21st Century Cures Act: Information Blocking

Introduction and Overview

Topics Covered

- Information blocking overview
- Access, exchange, and use of electronic health information (EHI)
- How to prepare for compliance

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Information Blocking Examples

- ○ Healthcare organization/hospital system refuses to exchange information with a non-affiliated organization or physician practice
- ○ Provider has the capability to provide same-day access to a EHI request but takes several days to respond
- ○ Requiring patient consent to exchange EHI for treatment when it is not required by law
- ○ Certified health IT developer refuses to share technical information needed to export data
- ○ Health Information Network/Health Information Exchange charges additional fees to exchange data or refuses to exchange data with non-Health Information Network/Health Information Exchange members
- ○ Charging a patient for electronic access to their health data

What is Information Blocking?

Information blocking is defined in the 21st Century Cures Act. In summary, information blocking is "a practice that…is likely to <u>interfere with, prevent, or materially discourage access, exchange, or use of electronic health information</u>," unless such practice is required by law (e.g., HIPAA), or it meets an exception established through federal rulemaking.

42 U.S.C. § 300jj-52(a)(1).

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Requests to Access, Use, and Exchange Electronic Health Information

- This rule does not require providers (or other entities) to release all information immediately, especially confidential information

- This rule is centered around responding and fulfilling requests to access, exchange, and use electronic health information
  - <u>Access</u>: Make EHI available for exchange, use, or both.
  - <u>Exchange</u>: Transmit EHI between and among technologies, systems, platforms, or networks
  - <u>Use</u>: Ability to understand and act upon access or exchanged EHI

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Government Agencies

- Department of Health and Human Services
  - Office of the National Coordinator for Health IT:
    - Creates and oversees health IT certification
    - Wrote and published the information blocking final rule
  - Office of the Inspector General:
    - Enforcement agency combating waste, fraud, and abuse
    - Will investigate allegations of information blocking against certified health IT vendors and HIE/HINs
  - Centers for Medicare and Medicaid:
    - Public payer and arbiter of annual fee schedules, Promoting Interoperability (formally Meaningful Use)
    - Programs require certified health IT to be used

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Information Blocking Actors
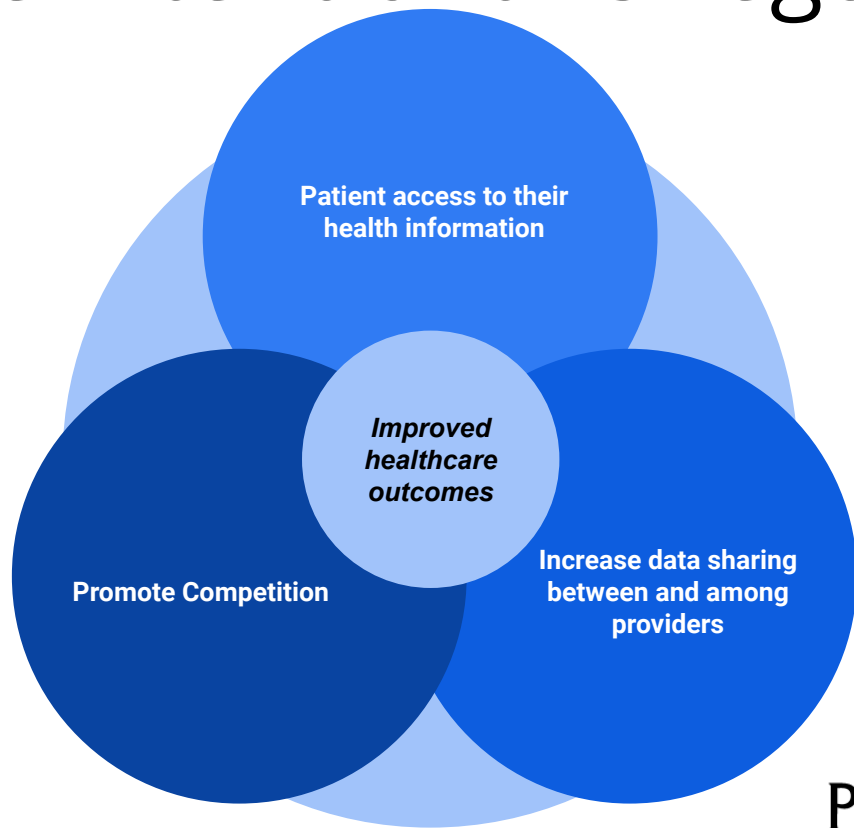
People and entities who are subject to the rule:

