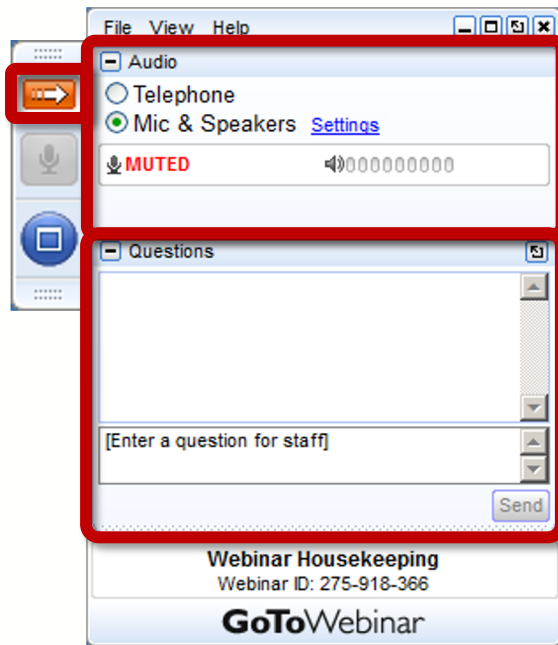# Information Blocking Compliance Bootcamp
Session 7: Compliance Part 2/Wrap-up
April 14, 2021

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
Principal
Digital Health Policy Advisors

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.
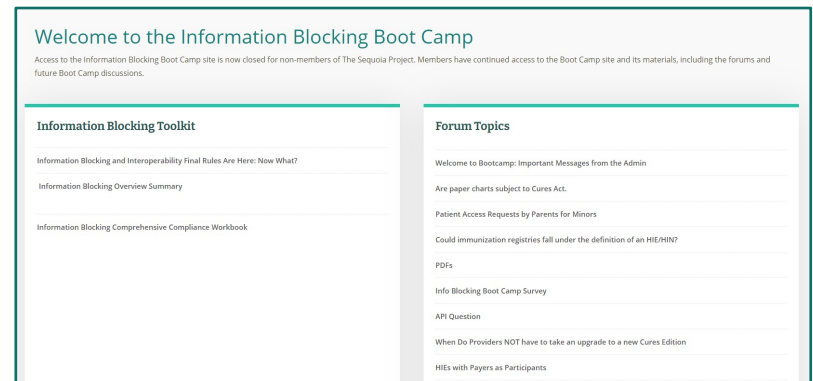
SECURE	INTEROPERABLE	NATIONWIDE

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
✓ Enforcement Issues	March 17, 2021
✓ Compliance: Part 1	March 31, 2021
7. Compliance: Part 2 and Wrap-Up	April 14, 2021

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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.

Welcome to the Information Blocking Boot Camp

Access to the Information Blocking Boot Camp site is now closed for non-members of The Sequoia Project. Members have continued access to the Boot Camp site and its materials, including the forums and future Boot Camp discussions.

Information Blocking Toolkit

Information Blocking and Interoperability Final Rules Are Here: Now What?

Information Blocking Overview Summary

Information Blocking Comprehensive Compliance Workbook

Forum Topics

Welcome to Bootcamp: Important Messages from the Admin

Are paper charts subject to Cures Act.

Patient Access Requests by Parents for Minors

Could immunization registries fall under the definition of an HIE/HIN?

PDFs

Info Blocking Boot Camp Survey

API Question

When Do Providers NOT have to take an upgrade to a new Cures Edition

HIEs with Payers as Participants

https://sequoiaproject.org/2021-information-blocking-bootcamp/

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
- ✓ March 24, 2021
- ✓ April 7, 2021
7. April 21, 2021

Quick Refresher-Compliance

- While not expressly required by Cures or the Final Rule, Actors should develop a compliance strategy to reduce the risk of violations, complaints, and enforcement actions
- The HHS OIG Compliance Framework is a reasonable place to start since the OIG is responsible for investigating information blocking allegations
- A compliance program will help Actors:
  - educate board, management, employees, contractors about information blocking requirements
  - identify and prioritize information blocking risks
  - document measures that the Actor takes to be compliant
- We reviewed the 7 elements of the OIG Framework and discussed some of the challenges that organizations may face depending upon whether they already have an existing compliance program or are developing a new one
- We provided an overview of the Sequoia Compliance Planning Workbook, which provides an outline of key compliance and implementation concepts
- We also reviewed the ONC Interim Final Rule with Comment, which extends the applicability (i.e., compliance) date from 11-2-120 to 4-5-21 and extends other dates for developers (and by implication providers)

Session 7: Compliance Part 2

Compliance First Steps—The Risk Assessment

What is My Risk?

