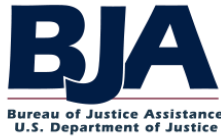




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Information Blocking: A Threat to Patient Care and Data Sharing

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Information Blocking

Tuesday, November 14

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Agenda

- Overview of Information Blocking
- Information Blocking Enforcement

Information Blocking - OIG History and Context



21st Century Cures Act

- Information Blocking definition
- Rulemaking for “reasonable and necessary activities”
 - ONC Cures Act Final Rule Exceptions
- Information Blocking Enforcement
 - OIG investigates
 - Enforcement dependent on actor type
 - Health care provider -> Provider Disincentives
 - Health IT developers of certified health IT & offers health IT-> Civil Money Penalty (CMP)
 - Health information network/exchange -> Civil Money Penalty (CMP)

Regulatory Definition

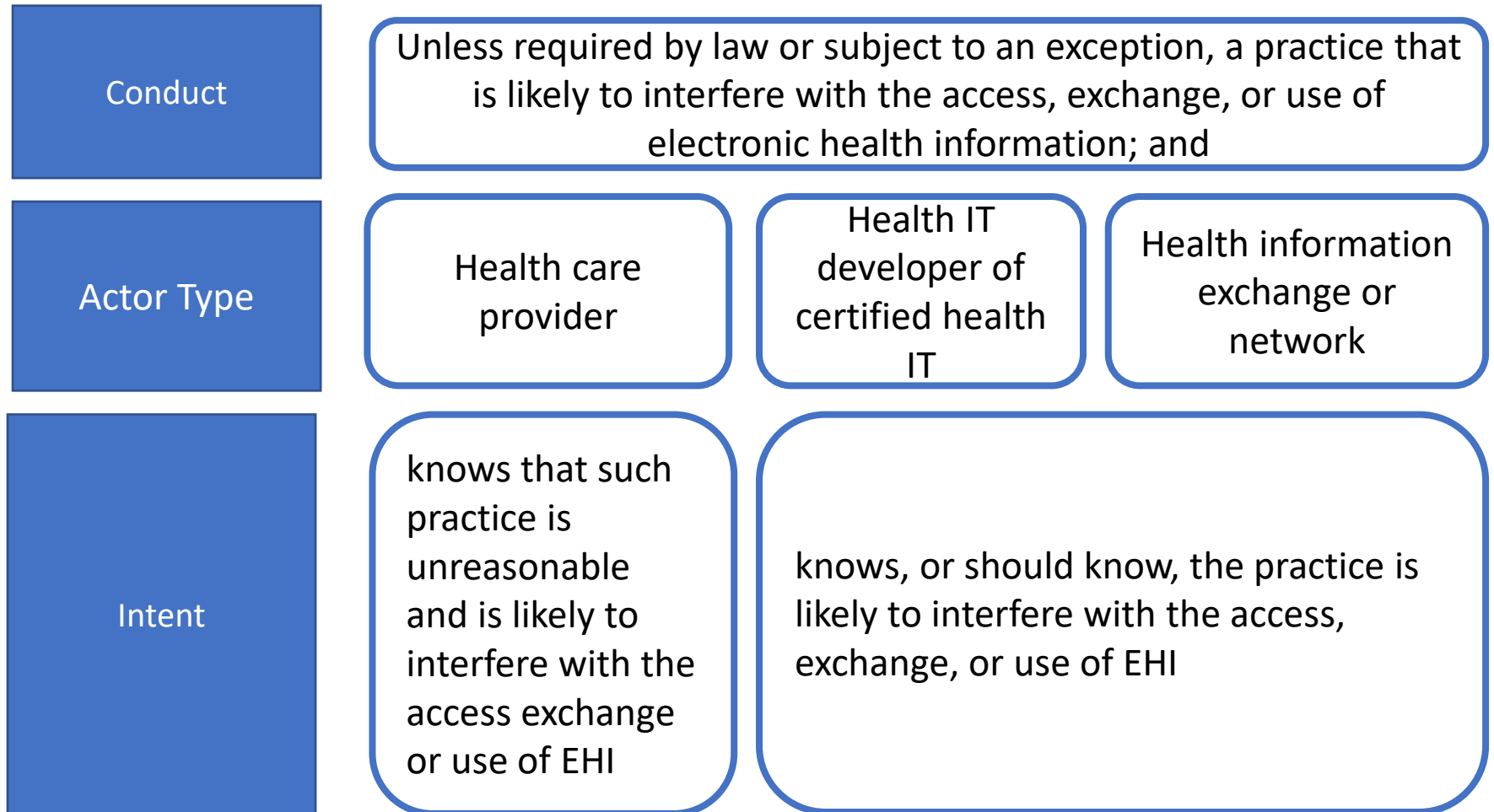
“Information blocking” means a practice that –

