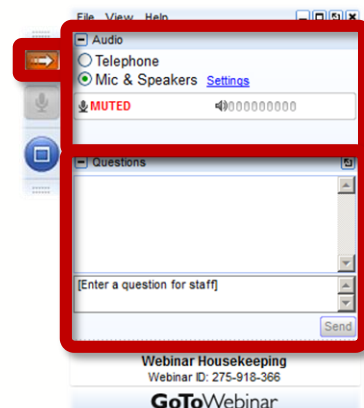




Follow-up Info Blocking and Interoperability Final Rules Webinar: Featuring Extended Q&A

4/17/2020

How To Participate Today



Your Participation

Open and close your control panel

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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
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Steve Gravely
Founder & CEO
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Principal
Digital Health Policy Advisors

Workgroup Representatives

Associations and Orgs - health IT community

- Anne Kimbol, HITRUST Alliance
- Mari Greenberger, HIMSS
- Lauren Riplinger, AHIMA
- Scott Stuewe, DirectTrust
- Samantha Burch, AHA
- Jeff Smith, AMIA
- Matt Reid, AMA
- Mari Savickis, CHIME
- Paul Uhrig, The Commons Project Foundation, Co-Chair

Consumers

- Ryan Howells, CARIN Alliance
- Deven McGraw, Ciitizen

Health Information Networks and Service Providers

- Angie Bass, Missouri Health Connect
- Dave Cassel, Carequality
- Laura Danielson, Indiana Health Information Exchange

Healthcare Providers / Physicians

- David Camitta, CommonSpirit, Co-Chair
- Eric Liederman, Kaiser Permanente

Legal, Technology, Standards, and Policy Subject Matter Experts

- Josh Mandel, Microsoft
- Micky Tripathi, MaEHC

Payers

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

Public Health

- John Loonsk, APHL

Vendors

- Aashima Gupta, Google
- Cherie Holmes-Henry, EHRA/NextGen
- Rob Klootwyk, Epic
- Josh Mast, Cerner
- Jennifer Stoll, OCHIN
- Rita Bowen, MROCorp

Consultant

- Brian Ahier, MITRE Corporation

Federal Government

- Steve Bounds, SSA

Interoperability Matters Information Blocking Workgroup



Information Blocking Proposed Rule (March 2019)
Information Workgroup Comments to ONC
April 2019



*Phase 2 Topics: Summary of Discussion and
Observations Following Submission of Comments
from*
Information Blocking Workgroup Phase 2: Final Report
***Guidance to the Community and Implementation
Feedback to HHS***
Interoperability Matters
1/23/2020



Review of ONC's Final Rule

21st Century Cures: Information Blocking (Section 4004)

A **practice** that:

- Except as required by law or specified by the Secretary per ***rulemaking***), ***likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information*** (EHI); and
- If conducted by a **health IT developer**, exchange, or network, developer, exchange, or network ***knows, or should know***, that practice ***likely to interfere with, prevent, or materially discourage the access, exchange, or use of EHI***; or
- If conducted by a **health care provider**, provider ***knows*** that such practice is ***unreasonable*** and ***likely to interfere*** with, prevent, or materially discourage access, exchange, or use of electronic health information.

Information Blocking: Penalties and Enforcement

- **Health Care Providers:** Enforcement by CMS and the HHS OIG based on CMS incentive program attestations—*Penalties for false attestations*
- **Health IT Developers, HIEs, HINs:** Enforcement by ONC and/or HHS OIG—*Penalties for not meeting certification conditions or false attestations (certified health IT developers) and up to \$1 million civil monetary penalties (CMPs) per violation (developers, HIEs, HINs)*

