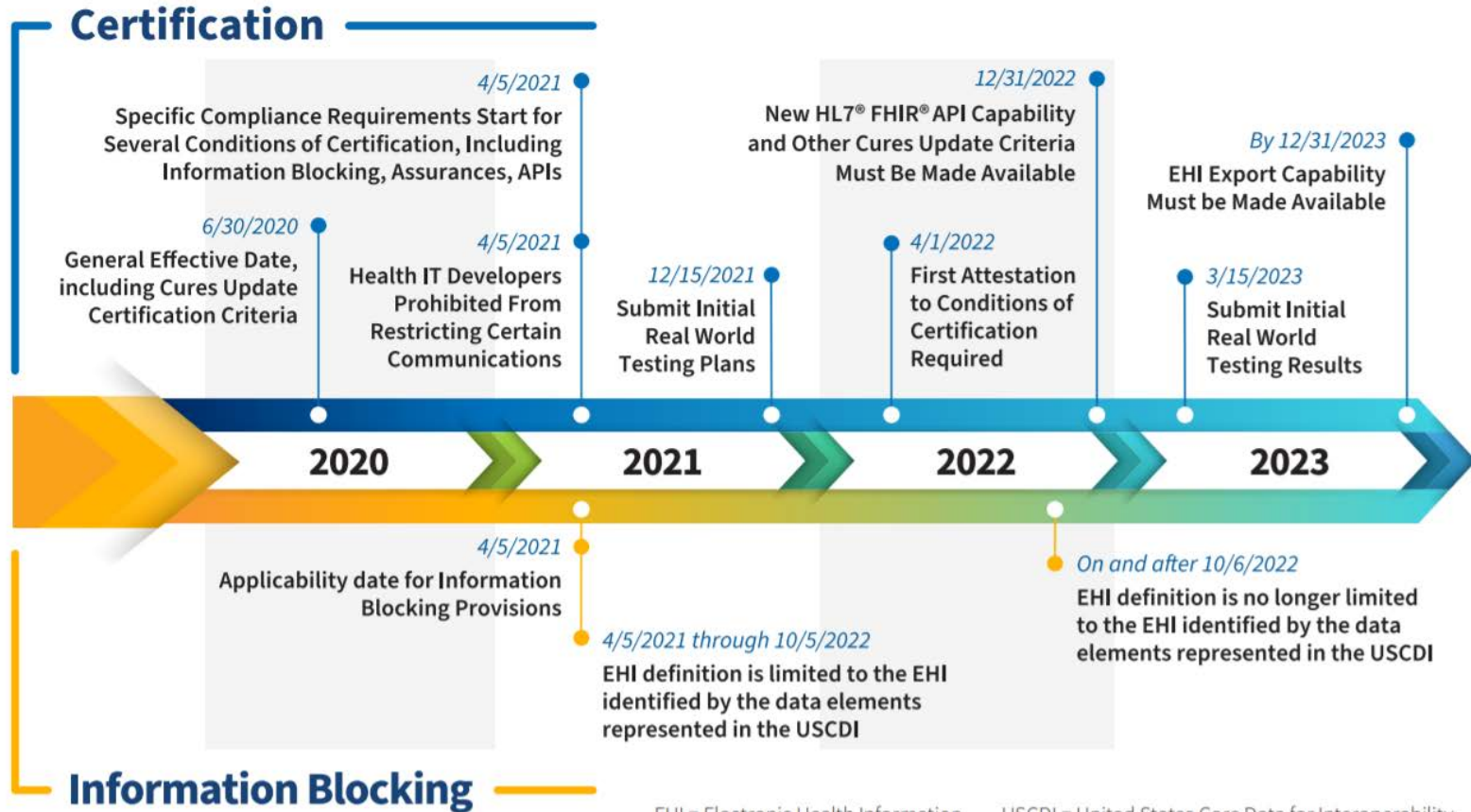
Electronic health information (EHI)

Electronic Protected Health Information as defined in 45 CFR 160.103 to the extent that it **would be included in a designated record set** as defined in 45 CFR 164.501, regardless of whether the group of records are used or maintained by or for a covered entity as defined in 45 CFR 160.103, but EHI shall not include:

1. Psychotherapy notes as defined in 45 CFR 164.501; or
2. Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

Until October 6, 2022, EHI is limited to information/data elements available in the USCDI version 1.

