Information Blocking Compliance Bootcamp
Session 5: How will Information Blocking be Enforced?
March 17, 2021

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How To Participate Today
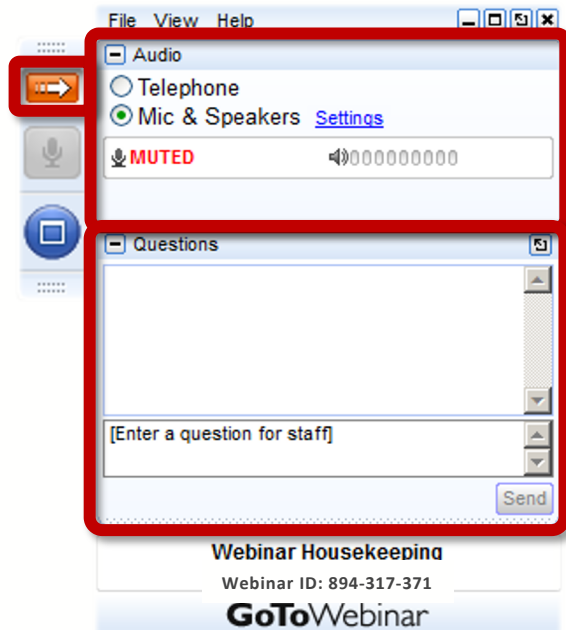
Your Participation

Open and close your control panel

Join audio:
- Choose "Mic & Speakers" to use VoIP
- Choose "Telephone" and dial using the information provided

Submit questions and comments via the Questions panel

Note: Today's presentation is being recorded and will be provided

Problems or Questions? Contact the Interoperability Matters Team at:

interopmatters@sequoiaproject.org

Meet The Sequoia Project Team

Mariann Yeager
CEO
The Sequoia Project

Steve Gravely
Founder & CEO
Gravely Group

Mark Segal
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About the Sequoia Project

The Sequoia Project is the independent, trusted advocate for nationwide health information exchange. In the public interest we steward current programs, incubate new initiatives, each with their own mission, governance, membership and structure, and educate our community.

SECURE

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NATIONWIDE

Information Blocking Compliance Bootcamp Sessions

✓	Information Blocking Overview	January 20, 2021
✓	Violating the Information Blocking Rule	February 3, 2021
✓	Exceptions: Part 1	February 17, 2021
✓	Exceptions: Part 2	March 3, 2021
5.	Enforcement Issues	March 17, 2021
6.	Compliance: Part 1	March 31, 2021
7.	Compliance: Part 2 and Wrap-Up	April 14, 2021

Bootcamp Materials

We have developed materials for you to use as part of the Bootcamp. These supplement, but do not replace, Bootcamp sessions.

- *Information Blocking Summary*—an extensive narrative that provides a comprehensive discussion of:
  - The legal authority for Information Blocking in the CURES Act, the ONC Final Rule, and the OIG Proposed Rule;
  - Key definitions and the exceptions.
- *Compliance Planning Workbook*—a comprehensive discussion of how to approach organizational compliance and implementation for Information Blocking with checklists, examples and suggestions.

https://sequoiaproject.org/2021-information-blocking-bootcamp/
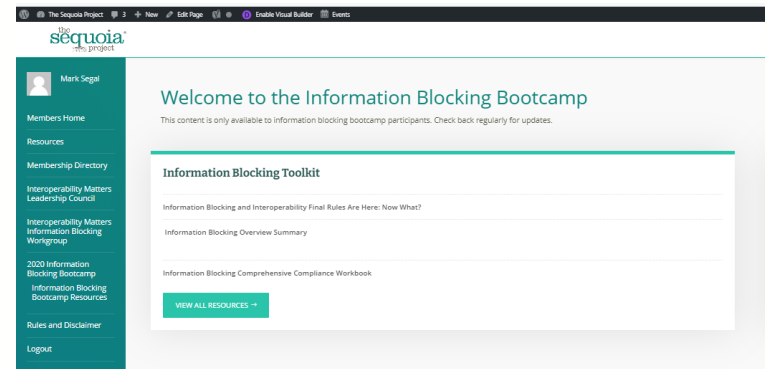
Certificate of Participation

- Sequoia has invested extensive resources into this Bootcamp to provide participants with an excellent orientation to Information Blocking

- The core faculty, Steve Gravely and Mark Segal, are experts on the Information Blocking provisions

