

Information Blocking

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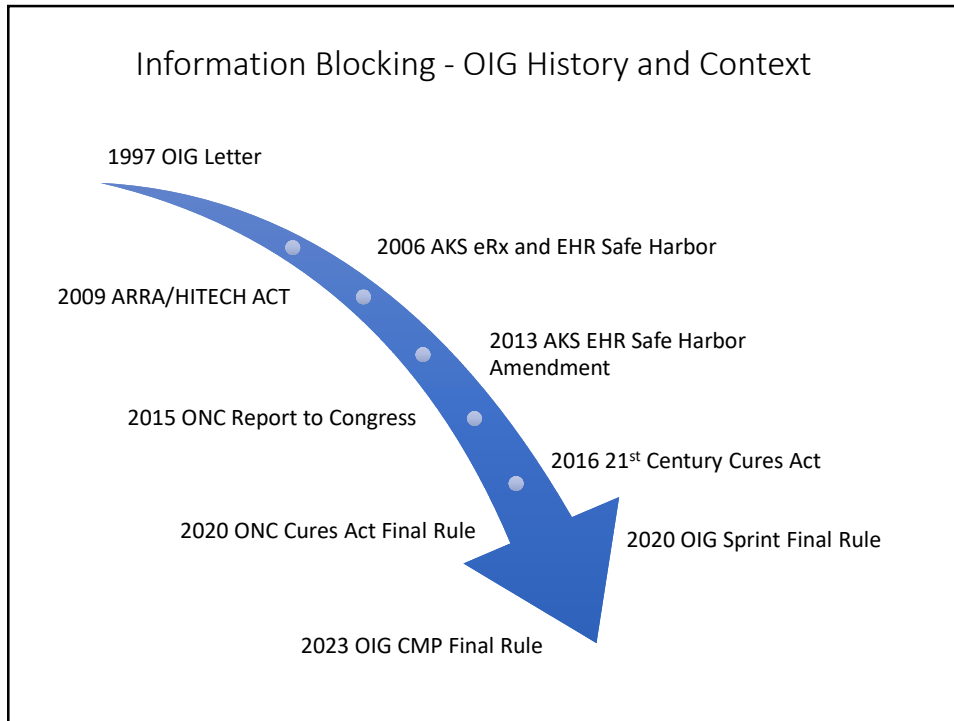
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Agenda

- Overview of Information Blocking
- Update on Pending and Future Rulemaking
- Information Blocking Enforcement

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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)

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Regulatory Definition

“Information blocking” means a practice that –

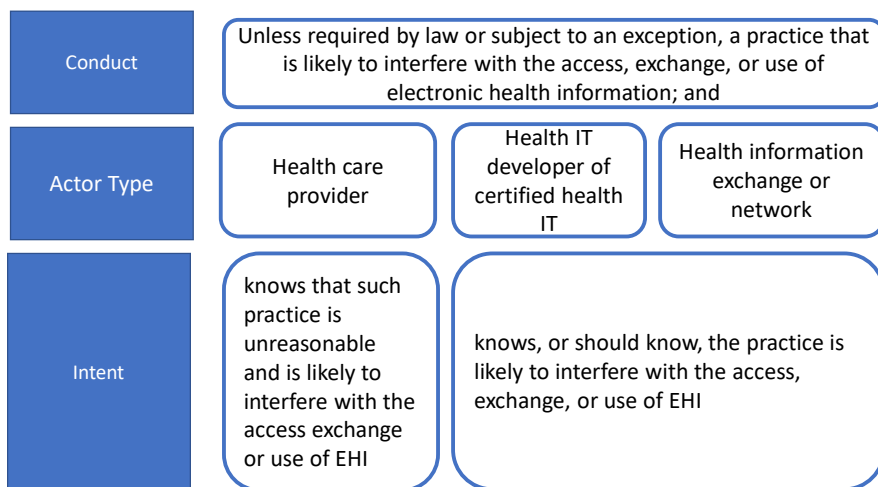
(1) Except as required by law or covered by an exception set forth in subpart B or subpart C of this part, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

(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

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Information Blocking Elements



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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

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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.

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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

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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.

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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

Health information exchange or network

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

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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

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

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Preventing Harm Exception

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Security Exception

Infeasibility Exception

Health IT Performance Exception

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Preventing Harm Exception

- Preventing Harm Exception requires an actor to meet (a) and (b), one condition from each section of (c), (d), and (f), and as applicable (e)
 - (a) Reasonable belief
 - (b) Practice Breadth
 - (c) Type of Risk – 2 different types
 - (d) Type of Harm – 4 different types
 - (e) Patient right to request review of individualized determination
 - (f) Practice implemented based on an organizational policy or a determination specific to the facts and circumstances

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Privacy Exception

- Privacy Exception requires the practice to meet all of the requirements of one of the subexceptions in (b) through (e)
- (a) Definitions
- (b) Sub-exception Precondition not satisfied
- (c) Sub-exception Health IT developer of certified health IT not covered by HIPAA
- (d) Sub-exception Denial of an individual's request for their EHI consistent with HIPAA Right of Access Provision
- (e) Sub-exception Respecting an individual's request not to share information

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Security Exception

- Security Exception requires the practice to meet the conditions of paragraphs (a), (b) and (c), and either (d) or (e)
 - (a) Directly related to safeguarding the confidentiality, integrity, and availability of EHI
 - (b) Tailored to the specific security risk being addressed
 - (c) Implemented in a consistent and non-discriminatory manner
 - (d) Implementation of an organizational security policy
 - (e) No implementation of an organizational security policy

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Infeasibility Exception

- Infeasibility Exception requires that the practice is due to a condition in (a) and meets the requirement of (b)
- (a) Conditions -
 - (1) Uncontrollable Event;
 - (2) Segmentation; or
 - (3) Infeasibility under the circumstances;
- (b) The actor provides a requestor within ten business days of receipt of the request the reason(s) why the request is infeasible

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Health IT Performance Exception

- An actor's practice must meet a condition in (a), (b), (c), or (d)
- (a) Maintenance and improvements to health IT
- (b) Assured level of performance
- (c) Practices that Prevent Harm
 - Refers to the Preventing Harm Exception
- (d) Security-Related practices
 - Refers to the Security Exception

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

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

Content and Manner Exception

Fees Exception

Licensing Exception

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Content and Manner Exception

- The practice must meet all of the following conditions
- (a) Content Condition
 - Applies to conduct prior to October 6, 2022
- (b) Manner Condition
 - Manner Requested
 - Alternative Manner

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Fees Exception

- The practice must meet the conditions of (a), not include an excluded fee in (b), and, as applicable, meet the condition of (c)
- (a) Basis for Fees
- (b) Excluded Fees
- (c) Compliance with Conditions of Certification

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Licensing Exception

- An actor's practice will not be considered information blocking when the practice meets all of the following conditions:
 - (a) Negotiating a license conditions
 - (b) Licensing conditions
 - (c) Additional conditions relating to the provision of interoperability elements

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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>

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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!

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Information Blocking Enforcement

OIG's CMP Final Rule

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Penalties provisions of the Cures Act

(2) Penalties

(A) Developers, networks, and exchanges

OIG's Final Rule

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

(B) Providers

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

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

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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

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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

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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

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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

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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 PHSAA
 - (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

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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.

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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.

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Violation Example: Multiple requests, 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.

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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.

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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.

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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.

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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

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Enforcement-related Miscellanea

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

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