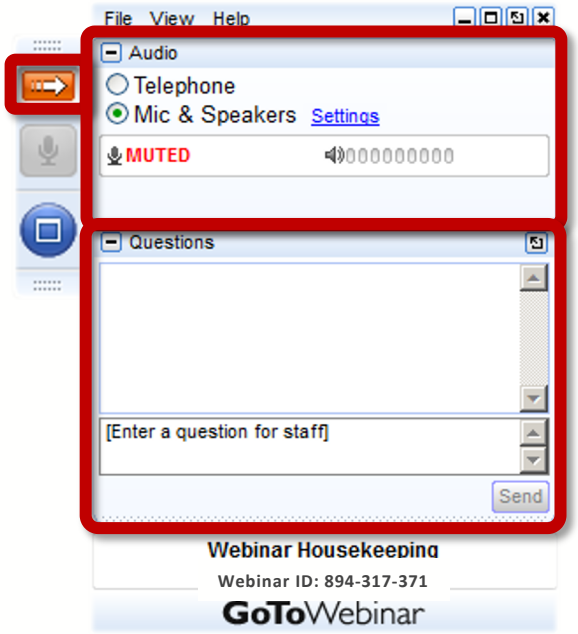
Information Blocking Compliance Boot Camp
C-suite Orientation and Session 1
January 20, 2021

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

Boot Camp Goal and Objectives: Why Participate

Goal

The Boot Camp will provide carefully vetted, substantive resources and relevant information about requirements of the Information Blocking regulations and approaches to enhance effective and compliant organizational responses.

Objectives

1. Provide in-depth study of the Cures Act and the ONC and OIG Information Blocking rules, focusing on which organizations are Actors, prohibited practices, key definitions, regulatory exceptions, and penalties/"disincentives."
2. Deliver practical and useful guidance and tools to help participants design and implement regulatory compliance and implementation plans in their organizations.
3. Promote information sharing among participants during and after sessions.
4. Create a *Community of Interest* to encourage Boot Camp participants to continue sharing learnings and best practices after the Boot Camp concludes.

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.

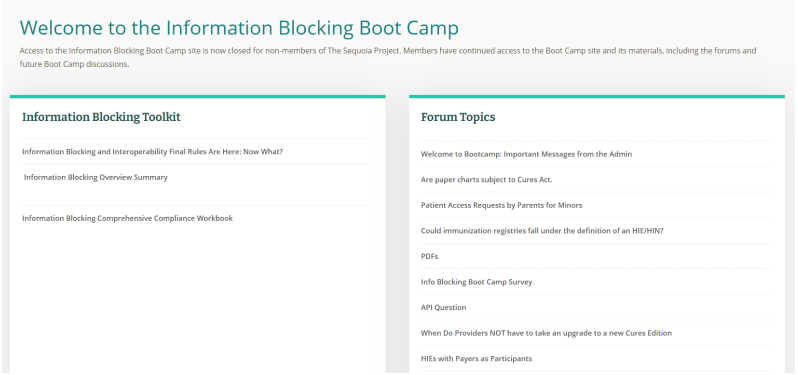
Information Blocking Compliance Boot Camp Sessions

1.	Information Blocking Overview	January 20, 2021
2.	Violating the Information Blocking Rule	February 3, 2021
3.	Exceptions: Part 1	February 17, 2021
4.	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 Boot Camp 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 Boot Camp sessions
- All participants that attend each Boot Camp session will receive a **Certificate of Completion** as tangible evidence of their achievement

Information Blocking Compliance Boot Camp: Office Hours

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

1. January 27, 2021
2. February 10, 2021
3. February 24, 2021
4. March 10, 2021
5. March 24, 2021
6. April 7, 2021
7. April 21, 2021

Session 1 Goals

- ✓ Provide important administrative information to participants about the Boot Camp
- Provide a high-level discussion of Information Blocking for C-suite representatives from each Boot Camp participant
- Proceed to an in-depth discussion of the following topics:
  - What is Information Blocking?
  - Who is subject to the Information Blocking provisions?
  - What are the realistic risks and opportunities?

2021 Workgroup Representatives

Associations and Orgs - health IT community
- Jeff Coughlin, HIMSS
- Lauren Riplinger, AHIMA
- Scott Stuewe, DirectTrust
- Samantha Burch, AHA
- Matt Reid, AMA
- Andrew Tomlinson, CHIME

Consumers
- Ryan Howells, CARIN Alliance
- Deven McGraw, Ciitizen

Health Information Networks and Service Providers
- Melissa Soliz, Missouri Health Connect
- Dave Cassel, Carequality
- Ammon Fillmore, Indiana Health Information Exchange – Co-chair

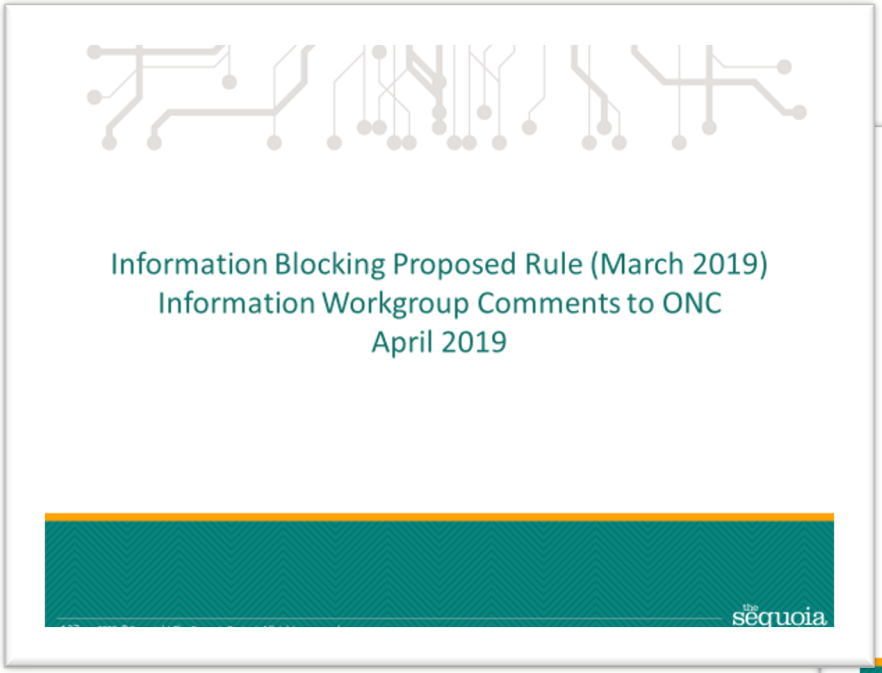
Healthcare Providers / Physicians
- David Camitta, CommonSpirit
- Eric Liederman, Kaiser Permanente
- Paul Uhrig, Bassett Health Network, Co-Chair