- The written materials have been carefully vetted for accuracy and objectivity

- Each session will include vital information and time for group discussion

- Participants are encouraged to share ideas and information outside of the bootcamp sessions

- All participants that attend each bootcamp session will receive a **Certificate of Completion** as tangible evidence of their achievement

Information Blocking Compliance Bootcamp: Office Hours

Between 3pm and 4pm ET on the following dates:

- ✓ January 27, 2021
- ✓ February 10, 2021
- ✓ February 24, 2021
- ✓ March 10, 2021
5. March 24, 2021
6. April 7, 2021
7. April 21, 2021

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Quick Refresher-Exceptions

- An exception is a practice that would otherwise implicate information blocking but is permitted because the practice serves a greater public policy purpose
- ONC developed **8 exceptions** each with its own very specific requirements. An Actor **must comply with each requirement of an applicable exception**
- Actors should document how they are complying with each of the requirements in an exception
- **Failure to meet an exception does not mean that the Actor is automatically engaged in information blocking**
  - Is the practice required by law?
  - Did the Actor have the requisite knowledge and intent to violate the Information Blocking Rule
    - If the Actor is a healthcare provider, did the Actor have actual knowledge that the practice was unreasonable and was "substantially likely" to interfere with access, exchange or use of EHI
    - If the Actor is a HIN/HIE or a developer, did the Actor know or should have known the practice is "substantially likely" to interfere with access, exchange or use of EHI
    - The individual facts and circumstances will be essential as will the Actor's documentation

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Quick Refresher-Exceptions
What Eight Exceptions are Identified by ONC and How are they Organized?

Not Fulfilling Requests to Access, Exchange, or Use EHI

1. Preventing Harm
2. Privacy
3. Security
4. Infeasibility
5. Health IT Performance

Procedures for Fulfilling Requests to Access, Exchange, or Use EHI

6. Content and Manner
7. Fees
8. Licensing

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Quick Refresher-Exceptions

- Last session we covered 4 exceptions: Content and Manner, Fees, Licenses, and Infeasibility

- The Content and Manner is a **"gateway exception"** and Actors should consider using it first in many cases, BUT this sequencing can create problems with the Infeasibility Exception, which must be asserted within 10 business days of the request for EHI

- **If you use the "alternative manner" track of Content and Manner, any fees must still comply with the Fees Exception and any licenses must comply with the License Exception**

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Session 5: Enforcement

Session Goals

- How will the Information Blocking Rule will be enforced?

- Is there a private right of action?

- What is the role of the OIG?

- What types of complaints are likely to be turned into investigations?

- What are Civil Monetary Penalties (CMPs) and who is subject to them?

- Is there a right to appeal imposition of CMPs?

How will the Information Blocking Rule be Enforced?

- Cures amended the Public Health Services Act (42 U.S.C. 300jj-52) to authorize the HHS Office of Inspector General (OIG) to investigate claims of information blocking and recommend imposing Civil Money Penalties

- Cures also authorizes OIG to investigate claims that health IT developers or others offering certified health IT have submitted "false attestations" under the ONC Health IT Certification Program which requires an attestation every 6 months that the developer or offeror has not engaged in information blocking

- In addition, ONC will enforce certification-related obligations (for information blocking and other issues) for developers of certified health IT

- ONC and OIG have worked together extensively to develop an enforcement framework

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How will the Information Blocking Rule be Enforced?

- OIG issued a **Proposed Rule on April 24,** 2020 to implement Cures provisions expanding its authority to investigate information blocking claims and recommend Civil Money Penalties
  - OIG states in the Proposed Rule that it is specifically relying upon the ONC Final Rule, so these should be read together
  - **OIG has not yet issued a Final Rule**
- What about healthcare provider "disincentives"
  - Different from Civil Money Penalties
  - Will be a sanction imposed on actors that are healthcare providers for information blocking violations
  - Do not know what these disincentives will be, no proposed rule yet

What is the HHS OIG?

