

Unlocking Patient Data to Avoid Information Blocking

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Information Blocking Topics

Background and compliance deadlines

What is Information Blocking (IB), and what exceptions apply?

Consequences of IB and enforcement

Examples of common data sharing / withholding practices and how to address them

Practical tips and prioritizing compliance steps to avoid IB



IB Rule is a Paradigm Shift

- The Information Blocking Rule (IB Rule) represents a paradigm shift from the conservative approach of “when in doubt don’t disclose”
 - HIPAA rules specify when PHI “may” be disclosed.
 - To avoid information blocking (IB), actors may need to start with a **presumption that EHI must be disclosed** unless otherwise required by law or an exception.
 - **Change from “may disclose” to “shall disclose unless an exception applies.”**
- For clinicians, a significant effect of the rule will be to require electronic release of **most electronically-maintained** clinical notes and test results to patients and their representatives **quickly and inexpensively.**



Why Was IB Rule Created?

- “Information blocking” provisions of 21st Century Cures Act responded to concerns about health industry practices that **unreasonably limited the availability and use of electronic health information (EHI) for permitted purposes**, including:
 1. Contract terms/policies restricting individuals’ right to access PHI for permitted purposes.
 2. Prices/fees making exchange/use of PHI cost prohibitive.
 3. Non-standard implementation of health IT that substantially increases cost, complexity, or burden of sharing data.
 4. Health IT development/implementation that is likely to:
 - Lock-in users or information or prevent sharing between IT systems or providers;
 - Encourage fraud, waste, or abuse; or
 - Prevent innovations and advancements.

Purposes of Final IB Rule

- **Patients:** Right of Access to their Chart, Supporting Patient Privacy and Security, the Ability to Shop for Care and Avoid Bankruptcy
- **Doctors and Hospitals:** Making Patient's Chart Data Requests Easy and Inexpensive, Allowing Choice of Software, Implementation
- **Patients, Doctors, and Hospitals:** Improving Patient Safety
- **Health IT Developers:** Minimizing API Development and Maintenance Costs, Protecting Intellectual Property
- **American Public:** Maximizing Innovation, Transparency in Health Care
- Source: ONC Presentation on 21st Century Cures Act, available here

Compliance Deadlines

- “Applicability Date” – was six months after publication of final rule (11/2/2020); delayed due to COVID-19 until **4/5/2021**
- Enforcement Date
 - For IT developers, HIEs, civil monetary penalties (CMPs) will not begin until established by OIG rulemaking; no penalties until the OIG rule is final.
 - For providers, HHS still must develop rule to outline disincentives/penalties for IB.
- Limited definition of EHI (EHI identified by the data elements represented in the USCDI standard) applies until **10/6/2022**



Definition of Information Blocking

- **(a) Information blocking means a practice that—**
 - **(1) Except as required by law or covered by an exception, is likely to interfere with access, exchange, or use of electronic health information; and**
 - **(2) If conducted by a health information technology developer, health information network or health information exchange, such developer, network or exchange knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI; or**
 - **(3) If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with the access, exchange, or use of EHI.**
- **(b) Until October 6, 2022,** EHI for purposes of paragraph (a) of this section is limited to the EHI identified by the data elements represented in the USCDI standard adopted in § 170.213.

Elements of Information Blocking

Actor regulated by the information blocking provision

Practice involves **EHI**

Practice is **likely to interfere with, prevent, or materially discourage** access, exchange, or use of EHI

Requisite **knowledge** by the actor

Practice is not required by law

Practice is not covered by an exception

EHI Definition

- EHI is ePHI contained in a “designated record set” (DRS), as defined by HIPAA.
- DRS is defined as records maintained by or for a **covered entity** that are:
 - Medical and billing records of a **covered health care provider**;
 - Specific **health plan** records such as enrollment, payment, claims, etc.; or
 - Records used by a **covered entity** to make decisions about individuals.
- **EHI excludes:**
 - **Psychotherapy notes**
 - **Information compiled in anticipation of in civil/criminal/administrative proceeding**



USCDI Elements

- Until 10/6/2022, actors must share **at least** the EHI data elements
- reflected in USCDI. Categories (elements):
 - Allergies & Intolerances (3)
 - Assessment and Treatment Plan;
 - Care Team Members;
 - Clinical Notes (8);
 - Goals;
 - Health Concerns
 - Immunizations;
 - Laboratory (2);
 - Medications
 - Patient Demographics (15);
 - Problems;
 - Procedures;
 - Provenance (2);
 - Smoking Status;
 - Unique Device Identifier(s) for Patient Implantable Device(s);
 - Vital Signs (12).