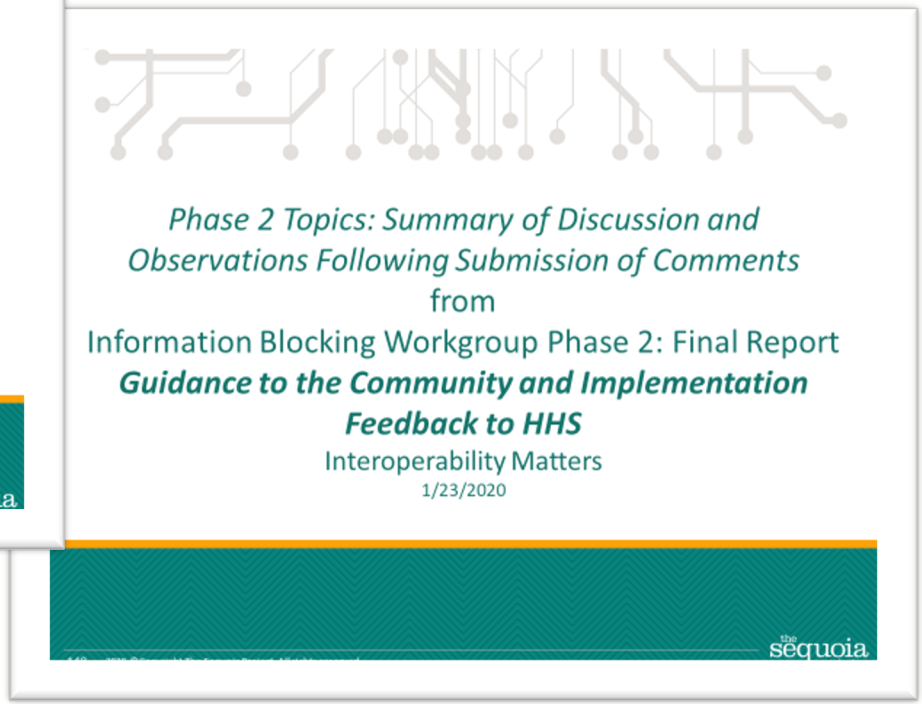
Payers
- Nancy Beavin, Humana
- Danielle Lloyd, AHIP
- Matthew Schuller, BCBSA

Developers
- Cherie Holmes-Henry, EHRA/NextGen
- Alya Sulaiman, Epic
- Josh Mast, Cerner
- Jennifer Stoll, OCHIN
- Rita Bowen, MROCorp
- Micky Tripathi, Arcadia.io
- Amy Ming, Greenway Health

