Decoding the Information Blocking Proposed Rule and Preparing for Compliance

The Interoperability Matters Information Workgroup

12/5/2019

Agenda

- Information Blocking Work Group
- Key Perspectives from Phase II Work
- Compliance and Implementation Plan Framework
- Next Steps
- Q&A

Information Blocking Workgroup: Purpose

- ✓ Provide input into Sequoia comments to ONC on proposed rule
- ✓ Identify practical, implementation-level implications of proposed ***and final*** information blocking rules, which may or may not be consensus positions
- ✓ Facilitate ongoing discussions to clarify information blocking policies and considerations prior to ***and after the Final Rule***

Workgroup Representatives

Associations and Orgs - health IT community
- Anne Kimbol, HITRUST Alliance
- Mari Greenberger, HIMSS
- Lauren Riplinger, AHIMA
- Scott Stuewe, DirectTrust

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

Consultant
- Brian Ahier, MITRE Corporation

Federal Government
- Steve Bounds, SSA

Health Information Networks and Service Providers
- Angie Bass, Missouri Health Connect
- Dave Cassel, Carequality
- Laura Danielson, Indiana Health Information Exchange
- Paul Uhrig, Surescripts, Co-Chair

Healthcare Providers / Physicians
- David Camitta, CommonSpirit, Co-Chair
- Eric Liederman, Kaiser Permanente
- Matt Reid, AMA
- Mari Savickis, CHIME

Legal, Technology, Standards, and Policy Subject Matter Experts
- Jodi Daniel, Crowell & Moring, LLP
- 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

Informatics
- Doug Fridsma, AMIA

Safety Net Providers / Service Provider
- Jennifer Stoll, OCHIN

Release of Information Company
- Rita Bowen, MROCorp

Information Blocking Workgroup—Phase 2

Overall approach: Focus on implementation and compliance implications of ONC proposed rule elements and likely outcomes. Not relitigating comments.

- ✓ Meeting 1 (6/20) Review comments submitted and proposed workplan
- ✓ Meeting 2 (8/2) HIE/HIN and Other Key Definitions
- ✓ Joint Workgroup & Leadership Council (8/21)
- ✓ Meeting 3 (9/13) Information Blocking Practices
- ✓ Meeting 4 (10/11) Recovering Costs/RAND Licensing
- ✓ Meeting 5 (11/8) Compliance Plans
- • Meeting 6 (12/13) Phase 2 Review, Implementation Plans, Compliance Plans (cont.)

Deliverable: Summary of Phase 2: Guidance to the Community and Implementation Feedback to ONC

Phase 2 Topics: Discussion Summary

Implementation & Compliance Implications/Needs

ONC and CMS Rules in Final OMB Clearance

AGENCY: HHS-CMS
TITLE: Interoperability and Patient Access (CMS-9115-F)
STAGE: Final Rule
RECEIVED DATE: 09/26/2019

RIN: 0938-AT79
ECONOMICALLY SIGNIFICANT: Yes
LEGAL DEADLINE: Statutory

Status: Pending Review

AGENCY: HHS-ONC
TITLE:21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program
STAGE: Final Rule
RECEIVED DATE: 10/28/2019

RIN: 0955-AA01
ECONOMICALLY SIGNIFICANT: Yes
LEGAL DEADLINE: None

Status: Pending Review

Common ONC NPRM Public Comment Themes: Look for Outcomes in Final Rule

- Significant burden on actors
- Revise NPRM and submit for second set of comments
- Delay Effective Date to enable changes
- Clarify enforcement
- Exceptions: Some see as loopholes, others as too restrictive
- Information Blocking definition too broad
- HIE/HIN definitions confusing
- EHI definition widely panned; use PHI
- Pricing/contracting too restrictive, excessive documentation, could distort markets

Key Definitions and Concepts

Information Blocking: ONC §171.103

Very Broad

Information blocking.

Information blocking means a practice that—

(a) Except as required by law or covered by an exception set forth in subpart B of this part, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

(b) 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

(c) 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.