Appendix A: USCDI v1 Summary of Data Classes and Data Elements



* elements updated or added in the 2019-revised version of US Core Data Interoperability specification.



Examples of Practices that Implicate IB

- Hospital's internal policies require staff to obtain patient's written consent before sharing patient's EHI with unaffiliated providers for treatment, where consent is not required by law.
- Practice's failure, upon patient's request, to forward patient's EHI to former shareholder of practice who recently joined competitor practice.
- Although EHR developer's patient portal has capability to allow patients to directly transmit EHI to third parties, developer's customer (provider) chooses not to enable this function.
- Practice provides information in non-machine readable format.
- Practice ignores or unreasonably delays responding to request for EHI.

A Note About Exceptions

Exceptions that involve <i>not fulfilling</i> requests to access, exchange, or use EHI	Exceptions that specify <i>procedures for fulfilling</i> requests to access, exchange, or use EHI
*Preventing Harm	Content and Manner
*Privacy	*Fees
Security	Licensing
*Infeasibility	
Health IT Performance	

Preventing Harm Exception

- **When will a practice that will likely interfere with making EHI available in order to prevent harm to a patient or other person *not* be considered IB?**
- Actor must reasonably believe the practice would “SUBSTANTIALLY reduce” a risk of harm that otherwise would arise from making EHI available, and the practice must be no broader than necessary to reduce the risk of harm.
- Practice that prevents harm should be based on written policy **or** individualized determination of risk of harm in a given instance.
 - **Such determination need not be a formal written evaluation.**
- **Harm must be physical harm.**



Preventing Harm Exception

- Different standards of harm depending on type of harm and who is affected

Whose EHI, Whose Access, Type of Harm	Harm Standard
Practice interferes with AEU of patient's EHI by legal representative, and practice is based on individualized determination of risk of harm	Substantial harm to the individual or another person
Practice interferes with AEU of EHI referencing another person by patient/legal representative, and practice is based on individualized determination of risk of harm	Substantial harm to the other person
Practice interferes with AEU of patient's EHI by patient, and practice is based on individualized determination of risk of harm or to reduce risk of corrupt or mismatched data	Harm to life or physical safety of individual or another person
Practice interferes with AEU of patient's EHI by legal representative to reduce risk of corrupt or mismatched data	Harm to life or physical safety of individual or another person



Preventing Harm Exception - Nuances

- Who determines whether harm is likely?
 - HIE or hospital may rely on health care provider's determination that disclosure of EHI would endanger patient or another, **unless and until HIE or hospital learns that determination has changed.**
 - Someone other than provider may make determination of risks relating to corrupt data or data that misidentifies patient.
- Policies that delay provision of test results to patients may be successfully challenged under this exception.
 - **What does it mean to delay the provision of test results to patients?**



Privacy Exception

- **When will a practice of not fulfilling a request for EHI to protect a person's privacy *not* be considered IB?**
- Four sub-exceptions, one of which must be followed:
 - *Practices that satisfy preconditions prescribed by [privacy] laws (e.g., consents or authorizations);
 - Certain practices not regulated by HIPAA but which implement documented and transparent privacy policies (e.g., app developer);
 - *Denial of access practices specifically permitted under HIPAA (45 CFR 164.524); or
 - *Practices that comply with a person's request not to share information (45 CFR 164.522).
- Actor's practice must be tailored to specific privacy risk/interest being addressed and implemented in consistent and non-discriminatory manner.

Security Exception

- **When will a practice of interfering with availability of EHI to protect the security of EHI *not* be considered IB?**
- The practice must be:
 - Directly related to safeguarding the confidentiality, integrity, and availability of EHI.
 - Tailored to the specific security risk being addressed.
 - Implemented in a consistent and non-discriminatory manner.
- Additionally, the actor must either have a policy addressing the practice or make an individualized determination that the security of EHI would be adversely affected.
- **Caution:** ONC notes that security practices which exceed minimum HIPAA Security Rule conditions implicate the IB rule.



Infeasibility Exception and Nuances

- **When will a practice of not fulfilling a request for EHI due to infeasibility *not* be considered IB?**
 - Disaster/other uncontrollable event;
 - Where required segmentation of data is not possible; or
 - Where fulfilling request is impossible under the circumstances.
- Actor **cannot** consider:
 - Whether manner requested would facilitate competition with actor; or
 - Whether manner requested prevented actor from charging or reduced a fee
- Where infeasibility determination made, actor must notify requestor **in writing** detailing why fulfilling request is infeasible.
 - Written notice must be provided to requestor **within 10 business days**.
 - How detailed must this response be?