Federal Government
- Steve Bounds, SSA

Interoperability Matters Information Blocking Workgroup



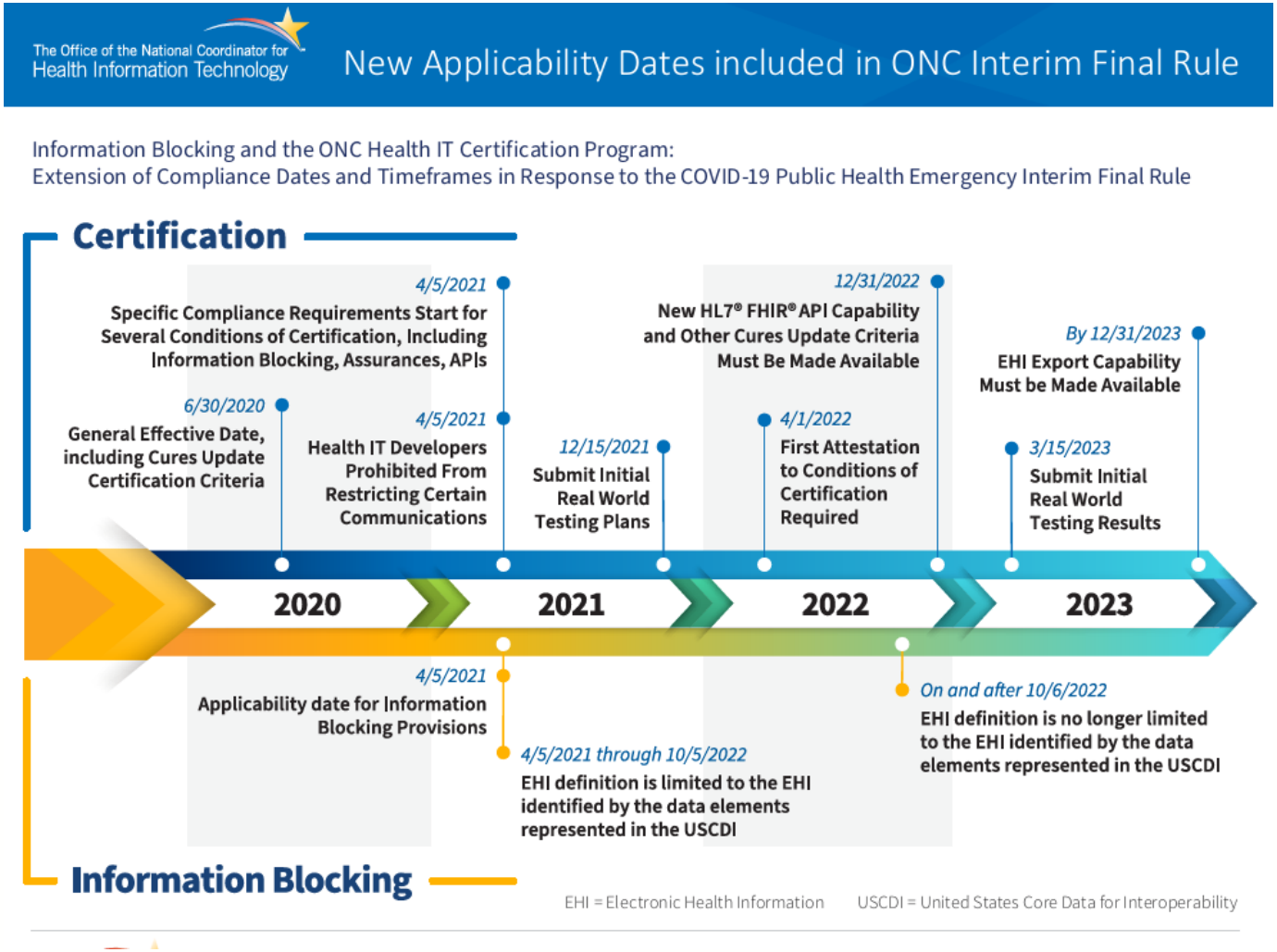


C-suite Orientation

Information Blocking: Why is it an Urgent Matter for Healthcare Leaders?

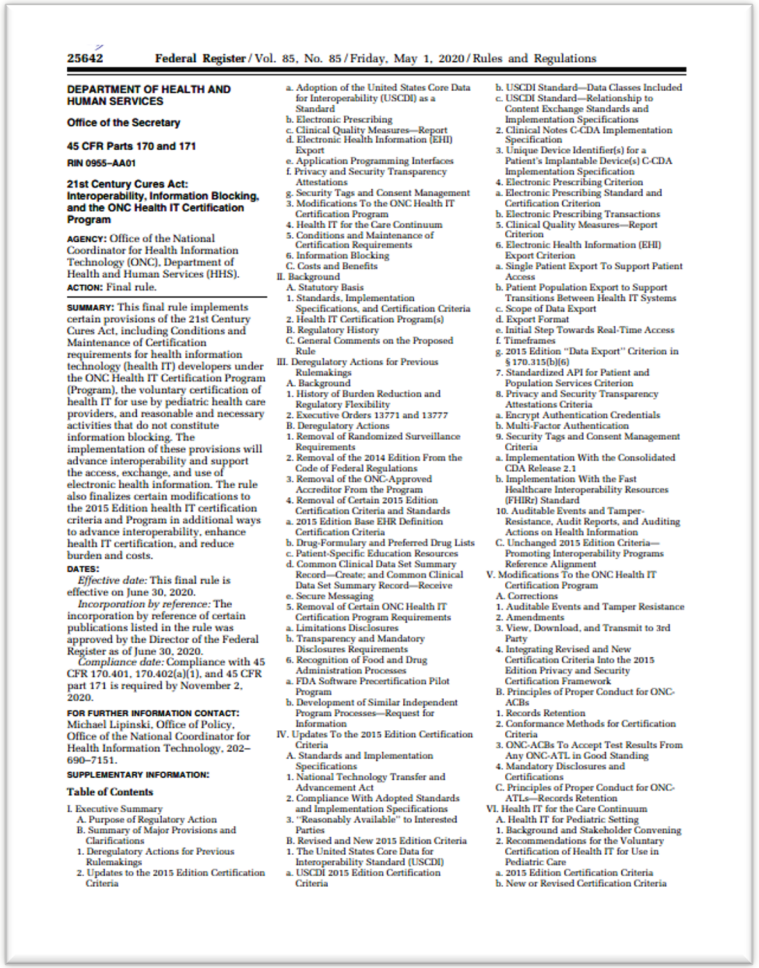
- In December 2016, Congress passed the 21st Century Cures Act (Cures)
- Based on widespread input to Congress, Cures prohibited "Information Blocking" and required actions to increase interoperability
- Cures defines "information blocking" as: **practices** that:
  - prevent or materially discourage the **access, exchange or use of electronic health information** (EHI); and
  - for which the **Actor knows**, or [for some actors] **should know**, are **likely to interfere** with EHI **access, exchange, or use**
- Cures defines penalties for certain Actors (**up to $1 million per violation**) and requires HHS (i.e., Office of the National Coordinator for Health IT—ONC) to issue regulations
- **The compliance date for the ONC regulations was initially November 2, 2020 and was moved, this past November, to April 5, 2021**

ONC Final Rule: Key Dates (Updated)



21st Century Cures and Interoperability: Regulations

- In March 2021, ONC issued a Final Rule implementing several Cures health IT provisions (published in the *Federal Register* 5/1/2021)
  - ***21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*** (Proposed Rule, March 2019)
  - This rule addresses information blocking and certification relevant to interoperability
  - It defines terms in Cures and sets the stage for enforcement



25642 Federal Register / Vol. 85, No. 85 / Friday, May 1, 2020 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 170 and 171

RIN 0955–AA01

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule implements certain provisions of the 21st Century Cures Act, including Conditions and Maintenance of Certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions will advance interoperability and support the access, exchange, and use of electronic health information. The rule also finalizes certain modifications to the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

DATES:

Effective date: This final rule is effective on June 30, 2020.

Incorporation by reference: The incorporation by reference of certain publications listed in the rule was approved by the Director of the Federal Register as of June 30, 2020.

Compliance date: Compliance with 45 CFR 170.401, 170.402(a)(1), and 45 CFR part 171 is required by November 2, 2020.