- **Mission**: Provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve

- **Goals and Objectives:**
    - Fight fraud, waste and abuse;
    - Promote quality, safety and value; and
    - Advance excellence and innovation

- **History:** Formed in 1976 and charged with investigating waste, fraud, and abuse in Medicare, Medicaid and over 100 other HHS programs, the HHS OIG is the largest OIG in the entire federal government with over 1600 staff members

No "Private Right of Action"

- Cures does not support a "private right of action" so you cannot sue an Actor for alleged information blocking
  - Your remedy is to file a complaint with ONC and/or the OIG
  - You can also try to work with data holder (e.g., Content and Manner exception)
- This approach is consistent with HIPAA, the Federal False Claims Act, the Anti-kickback Statute and the Stark Law, none of which allow a "private right of action"
- The HHS OIG is responsible for investigating allegations of information blocking and deciding when to recommend Civil Money Penalties
- The OIG Proposed Rule states that it will work with ONC and OCR to "consult, confer and coordinate"
  - OIG may refer cases to OCR (e.g., HIPAA patient right of access)
  - OIG may also refer cases to to-be-determined enforcement process for providers

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How Will the OIG Decide Which Complaints to Investigate? (1)

- The OIG will not investigate every complaint
- The Proposed Rule lists factors that OIG will use to decide when to launch an investigation:
  - Did the conduct result in, cause, or have the potential to cause patient harm?
  - Did the conduct significantly impact a healthcare provider's ability to care for patients?
  - Was the conduct of long duration?
  - Did the conduct cause financial loss to any federal healthcare program or other government or private entities?
  - Was the conduct performed with actual knowledge?

How Will the OIG Decide Which Complaints to Investigate? (2)

- The focus on patient harm is noteworthy; it shows that ONC and OIG are concerned that information blocking can harm patients

- We can infer from the OIG Proposed Rule what claims OIG will prioritize

- OIG says that it will not bring enforcement actions for "innocent mistakes"

Civil Money Penalties

- Civil Money Penalties (CMPs) are fines imposed by HHS for violations

- CMPs can be imposed by OIG on Developers and HIEs/HINs

- Providers are not subject to CMPs unless they also qualify as an Actor, either as an HIE/HIN or Developer

- OIG recommends CMPs to the HHS Secretary, up to $1M per violation

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CMPs and Healthcare Providers

- "**This proposed rule does not apply to health care providers** who engage in information blocking.[1]"

- ". . . **providers that also meet the definition of a health information exchange or health information network as defined in the ONC Final Rule would be subject to information blocking CMPs**."

- "**Once established**, OIG will coordinate with, and send **referrals to, the agency or agencies** identified in **future rulemaking by the Secretary** that will apply the **appropriate disincentive for health care providers that engage in information blocking**, consistent with sec. 3022(b)(2)(B)."

""[1] While health care **providers are not subject to information blocking CMPs, many must currently comply with separate statutes and regulations related to information blocking**."

MACRA (2015) requires a provider to "demonstrate that it has not knowingly and willfully taken action to limit or restrict the compatibility or interoperability of Certified Electronic Health Record (EHR) Technology."

CMS "established and codified **attestation requirements to support the prevention of information blocking, which consist of three statements** containing specific representations about a health care provider's implementation and use of Certified EHR technology" that **do not reference "information blocking" nor its Cures/ONC definition**

The Sequoia Project letter emphasized the need for greater OIG clarity on how it will handle information blocking complaints regarding providers, especially in the absence of the forthcoming rule on provider disincentives and referrals.

Federal Register / Vol. 85, No. 80 / Friday, April 24, 2020 / Proposed Rules **22981**

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How Will OIG Determine the Number of Violations Subject to CMPs?

- CMPs can be imposed for each "violation"

- OIG Proposed Rule would define "violation" as each "practice" that is "information blocking," using definitions in ONC Final Rule

- When investigating information blocking, OIG will assess facts and circumstances on a case-by-case basis, which may lead to determination of multiple violations

- Let's review some examples from the OIG Proposed Rule

OIG Examples of a Single Violation

- A health care provider notifies its health IT developer of its intent to switch to another EHR system and requests a complete electronic export of its patients' EHI via the capability certified to in 45 CFR § 170.315(b)(10). The developer refuses to export any EHI without charging a fee. **The refusal to export EHI without charging this fee would constitute a single violation.**

- A health IT developer (D1) connects to a health IT developer of certified health IT (D2) using a certified API. D2 decides to disable D1's ability to exchange information using the certified API. D1 requests EHI through the API for **one patient** of a health care provider for treatment. As a result of D2 disabling D1's access to the API, D1 receives an **automated denial of the request. This would be considered a single violation.** [Note the focus on a refusal for a single patient by another developer.]

- **OIG states that the number of patients affected is relevant to the size of the CMP recommended**

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OIG Examples of Multiple Violations (1)

- A developer's software license agreement with one customer prohibits the customer from disclosing to its IT contractors certain technical interoperability information (i.e., Interoperability elements), without which the customer and the IT contractors cannot access and convert EHI for use in other applications.