- A key part of any compliance program is assessing your risk for information blocking liability
- Actors should conduct a risk assessment to identify these risks
  - Are you an Actor? (or include multiple Actor-types)
  - What Interoperability Elements are controlled by the organization?
  - What EHI is included in the organization's products or services?
  - How does the organization access, exchange and use EHI and with whom?
  - What standards for EHI has the organization implemented, especially those recognized or adopted by the federal government (e.g., C-CDA, USCDI, HL7® FHIR®, etc.).
  - What specific practices does the organization engage in that ONC has identified as potential information blocking?
  - For all practices identified, which ones are required by law?
  - For practices not required by law, can you fit them within one of the eight exceptions?
  - If you cannot fit within an exception, can you document that you do not have any intent to engage in information blocking?

Are You an Actor?

- This is the first step, since information blocking ONLY applies to organizations or individuals that are Actors
- 3 types of Actors:
  - Healthcare providers—pretty clear and very broadly defined
  - Developers of certified health IT—a bit more complicated, anyone who "develops or offers" health IT that is certified by ONC
    - We discussed that "offering" certified health IT is broadly defined and includes resellers/re-licensors
    - Developing or offering only 1 certified health IT module makes the organization an Actor
    - Can be an Actor (for past practices) even if no longer have certified health IT
  - HIN/HIE—the most ambiguous and will present challenges
    - A "functional" definition, not dependent on organizational structure
    - Control over how information is exchanged is key
- One organization can include multiple Actor-types

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What Interoperability Elements are Controlled by The Organization?

- The ONC Final Rule defines a broad set of *interoperability elements* that can implicate information blocking:
  - Hardware, software, integrated technologies or related licenses, technical information, privileges, rights, intellectual property, upgrades, or services;
  - That (1) may be necessary to access, exchange, or use electronic health information; and (2) is/are controlled by the actor, which includes ability to confer all rights and authorizations necessary to use the element to enable the access, exchange, or use of electronic health information.
- The interoperability elements controlled by your organization will play a major role in defining risk and compliance needs
- Note, some interoperability elements used by the organization but not controlled by the organization (e.g., IP licensed from a third party)

What EHI is Included in the Organization's Products or Services?

- Information blocking obligations and risks extend to EHI controlled by the Actor

- The initial definition (until 10/6/2022) is focused on USCDI data elements

- The definition effective on or after 10/6/2022 is ePHI that would be included in a Designated Record Set

- EHI does not include (1) psychotherapy notes as defined in HIPAA; (2) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; or (3) de-identified health information (per HIPAA)

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How Does the Organization Access, Exchange and Use EHI and with Whom?

- The answer will depend on what type of Actor you are
  - Healthcare providers create EHI, share it with others and receive it from others and use it, they also must honor patient preferences and provide access to patients and their representatives, and other authorized requesters
  - HIEs/HINs do not create EHI but support exchange of and access to EHI, may also use EHI for value-added services offered to members
  - Developers provide health IT products that enable the access, exchange and use of EHI
- You will want to identify current and potential organizations or individuals who are likely to request access, exchange or use

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What Standards for EHI has the Organization Implemented?

- Relevant standards especially include those recognized or adopted by the federal government (e.g., HL7® C-CDA, USCDI, HL7® FHIR®, etc.)

- The standards supported will be relevant to obligations under the ONC certification program and CMS incentive programs

- They are also especially relevant for use of the Content and Manner exception

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What Specific Practices Does the Organization Engage In That ONC Has Identified as Potential Information Blocking?

- ONC identified 49 specific practices and examples that "could implicate" information blocking

- The diversity of these practices make it very challenging to identify which practices your organization may engage in

- REMEMBER—the practices and examples that ONC identified are NOT exhaustive

- Your focus should be on ANY act or omission that interferes with access, exchange or use of EHI

- Do not be discouraged if the list is long, it is better to be aware of practices that may create information blocking risk

- These identified practices will provide your organization with a roadmap for how you approach compliance by addressing each practice

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For All Practices Identified, Which are Required by Law?