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION:

Table of Contents

Who is Subject to Information Blocking Enforcement: Cures "Actors" Are Defined by the ONC Regulation

- Health Care Providers– Extremely broad definition
- Health IT Developers of Certified Health IT – Focus is on those with any certified health IT (but enforcement not limited to the certified health IT)
- Health Information Network (HIN) or Health Information Exchange (HIE) – Combined into one category in the Final Rule and is a functional definition that focuses on what the entity does rather than how it is structured

Information Blocking Revolves Around Practices

Information blocking **practices** include both an affirmative act or a failure to act and may include:

- Restricting authorized access, exchange, or use of EHI
- Implementing HIT in **nonstandard** *ways*
- Implementing HIT in ways that are likely to:
  - Restrict **access, exchange, or use** of **electronic health information (EHI)**, including for ***exporting complete information sets*** or ***transitioning between HIT systems***; or
  - Lead to fraud, waste, or abuse, or ***impede innovations and advancements*** in access, exchange, and use

The Final Rule identified "reasonable and necessary" activities (Exceptions) that are not information blocking (as called for by Cures) and "practices" and examples

Information Blocking: Penalties and Enforcement

- Health IT Developers, HINs/HIEs: Enforcement by ONC (developers) and/or HHS OIG—Penalties for not meeting certification conditions or false certification attestations (developers) and up to $1 million civil monetary penalties (CMPs) per violation (developers, HINs/HIEs)
- Health Care Providers: Enforcement and "disincentives" to be determined by forthcoming HHS rules, adding to existing CMS and OIG enforcement of CMS incentive program attestations re: "information blocking" required by MACRA legislation

Applicability (Compliance)—From 11/2/2020 to 4/5/2021
Enforcement by OIG after forthcoming Final Rule and TBD for providers
Certification enforcement (ONC) delayed twice—4/5/2021

The ONC Final Rule Also Establishes New Data Access Requirements for Developers of Certified Health IT

- Standardized Application Programming Interfaces (API) for patient and population services
  - Must be available to providers by 12/31/2022
  - ONC does not address or require provider adoption timing, CMS addressed in CY 2021 fee schedule rule and aligned with ONC must-use for QPP/PIP for 90-day reporting periods in 2022
  - Replaces/updates 2015 edition "open API" requirements
  - Requires USCDI v1 data set, HL7® FHIR® 4.0.1, other standards & implementation specifications
- Conditions and Maintenance of Certification for ONC Health IT Certification Program
  - Most in effect nine months after Final Rule publication
  - Information Blocking
  - APIs (API access and fee limits)
  - Assurances and attestations

Will require compliance by developers, providers, HINs/HIEs and provide new data access opportunities, including an app ecosystem

Planning is Essential

- Organizations that are Actors or interact with Actors face many risks and opportunities from the Information Blocking prohibition and open API requirements
- They will need formal, organization-wide plans for compliance, operational and business responses to the Final Rule
- Actors must avoid engaging in practices that result in Information Blocking or be sure that any practices fit within one of the Information Blocking exceptions: a formal compliance plan will help Actors do this
- **Effective responses to the Information Blocking rules require sponsorship, direction, and funding from the governing body and the C-suite**

How Sequoia Can Help

- Build an informed and engaged **Community of Practice**
- Reduce the organizational costs of “going it alone”
- Provide curated resources to the Community
- Facilitate two-way communications between regulators and the healthcare community
- Focus on ensuring that industry responses to the Information Blocking rules enhances and does not hinder continued growth in interoperability

Discussion

Information Blocking: The Foundations

What is Information Blocking?

How is Information Blocking Defined?

Information Blocking is a **practice** that—

Except as **required by law** or covered by an **exception**, is likely to **interfere with, prevent, or materially discourage access, exchange, or use** of **electronic health information**; **and**

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

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**.

Let's Break Down the Components of the Definition and What They Mean Based on the ONC Final Rule

- "**Practice**"–Defined as "an act or omission" by an Actor
  - The definition of "practice" focuses on what an Actor does or fails to do versus what it meant to do
  - Under this definition, the actual conduct of the Actor will be examined to decide whether the Actor engaged in Information Blocking (whether through affirmative action or through inaction)
  - This term is extremely broad and can include business practices, technology, and/or how the Actor is structured

Let's Break Down the Components of the Definition and What They Mean Based on the ONC Final Rule

- "**Likely to interfere, prevent, or materially discourage**" – The term "**interfere**" is defined in the Final Rule to mean "**prevent**, **materially discourage, or otherwise inhibit**." (Admittedly, there is some circularity in this definition.) However, the most important word to focus on here is "**likely**."
  - ***Actual interference is not required to meet the definition of Information Blocking***
  - Practices that have a mere ***likelihood*** of interfering with the access, use, or disclosure of EHI are considered to be Information Blocking and are prohibited
  - The government does not need to show that an Actor *actually* prevented, discouraged, or inhibited access, exchange, or use of EHI
  - **It is enough to violate the Information Blocking statute if an Actor's practices are *likely to interfere with, prevent, materially discourage, or otherwise inhibit* access, exchange, or use of EHI**

Let's Break Down the Components of the Definition and What They Mean Based on the ONC Final Rule

- "**Access, exchange, or use**" –The Information Blocking Rule does not only apply to the sharing of electronic health information (EHI) between networks; it also extends to the access and use of EHI within and across healthcare organizations.
  - "**Access**" means "the ability or means necessary to make electronic health information available for exchange or use"
  - "**Exchange**" means "the ability for electronic health information to be transmitted between and among different technologies, systems, platforms or networks
  - "**Use**" means "the ability for electronic health information, once accessed or exchanged, to be understood and acted upon." (includes write access)

Let's Break Down the Components of the Definition and What They Mean Based on the ONC Final Rule

- **EHI generally tracks the HIPAA definition of electronic protected health information (ePHI)**, which is protected health information transmitted or maintained in electronic media to the extent it would be in a HIPAA-defined **designated record set**
  - EHI is limited to USCDI v1 data elements until October 6, 2022
  - USCDI v1 standards are not required
- This definition applies regardless of whether the records are used or maintained by or for a HIPAA covered entity
- 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)

What is the Designated Record Set (DRS)?

Designated record set as defined in HIPAA means:

(1) A group of records maintained by or for a covered entity that is:

(i) The medical records and billing records about individuals maintained by or for a covered health care provider;

(ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or

(iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.

