21ˢᵗ Century Cures Act:

Information Blocking and CMS Interoperability Compliance by April 5, 2021

Agenda

- Overview of the 21st Century Cures Act and the Final Rules from ONC and CMS

- Providing access to patient data & Information Blocking
  - Patient data access
  - What is Information Blocking?
  - Eight approved exceptions

- Public reporting – annual attestation

- Digital contact information

- Admission, discharge, and transfer event notifications

Overview
How did we get here?

- **The 21st Century Cures Act (2016)**
  - Codified at 42 U.S.C. 300jj-52 et seq.
  - Response to limitations on data sharing in health care
  - Congressional report uncovered data silos and barriers to access patient EHI

- **ONC Rule**

- **CMS Rule**

This is a HIPAA paradigm shift. The new presumption is EHI disclosure unless otherwise required by law or an exception to the Information Blocking rule.

Information Blocking
Access to Patient Data

Providers are required to make patient data available, to:

- Patients
- Other providers
- Third parties (e.g. apps)

Information Blocking
Definition

Information Blocking

A practice that, except as required by law or covered by exception, is *likely* to *interfere with access, exchange, or use* of electronic health information (EHI)

45 C.F.R. 171.103(a)(1)

Information Blocking
Patient's Right of Access

Focus on Patient's Right of Access

- Right to access/direct EHI under HIPAA

- Facilitate authorization/consent

- Note recent and repeated OCR Announcements of HIPAA enforcement

- Patient education about privacy and security risks of 3rd party apps they choose to use to access EHI

- Information Blocking speeds up timeline to deliver EHI
    - "Without unnecessary delay"

Information Blocking
How to make data available

- Broad scope – rules favor broad access, exchange, and use of EHI

- Prepare for multiple types of requests and requesters

- Make and document plans regarding:
  - How you will respond to requests "without unnecessary delay"
  - What you will share – minimum is USCDI
  - The format in which you will share the data
  - When you won't be able to make data available

Information Blocking
US Core Data for Interoperability (USCDI)

Know what data should be available for access

- By April 5, 2021, minimum is USCDI

- By October 6, 2022, expanded data catalog

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

Assessment and Plan of Treatment
- Assessment and Plan of Treatment

Care Team Members
- Care Team Members

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals
- Patient Goals

Health Concerns
- Health Concerns

Immunizations
- Immunizations

Laboratory
- Tests
- Values/Results

Medications
- Medications

Patient Demographics
- 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

Problems
- Problems

Procedures
- Procedures

Provenance
- Author Time Stamp
- Author Organization

Smoking Status
- Smoking Status

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

Vital Signs
- 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)

Information Blocking
Preferred formats & your health IT vendors

- Share EHI in the format patients specify

- ONC's goal is that FHIR APIs be among the options

- Health IT developers (e.g. EHR vendors) will be required to make APIs available in their products to support exchange of EHI, enforcement begins August 2022
  - Providers should then make these APIs available for data access

- Talk to your vendors now, get in queue for upgrades

Information Blocking In Practice

Case-by-Case Review

Each practice that implicates Information Blocking analyzed on a case-by-case basis

Facts and circumstances analysis includes practices that:

- Prevent access
- Increase cost of access
- Add difficulty or burden to access
- Limit utility, efficacy, or value of EHI by decreasing integrity, quality, completeness, or timeliness of EHI

85 Fed Reg at 25841 (May 1, 2020)

Practice

Focus on practices that *may* implicate the Information Blocking Rule

Examples

Interference with:

- Patients' access to their own EHI
- Treatment and care coordination between providers
- Payers seeking to assess clinical value
- Quality Improvement/Population Health management by providers
- Patient safety and public health

Information Blocking
Exceptions (8)

Denial of request to access, exchange, or use EHI based on:

- **Preventing harm:** reasonable belief practice will reduce risk of harm

- **Privacy:** denial of access pursuant to State and Federal privacy law

- **Security:** directly related to safeguarding EHI

- **Infeasibility:** due to technical limitations, uncontrollable events, or inability to segment EHI

