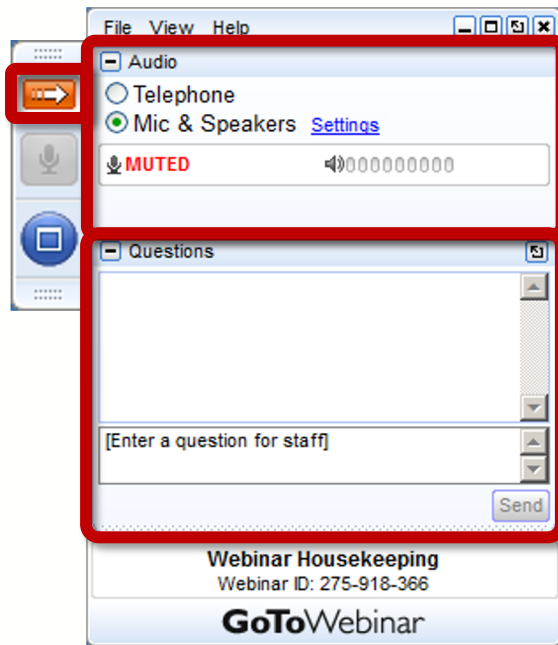# Information Blocking Compliance Bootcamp
Session 6: Compliance Part 1
March 31, 2021

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
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About the Sequoia Project

The Sequoia Project is an 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
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/2020-information-blocking-bootcamp/
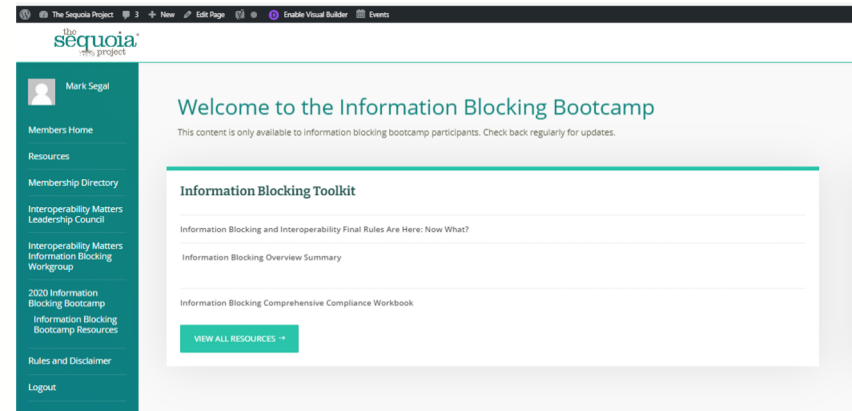
Information Blocking Compliance Bootcamp: Office Hours

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

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

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Quick Refresher-Enforcement

- Responsibility for enforcement of information blocking matters is shared between ONC and the HHS OIG
  - OIG investigates complaints of information blocking for all actors and false attestations by developers of certified health IT
  - ONC enforces Conditions of Certification for developers of certified health IT, including those related to information blocking
- OIG Proposed Rule provides factors that OIG will consider in deciding which complaints to investigate and when to impose a CMP
  - Patient harm and interference with the delivery of care are key considerations
- CMPs may be up to $1M per violation and we discussed single v. multiple violations
- You can appeal OIG decisions to an ALJ and eventually into federal court

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Session 6: Compliance Part 1

Developing a Compliance Framework for the Information Blocking Rule

What is Compliance?

- Encyclopedia.com: "Keeping a watchful eye on an ever–changing legal and regulatory climate and making the changes necessary for the business to continue operating in good standing"

- Modern compliance emerged around 1991 when the U.S. Sentencing Commission updated its Federal Sentencing Guidelines

- U.S. Federal Sentencing Commission sets rules that U.S. Federal Courts must follow in determining sentences for federal criminal defendants

- Federal Sentencing Guidelines for Organizations (FSGO) applies to corporate defendants for acts of its employees, contractors or agents

- A bona fide compliance plan is a mitigating factor for a sentencing

- FSGO identifies components of a bona fide compliance plan

What are My Compliance Obligations for Information Blocking?