(2) The term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

The scope of a DRS can vary by patient, health care organization/covered entity, and situation

USCDI v1 Summary of Data Classes and Data Elements

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment
- Assessment and Plan of Treatment

Care Team Members
- Care Team Members

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals
- Patient Goals

Health Concerns
- Health Concerns

Immunizations
- Immunizations

Laboratory
- Tests
- Values/Results

Medications
- Medications

Patient Demographics
- First Name
- Last Name
- Previous Name
- Middle Name (incl Middle Initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address

Problems
- Problems

Procedures
- Procedures

Provenance
- Author Time Stamp
- Author Organization

Smoking Status
- Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a Patient's Implantable Device(s)

Vital Signs
- Diastolic Blood Pressure
- Systolic Blood Pressure
- Body Height
- Body Weight
- Heart Rate
- Respiratory Rate
- Body Temperature
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2 - 20 Years)
- Weight-for-length Percentile (Birth - 36 Months)
- Head Occipital-frontal Circumference Percentile (Birth - 36 Months)

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 the ability to confer all rights and authorizations necessary to use the element to enable the access, exchange, or use of electronic health information.

Q&A on Access, Exchange, and Use; EHI; and USCDI

Please explain "write" access requirements on API Information Blocking. Isn't the API certification "read-only?"

The requirement for the revised API technical *certification* requirements includes only "read" access. The definition of "use" in the Information Blocking Rule preamble includes "write" access without reference to specific technical requirements, subject to the applicability of exceptions like Content and Manner or Infeasibility.

What is the impact, in terms of any API requirements, for HIEs that don't offer a portal for patient access?

HIEs that don't have ONC-certified APIs do not need to implement APIs, FHIR-based or otherwise, but must respond to requests for access, exchange, or use consistent with the interoperability elements they control for EHI and the Content and Manner and Infeasibility" exceptions. Note that an HIN/HIE that is also a CMS-regulated health plan would have CMS-defined API requirements for its health plan functions.

Q&A on Access, Exchange, and Use; EHI; and USCDI

If the USCDI doesn't have to be implemented until December 31, 2022 for certified health IT, what does it mean that the scope of EHI subject to Information Blocking requirements is restricted to EHI defined as USCDI data elements until October 6, 2022? (e.g., if provenance isn't implemented in the USCDI certification until the end of 2022, is it Information Blocking if provenance isn't implemented in April 2021?)

The USCDI, including specified standards, does not need to be implemented into certified health IT until December 31, 2022. However, the data elements in the USCDI (but not specific codes and standards) are in force for Information Blocking six months after publication. These would include “provenance” as a data element but not the ONC specified standards for provenance.

If specific data elements (or specific data) are not available in EHI controlled by the Actor, it appears that they would not be subject to an Information Blocking complaint for those data elements. The focus of Information Blocking is enabling access, exchange, or use of data controlled by an Actor. The Content and Manner exception may be appropriate for any Actor who cannot meet a request in the manner specified if that request includes the full USCDI definition.

Q&A on Access, Exchange, and Use; EHI; and USCDI

How much legacy EHR data is a provider required to provide through APIs if only some discrete data were converted into the current EHR and the rest remain in PDF format?

Specific provider API data element requirements would come from CMS incentive program API requirements. These would likely focus on available data in electronic form that are in the USCDI (or the CCDS now). We suggest that you look to current CMS requirements here. For Information Blocking, there is no specific API requirement, other than discouraging non-standard interoperability elements, and the Content and Manner and Infeasibility exceptions would come into play for such legacy data, for which alternate means of availability might be needed. Note that PDF data would likely qualify as EHI, at least when the DRS-based EHI definition is in place but at the same time, PDF data would not, however, likely meet the definition of "machine readable" in the Content and Manner exception]

What technologies must be used to share this greatly expanded set of data in the Designated Record Set per the EHI definition?

For technologies for certified health IT, and those who must use certified health IT, the minimum technologies are the USCDI, FHIR 4.0.1 APIs and associated standards and implementation guides specified by ONC. EHI is, however, broader than USCDI, and there is no requirement to use APIs or other technology, other than discouraging non-standard interoperability elements. The Content and Manner and Infeasibility exceptions would come into play for technology to access EHI.

Is the Common Clinical Data Set (CCDS) still viable until the full USCDI it is ready?

Yes. You must use *data elements* in the USCDI, but not associated standards and code sets, to comply with Information Blocking. CCDS continues for certified health IT until USCDI is fully implemented.

ONC FAQs on EHI

Q: For the period of time when information blocking is "limited to the United States Core Data for Interoperability (USCDI)," how is an actor expected to fulfill a request for the USCDI if they do not yet have certified health IT in place that includes an API with the USCDI standard?

- An actor is not automatically required to fulfill a request using the specific content and vocabulary standards identified in the United States Core Data for Interoperability (USCDI) standard for the representation of data classes and data elements, nor are they required to use certified technology or any specific functionality. The information blocking definition (45 CFR 171.103) provides that before October 6, 2022, electronic health information (EHI) is limited to the subset of EHI represented by the data elements identified by the USCDI standard. This limitation of EHI for purposes of the information blocking definition is not contingent on whether those data elements are recorded or represented using specific content and vocabulary standards in the USCDI standard in 45 CFR 171.213. On and after October 6, 2022, the information blocking regulation in 45 CFR part 171 pertain to all EHI as defined in 45 CFR 171.102.
- **Again, the information blocking regulation does not require the use of any specific standard or functionality.** Instead, the "Content and Manner" exception, 45 CFR 171.301, outlines a process by which an actor may prioritize the use of standards in fulfilling a request for EHI in a manner that supports and prioritizes the interoperability of the data. This means that, for the purposes of information blocking, before October 6, 2022, an actor may fulfill a request with the EHI identified by the data elements represented in the USCDI standard, first in the manner requested and, if not, in an alternate manner agreed upon with the requestor, following the order of priority specified in the exception.

ONC FAQs on EHI

Q: Is electronic health information (EHI) that is covered by the information blocking regulation limited by when the information was generated?