- **Health IT performance:** unavailability due to maintenance/performance needs

Procedures for fulfilling request to access, exchange, or use EHI:

- **Content and Manner:** fulfill request for EHI as requested unless technically unable to do so or with agreement

- **Fees:** reasonably related to cost

- **Licensing:** related to protecting investment in HIT innovation

Information Blocking
Exceptions
Denial of Request

Privacy

Denial of access pursuant to HIPAA/other law

- Required preconditions
- Authorization/Consent Efforts

How to prepare

Review and update:

- Authorization/Consent process
- Right of access and Personal Representatives
- Minors Rights
- Request for privacy protection or confidential communications
- Process for denying requests

Infeasiblity

Resulting from:

- Technological limitations
- Uncontrollable events
- Inability to segment EHI
- Infeasibility under the circumstances

If unable to fulfill a request, must provide written notice within ten (10) business days of request

How to prepare

- Create and use infeasibility decision tree/process
- "Notice of Infeasibility" to notify requestor of denied request

Preventing Harm

- Reasonable belief
- Practice will substantially reduce risk of harm (physical harm, threat to life)

Determined:

- On individual basis by professional judgement of licensed provider

OR

- By concern for mismatched, corrupt, or erroneous EHI under policy

How to prepare

- Develop organizational policy to address
- Create and use harm decision tree/process
- Coordinate with HIPAA Policies

Information Blocking
Exceptions
Denial of Request

Security

Directly related to safeguarding EHI

Tailored to risks

Consistent and non-discriminatory implementation

How to prepare:

- Review and update security policies and processes
- Review and update security response plan
- Evaluate and monitor for new security risks

Health IT Performance

Unavailability due to:

- Addressing maintenance/performance needs
- Routine/scheduled security maintenance

Consistent non-discriminatory implementation

How to prepare:

- Do not take incoming EHI "off line" as a default
- Delay for data "mapping" allowed

Information Blocking
Exceptions
Procedures for fulfilling

Content and …

USCDI Standard (4/5/2021) → Full EHI (10/6/2022)

- [\US Core Date for Interoperability (USCDI) Standard](#)
  - Listed under "Clinical Notes"
- Full EHI (defined in §171.102)

How to prepare

- Determine whether USCDI data will be provided (until Oct 5, 2022 deadline) or elect to provide all EHI requested
- Work with vendors

Manner

Fulfill request in manner requested *without unnecessary delay* unless

- Technically unable to do so
- Agreement reached with requestor

Review rule priorities for alternative manner

How to prepare

- Evaluate technology to know capabilities are available
- Create and use decision tree/process for alternate manner exception

Information Blocking
Exceptions
Procedures for fulfilling

Fees are prohibited when:

Electronic access to EHI is available with no manual effort required

EHI export or conversion fees were not previously agreed to in writing

Fees

- Objective and verifiable criteria
- Reasonably related to cost
- Reasonably allocated

How to prepare

- Identify arrangements where a "fee" may be charged for EHI requests
- Ensure fee complies with exception, HIPAA and State law
- Develop objective fee schedule for EHI requests

Licensing

Non-discriminatory and objective licensing conditions to allow third-party access, use, exchange of EHI

Protect HIT innovation

Must begin licensing negotiations within *10 business days* and negotiate within *30 business days*

How to prepare

- Determine who is responsible for licensing agreements for EHI
- Review and ensure licensing agreements comply with exception
- Develop and use licensing agreement template

Information Blocking
Exceptions

Not an automatic violation

Failure to meet elements of an Information Blocking Rule Exception does not mean Information Blocking occurred.

- Did the practice rise to the level of interference?
- Did the provider have *knowledge* that the practice would interfere with, prevent, or materially discourage access, exchange, or use of EHI?

Information Blocking
Knowledge Standard

- Health care providers must *know* that the practice is *unreasonable* and *likely to interfere* with, *prevent*, or *materially discourage* the access, exchange, or use of EHI

- **Enforcement/penalties:** HHS oversight, providers referred to "appropriate agency" to be subject to "appropriate disincentives"

- Online complaint process implemented by ONC

Information Blocking Examples

Example 1

Health care provider has *capability* to provide *same-day access* to EHI in the form and format requested by a patient or a patient's provider, but *takes several days* to respond.