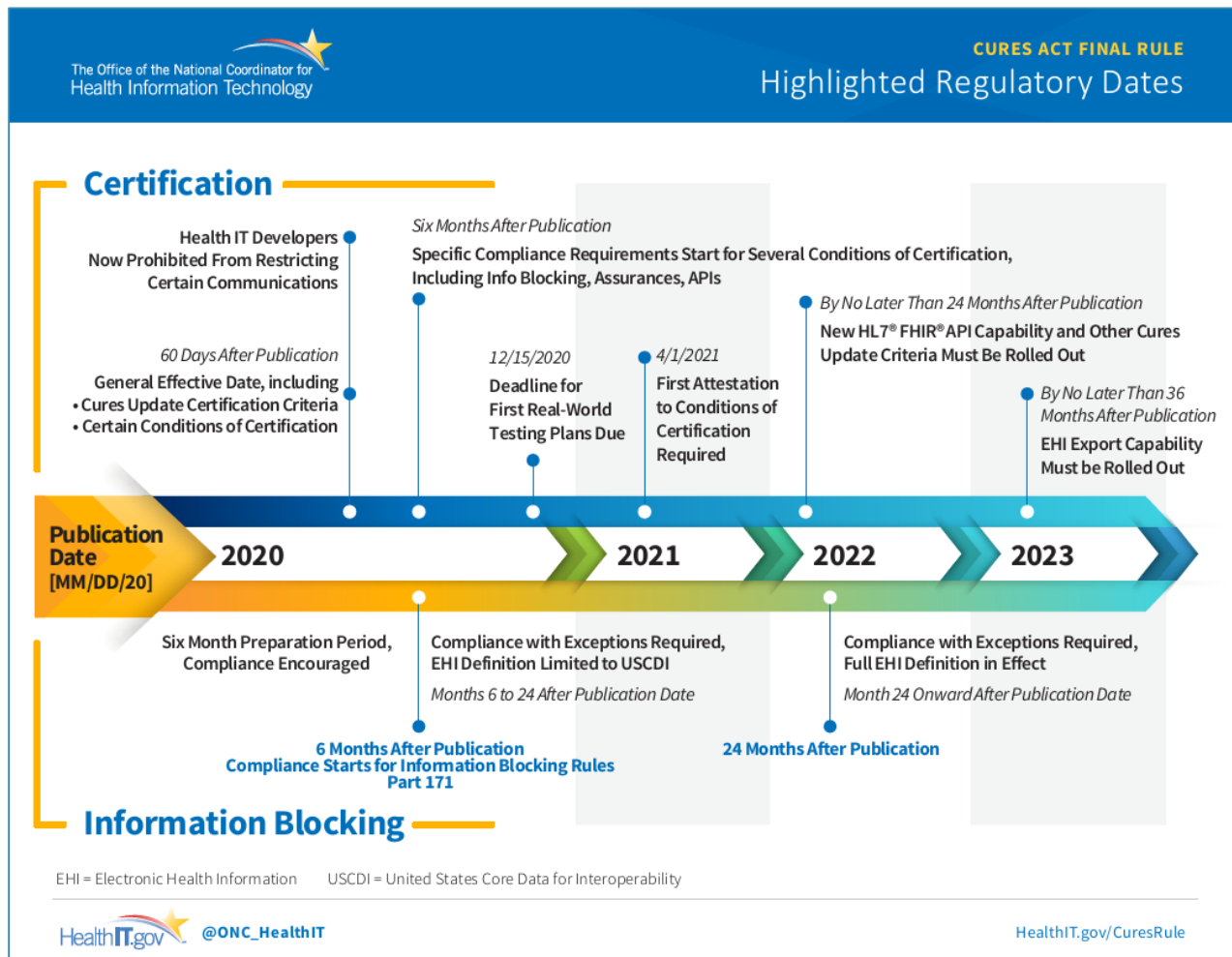
Major Changes from Proposed Rule and Other Highlights: Information Blocking—Key Building Blocks

- **Timing and Enforcement**
 - Compliance date for information blocking six months after *Federal Register* publication
 - Delayed pending new compliance date and OIG CMP final rule (NPRM at OMB 1/23/2020)
- **HIE/HIN**
 - Combined and narrowed (but still broad applicability and some ambiguity)
- **EHl (For Information Blocking and Otherwise)**
 - *Data elements* in USCDI for 24 months after publication
 - Then narrowed from Proposed Rule to ePHI in Designated Record Set
- **USCDI**
 - *Data elements* for information blocking six months after rule publication
 - Must implement in *certified HIT* within 24 months of publication
 - A few revisions from proposal but ONC did not accept most calls to expand v1
 - Among other sources, will look to HL7 FHIR “Patient Compartment” for possible expansion
- **Access, Exchange or Use; Interoperability Element**
 - Simplified and clarified
- **Certification**
 - Maintained use of 2015 edition, with limited modifications
 - Eliminated several criteria, mostly as proposed
 - Revised standards and API criteria
 - Information blocking timing and other Conditions of Certification 6 months after publication

Major Changes from Proposed Rule and Other Highlights: Information Blocking—Exceptions

- Revised titles and content to simplify
- New Content and Manner Exception
 - Draws from proposed exceptions and reduces fee and licensing exception impact
- Multiple other revisions but intent largely unchanged

ONC Final Rule: Key Dates



Information Blocking Exceptions

Not fulfilling requests to access, exchange, or use EHI

1. Preventing Harm
2. Privacy
3. Security
4. Infeasibility (Timely response needed)
5. Performance

Procedures for fulfilling requests to access, exchange, or use EHI

6. Content and Manner
7. Fees
8. Licensing

Complaint Process and Enforcement

- ONC and OIG are actively coordinating on establishing referral policies and procedures to ensure timely and appropriate flow of information re: information blocking complaints
- They coordinated timing of final rule effective date and start of enforcement, including for Conditions of Certification related to information blocking (6 months from publication)
- CMP enforcement will not begin until set by future OIG notice and comment rulemaking (Proposed Rule cleared OMB and forthcoming)
 - Actors are not subject to CMPs until OIG rule final
- At a minimum, enforcement would not begin sooner than the compliance date of the information blocking provision (6 months after publication) and will depend on when the CMP rules finalized
- **Conduct before that time not subject to information blocking CMPs**