- **No, the definition of electronic health information (EHI) is not limited by when the information was generated.** Before October 6, 2022, an actor must respond to a request to access, exchange, or use EHI with, at a minimum, the requested EHI that they have and that can be identified by the data elements represented in the United States Core Data for Interoperability (USCDI), regardless of when the information was generated. On and after October 6, 2022, an actor must respond to a request to access, exchange, or use EHI with EHI as defined in 45 CFR 171.102, **regardless of when the information was generated. For example, an actor who has the necessary technical capability to do so is required to fulfill a request to access, exchange or use EHI that they have and could appropriately disclose in response to that request even if the EHI was generated before the ONC Cures Act Final Rule was published and even if the EHI was generated before the Cures Act was enacted by Congress.**

ONC FAQs on EHI

Q: Is an actor required to fulfill a request for access, exchange or use of EHI with all the EHI they have for a patient or should the amount of EHI be based on the details of the request? In addition, what if an actor only maintains some of the requested information electronically?

- **The fulfillment of a request for access, exchange or use of EHI, including what EHI is shared, should be based on the request**. However, any activity by the actor that seeks to artificially restrict or otherwise influence the scope of EHI that may be requested may constitute interference and could be subject to the information blocking regulation in 45 CFR part 171.
- In terms of fulfilling requests for EHI, it is important to remember that the requirement to fulfill requests for access, exchange, and use of EHI is in any case limited to what the actor may, under applicable law, permissibly disclose in response to a particular request. **Under the information blocking regulation in 45 CFR part 171, the actor is only required to fulfill a request with the requested EHI that they have and that can be permissibly disclosed to the requestor under applicable federal and state law. However, for protected health information they have, but do not maintain electronically, all HIPAA requirements would still be applicable, including the right of access.**

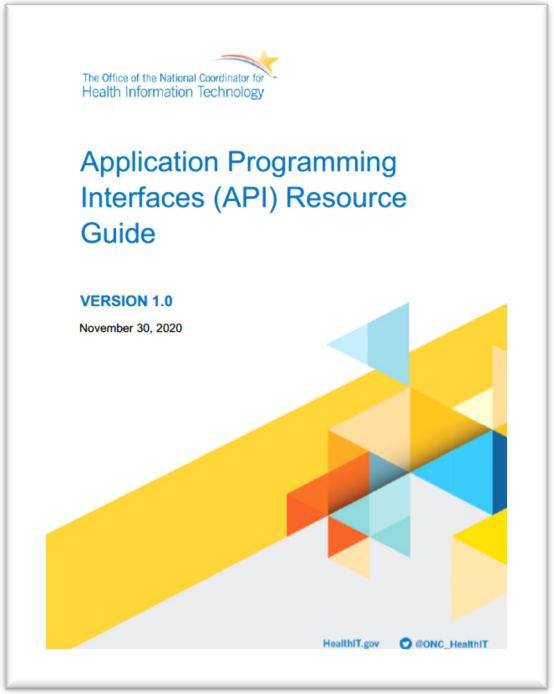
The ONC Final Rule Also Establishes New Data Access Requirements for Developers of Certified Health IT, per Cures

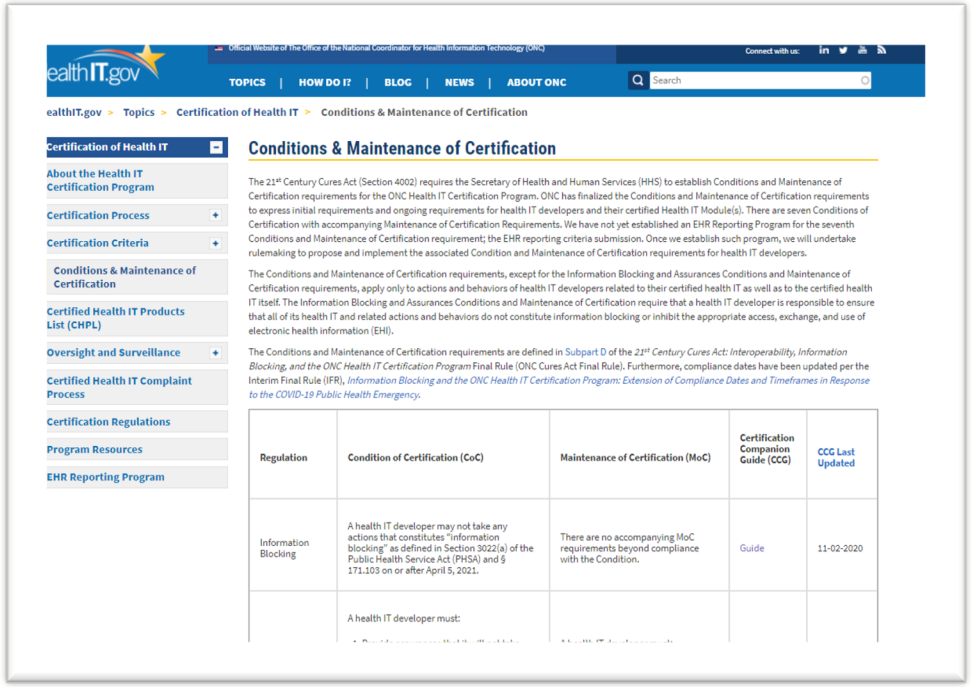
- **Standardized Application Programming Interfaces** (**APIs**) for **patient and population** services
  - Development and availability by 12/31/2022 Note: ONC does not address or require provider adoption timing; CMS addresses on CY 2021 fee schedule final rule
  - Replaces "open API" requirements in 2015 edition certification requirements
  - Requires **USCDI v1 data set**, **HL7® FHIR® 4.0.1,** other standards, and implementation specifications

- **Conditions and Maintenance of Certification for ONC Health IT Certification Program**
  - Some effective 60 days after Final Rule publication and others 4/5/2021 or later
  - Information Blocking
  - Assurances
  - Communications
  - APIs (API access and fee limits)
  - Real World Testing
  - Attestations
  - (Future) EHR Reporting Criteria Submission

These provisions will require compliance by developers, (and indirectly providers and HINs/HIEs) and provide new data access opportunities, including an app ecosystem

The ONC Final Rule Also Establishes New Data Access Requirements for Developers of Certified Health IT, per Cures





ONC has published detailed technical certification resources relevant for developers and others

Discussion

Who is Subject to the Rule?