➢ Healthcare providers
  ○ PCC clients

➢ Certified Health IT vendors
  ○ PCC is not subject to the rule...yet

➢ Health Information Networks/Health Information Exchanges
  ○ Great news!

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Penalties Structure

The ONC Final Rule compliance date is *April 5, 2021*, however, the penalty structure is still in development...

Actor	Enforcement Agency	Penalties and Start Date
Healthcare Providers	Centers for Medicare and Medicaid	Penalties: TBD Start Date: TBD
Certified Health IT Vendors	Office of the Inspector General	Penalties: up to $1million per infraction Start Date: TBD
Health Information Exchanges and Health Information Networks	Office of the Inspector General	Penalties: up to $1million per infraction Start Date: TBD

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What is the intent of this regulation?

Three Focus Areas

Part 171: Information Blocking	Part 170: Health IT Certification	Part 170: Conditions & Maintenance of Certification
Prohibition of interfering with access, exchange, and use of electronic health information (EHI)	Retired, revised, and created new certification criterions; referred to as 2015 Cures Edition	Includes six sets of requirements necessary to maintain health IT certification

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USCDI and ePHI

- **USCDI**: (United States Core Data for Interoperability)
  - Standardized set of health data classes and elements for interoperable health information exchange
  - CCDA currently uses the Common Clinical Data Set (CCDS) - The USCDI includes CCDS and more

- **ePHI**: (Electronic Protected Health Information)
  - Represents the same data that a patient would have the right to request a copy of pursuant to the HIPAA Privacy Rule

Until October 6, 2022, information blocking is limited to the data elements included in the USCDI, after October 6, 2022 the information blocking requirements expand to include all ePHI

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USCDI Example

USCDI v1 Summary of Data Classes and Data Elements

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment
- Assessment and Plan of Treatment

Laboratory
- Tests
- Values/Results

Medications
- Medications

Patient Demographics

Smoking Status
- Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a

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Information Blocking & Other Regulations

- Information Blocking does not supersede HIPAA, SAMHSA, or other state and regional regulations

- HIPAA also includes intent to provide patients access to their health information, while protecting and securing it . The P is for portability!

- These are Federal laws, always check local and state laws for additional regulations to ensure compliance!

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Information Blocking Exceptions

ONC defined eight exceptions when it may be appropriate to NOT comply with the information blocking rule, or alter the way in which EHI is accessed, exchanged, or used
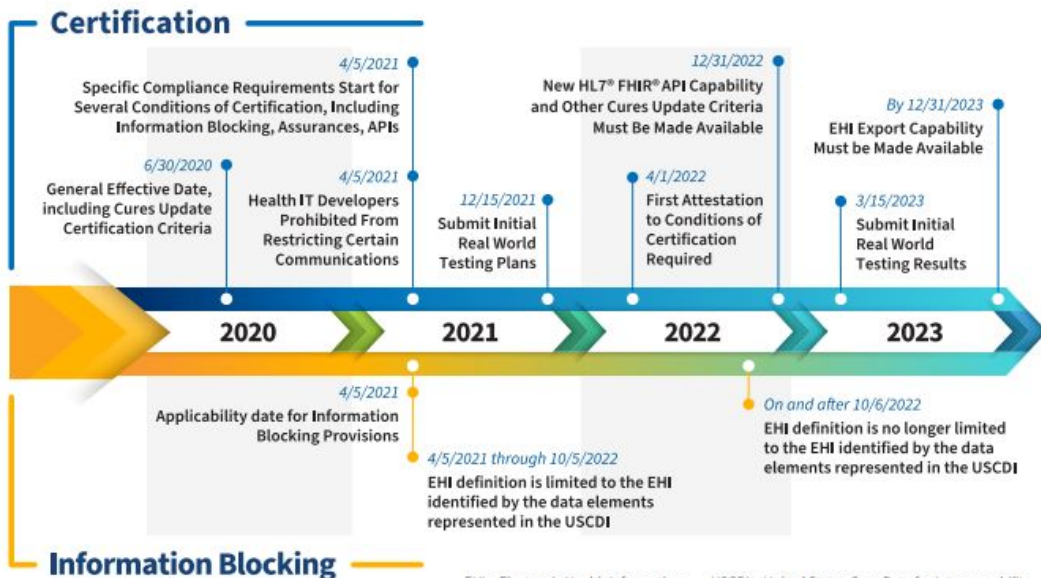
- Exceptions that involve not fulfilling requests:
  - Preventing Harm
  - Privacy
  - Security
  - Infeasibility
  - Health IT Performance
- Exceptions and procedures for fulfilling requests to access, use, or exchange EHI:
  - Content and Manner
  - Fees
  - Licensing