Maintenance of Certification: Information Blocking

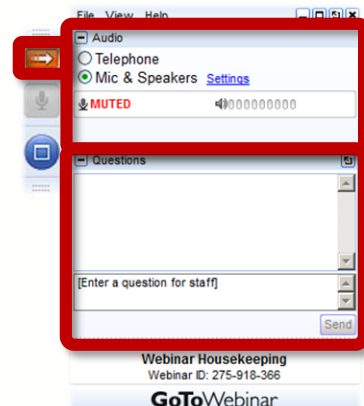
- Per Cures, ONC finalizes Conditions and Maintenance of Certification for ONC Health IT Certification Program—some relate directly or indirectly to information blocking*
 - Information Blocking*
 - Assurances *
 - Communications
 - Application Programming Interfaces (APIs)*
 - Real World Testing
 - Attestations*
 - (Future) Electronic Health Record (EHR) Reporting Criteria Submission

Note: In some cases, such as API pricing, criteria are more stringent than general information blocking provisions (e.g., fee record keeping) but must also be met to satisfy information blocking exceptions.



Questions

How To Submit Additional Questions Today



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Many of you already asked questions during or after our prior webinars or for today's webinar

Key Questions from Webinars

Who do the Rules Apply To: Actors: HIE/HIN, Payors, etc.?

- Do Public Health programs meet the definition of an HIE/HIN and therefore become subject to the information blocking requirements?
 - 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?
- How does this Rule apply to Payers (e.g., health insurance companies)?
- How do the ONC information blocking rules apply (and to be implemented by) entities that may not have a direct patient/provider relationship, such as a laboratory or consulting physician?
- 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)?
- Clearinghouses exchange far more data than just claims. Does the exclusion of clearinghouses include any information exchanged by health care clearinghouses, or just claim data?

Key Questions from Webinars

EHI and USCDI

- If the USCDI doesn't have to be implemented for 24 months after publication of the Final Rule, what does it mean that information blocking scope is restricted to EHI (defined as USCDI data elements) for the first 24 months after publication of the Final Rule (e.g. if provenance isn't implemented until the 24 months, is it information blocking if provenance isn't implemented at month 6?)

Access, Exchange, Use

- Please explain “write” access requirements on API information blocking? Isn't it just “read-only”?
- What is the true impact for HIEs that do not have patient access to portal in terms of API requirements?

Key Questions from Webinars

Is it Information Blocking?

- If a state HIE asked the hospitals in that state to participate (and offered to cover associated expenses), and the hospitals declined, would this action by the hospitals be considered information blocking?
- If a group of providers refused to permit an HIE to provide de-identified data for evaluation of a program or service of a provider, does that refusal constitute data blocking?
- If providers refused to permit an HIE to send batch downloads of patient information for purposes of quality measurement, would that be data blocking?
- If organizations refuse to do setup for Summary of Care measures, is that information blocking?
- Some Hospitals are only sending ADTs and not sending other data types to their HIEs, will this be considered as information blocking?
- Would a clinical registry operated by a third-party, such as a health care quality collaborative operating a clinical registry and offering quality measurement and reporting services to provider entities (i.e., healthcare operations), generally not be considered an HIN/HIE and fit the criteria of bilateral exchange?

Key Questions from Webinars

Fee Exception

- Why is the language in 171.301(b)(2) regarding fees being prohibited for electronic access of an individual's EHI by "another person or entity designated by the individual" not in conflict with the recent DC District Court decision on the Ciox v. Azar case related to fees charged to third parties in which an individual directs his/her health information be transmitted?
 - The nuance may be the definition of electronic access in Part 171: to mean an internet-based method that makes the EHI available at the time the EHI is requested and where no manual effort is required to fulfill the request. If this is not the type of access requested by the individual, the HIPAA fee decision of the court may apply.
 - If I was a lawyer that did malpractice cases, I would procure a consumer-facing app that uses FHIR R4 and provide that to my client to access the client's EHI.

Implementation and Enforcement Dates

- Has any consideration been given to pushing out any dates due to COVID-19 activities?
- My understanding from the briefing at the March HITAC is that the compliance date for information blocking per se is not tied to when the OIG's enforcement and CMP rule is final.
 - The actual enforcement of the information blocking provision and CMPs may be delayed and the rule indicates enforcement would be no earlier than the 6-month compliance date. It was not very clear in the rule and ONC should clarify this in an FAQ.
 - One could say a compliance date that has no enforcement in effect is equivalent to a compliance delay. For a health care provider, getting started on coming into compliance with the Information Blocking provision sooner rather than later is better now that the rule is out.

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