Who Are the "Actors" Subject to Information Blocking Enforcement as Defined by ONC Regulation?

1. Health Care Providers
2. Health IT Developers of Certified Health IT
3. Health Information Network (HIN) or Health Information Exchange (HIE)

Who Are the "Actors" Subject to Information Blocking Enforcement as Defined by ONC Regulation?

Health Care Providers	Same meaning as "health care provider" at 42 U.S.C. 300jj—includes hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center, renal dialysis facility, blood center, ambulatory surgical center, emergency medical services provider, Federally qualified health center, group practice, pharmacist, pharmacy, laboratory, physician, practitioner, provider operated by, or under contract with, the IHS or by an Indian tribe, tribal organization, or urban Indian organization, rural health clinic, a covered entity ambulatory surgical center, therapist, and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.

Who Are the "Actors" Subject to Information Blocking Enforcement as Defined by ONC Regulation?

Health IT Developers 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 a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator pursuant to 42 U.S.C. 300jj-11(c)(5) (ONC Health IT Certification Program).

Who Are the "Actors" Subject to Information Blocking Enforcement as Defined by ONC Regulation?

Health Information Network or Health Information Exchange	Health information network or health information exchange means 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.

More Detail for the HIN/HIE Definition

- Exchange must be among more than two **unaffiliated** individuals or entities, besides the potential HIN/HIE, able to exchange with each other
- The organization must facilitate exchange for HIPAA-defined data for **Treatment, Payment, or Health Care Operations** (TPO)
  - Once an individual or entity is defined as an HIN/HIE, **information subject to Information Blocking enforcement is not limited to TPO**
- The definition:
  - Is intended to ensure that it does not unintentionally cover "essentially bilateral exchanges" in which an intermediary is "simply" performing a service on behalf of one entity in providing EHI to one or more entities and no "actual exchange" is taking place **among all entities** (ONC)
  - "Should clearly exclude entities that might have been included under the proposed definitions, such as social networks, internet service providers, and technology that solely facilitates the exchange of information among patients and family members" plus "traditional" claims clearinghouse functions (ONC)

Q&A on Actors

Do the requirements apply to only entities with data subject to HIPAA or data outside of HIPAA (that may have been disclosed by a HIPAA-covered entity)?

Information Blocking requirements are not limited to organizations with data subject to HIPAA so long as they meet a definition of an Actor. ONC is clear that the definition of EHI as HIPAA-defined ePHI in a Designated Record Set (DRS) is not limited to ePHI held by HIPAA covered entities.

ONC states that *". . . the reference to the three types of activities does not limit the application of the HIN/HIE definition to individuals or entities that are covered entities or business associates (as defined in HIPAA)."* (p. 624). In addition, ONC states that: *"We have defined EHI (§ 171.102) to mean electronic protected health information (ePHI) as the term is defined for HIPAA in 45 CFR 160.103 to the extent that the ePHI would be included in a designated record set as defined in 45 CFR 164.501 (other than psychotherapy notes as defined in 45 CFR 164.501 or information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding), regardless of whether the group of records are used or maintained by or for a covered entity as defined in 45 CFR 160.103."*

Q&A on Actors

Do public health programs meet the definition of an HIN/HIE and, therefore, become subject to the Information Blocking requirements? Also, some programs (e.g., immunization registries) collect data from multiple sources (multiple provider organizations) and share with providers. Does this qualify as facilitating exchange by more than two entities?

It depends. First, in order to be an HIN/HIE, a public health program would need to exchange data for treatment, payment, or operations as defined by HIPAA. If it does, according to ONC in the Final Rule and as explained in public presentations and webinars, the next key question is whether the providers who share information with the public health program are also using the public health program to exchange with each other. If they are not, the public health program/registry is not operating as an HIN/HIE, but if they are, it may very well qualify as an HIE/HIN.

Clearinghouses exchange far more data than just claims. Does the exclusion of clearinghouses from the definition of an HIN/HIE include *any information* exchanged by health care clearinghouses, or just claim data?

The focus of the exclusion of "traditional" clearinghouses seems to be the nature of exchange (i.e., is it a "traditional clearinghouse function") and not the nature of the data, for data that are otherwise EHI. The issue is whether providers who share data with the clearinghouse use the clearinghouse to exchange with each other.

Q&A on Actors

How does this rule apply to payers (e.g., health insurance companies) and can an organization qualify as more than one type of Actor?

Payers are not a defined Information Blocking Actor. In the Final Rule, and as reinforced in an FAQ, ONC declined, however, to exclude certain categories of organization, such as payers, from the "functional" HIN/HIE definition (or from other actor types).

A payer might have lines of business that qualify it as an Actor, for example as a provider or an HIN/HIE. If so, the payer's activities in those lines of business may qualify the payer as an Actor subject to Information Blocking compliance for those functions, where the organization controls interoperability elements for access, exchange, or use of EHI.

Similarly, ONC in the proposed rule states that a provider organization could also qualify as an HIN/HIE if it exercises control over HIN/HIE functions, but only for the HIN/HIE functions; it would be treated as a provider when it functions as a provider. This is a somewhat different issue than the scenario of developer organizations, whose lines of business subject to Information Blocking are not limited to the certified health IT.

Overall, it appears that ONC will focus on the actions of an organization that align with one of the Actor categories and not apply all actions of the organization to that single category.

ONC FAQs on Actors

Q: Does the information blocking regulation apply to an individual or entity that does not develop any products certified under the ONC Health IT Certification Program if that individual or entity resells or re-licenses select certified health IT developed by others?