Electronic Health Information (EHI) §171.102

- *Electronic protected health information* (defined in HIPAA), and any other information that:
  - Identifies individual, or with respect to which there is a reasonable basis to believe the information can be used to identify individual; and
  - Transmitted by or maintained in electronic media (45 CFR 160.103) that;
  - Relates to past, present, or future health or condition of an individual; provision of health care to an individual; or past, present, or future payment for the provision of health care to an individual.
  - Not limited to information created or received by a provider
  - Not de-identified health information per 45 CFR 164.514(b)
- Could include price information; ONC has RFI on including price information in EHI re: information blocking

Interoperability Element §171.102

Very Broad

1. Any functional element of a health information technology, whether hardware or software, that could be used to access, exchange, or use electronic health information for any purpose, including information transmitted by or maintained in disparate media, information systems, health information exchanges, or health information networks.
2. Any technical information that describes functional elements of technology (such as a standard, specification, protocol, data model, or schema) and that a person of ordinary skill in the art may require to use functional elements of the technology, including for developing compatible technologies that incorporate or use functional elements.
3. Any technology or service that may be required to enable use of a compatible technology in production environments, including but not limited to any system resource, technical infrastructure, or health information exchange or health information network element.
4. Any license, right, or privilege that may be required to commercially offer and distribute compatible technologies and make them available for use in production environments.
5. Any other means by which EHI may be accessed, exchanged, or used.

Actors §171.102

Very Broad

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.
Health IT Developers of Certified Health IT	An individual or entity that develops or offers health information technology (as that term is defined in 42 U.S.C. 300jj(5)) and which had, at the time it engaged in a practice that is the subject of an information ~~blocking claim, health information~~ technology (one or more) certified ~~under the~~ ONC Health IT Certification Program
Health Information Exchanges	Individual or entity that enables access, exchange, or use of electronic health information primarily between or among a particular class of individuals or entities or for a limited set of purposes
Health Information Networks	Health Information Network or HIN means an individual or entity that satisfies one or both of the following— (1) Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities (2) Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities

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HIE/HIN Definitions: Who Might be Unexpectedly Included?

- **Provider organizations**, especially those in ACOs where data sharing essential;
- **Payers** (HIEs/HINs, even under HITAC revision, especially with focus on "agreements");
- "**Individuals**" who "substantially influence" policies (e.g., HIM professionals, privacy officers);
- **Release-of-Information vendors**;
- **Interoperability and interface vendors** and any **organization with "integration" in name or mission**, for example:
  - **Third party integrators** working with health plans and providers
  - Companies providing **technology and technology support for HIEs and HIT developers**;
- **Clinical registries (**many need to use non-standard data elements and terms);
- **Companies that rely on remote data access** for their core functionality, such as analytics and clinical decision support vendor**s**;
- **Standards Development Organizations** (SDOs) and other **organizations that define policies and standards** for the industry; and
- **Digital wellness vendors**

Information Blocking Practices

ONC Practice Categories and Selected, Edited Examples

- Restrictions on Access, Exchange, or Use
  - Requiring consent to exchange EHI for treatment even though not required by law
- Limiting or Restricting the Interoperability of Health IT
  - Developer prevents (e.g., by exorbitant fees unrelated to costs or by technology) third-party CDS app from writing EHI to EHR as requested by provider
- Impeding Innovations and Advancements in Access, Exchange, or Use or Health IT-Enabled Care Delivery
  - HIN charges additional fees, requires more stringent testing or certification requirements, or imposes additional terms for participants that are competitors, are potential competitors, or may use EHI obtained via the HIN in a way that facilitates competition with the HIN
- Rent-Seeking and Other Opportunistic Pricing Practices
  - Analytics company provides services to customers of developer of certified health IT and developer insists on revenue sharing that exceeds its reasonable costs
- Non-Standard Implementation Practices
  - Actor chooses not to adopt, or to materially deviate from, relevant standards, implementation specifications, and certification criteria adopted by the Secretary

Are ONC Practice Examples Unambiguous and Specific?