Example 2

Patient portal offers capability for patients to *directly transmit or request direct transmission* of EHI to third party but health care *provider chooses not to enable* capability.

Example 3

Health system's internal policies or procedures *require staff to obtain written patient consent* before sharing EHI with unaffiliated providers for treatment, when *not required by state or federal law*

Information Blocking
The Future

Information Blocking is a new paradigm for everyone, not just a tech issue!

Evolving landscape:

- ✓ **Enforcement**

- ✓ **Penalties**

- ✓ **Interpretations developing over time**

- ✓ **Minors Records**

- ✓ **Part 2 Rule changes**

- ✓ **Application of state and federal laws**

- ✓ **Additional ONC FAQs and guidance**

CMS Interoperability
Public Reporting

- In annual attestation process, providers will be required to attest that they are not Information Blocking

- Applies to eligible providers participating in the Medicare Merit-based Incentive Payment Program (MIPS) or the Advanced Alternative Payment Model (AAPM), and eligible hospitals that participate in both the Medicare and Medicaid Promoting Interoperability Programs (PIP)

- CMS will publicly report the names of providers and hospitals that may be information blocking based on attestation

CMS Interoperability
Digital contact information

- Ensure you have digital contact information (e.g. direct address), register it with the National Plan and Provider Enumeration System (NPPES)

- Register for an account with the NPPES, regularly review and update your record at https://npiregistry.cms.hhs.gov.

- CMS will publicly report the names of providers who do not list/update their digital contact information.

CMS Interoperability
ADT notifications

- For hospitals only
  - Must send real-time notifications of admission or discharge from ED or inpatient unit to patient-identified providers

- Primary care and post-acute providers
  - Expect notifications beginning May 1, 2021 or sooner

Preparing for compliance

* See Information Blocking checklist in post-presentation materials

- Develop a committee and work plan - include compliance, legal, IT, and operations functions

- Draft policies and procedures that support making data accessible and document necessary exceptions

- Talk to your vendors, get health IT up-to-date

- Educate leaders and staff

Thank you for joining.

Look for an overview document with preparation checklist, and a link to the recorded webinar, in your email at the beginning of next week.

Have questions?

You can contact:

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Maurine Gilbert at VITL at mgilbert@vitl.net

Information Blocking
Government Resources

21st Century CURES Act

IB Rule: 42 CFR Part 171 *et seq.*

https://www.law.cornell.edu/cfr/text/45/part-171

HealthIT.gov (ONC)

https://www.healthit.gov/topic/information-blocking

Interoperability (CMS)