Yes. For purposes of the information blocking regulation, a "health IT developer of certified health IT" is defined in 45 CFR 171.102. With the sole exception of a health care provider that self-develops certified health IT for their own use, this definition is met by any individual or entity that develops or offers health IT certified under the ONC Health IT Certification Program. If an individual or entity that offers certified health IT for any period of time on or after the applicability date of 45 CFR part 171, then they would be considered to be a "health IT developer of certified health IT" for purposes of their conduct during that time. The information blocking provision would not apply to conduct the individual or entity engaged in after they no longer have or no longer offer any certified health IT. However, claims of information blocking with respect to conduct occurring while the individual or entity had certified health IT could be acted upon by HHS after the individual or entity no longer had or offered certified health IT. (See also ONC Cures Act Final Rule page 85 FR 25797)

Discussion

Risk and Opportunities

Organizational Risks are Extensive

- Stiff Fines and penalties
- Reputational risk
- Implementation and compliance costs
- Enforcement and regulatory uncertainty and conflicts (e.g., Cures vs. HIPAA)
- High EHI request volume
- Challenges in finding expertise and resources
- Many providers will seek to be patient information stewards, concerned about vetting apps and API access
- Audits may show that what seemed compliant was not, with unexpected liability

Addressing These Risks

- Actors and potential actors should review all implementation and compliance issues
- Plan for the worst case
- Exceptions will require policies and procedures, *in workflows*
- Evaluate implications and obligations for parties with which you do business: threats and opportunities
- Expect the rule to be “weaponized” by some seeking data access and by competitors

Organizational *Opportunities* Will Also Be Created

- Cures will also provide competitive opportunities for innovative healthcare organizations and health IT developers
- Organizational responses to Information Blocking and API requirements, and standards like the U.S. Core Data for Interoperability (USCDI), will enable greater data access and integration of apps with existing health IT
- 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

Discussion

Coming Up

Logistics and Reminders

Class Logins

- Use the same GoToWebinar login as you used today for all classes
- Logins are used to track attendance for certificate of completion
  - Please do not share your login with others
  - If you miss a class, watch the recording to receive attendance credit

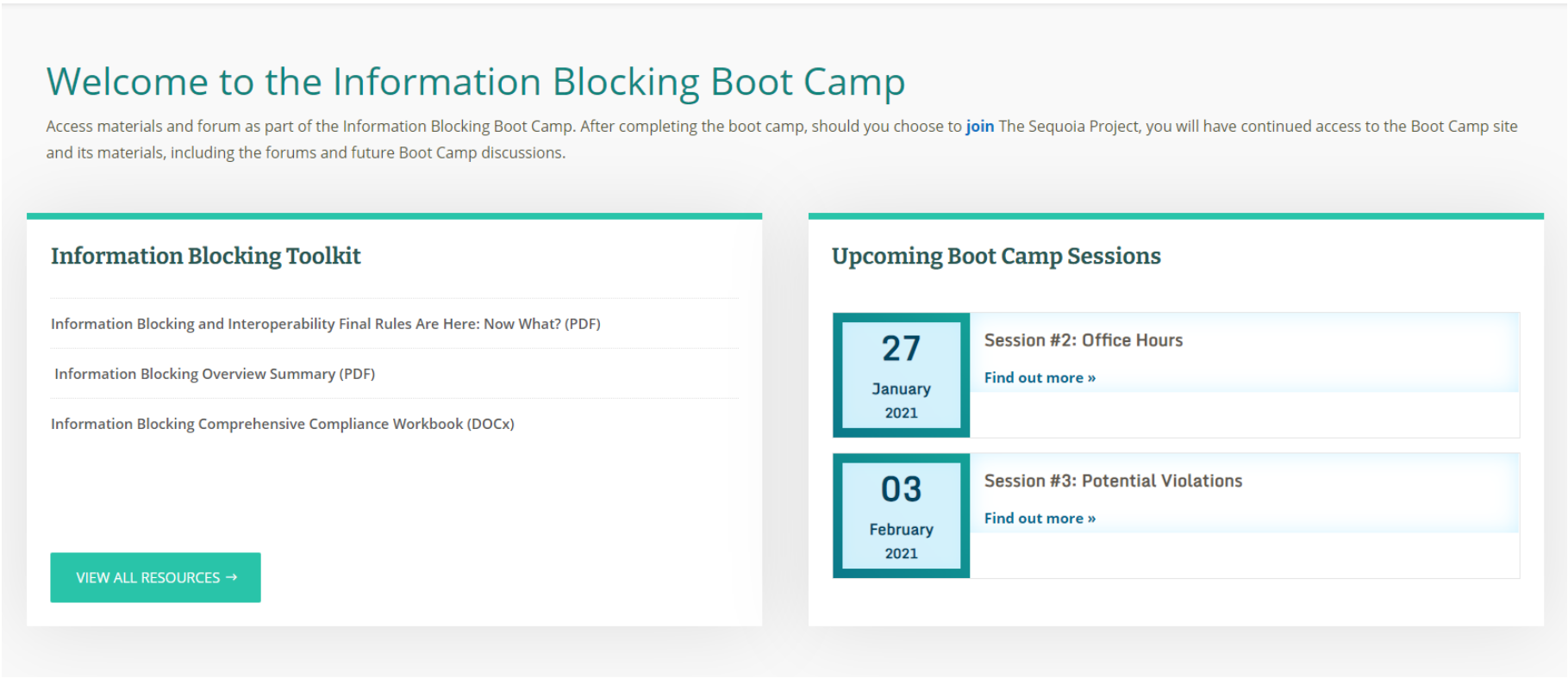
Office Hour Logins

- Use the credentials included in your calendar invitation.
  - All students have the same login because attendance is optional but encouraged

Website Login

- https://sequoiaproject.org/2021-information-blocking-boot-camp/
- Members: Use your normal member login credentials
  - Non-members and first-time users: Select “password reset” and use your work email address to complete account set-up.

Boot Camp Participant Website Is Your Resource For Session Recordings, Slides, Forums, and Exclusive Materials



Session 2: How Could an Organization Violate the Information Blocking Rule?

- This session will explore how an organization could violate the Information Blocking rules
- We will discuss the types of conduct that could get you into trouble and explore the idea of “practices”
- We will include examples and discuss what ONC has said about practices, and why this provides a roadmap for your organization’s compliance planning

Interoperability Matters

https://sequoiaproject.org/interoperability-matters/