- Examples generally reasonable given statutory and regulatory information blocking definitions, though still some ambiguity
- Examples appear to be catalog of complaints to ONC and can be seen as high priority concerns that will motivate enforcement and compliance

Do You Disagree With Any ONC Identified Practices?

- References to “optional” vs. “required” standards don’t align with optionality use for implementation guides or implementers
- “Health system policy requiring consent to exchange EHI for treatment even though not required by law”: multiple federal/state laws at play
- Is provider decision to not acquire/use a capability information blocking?
- Vendor obligation to offer interoperability enhancements?
- Provider’s conservative approach to HIPAA compliance may be within accepted legal and compliance approaches, especially given ongoing and recent concerns with OCR enforcement

Missing Examples?

- Vendors charging providers to develop or implement data segmentation capabilities or other regulatory support
- More definition on “reasonable” costs/fees
- “Without special effort“
- *Writing* to an EHR as “use”
- Is unreadable C-CDA information blocking and what makes it unreadable, vendor actions or sending organization practices?

Given “practices” and examples, Information blocking will be “weaponized” via private party negotiations, creating de facto, private-sector, enforcement

Recovering Costs/RAND Licensing

Additional Documentation Burdens for Cost-based Pricing

- Major departure from current practice and likely burden
- Level of burden driven by "interoperability elements" subject to information blocking in final rule/needing exception (e.g., API used for data access vs. entire EHR)
- Uncertain accounting granularity: more granular=greater burden
- May need detailed information on clients to justify cost/price in factors like "similarly situated"
- How often will pricing need revision as costs recovered?
- *ONC should consider higher-level approach focusing on non-discriminatory, transparent and consistent pricing without needing detailed cost accounting*

Terms Likely To Be Most Problematic (e.g. “Reasonable”)

- Need clear definition of terms, especially “reasonable” costs
- Ambiguity of key terms and pricing-related exception issues, could have a chilling effect to business entry and conduct
- Higher-level focus on pricing transparency can offset need for terms needed for detailed cost accounting approach

Issues With Cost Allocation Across Customers

- Cost allocation across customers challenging; need to allocate and reflect in prices could radically alter business practices
- Impossible for developers to know which customers will want technology under development when pricing determined
- Should costs only be allocated over actual customers or over potential customer base?
- *Again, higher-level focus on non-discrimination could obviate need for detailed cost allocation*

Pricing Based on Customer Size as Preferred Approach

- Non-profit pricing partially grounded in expected costs but also reflects need to invest in future projects
- Pricing on customer/member size common for non-profits (e.g., industry collaboratives and HIEs)
- Non-profits would need to invest in detailed cost and market analyses to rigorously assess role of size as cost proxy

Familiarity With RAND Licensing

- Very low familiarity among workgroup members
- While often used by SDOs, not clear RAND a good fit for licenses to software that developers selling to customers

Software Sold Via License That Could Be Subject To RAND

- Much health IT software sold via a new or existing license
- Compliance will likely increase costs
- Need clarity on when cost vs. RAND exception apply and opportunities for strategic choice of either exception
- Need for clarity on scope of interoperability elements (e.g., API or interface vs entire EHR) to which exception relevant
- Challenging to respond to license requests in 10 business days

How Long To Review/Revise Pricing and Licensing?