How to Prepare PCC Practices

- Review and update policies that include information about data access, exchange, and use (e.g. HIPAA policy)
- Review existing fee structure: While "reasonable" fees are permissible for some activities, charging a patient for electronic access to their health information is prohibited
- Appoint an Information Blocking Officer; this is not a requirement of the regulation, however it is ideal to have a point person to review and update policies, as well as answer questions
- Review the information blocking exceptions and define policies to use them; determine where and how exceptions will be documented, logged, and retained
- Teach everyone in your practice/organization how to recognize and act upon a request to access, exchange, or use electronic health information

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Q & A

Do we have to make all of our lab results accessible to patients in the portal?

It is not a requirement of the rule to make all lab results accessible to patients in the portal, it is your choice to do so or not. If a patient requests their lab results via the portal and you do not provide them, this is information blocking. You must acknowledge and respond to all requests for electronic health information. If you are unable to fulfill them in the manner they are requested, or have an additional reason for not fulfilling the request, please refer to the information blocking exceptions for additional guidance. The link to the ONC Information Blocking exceptions Fact Sheet is here: Cures Act Final Rule: Information Blocking Exceptions (healthit.gov)

Our clinicians store confidential information in various places in PCC EHR. Do we need to make all of those notes available to patients?

The information blocking rule does not supersede the HIPAA privacy and security rules. It is not a requirement of the rule to release all confidential information available to patients (or their guardians). Please refer to the information blocking exceptions to understand more about the circumstances to withhold information. The link to the ONC Information Blocking exceptions Fact Sheet is here: Cures Act Final Rule: Information Blocking Exceptions (healthit.gov)
The ONC FAQ includes a question and answer regarding patient confidentiality when the patient is a minor: Information Blocking FAQs (healthit.gov)

Q & A

Do we need to enable portal access to our patients if they request access?

Yes, if a patient requests portal access, it must be granted if you have the portal enabled. Additionally, if your practice does not have the portal enabled it is strongly recommended that you do so. If you do not have it enabled, you may choose to use the infeasibility exception, however it is not wise to use this exception for an extended period of time if you do have the ability to enable it and have chosen not to.

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Resources

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

Interim Final Rule:
https://www.federalregister.gov/documents/2020/11/04/2020-24376/information-blocking-and-the-onc-health-it-certification-program-extension-of-compliance-dates-and

OIG Proposed Rule:
https://www.federalregister.gov/documents/2020/04/24/2020-08451/grants-contracts-and-other-agreements-fraud-and-abuse-information-blocking-office-of-inspector

ONC Cures Site: https://www.healthit.gov/curesrule/

ONC Cures Rule FAQs: https://www.healthit.gov/curesrule/resources/information-blocking-faqs

ONC Cures Rule Fact Sheets: https://www.healthit.gov/curesrule/resources/fact-sheets

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Questions?