When



How to avoid information blocking?

Information Blocking Exceptions

Exceptions that involve not fulfilling requests to access, exchange, or use EHI

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

1) Preventing Harm Exception

6) Content and Manner Exception

2) Privacy Exception

7) Fees Exception

3) Security Exception

8) Licensing Exception

4) Infeasibility Exception

5) Health IT Performance

Preventing Harm Exception

- This exception applies if the Actor **reasonably believes** that the alleged practice **will substantially reduce the risk of harm to a patient or another person**. In utilizing this exception, the Actor must limit its use to be no broader than necessary to substantially reduce the risk of harm.
- The risks to be addressed by this exception are **case-by-case determinations by a licensed health care professional** with a current or prior clinical relationship with the patient, and data errors.
- Any **determination of risk by a health care provider is subject to review** and must be based on an organizational policy or a determination specific to the facts or circumstances.

Privacy Exception

This exception applies where providing the access, exchange or use of the EHI would violate a state or federal privacy law. In order to utilize this exception, one of four preconditions must be satisfied:

1. the Actor or the patient have not met a precondition for release set forth in the applicable privacy law;
2. if the Actor is a Health IT Developer of Certified Health IT not subject to HIPAA, the practice promoting privacy must be set forth in a privacy notice provided to the individual before using the technology and comply with applicable laws;
3. the access request is denied pursuant to HIPAA regulations; or
4. the request is denied due to an individual's request that the individual's information not be shared.

Infeasibility Exception

This exception applies when legitimate practical challenges limit an Actor's ability to comply with a request because the Actor was unable to obtain the requisite technological capabilities, legal rights or other means necessary to enable access, exchange or use. For a circumstance to be infeasible one of the following must exist:

- the request cannot be fulfilled 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;
- the information requested cannot be unambiguously separated from other EHI that cannot be released;
- the actor can demonstrate through a contemporaneous written record its consistent and non-discriminatory consideration of the factors leading to the infeasible circumstance.

Content and Manner Exception

CONTENT: The content that the Actor must provide prior to October 2022 is limited to the data elements in the United States Core Data for Interoperability (“USCDI”) standard. As of October 6, 2022, the Actor must respond to requests with all EHI.

MANNER: If the Actor cannot technically fulfill the request as requested, or cannot reach agreeable terms with the requestor for the manner of fulfillment, the Actor must fulfill the request without unnecessary delay in the first of the following that is technically feasible: (i) using certified technology as specified by the requestor; (ii) using a content and transport standard that has been published by the federal government, or an ANSI accredited standard organization; or (iii) using an alternative machine-readable format agreed upon with the requestor.

Fees Exception

This exception permits the Actor to charge fees that are not opportunistic (not including reasonable profits) or exclusionary practices interfering with access, exchange or use of EHI.

- Any fees that are assessed by the Actor must be based on objective and verifiable criteria that are uniformly applied for all similarly situated Requestors, must be reasonably related to the Actor's cost of providing the access, use or exchange and be reasonably allocated among all similarly situated persons.
- Additionally, the fee cannot be based upon: (i) the competitive nature of the Requestor; (ii) the sales, profits, revenues or other value the Requestor derives from the use, access or exchange of EHI; (iii) costs the Actor incurred in designing or implementing the health IT in a non-standard way; (iv) intangible asset costs other than actual development or acquisition costs; and (v) opportunity costs unrelated to the access, exchange or use of the EHI.

What do you do now?

- This Rule is intended to be disruptive...
- Know Your Timelines:
 - Compliance Deadlines vs. Enforcement Deadlines
- Are your individuals or entities “Actors”
 - Multiple Actors?
- Evaluate whether certain Business Associate Agreements must be revised.
- Watch for additional guidance rules from the ONC, CMS, and OIG.

What do you do now?

- Form the Information Blocking Committee
- Develop the IB Workplan
- Policy and procedure review
- Develop the IB request workflow
- Educate stakeholders
 - Resistance to purpose is itself violation
 - Treatment must be consistent and non-discriminatory
 - Board and Committee Members of Health Information Organizations must be particularly aware
- Incorporate compliance into IT planning



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