(1) Except as required by law or covered by an exception set forth in subpart B or subpart C of this part, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

(2) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that the practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; or

(3) 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

Information Blocking Elements



Conduct

Unless required by law or subject to an exception, a practice that is likely to interfere with the access, exchange, or use of electronic health information; and

Actor Type

Health care provider

Health IT developer of certified health IT

Health information exchange or network

Intent

knows that such practice is unreasonable and is likely to interfere with the access exchange or use of EHI

knows, or should know, the practice is likely to interfere with the access, exchange, or use of EHI

Conduct

- Unless required by law or subject to an exception,
- a practice that is likely to interfere with the access, exchange, or use of electronic health information;

ONC has defined “practice” and “electronic health information,” as part of its regulations

Actor Type: Health Care Provider

- has the same meaning as “health care provider” in 42 U.S.C. 300jj, which includes but is not limited to
 - Physicians;
 - Group practices;
 - Pharmacies;
 - Laboratories;
 - Hospitals;
 - Skilled nursing facilities;
 - Ambulatory surgical centers;
 - Federally qualified health centers;
 - Home health entities;
 - Renal dialysis facilities;
 - Blood centers;
 - Provider contracted with IHS;
 - Tribal organizations;
 - Rural health clinics;
 - Therapists; and
 - Any other category of health care facility, entity, practitioner, or clinician as deemed appropriate by the Secretary.

Actor Type: Health IT Developer of Certified Health IT

- 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 the ONC Health IT Certification Program

Actor Type: Health Information Exchange or Network

- 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.

Intent – Depends on Actor Type

Health care
provider

knows that such practice is unreasonable and is likely to interfere with the access exchange or use of EHI

Health IT
developer of
certified health IT

knows, or should know, the practice is likely to interfere with the access, exchange, or use of EHI

Health
information
exchange or
network

Exceptions

- Offer actors certainty that such practices will not be considered information blocking, if the actor satisfies all applicable requirements and conditions of the exception at all relevant times

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

Preventing Harm Exception

Privacy Exception

Security Exception

Infeasibility Exception

Health IT Performance Exception

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

Content and Manner Exception

Fees Exception

Licensing Exception

ONC Guidance Documents

- ONC has released 51 FAQ's regarding information blocking, including
 - Interference
 - Electronic Health Information
 - Actors
 - Exceptions
 - Reporting claims of information blocking
 - Enforcement
 - This information can be found on the ONC website at:
<https://www.healthit.gov/faqs>

Pending ONC Rulemaking

- HTI-1: “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing” (RIN 0955-AA03)
- Establishment of Disincentives for Health Care Providers who Have Committed Information Blocking (RIN 0955-AA05)
- Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (RIN 0955-AA06)
- Check reginfo.gov for more information!

Agenda

- Overview of Information Blocking
- **Information Blocking Enforcement**

Penalties provisions of the Cures Act

(2) Penalties

(A) Developers, networks, and exchanges

Any [health IT developer of certified health information technology or other entity offering certified health IT...or a health information exchange or network] that the Inspector General following an investigation conducted under this subsection, determines to have committed information blocking shall be subject to a civil monetary penalty

OIG's Final Rule

(B) Providers

Any [health care providers] determined by the Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking

Proposed Rule:
Establishment of
Disincentives for Health
Care Providers who Have
Committed Information
Blocking (RIN 0955-AA05)

General process for administrative cases and civil monetary penalties

- 1) Complaint or referral received
- 2) Investigation
- 3) Informal notice / potential settlement negotiation
- 4) Notice of penalties to defendant consistent with 42 CFR 1003.1500
- 5) Appeal of penalty to Departmental Appeals Board consistent with 42 CFR 1005.2

Information Blocking Complaints

- Submission of Complaints
 - To ONC
 - To OIG
- Potential Referrals by OIG
 - To the Office of the National Coordinator
 - To the Office for Civil Rights
 - To the Federal Trade Commission
 - To the Centers for Medicare & Medicaid Services
 - To the Department of Justice

OIG's Enforcement Priorities

- Enforcement priorities are:
 - (1) resulted in, is causing, or had the potential to cause patient harm;
 - (2) significantly impacted a provider's ability to care for patients;
 - (3) was of a long duration;
 - (4) caused financial loss to Federal health care programs, or other government or private entities; or
 - (5) was performed with actual knowledge.
- Enforcement priorities are not dispositive
- Each allegation will be reviewed on the specific facts and circumstances

