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Complying With the New ONC Final Rule

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Complying with ONC's Information Blocking Rules

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October 8, 2020



- Current Deadline – November 2, 2020
- 3 month enforcement discretion period until February 2, 2021
- OMB currently reviewing further extension
- OIG still working on civil monetary penalties (CMPs) and “appropriate disincentives”



DON'T MISS
the DEADLINE



PENALTY



- OIG is proposing that enforcement of information blocking will not begin until 60 days after its regulation becomes final or date in final rule
- OIG refers health care providers to **appropriate agency for appropriate disincentives**
- Health IT / EHRs – **CMPs** up to \$1 million for HIT providers and data networks
- The ONC has stated that there is a **3-month enforcement discretion period** after the November 2, 2020 deadline, to allow health care providers to focus on other priorities during the COVID-19 pandemic



DON'T MISS
the DEADLINE



PENALTY



- Further, enforcement of information blocking civil monetary penalties will not begin until the OIG has had the opportunity for notice and comment rulemaking on what may constitute **appropriate disincentives**
- Applies to all providers – not just federal program participants
- Future rulemaking. Medicare / federal reimbursement deductions; public “shaming”, False Claim Act liability.

- Information blocking is a practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI).
- Actors
 - Health Care Providers
 - Health IT Developers
 - HINs / HIEs

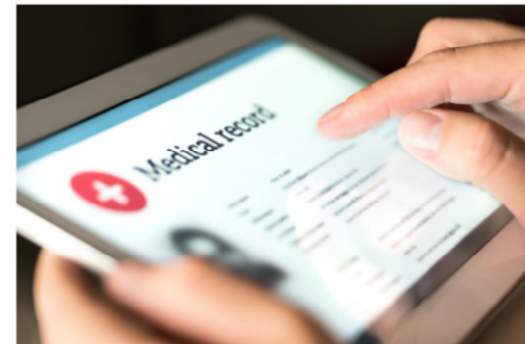


- Entity (or has control or discretion over an entity) that
- Facilitates the exchange of EHI among two or more unaffiliated providers for
- Treatment, payment or health care operations purpose



What Data - EHI?

- First 2 Years – Only USDCI Data
- Universe of EHI ...
- Medical records, billing records, payment and claims records
- Health plan enrollment records
- Case management records
- Other records used, in whole or in part, by for a covered entity to make decisions about individuals



EHI Does Not Include

EHI Does Not Include:

- Psychotherapy notes as defined in 45 CFR 164.501
- Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding
- De-identified health information



U.S. Core Data for Interoperability


- First two years - EHI access, exchange, and use requirements restricted to the [US Core Data for Interoperability](#) (USCDI)
- USCDI - 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 exchanged
- For example, Date of Birth is a Data Element rather than its component Day, Month, or Year, because Date of Birth is the unit of exchange
- <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>

USCDI v1

Assessment and Plan of Treatment 

Care Team Members 

Clinical Notes ***NEW** 

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

Goals 

- Patient Goals

Health Concerns 

Immunizations 

Laboratory 


- Tests
- Values/Results


Medications 


- Medications
- Medication Allergies

Patient Demographics 


- First Name
- Last Name
- Previous Name
- Middle Name (including middle initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Address ***NEW**
- Phone Number ***NEW**


Problems 


Procedures 

Provenance ***NEW** 

- Author
- Author Time Stamp
- Author Organization

Smoking Status 

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
- Pediatric Vital Signs ***NEW**
 - BMI percentile per age and sex for youth 2-20
 - Weight for age per length and sex
 - Occipital-frontal circumference for children >3 years old

USCDI data classes and elements. Source: [HIMSS Report](#)



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

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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

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

Practical and Implementation Considerations

- **Turns HIPAA on its head** by requiring health-care providers and their business associates to share data in most instances where HIPAA permits, but does not require, the disclosure
- HIPAA **historically** required business associate agreements to establish permissible uses and disclosures of PHI and to prohibit uses and disclosures not permitted or required by law
- **Now**, when the law **permits** the access to or exchange of EHI, disclosure often will be **required**

Practical and Implementation Considerations

- Rule requires in several places that the policies be implemented in a **consistent and non-discriminatory manner**
- If delay or denial of information may be considered interference, **compliance with an exception** may be necessary to avoid information blocking claims
- The information blocking rule will place **pressure on all actors to streamline their technology and data contracting protocols** for technology tools and data sharing projects involving EHI

Practical and Implementation Considerations

- Data-sharing projects will be particularly reliant on the **content and manner exception** to fulfill data requests
- Particularly relevant regarding requests from **patients and third parties acting on their behalf, as well as the actor's competitors**
- To the extent the negotiation strategy instead requires reliance on the licensing or fee exceptions, **consider reasonable licensing terms and allowable fees in advance** to streamline your time frames for negotiating license conditions on non-discriminatory terms

Practical and Implementation Considerations

- Covered entities and their business associates should **update their privacy and security policies** and modify their release of information and data-sharing practices that prohibit or delay that data sharing
- In several places, the rule requires that organizational **policies be in writing (for example, in the Preventing Harm, Privacy and Security Exceptions)**

Practical and Implementation Considerations

- Although the ONC notes that the information blocking rule does not itself require actors to violate their business associate agreements and associated service level agreements, actors **cannot use these agreements to limit EHI disclosures in an arbitrary manner**
- Will take time for changes to **work their way through BAAs**
- Consider applicability of BAA language regarding **modifications to laws**



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