- You will want to consider both state or federal law
- If a practice is required by law (not simply permitted), then it is not information blocking
- But, an Actor will need to prove that its practice is actually required by law, which could be challenging since laws are not always clear
- Business Associate Agreements are binding contracts and also implement HIPAA and other applicable laws and regulations
  - ONC has stated that the Information Blocking rules do not require actors to violate BAAs, but also that a BAA itself could implicate information blocking
- Here are some examples:
  - HIPAA requirements to respect patient decisions about how their information is shared (e.g., not sharing EHI for out-of-pocket services with health plans)
  - State laws that provide additional protection (including restrictions on timing and method of disclosure) to certain types of information such as behavioral health, sexually transmitted diseases and genetic information
  - Consent requirements under state or federal law
  - State law "opt-in" or "opt-out" requirements for having their information shared via HIEs/HINs

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For Practices Not Required By Law, Does It Fit Within An Exception?

- ONC identified 8 exceptions, each with its own specific requirements

- Remember that you must meet all of the requirements of an applicable exception (or an identified sub-exception) in order to assert it

- Content and Manner will certainly be used frequently and its addition reflects an effort by ONC to give Actors some flexibility and to avoid the need to use the Fees or Licensing exceptions

- Other exceptions are narrower in scope or have a higher bar for use, like the Preventing Harm or Security exceptions

- It is critical that you document how you are meeting the requirements of every exception that you are going to claim applies to the practices in which you engage

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What About Knowledge and Intent?

- Knowledge and Intent are essential elements of an information blocking violation
- The knowledge and intent standard differs based on the type of Actor involved
    - For Actors that are healthcare providers, the Actor must have actual knowledge that its practice will materially interfere with access, exchange or use of EHI
    - For Actors that are either HIEs/HINs or developers of certified health IT, the Actor must either know or should have known that its practice will materially interfere with access, exchange or use of EHI
    - ONC's regulations look for discriminatory or anti-competitive intent
    - OIG says in its Proposed Rule that it will not impose civil money penalties for "innocent mistakes"
- This factor makes it important that you document your intent and expected impact on access, exchange, or use whenever you identify a real or potential practice, in case you are investigated in the future

Risk Assessment Output

- Effective risk assessment takes time and resources—do not underestimate this!

- The risk assessment should identify key vulnerabilities in your organization and provide a roadmap for corrective action

- This roadmap can be used by your compliance committee or task force to decide how to address practices that present compliance or business risk

- Remember to DOCUMENT, DOCUMENT, DOCUMENT!

IB Workgroup Feedback on Compliance

The Sequoia Information Blocking Work Group asked its members to share their information blocking compliance activities. Here are some of the key take-aways:

- **Act now—**information blocking is complex and affects nearly every aspect of an Actor's organization and operations. Do not wait until the last minute to start doing a risk assessment and developing a compliance plan.

- **Educate, educate, educate**—your governing body, C-suite, employees and external contractors need to understand what information blocking requires

- **Be creative**—use engagement tools that capture the attention of your audiences. "Table-Top Exercises" are an excellent tool to help provide examples of "real-world" information blocking situations.

- **Document, document, document**—We have said this repeatedly, but it is essential

Compliance is One Part of a Broad Overall Approach

- Take a broad "implementation" approach rather than one solely focused on legal or compliance issues or teams

- Consider creating a "project" with C-suite sponsorship

- Recognize the breadth and depth of organizational implications

- In addition to your lawyers or compliance team, addressing risks and opportunities should involve the following, depending on actor-type/focus:

  - HIM
  - Product management and development
  - IT and engineering
  - Privacy and Security officers
  - Finance
  - Marketing and pricing teams
  - Contract management and licensing
  - Client management and services teams
  - Communications (internal and external)

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Approach Risk Assessment as Part of a Comprehensive and Systematic Compliance and Implementation Process

What About Opportunities?

- We have talked a lot about risk and liability, but does information blocking also create opportunities?

- Yes, for actors, non-actors, and patients

- ONC's Final Rule will provide competitive opportunities for innovative healthcare organizations, HIEs/HINs and developers to differentiate themselves, including in how information blocking compliance and implementation are addressed

- More generally, organizational responses to information blocking and API requirements, and use of standards like HL7 FHIR and USCDI, will enable greater data access and integration of apps with existing health IT

- This increased data access and integration will enable a broader app economy, new technology approaches, data for artificial intelligence/machine learning, and broader and more useful provider/patient data use

Wrap Up

- Thank you for participating!

- How to stay connected

- What's next?