Content and Manner Exception

- **When will an actor's practice of limiting content of response to, or manner in which to fulfill, a request to AEU EHI *not* be considered IB?**
- Content – Until 10/6/2022, actor must provide at least EHI identified by data elements represented in USCDI standard; thereafter, must provide all EHI.
- Manner – Actor must fulfill request “in any manner requested,” unless technically unable or cannot reach terms with requestor.
 - “Technically unable to fulfill” request in manner requested should be read literally.
- If technically unable, actor should try to reach agreeable terms with requestor **without unnecessary delay**.
 - In this way, actor is not required to comply with Fees or Licensing Exceptions.

Fees Exception

- **When will charging fees making EHI available *not* be considered IB?**
- Fees charged must be:
 - Based on objective, verifiable criteria uniformly applied to all similarly situated requestors;
 - Reasonably related to costs of making EHI available;
 - Reasonably allocated among all similarly situated requestors (so sliding fee scales ok); and
 - Based on costs not already recovered for same instance of service to requestor
- **Fees can't be based on:**
 - Possible competition by requestor;
 - Profit or revenue that requestor may derive that exceeds actor's reasonable cost; or
 - Costs actor incurred because health IT was designed/implemented in a non-standard way.
 - Three other factors.

Fees Exception - Nuances

- Where individual, personal representative, or legal representative seeks electronic access to EHI, actor may not charge a fee.
 - “Electronic access” means internet-based method that makes EHI available at time requested and **where no manual effort is required to fulfill request.**
- Actor may charge fees that result in reasonable profit.
- At time of sale/license of health IT, actor must agree in writing on fee for export/conversion.
 - What does it mean to do this?



Consequences of IB and Enforcement

- Cures Act penalties for IB
 - Health IT developers, HIEs subject to CMPs of up to \$1 million per violation, as well as possible certification ban
 - Health care providers subject to “appropriate disincentives” (some suggestion this could be based on false attestations for CMS incentive programs)
- ONC is implementing an online complaint process, available at <https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/6/create/67>



Common Privacy/Risk of Harm Concerns

- Sharing records regarding abuse.
- Sharing minors' information through patient portal.
- Sharing substance use disorder information subject to 42 CFR Part 2 where patient has not consented.
- Sharing lab or genetic test results with patients before ordering provider can review.
- Options for addressing privacy/risk of harm concerns:
 - Institutional policy (narrowly tailored)
 - Individualized determinations
 - Pre-counsel individuals about implications of receiving test results before provider has had chance to review

Practical Tips

- Clinicians who do not use EMR do not have to make information available electronically through a portal, but may have to scan and provide PHI upon request.
- Clinical notes that must be made available are not limited to notes of physicians but apply to notes made by other professionals.
- **Draft** notes and lab results pending confirmation may not be appropriate to disclose until they are finalized.
- How process of creating notes will be impacted depends on EMR used.
- Whether a hospital EMR's rules regarding IB apply to non-employed clinicians depends on how the clinicians access and use the EMR.
 - If clinician engages in IB using hospital's EMR, if hospital can show IB activity was caused by clinician's act or omission, clinician can be held responsible.



Priority Compliance Steps

- Evaluate contracts, policies, and practices involving EHI for possible IB and determine if applicable law prohibits access or if an exception applies.
- Establish processes to evaluate and respond to requests for access to EHI, and determine permissible charges for, and limitations on, such access.
- Establish processes for documenting when a practice that interferes with the access, use, or exchange of EHI falls within an IB exception.
- Compare your HIPAA policies to IB requirements, and update policies where needed to comply with IB requirements and fit processes into IB exceptions.
 - How are you handling preconditions to disclosure required under state law (e.g., consent for mental health, HIV/AIDs, or substance use disorders)?
 - When is access to EHI denied due to risk of harm?

Priority Compliance Steps (cont.)

- Create policy/process for notifying patients that their consents or authorizations require modifications to be effective.
- Create policy to assure response to infeasible requests within 10 business days.
- Evaluate how technology is implemented (avoid disabling or restricting sharing and non-standard implementations).
- Plan to educate entire workforce on IB, addressing:
 - What IB is and why it's important to avoid IB
 - Common examples of practices that are prohibited as IB
 - IB exceptions, and how they may be used to avoid IB
 - To whom concerns, questions, or complaints about IB should be directed



Priority Compliance Steps (cont.)

- If applicable, establish policies for responding to requests from third parties for licenses.
- Assess whether pricing/fees in contracts affecting access to EHI or licensing interoperability elements are appropriate or need modification.
- Remain aware of current IB regulations and guidance. Additional IB resources include:
 - ONC website: <https://www.healthit.gov/topic/information-blocking>
 - ONC FAQs: <https://www.healthit.gov/curesrule/resources/information-blocking-faqs>
 - OpenNotes: <https://www.opennotes.org/>



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