- Neither the Cures Act nor the Information Blocking Final Rule expressly require that an Actor have a compliance program

- Actors that violate the Information Blocking provisions are subject to penalties as we reviewed in Session # 5:
  - For HIN/HIEs and Developers of certified health IT—Civil Money Penalties of up to $1M per violation
  - For health care providers (as defined in the Final Rule)—"additional disincentives," which have not yet been determined as of today
  - Developers of certified health IT are also subject to ONC certification enforcement.

- **A bona fide compliance program is an important part of an Actor's overall plan to minimize its risk**

Most Actors have Experience with Corporate Compliance Programs

Healthcare provider compliance programs generally focus on multiple areas:

1. Fraud & Abuse, primarily:
   - Antikickback Statute (AKS)
   - Physician Self-Referral (Stark)
   - False Claims Act (FCA)
   - Analogous state laws
2. Privacy & Security, primarily:
   - HIPAA and 42 CFR Part 2
   - State laws and regulations
3. Facility and clinical staff rules and regulations
4. Patient Safety
5. Corrective Action Plans—as required
6. Medical and Medicaid incentive programs (MU, QPP, PIP, MIPS, etc.)

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What Do Compliance Programs Look Like in Today's Healthcare Environment?

- **HINs, HIEs, and other networks and frameworks** may not have a formal compliance program, but they must protect PHI as a HIPAA business associate of their covered entity members
- **Software developers** often have compliance programs for data privacy and security, HIPAA, ONC certification, quality, patient safety, FDA and international safety regulators, corrective action plans (as required)
- **Healthcare Payor** (not generally actors) compliance programs tend to focus on:

    1. State bureau of insurance regulation
    2. Medicare regulation of Medicare Advantage plans
    3. State Medicaid regulation of Medicaid Managed Care Plans
    4. ERISA
    5. ACA requirements
    6. Data privacy and security

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Where Do I Start with Information Blocking Compliance?

- There is no single "correct" way to approach compliance, Actors should decide what works best in their organization

- The OIG has developed a compliance framework for the healthcare industry that is widely considered to be a good model to follow

- Why use the OIG framework?

  - The OIG model compliance plans have been in use for over 10 years and healthcare industry organizations have built compliance programs based on this guidance

  - The OIG is responsible for enforcing violations of the Information Blocking Rule (in collaboration with ONC)

  - The OIG framework is based on the FSGO, which has been used widely by the US Federal Courts in a variety of cases

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OIG Compliance Program Framework—7 elements

- Written **standards of conduct** that affirm organization's commitment to achieving and maintaining compliance
- Designation of a **corporate compliance officer and other bodies** that report directly to the CEO and governing body
- Regular and effective **education and training** for staff
- Implement a **complaint process** that protects anonymity of the person reporting (e.g., "hotline")
- Effective **response to complaints** and discipline of those who break rules
- **Monitoring** compliance program for effectiveness
- **Investigate and remediate** systemic problems

Information Blocking Compliance Framework

Element #1 - Written standards of conduct that affirm organization's commitment to achieving and maintaining compliance

- These should be very specific and cover applicable state and federal law/regulations, "interoperability elements," "practices," and "exceptions," especially ensuring that exceptions are met and documented

- Address:
  - Who is responsible for creating these written standards of conduct?
  - Do they understand the Information Blocking Rule?
  - Who will approve the standards of conduct?
  - Who is responsible for keeping standards of conduct current?

Information Blocking Compliance Framework

Element #2 - Designation of a corporate compliance officer and other bodies that report directly to the CEO and governing body

- For Actors with existing corporate compliance plans, address:
  - Where does the Information Blocking compliance function reside?
    - Current compliance programs may operate in siloes
  - What is unique about the Information Blocking Rule that compliance plans must address?
  - Are there organizational barriers to implementing Information Blocking compliance?
- For Actors without existing corporate compliance plans, how should they approach senior responsibility for compliance with the Information Blocking Rule?