  The developer also chooses to perform maintenance on the health IT that it licenses to the customer at the most inopportune times because the customer has indicated its intention to switch its health IT to that of the developer's competitor.

  For this specific circumstance, one violation would be the contractual prohibition on disclosure of certain technical interoperability information and the second violation would be performing maintenance on the health IT in a discriminatory fashion. Each violation would be subject to a separate penalty.

OIG Examples of Multiple Violations (2)

- A developer requires vetting of third-party applications before the applications can access the developer's product. The developer denies applications based on the functionality of the application.

  There are multiple violations based on each instance the health IT developer vets a third-party application because each practice is separate and based on the specific functionality of each application. Each of the violations in this specific scenario would be subject to a penalty.

Single v. Multiple Violations-$$$ at Stake!

- For the examples illustrating multiple violations, ONC notes that important facts, in determining the number of violations, are the **discrete practices** that each meet elements of the information blocking definition

- In the first example, the developer engages in two separate practices: (1) prohibiting disclosure of technical interoperability information and (2) performing maintenance on the health IT in a discriminatory fashion
  - Each practice would meet the definition of information blocking separately and therefore, the first example is a two-violation scenario

- In the second example, the health IT developer vets each third-party application separately and makes a separate decision for each application.
  - For each denial of EHI access based on *discriminatory* vetting, there is a practice that meets the definition of information blocking and each denial of access would be a separate violation

How will OIG determine the amount of a CMP?

- If OIG finds one or more violations of the Information Blocking provisions, it must then decide the amount of the CMP up to the cap of $1M **per violation**

- OIG will determine the amount of CMP based on the following factors:
  - Nature and extent of information blocking
  - Harm from information blocking
  - Number of patients affected
  - Number of providers affected
  - Duration of information blocking calculated as the number of days the blocking persists

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What Processes Govern the OIG Imposition of Sanctions?

- OIG must provide notice to an Actor of proposed sanctions per 42 CFR Part 1003(o)

- Notice **must** describe:
  - The violation(s) that are the basis of the imposition of CMP
    - For information blocking, this notice would include the practices that OIG identified in its investigation
  - The reasons that OIG is imposing the CMP
  - Factors and circumstances that OIG considered in determining the amount of the CMP
    - This notice will include the factors discussed in a previous slide

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Can an Actor Challenge an OIG Decision?

- OIG decisions to impose CMPs can be challenged via an appeal under 42 CFR Part 1005

- Actor must file an appeal with the HHS Departmental Appeals Board within 60 days of receipt of the notice of the imposition of the CMP
  - Timely filing is mandatory! Actor entitled to a "fair and impartial hearing" before an Administrative Law Judge (ALJ)

- Actor can be represented by legal counsel, conduct discovery, present evidence and have witnesses

- Judicial review is allowed BUT:
  - Only after the ALJ process is exhausted absent extraordinary circumstances
  - Only the issues that an Actor raised with the ALJ

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ONC Enforcement for Developers (1)

- Cures provides expanded certification authority for ONC to establish Conditions and Maintenance of Certification requirements for health IT developers *that go beyond the certified health IT itself*

- New Conditions and Maintenance of Certification requirements in section 4002 of Cures focus on actions and business practices of health IT developers:

  - Information blocking and appropriate access, use, and exchange of electronic health information

  - Technical interoperability (e.g., APIs and real-world testing)

ONC Enforcement for Developers (2)

- Per Cures, ONC finalized an enforcement framework outlining a corrective action process to review potential or known instances where a Condition or Maintenance of Certification requirement was not met by a developer
  - ONC direct review of Conditions and Maintenance of Certification
  - ONC will use processes previously codified in §§ 170.580 and 170.581 for direct review, along with revisions and additions to incorporate enforcement and reflect congressional intent in Cures
  - ONC may coordinate review of a claim of information blocking with OIG or defer to OIG to lead review, and may rely on OIG for basis of direct review
- Possible steps: notice of potential non-conformity, corrective action plan, suspend or terminate certification for Health IT Module or certification ban (each appealable), reinstatement

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Coming Up In Session 6

Compliance

- In Session 6 we will discuss the key challenges for Actors as they develop compliance programs for information blocking

- We will discuss the OIG Compliance Framework and how it could be a reference tool for information blocking compliance

- We will share feedback from The Sequoia Project Information Blocking Work Group on compliance initiatives