Enforcement Start & Scope

- Enforcement of CMPs began September 1, 2023
- Conduct occurring before September 1, 2023 not subject to CMPs
 - OIG may evaluate allegations based in part on the volume of claims relating to the same (or similar) conduct by the same actor
- Scope
 - Health IT developers of Certified Health IT
 - Health Information Networks or Exchanges

Investigations

- For over 35 years, OIG has conducted other CMP investigations and enforcement
- Investigations will use similar methods and techniques appropriately tailored to each complaint's facts and circumstances
- 2021 Amendment to the PHSA
 - (4) APPLICATION OF AUTHORITIES UNDER INSPECTOR GENERAL ACT OF 1978.—In carrying out this subsection, the Inspector General shall have the same authorities as provided under section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).
 - Section 6 of The Inspector General Act of 1978
 - Documentary Subpoena
 - Testimonial Subpoena

Final Rule – Basis & Amount

- The OIG may impose a civil money penalty against any individual or entity described in 45 CFR 171.103(b) that commits information blocking, as defined in 45 CFR part 171.
 - Individual or entity types in 45 CFR 171.103(b)
 - Health IT developer of certified health IT
 - Health information exchange or network
 - Information blocking as defined in 45 CFR part 171
 - Except as required by law or otherwise meet an exception
 - “is likely to” interfere with...
 - “Knows, or should know”
- The OIG may impose a penalty of not more than \$1,000,000 per violation
 - For this subpart, violation means a practice, as defined in 45 CFR 171.102, that constitutes information blocking, as defined in 45 CFR part 171.
 - Practice means an act or omission by an actor.

Violation Example:

One request, one practice

- A health IT developer (D1) connects to an API supplied by health IT developer of certified health IT (D2). D2's API has been certified to 45 CFR 170.315(g)(10) (standardized API for patient and population services) of the ONC Certification Program and is subject to the ONC Condition of Certification requirements at 45 CFR 170.404 (certified API technology). A health care provider using D1's health IT makes a single request to receive EHI for a single patient via D2's certified API technology. D2 denies this request.
- OIG would consider this a single violation by D2 affecting a single patient.
- The violation would consist of D2's denial of the request to exchange EHI to the provider through D2's certified API.

Violation Example:

Multiple patients, one practice

- A health care provider using technology from a health IT developer (D1) makes a single request to receive EHI for 10 patients through the certified API technology of a health IT developer of certified health IT (D2).
- D2 takes a single action to prevent the provider from receiving any patients' information via the API.
- OIG would consider this as a single violation affecting multiple patients.
- This is a single violation as D2 took a single action to deny all requests from the provider. The number of patients affected by the violation would be considered when determining the amount of the CMP.

Determining the CMP amount

- Factors taken into consideration
 - The nature and circumstances of the violation
 - The degree of culpability of the person against whom a civil monetary penalty is proposed
 - E.g. “Knows, or should know”
 - Self-disclosure protocol
 - The history of prior offenses
 - Other wrongful conduct
 - Such other matters as justice may require
 - The nature and circumstances of the information blocking including the number of patients affected, the number of providers affected, and the number of days the information blocking persisted
 - The harm resulting from such information blocking, including the number of patients affected, the number of providers affected, and the number of days the information blocking persisted
- Factors are not double counted.

Violation Example:

Multiple violations for multiple patients

- A health care provider using health IT supplied by a health IT developer (D1) makes multiple, separate requests to receive EHI for several patients via certified API technology supplied by a health IT developer of certified health IT (D2). Each request is for EHI for one or more patients.
- D2 denies each individual request but does not set up the system to deny all requests made by the health care provider through D2's certified API technology. Thus, D2 is taking separate actions to block individual requests.
- Each denial would be considered a separate violation. The number of patients affected by each violation would be considered in determining the amount of the penalty per violation. The action or actions taken by D2 in response to the health care provider's requests provide the basis for assessing whether a practice constitutes a single or multiple violations.

Penalty amounts are per violation

- Health care provider using D1's health IT made:
- One request for one patient's EHI
- One request for three patients' EHI
- One request for five patients' EHI
- D2 denies each individual request
- There would be three separate violations
- The penalties may vary due to the number of patients affected by each violation.

Information Blocking Resolution

- Informal Notice / Monetary Settlement
- Demand Letter
- Appeal of Demand
 - Pursuant to the Cures Act, the process for CMPL actions at 1128A(c) applies
 - The process is governed by OIG's regulations at 42 CFR 1005.2

Enforcement-related Miscellanea

- Information Blocking Self-Disclosure Protocol
- Advisory Opinions
 - ONC 2024 Budget Request



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