https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index

OCR Health Information Privacy

https://www.hhs.gov/hipaa/index.html

USCDI Standards

https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi

Information Blocking
Other Resources

AMA

https://www.ama-assn.org/topics/ehr-interoperability

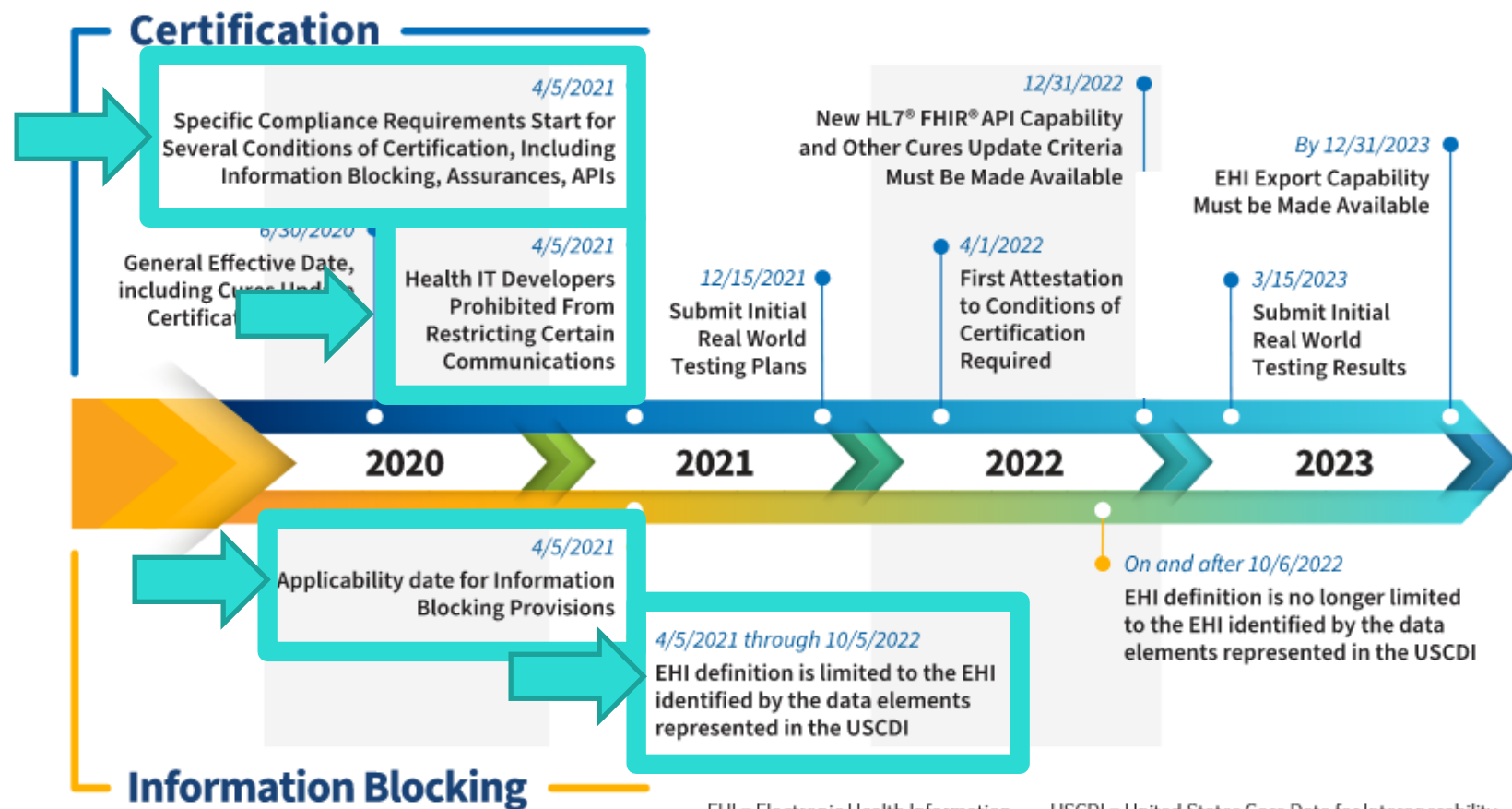https://www.ama-assn.org/system/files/2021-01/information-blocking-part-1.pdf

ACP

https://www.acponline.org/practice-resources/business-resources/health-information-technology/interoperability-and-information-blocking-regulations

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

Certification

4/5/2021
Specific Compliance Requirements Start for Several Conditions of Certification, Including Information Blocking, Assurances, APIs

6/30/2020
General Effective Date, including Cures Update Certification

4/5/2021
Health IT Developers Prohibited From Restricting Certain Communications

12/15/2021
Submit Initial Real World Testing Plans

12/31/2022
New HL7® FHIR® API Capability and Other Cures Update Criteria Must Be Made Available

4/1/2022
First Attestation to Conditions of Certification Required

By 12/31/2023
EHI Export Capability Must be Made Available

3/15/2023
Submit Initial Real World Testing Results

2020 **2021** **2022** **2023**

4/5/2021
Applicability date for Information Blocking Provisions

4/5/2021 through 10/5/2022
EHI definition is limited to the EHI identified by the data elements represented in the USCDI

On and after 10/6/2022
EHI definition is no longer limited to the EHI identified by the data elements represented in the USCDI

Information Blocking

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