- Key issue is when information blocking liability begins – final rule effective date or will there be a grace period?
- Time needed will depend on scope of interoperability elements subject to exceptions
- If must revisit all agreements & pricing, very complex and time consuming – initial period and additional ongoing review
- Need to establish and document processes for timely handling

Summing Up

Implications for Organizational Priorities

- Actors and *potential actors* should think about all issues with compliance and implementation
- Plan for the worst case
- Ambiguous definitions & policies makes compliance planning harder
- Exceptions require policies & procedures, in workflows
- Think about information blocking implications and obligations for parties with which you do business; threats & opportunities
- Challenging for smaller practices to find needed expertise/ resources
- Physicians, clinicians, & provider organizations will want to be stewards of patient information and have concerns about vetting apps and API access, despite OIG HIPAA right of access guidance
- Some organizations may face high volume of information requests, with challenges handling volume
- Audits may later show what you thought was sufficient was not good enough, with unexpected liability

Developing a Compliance Framework for the Information Blocking Rule

Why is Compliance Important?

- Actors face **substantial penalties** for violating the Cures Act prohibition on information blocking
- Actors have the **burden of proof** that their practices which restrict the free flow of health information fit within one of the 7 exceptions
- Software developers **must attest** to ONC that they are not engaged in information blocking and inaccurate attestations will result in sanctions
- Compliance will not "just happen" without planning and effort

OIG Compliance Program Framework - 7 elements

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

Information Blocking Compliance Framework

- Why use the OIG framework?
  - The OIG model compliance plans have been around for over 10 years and healthcare industry organizations have built their compliance programs based on this guidance
  - Using the OIG elements also makes sense because the OIG is responsible for enforcing violations of the Information Blocking Rule (in collaboration with ONC)
  - The OIG framework is based on the Federal Sentencing Guidelines for Organizations which has been used widely by the US Federal Courts in a variety of cases

Key compliance challenges

- Who “owns” Information Blocking compliance in complex organizations where compliance functions are spread across multiple departments?
- Will smaller Actor organizations be overburdened since they lack the resources of larger organizations?
- Educating the governing body, c-suite, staff, contractors, vendors and others about Information Blocking compliance is problematic since this is still very new with little expertise
- How are Actors supposed to balance the inherent tension between protecting the privacy and security of health information and the mandate to not engage in information blocking>

Implementation Planning

Organization-Wide Information Blocking Plan: Adapt to Actor-Type, Organizational Scale, and Organization (1)

- ❑ Are you an "actor" and if so for which units; if "Yes," create organizational "information blocking" project
- ❑ Identify affected teams and personnel, including contractors
- ❑ Designate an overall senior executive project owner/champion
- ❑ Establish a project management process (e.g., PMO)
- ❑ Establish internal reporting processes
- ❑ Identify/designate/train internal SMEs
- ❑ Identify external resources
- ❑ Review proposed & final rule, ONC website, industry resources

Organization-Wide Information Blocking Plan: Adapt to Actor-Type, Organizational Scale, and Organization (2)

- ❑ Identify business risks and opportunities
- ❑ Identify risk mitigators and develop a risk management model
- ❑ Evaluate applicable *exceptions* and needed actions by team
- ❑ Identify needed/desired compliance and business actions
- ❑ Identify needed changes to contracts, agreements, licenses
- ❑ Review interoperability and data access strategies
- ❑ Review and update release of information policies
- ❑ Develop policies, procedures, training, communications plan
- ❑ **Integrate with compliance plan and process**

Next Steps

Looking Ahead

- Final Rule likely by end of year/early January
- Final Rule will likely keep key provisions, with revisions, more flexibility and relaxed timing
- Most provisions effective 60 days after final rule
- Others: 26 months after final rule (e.g., API technology criteria)
- Timing for some provisions could change in final rule or after
- Extended period of regulatory and compliance uncertainty
- Community will need guidance on implementation to meet requirements and reduce compliance uncertainty and costs
- Scarcity of qualified legal advice and a lack of guidance and case law to support legal interpretations

Next Steps

- Finalize Phase 2 PowerPoint Deliverable by January 2020 and share with:
  - Workgroup, Interoperability Matters Leadership Council, Sequoia Project Board
  - HHS
  - Public Forum participants and broader stakeholder community
- Start Phase 3
  - Calls scheduled through May 2020
  - January: Discuss Final Rule and implementation topics and approaches for focus in 2020

Closing Discussion

Interoperability Matters

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