Information Blocking Compliance Framework

Element #3 - Regular and effective education and training for staff

- Focus on those who deal with "interoperability elements" and "practices" (e.g., Board and C-suite, HIM, release of information, development, pricing and licensing, commercial and marketing teams, compliance, legal, interface engineers, contractors, etc.)
  - Likely very broad and deep scope within the organization
- Consider different levels of education and training for the governing body, executive management, operational management, and staff
- Materials must be clear and understandable
- Given the complexity of the Information Blocking Rule, how can Actors create effective education and training tools?
- Keeping detailed records of all education and training is essential, including attendance

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Information Blocking Compliance Framework

Element #4 - Implement a complaint process that protects anonymity of the person reporting (e.g., "hotline")

- For Actors with existing compliance programs, this function should already exist, but it is often outsourced to vendors that might not be aware of Information Blocking requirements

- Actors that **do not** have existing compliance programs will need to evaluate how best to provide this function

- Confidentiality of reporting is essential to foster an environment in which people will report concerns

- No retaliation!

Information Blocking Compliance Framework

Element #5 - Effective response to complaints (internal and external) and discipline of those who break rules

- Complaints must be investigated thoroughly and not "swept under the rug"

- Key issue: Did we violate the Information Blocking Rule and if so, what was knowledge and intent?

- Compliance functions need tools to help them conduct effective investigations that stay on track

- Corrective action is part of this process
    - For smaller companies, discipline can be an issue

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Information Blocking Compliance Framework

Element #6 - Monitoring the compliance program for effectiveness

- Important, but sometimes overlooked, requirement

- OIG will look for documentation that an Actor has evaluated its compliance program at least annually to identify its effectiveness

- What challenges do you see with this element?

Information Blocking Compliance Framework

Element #7 - Investigate and remediate systemic problems

- This element applies to the compliance program operation
- If you identify shortcomings with your compliance program, you must correct them and document your correction(s)
- Some examples of risks and shortcomings may be helpful:
  - Information Blocking complaints are always found to be without merit
  - Those who submit complaints are disciplined
  - The compliance efforts are bogged down in multiple committees and no tangible progress is being made
  - Corrective action is not taken or, if taken, is not documented

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Sequoia's Compliance Planning Workbook

- The OIG framework is helpful, but where do I start?

- **For organizations that already have robust compliance programs**, these are often spread across the organization with different leaders and structures
  - This diffusion of effort complicates Information Blocking compliance, which will involve so many different parts of the organization

- **For organizations without compliance programs**, it could be challenging to develop a compliance plan while dealing with the pandemic

- Sequoia developed a **Compliance Planning Workbook** to help inform Actors, and others, about how they can develop compliance and regulatory implementation plans—Available on the Bootcamp website for downloading

- We outline an approach for compliance and implementation depending on what type of Actor you are and whether your organization already has a compliance program

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Sequoia's Compliance Planning Workbook Content

1. Using this Workbook
2. Information Blocking: A Quick Overview
3. Addressing Organizational Risks and Opportunities Will Require Planning
4. Compliance and Organizational Risks
5. Planning Checklists
   a. Actors and Plans
   b. Review Key Resources
   c. Business Risks
   d. Exceptions
   e. Business Opportunities
   f. Needed Actions
6. Conclusions
7. Appendix A: Back-up Detail for Compliance Planning
8. Appendix B: Back Up Detail for the Planning Checklist
9. Appendix C: Back Up Detail on the Exceptions for the Planning Checklist

Sequoia Compliance Planning Workbook
Key Concepts

- Are you an Actor?

- Does your organization already have a corporate compliance plan for other legal/regulatory compliance?

- How to adapt the OIG Guidance for your organization

- **Risk Assessment—an essential first step**

  – Identifying organizational risks

- Planning checklists to address these risks and needed compliance and implementation actions

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Compliance Takeaways

- An organized approach is critical
- C-suite support is essential
- Compliance takes time; it cannot be rushed
- Leverage the OIG Guidance, but it must be customized to your organization
- Get knowledgeable experts to complement your team
- **Document, document, document!!!!**

Coming Up In Session 7

Next Session

- We will continue discussing compliance and implementation of your regulatory response

- We will conduct a wrap up of the entire Bootcamp

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